EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2011
EMA/HMPC/111298/2011
Committee on Herbal Medicinal Products (HMPC)

Concept paper on the revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products[1] (EMEA/HMPC/71049/2007)

Draft

Discussion by HMPC Drafting Group on Quality	July 2010 October 2010 February 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
End of consultation (deadline for comments)	15 September 2011
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Comments should be provided using this template to hmpc.secretariat@ema.europa.eu

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

[1] Guidance on modules 2.3 and 3 as described in this guideline are also applicable to herbal medicinal products (HMPs) applications for marketing authorisation.

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1. Introduction (background)

This concept paper is concerned with the revision 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 (EMEA/HMPC/71049/2007).

This revision pertains to the presentation and content of the Module 3 on Quality (chemical, pharmaceutical and biological information) for traditional herbal medicinal products (THMPs) to help future applicants in their submission.

2. Scope

This guideline is applicable 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. However, guidance provided on modules 2.3 and 3 are also applicable to HMPs applications for marketing authorisation for human and veterinary use.

3. Problem statement

In the light of experience, there is a need to update this guideline to provide further clarification on the exact location of quality data requirements in the Module 3 on Quality of the CTD and to provide further explanations on the kind of information that is required from applicants at time of application.

Minor changes in the body of the current guideline will be introduced and two annexes will be added. The first annex will be a best practice guide describing the exact location of relevant parts of the documentation and the corresponding guidelines in the CTD Module 3 sections and the second annex will be a Module 3 mock-up.

4. Discussion (on the problem statement)

The quality of human and veterinary herbal medicinal products should be guaranteed and demonstrated in accordance with the existing requirements as set out in Annex I of Directive 2001/83/EC, as amended, Annex I of Directive 2001/82/EC, as amended, with specific herbal quality guidelines such as “Guideline on quality of herbal medicinal products/traditional herbal medicinal products” (CPMP/QWP/2819/00 Rev1) and “Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products” (CPMP/QWP/2820/00 Rev1) and, in addition, with current EU/ICH general quality guidelines for medicinal products that are applicable to THMPs.

There is a need to develop a common understanding of how these numerous legislative provisions on quality data requirements should be compiled in the Module 3 of applications in CTD format for THMPs.

It was acknowledged that the current headings of the CTD should remain unchanged but only supplemented by explanatory notes on how to use it for herbal medicinal products applications.

5. Recommendation

The guideline on the use of the CTD format in the preparation of a registration application for THMPs (EMEA/HMPC/71049/2007) should be revised to address the matters described under section 4.

Specifically the revised guideline and its two annexes (Best practice guide and Module 3 mock-up) should indicate the exact location in the Module 3 of the data described in the legislation on quality and should describe the kind of information that is required from the applicant.

The revised guideline will apply to THMPs for human use. Guidance provided on modules 2.3 and 3 are also applicable to HMPs applications for marketing authorisation for human and veterinary use.

6. Timetable

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

7. Resource requirements for preparation

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

8. Impact assessment (anticipated)

The revised guideline with its two annexes is expected to provide a better understanding on how Module 3 on Quality for THMPs should be presented. In addition, the Module 3 content will be better defined, as reference will be made to quality guidelines that are specific to THMPs as well as general quality guidelines that are applicable to THMPs. It will therefore provide benefits to applicants in the preparation of their submission and to competent authorities for the assessment of the applications.

Impacts on industry are expected with the development of this revised guideline. It should help preventing problems in preparation of Module 3 for THMPs before validation and potentially reduce the resources needed to compile an application.

The impact on the competent authorities is expected to facilitate the assessment of Module 3 for THMPs since the presentation of this module will be predefined. It will also reduce inconsistencies in expectations from the competent authorities with respect to the required documentation, because the revised guideline intends to address what kind of information should be submitted. Finally, it will result in a reduction in the resources needed to manage applications.

9. Interested parties

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

10. References to literature guidelines, etc

- Rules governing medicinal products in the European Union, Volume 2 Notice to Applicants, Volume 2B 'Presentation and content of the dossier'– incorporating the Common Technical Document (CTD)

- 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev.1, EMEA/CVMP/814/00 Rev.1)

- 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products'. (CPMP/QWP/2820/00 Rev.1, EMEA/CVMP/815/00 Rev.1)