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Committee on Herbal Medicinal Products (HMPC)

Concept paper on the second revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 1)

Discussion by Committee on Herbal Medicinal Products (HMPC)	September 2013 November 2013
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 November 2013
Start of public consultation	3 December 2013
End of consultation (deadline for comments)	15 March 2014

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

Keywords	HMPC; herbal medicinal products; traditional herbal medicinal products; herbal substances; herbal preparations; clinical

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1. Introduction

This concept paper is concerned with the revision of the clinical and non-clinical sections of the guideline on the use of the Common Technical Document (CTD) format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 1).

The revision pertains to the presentation and content of Modules 2, 4 and 5 of dossiers for traditional herbal medicinal products (THMPs) to help future applicants in their submissions.

2. Scope

This guideline is relevant to applications for traditional use registration of THMPs for human use.

The compilation of dossiers for marketing authorisation applications for HMPs is not covered by this guideline.

3. Problem statement

In the light of experience and the recent update to the quality sections of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products, there is a need to update this guideline to provide further clarification on the clinical and non-clinical requirements for THMP applications.

Some changes to the body of the current guideline will be introduced and further relevant references will be added at the end of the guideline.

4. Discussion (on the problem statement)

EMA guidance already exits to aid applicants in drafting Modules 2, 4 and 5 of traditional herbal medicinal product dossiers but this guidance needs to be incorporated into the Guideline on the use of the CTD format in the preparation of a registration application for THMPs (EMEA/HMPC/71049/2007).

It is acknowledged that further guidance is required to assist applicants in the provision of traditional use evidence as per article 16 c 1(c) of Directive 2001/83/EC. In particular there is a need to provide further guidance on the definition of a corresponding product in keeping with that provided in 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). In addition, and in keeping with the information provided in the "Regulatory Q&A on herbal medicinal products" (EMA/HMPC/345132/2010 Rev. 2), guidance is required for applicants to demonstrate how they can relate their product to a Community herbal monograph or Community list entry where relevant herbal preparations are listed with traditional medicinal use indications.

5. Recommendation

The Committee on Herbal Medicinal Products (HMPC) recommends that the guideline on the use of the CTD format in the preparation of a registration application for THMPs (EMA/HMPC/71049/2007 Rev. 1) should be revised to address the matters described under section 4.

The revised guideline will apply to THMPs for human use.

6. Proposed timetable

It is anticipated that a draft of the revised guideline would be available six months after adoption of the concept paper. The draft will be released for external consultation for three months. The revised guideline should be finalised six months after external consultation.

7. Resource requirements for preparation

The Rapporteur should prepare a draft of the revised guideline. Member States are invited to provide comments via their Committee and Working Party Members.

8. Impact assessment (anticipated)

It is intended that this guideline revision will provide further clarity to applicants regarding the clinical and non-clinical requirements for THMP dossiers. The impact on the competent authorities is that this guideline is expected to facilitate the assessment of Modules 2, 4 and 5 for THMPs and will therefore result in a reduction in the resources needed to manage applications.

The proposed second revision will replace 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMEA/HMPC/71049/2007 Rev. 1).

9. Interested parties

During the consultation period on the revised guideline, comments from parties concerned with the registration of THMPs will be welcome.

10. References to literature, guidelines, etc.

- The guideline on the use of the Common Technical Document (CTD) format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev 1).

- 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).

- Regulatory Q&A on herbal medicinal products" (EMA/HMPC/345132/2010 Rev. 2).