EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products

Concept paper on the revision of the "Guideline on the assessment of clinical safety and efficacy in the preparation of Community Herbal monographs for Well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations"

Agreed by Monograph and List Working Party (MLWP)	July 2015
Adopted by Committee on Herbal Medicinal Products for release for consultation	29 September 2015
Start of public consultation	16 October 2015
End of consultation (deadline for comments)	31 January 2016

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

Keywords	Herbal medicinal product, clinical safety, efficacy, traditional use registration, marketing authorisation, European Union herbal monographs

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. Introduction

In 2006, the "Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the community list for traditional herbal medicinal products/substances/preparations" (EMEA/HMPC/104613/2005) was published. The purpose of the guideline was to harmonise the assessment of efficacy and safety when preparing monographs for well-established and traditional herbal medicinal products in order to full fill tasks according to Article 16 h (3) and Article 16 f (1) of Directive 2001/83/EC as amended by Directive 2004/24/EC. Guideline EMEA/HMPC/104613/2005 has now been available for approximately 10 years and a considerable practical experience has been gathered during the preparation of more than 150 monographs.

2. Problem statement

In principle, the content of the guideline is still valid, but an update of the document to current standards is required taking into account advances over the last 10 years as well as established practice and legal interpretations. Developments and details in the assessment methodology have so far been mainly reflected in template revisions (e.g. Assessment report template EMA/HMPC/418902/2005 Rev. 5, monograph template EMA/HMPC/107436/2005 Rev. 7), but also other public documents such as the 'Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products in Community herbal monographs (EMA/HMPC/473587/2011).'

3. Discussion (on the problem statement)

Besides a general update of the document and a revision of the text to adequately describe the current practice of the HMPC and MLWP, there are three major points for consideration:

- Following legal interpretation by the European Commission, a public statement was issued by the HMPC in 2011. The public statement concerned therapeutic indications acceptable for traditional herbal medicinal products "after exclusion of serious conditions by a medical doctor" e.g lower urinary tract symptoms related to benign prostatic hyperplasia. This information should be included in the guideline.
- In 2014, a template with guidance notes for the development of uniform assessment reports was issued by the HMPC. The template introduced a detailed list of characteristics that should be assessed for each clinical study included in the assessment report. This list of study characteristics should be included and discussed in the guideline.
- The present guideline contains currently no details for specific considerations and data requirements related to use in special population groups to be considered during establishment of monographs for HMPs. Specific aspects on use in the e.g. paediatric and adolescent populations should be added to the guideline.

4. Recommendation

HMPC recommends revising the "Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the community list for traditional herbal medicinal products/substances/ preparations" as indicated above. In addition to the alignment with other documents and current

practice, other points based on assessment experience but also the use of monographs in national and European procedures may be considered during the revision aiming for improved clarity and transparency in some particular aspects of the assessment process.

5. Proposed timetable

The draft revised guideline is expected to be released for 3 month public consultation in 2Q-3Q 2016. After the external consultation the final guideline is expected to be available within 6-9 months.

6. Resource requirements for preparation

Two rapporteurs will be involved in drafting the revision. The draft is expected to be discussed at three to four meetings of the MLWP and at two to three meetings of the HMPC. If necessary the ORGAM DG of the HMPC will be involved for check of procedural aspects and consistency with other guidance documents.

7. Impact assessment (anticipated)

The guideline is primarily intended for use by HMPC and MLWP, but it also has a direct impact on the work of NCAs, applicants and interested parties. The monographs prepared according to the guideline will have an impact on public health as it will influence the approval and availability of (T)HMPs in the EU.

8. Interested parties

Before finalisation, the guideline will be made available for comments by interested parties during the period of public consultation. Comments, both on the concept paper but also the draft revised guideline will be taken into account. The revision is anticipated to support the understanding of the HMPC assessment serving as background document to facilitate comments on individual draft EU herbal monographs and supporting documents during public consultations.

9. References to literature, guidelines, etc.

- Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations; EMEA/HMPC/104613/2005
- Template for Assessment report for the development of European Union herbal monographs and European Union list entries EMA/HMPC/418902/2005 Rev. 5
- Template for a European Union herbal monograph EMA/HMPC/107436/2005 Rev. 7
- Public statement on the interpretation of therapeutic indications appropriate to traditional herbal medicinal products in Community herbal monographs EMA/HMPC/473587/2011