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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

CONCEPT PAPER ON CTD FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS

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1. INTRODUCTION

The revision of the pharmaceutical legislation introduces a simplified registration procedure for traditional herbal medicinal products and makes specific reference to the data requirements for such applications.

The preparation of a guideline on how to present the application for a traditional herbal medicinal product in Common Technical Document (CTD) format has been recognised as providing valuable information to help future applicants in their submission.

2. PROBLEM STATEMENT

The Directive 2001/83/EC as amended as regards traditional herbal medicnal products lays down the data requirements in Article 16c, as follows:

The application shall be accompanied by:

a) the particulars and documents:

i) referred to in Article 8(3) a) to h), j) and k)

ii) the results of the pharmaceutical tests referred to in the first[1] indent of Article 8(3)(i);

iii) the summary of product characteristics, without the data specified in Article 11(5)[2];

iv) in case of combinations, as referred to in Article 1(30) or Article 16a(2), the information referred to in Article 16a) 1) e) relating to the combination as such; if the individual data are not sufficiently known, the data shall also relate to the individual active ingredients;

b) any authorisation or registration obtained by the applicant in another Member State, or in a third country, to place the medicinal product on the market, and details of any decision to refuse to grant an authorisation or registration, whether in the Community or a third country and the reasons for any such decision;

c) bibliographical or expert evidence to the effect 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 Community. […]

d) a bibliographical review of the safety data together with an expert report, and where required by the competent authority, upon additional request, data necessary for assessing the safety of the medicinal product.

Annex I shall apply by analogy to the particulars and documents specified in point a).

In order to implement the provisions of the new legislation, it is necessary to outline the exact location of the above-mentioned data requirements for traditional herbal medicinal products in the

[1] This reads "second" in Directive 2001/83/EC as amended (amendment through of a corrigendum procedure by the European Commission)

[2] This reads "Article 11(4)" in Directive 2001/83/EC as amended (amendment through of a corrigendum procedure by the European Commission)

Common Technical Document and describe the kind of information that is required from applicants at time of application.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

There is a need to develop a common understanding as to how these legislative provisions on data requirements should be compiled for applications in CTD format for traditional herbal medicinal products.

It was acknowledged that the current headings of the CTD should remain unchanged but to introduce explanatory notes on how to use it for a traditional herbal medicinal product application.

It was also agreed to prepare such explanatory notes in line with the following revised guidelines:

- 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (EMEA/CPMP/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' (EMEA/CPMP/2820/00 Rev.1, EMEA/CVMP/814/00 Rev.1).

4. RECOMMENDATION

A European guideline should be developed to address the matters described under section 3. Specifically the guideline should define the exact location for the data defined in the legislation in Article 16c as well as describe the kind of information that is required from the applicant.

For the purpose it is also necessary to introduce explanatory notes on the current CTD format so as to make it more easily applicable for submissions of applications for traditional use registrations.

5. TIMETABLE

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

6. RESOURCE REQUIREMENTS FOR PREPARATION

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

7. IMPACT ASSESSMENT (ANTICIPATED)

The guideline is expected to provide a better understanding on how applications for traditional herbal medicinal products should be presented. It will therefore provide benefits to applicants in the preparation of their submission and to competent authorities for the assessment of the applications.

The impacts on industry are expected to be two-fold. Firstly, the development of this guideline should help preventing problems at validation of applications for traditional herbal medicinal products and potentially reduce the resources needed to compile an application.

The impact on the competent authorities is expected to be the facilitation of the assessment of applications for traditional herbal medicinal products since the presentation of such application will be predefined. It will also reduce inconsistencies in expectations from the competent authorities in respect to the required documentation as the guideline intends to address what kind of information should be submitted. Finally it will result in a reduction in the resources needed to manage these.

8. INTERESTED PARTIES

During the consultation period on the guideline, comments from parties concerned with the use of traditional herbal medicinal products will be welcome.

9. 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)