The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PUBLIC STATEMENT

Meeting of the EMEA Working Party on Herbal Medicinal Products

31 May-1 June 1999, EMEA London

In accordance with its mandate for 1999 adopted by the EMEA Management Board on 10 February 1999 (attached), the EMEA Working Party on Herbal Medicinal Products met at the EMEA offices in London on 31 May-1 June 1999. This was the seventh meeting of representatives from Members States, from the European Commission and European Parliament to continue ongoing activities on herbal medicinal products initiated by the previous ad hoc working group. In addition to observers from the European Pharmacopoeia, the working party welcomed new observers from Hungary, Poland and Romania present on behalf of all other CADREAC countries.

The European Commission representative updated members of the working party on current proposals for legislative initiatives clarifying in particular the requirements for bibliographic applications. Comments received by the EMEA Secretariat on the documents released for consultation in January 1999 were reviewed by the working party. The Note for guidance on specifications: test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products (EMEA/HMPWG/19/99), comments on the Commission Regulation (EC) No. 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation (EMEA/HMPWG/20/99), comments on the CPMP Note for guidance on stability testing after Type II variations to a marketing authorisation (EMEA/HMPWG/21/99) and comments on the European Commission guideline on dossier requirements for Type I variations (EMEA/HMPWG/22/99) were finalised.

An update of other draft documents (EMEA/HMPWG/17/99, EMEA/HMPWG/18/99 and EMEA/HMPWG/23/99) was prepared and will be made available by the EMEA. Finalisation of these documents will depend on the availability of the final versions of the 'European Parliament and Council Directive on Good Manufacturing Practice (G.M.P) guide for starting materials of medicinal products and inspection of manufacturers' and of the proposed amendment to modify the Annex of Council Directive 75/318/EEC regarding well-established medicinal use.

The working party heard a presentation from the European Society of Ethnopharmacology on its goals and activities, and agreed to continue to develop its contacts with learned societies and academic institutions. An exchange of information also took place with the Proprietary Association of Japan, which expressed a vivid interest in the activities of the working party.

The next meeting of the working party is scheduled for 28-29 October 1999, during which a public hearing with interested parties will take place to review the work achieved so far by the group and to anticipate future tasks as outlined in the attached mandate. During this meeting the working party will focus on its review of ESCOP monographs and the preparation of respective core-SPCs.

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MANDATE FOR THE EMEA WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

Introduction

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 in 1997 to address the issue of quality, safety and efficacy of these products. The group was composed of representatives of the Member States, of the European Parliament, the European Commission and observers from the European Pharmacopoeia. The group liased with the CPMP and integrated learned societies and industry's expertise in the development and manufacturing of such 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 the present mandate for the group to become a permanent working party of the EMEA. The report and mandate will be made available on the EMEA Internet site.

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;
  - 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 to the European Commission on relevant proposals for legislative amendments.

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Outcome of activities

- The working party will prepare on a regular basis draft proposals for update of existing requirements and guidelines to be released by the EMEA. Draft texts will be circulated first within the EMEA to the CPMP as well as to the European Commission. Unless serious objections are raised, these drafts will be released for consultation with Interested Parties (European learned societies such as ESCOP, Trade Associations such as AESGP, Health Professional and Consumer Organisations, etc...) and made public. After review of comments received during the consultation period from Interested Parties, the working party will prepare final documents for publication by the EMEA after consultation with the CPMP and European Commission. The European Commission will then include relevant texts in Volume 3 of the Rules governing medicinal products in the European Union for implementation by the Member States.
- 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 working party will present a yearly report to the EMEA Management Board on its activities, with proposals for new initiatives which will highlight, for the different actions, their respective timeframe and required resources, for recommendation to the European Commission, the Member States and to the EMEA, respectively. This yearly report will also be circulated to the European Parliament.

Meeting requests for 1999

The working group will meet on three occasions in 1999:

- 18-19 January 1999 (held)
- 31 May-1 June 1999 focusing on the finalisation of draft guidelines and on the preparation of core-SPCs for various herbal medicinal products based on the evaluation of ESCOP monographs and bibliographic data.
- October 1999 (to be announced) focusing on the continuation of the above activities and on the annual public hearing.

Availability of proper expertise in the field of pharmaceutical quality, preclinical and clinical safety and efficacy is necessary. When needed, Heads of Agencies will be requested to provide additional expertise through relevant experts to be invited.