The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

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MANDATE FOR THE EMEA WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

Introduction

In 1997 the European Parliament and the European Commission requested the creation of a working group on herbal medicinal products. On proposal of the EMEA Executive Director, the Management Board established an ad hoc working group on herbal medicinal products at the EMEA to address the issue of quality, safety and efficacy of these products.
Further to the report on the activities in 1997-1998 of the ad hoc working group on herbal medicinal products, the Management Board endorsed in February 1999 the following mandate for the group, which became a permanent working party of the EMEA, in keeping with the tasks laid down in Council Regulation (EEC) No 2309/93. The Management Board emphasised that it should become a CPMP working party.

The working party is composed of representatives of the Member States, the European Parliament, the European Commission and observers from the European Pharmacopoeia and from the Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries (CADREAC). The working party liases with learned societies and draws upon available expertise in the development and manufacturing of such products.

Mandate

The main thrust of the working party is to facilitate Mutual Recognition of marketing authorisations in the field of herbal medicinal products and to minimise CPMP arbitrations:

- By creating a forum for exchange of experience in the field of herbal medicinal products among Member States;
- By providing guidance for Competent Authorities for the assessment of herbal medicinal products;
- By providing guidance for applicants to Marketing Authorisations for herbal medicinal products.

To serve these purposes, the following tasks will be continued:

- development of new guidance and common criteria for interpretation how to adequately prove quality, safety and efficacy of herbal medicinal products, with particular reference to:
  - new scientific data;
  - well established use of herbal medicinal products as referred to in bibliographic applications for marketing authorisations making use of scientific literature, WHO, ESCOP and European Pharmacopoeia monographs where they exist.

- establishment and regular update of a common understanding of existing legislation and guidelines.
  In particular the working party will discuss:
  - the suitability of relevant parts of the Notice to Applicants;
  - the application of Community legislation on well established medicinal products to herbal medicinal products;
  - existing provisions in the Good Manufacturing Practice of herbal medicinal products and starting materials;

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- existing quality, safety and efficacy guidelines;
- the need to further develop European Pharmacopoeia monographs in collaboration with the European Pharmacopoeia.

- give advice upon request of the Mutual Recognition Facilitation Group (MRFG) and upon the request of the CPMP in case of arbitration on herbal medicinal products.

- give advice, upon request, to the European Commission on relevant proposals for legislative amendments.

Outcome of activities

- Any scientific guideline produced by the HMPWP on quality, safety and efficacy, which is adopted by the CPMP will be published on the EMEA website under the relevant CPMP WP, as for any other CPMP guideline, making reference to the work done by the HMPWP. The European Commission will then include the guidelines in the publication "Rules governing medicinal products in the European Union" for implementation by the Member States.

- Any other herbal specific document not approved by the CPMP will be published on the EMEA website under a separate window. The following disclaimer will be added to the window and in the document concerned: *"The views presented in this document are those of the HMPWP, which has been created as a forum for exchange of experience in the field of herbal medicinal products. This document is released for the purposes of transparency and has no legal force with respect to [Council Directive 65/65/EEC]."*

- Draft texts related to legislative matter or to the Notice to applicants (NTA) will be first circulated to the European Commission before being subject to consultation with Interested Parties. Final documents will be forwarded to the European Commission.

- Once a year the working party will exchange information, in public hearings, with relevant scientific European Learned Societies and Associations interested in the field of herbal medicinal products.

- The workplan of the HMPWP will be reflected in the framework of the EMEA Work Programme adopted by the Management Board.

- The working party will report annually on its activities in the framework of the EMEA Annual Report adopted by the Management Board.