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

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CPMP Working Party on Herbal Medicinal Products
Work programme 2004-2005

I. Meetings scheduled for 2004-2005

2004
- 2-3 February 2004
- 3-4 June 2004
- 8-9 November 2004

Two additional meeting dates were identified for April and September, to allow preparatory work by the HMPWP for the implementation of the future Directive on traditional herbal medicinal products, but these are subject to further confirmation.

2005
Dates to be determined.

II. Product related issues (such as support to Marketing Authorisation Assessment, Post-marketing Data Evaluation, Scientific Advice, Protocol Assistance).

The following table provides, the expected number per year of contribution (number of involvement in dossier) for Scientific Advice, Protocol Assistance, Product Assessment and Post-Authorisation issue (pharmacovigilance issue related to a product or a class of product).

	Expected contribution in Scientific Advice	Expected contribution in Protocol Assistance	Expected contribution in Product Assessment	Expected contribution in Post-authorisation issue
HMPWP	0	0	0	Pharmacovigilance Referrals

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III. CXMP Guidance documents

1. Quality-related guidance documents

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.

- Points to Consider on the biopharmaceutical characterisation of herbal medicinal products
  Action: Document to be finalised after receipt of comments from Interested Parties (release for consultation in July 2003)

- Compilation of general quality questions answered by the HMPWP (EMEA/18123/00)
  Action: Constant update of the Q/A-document in the light of new questions and criteria, and inform QWP accordingly

- Points to consider on good agricultural and collection practice for starting materials of herbal origin (EMEA/HMPWP/31/99)
  Action: Document to be revised on the basis of the final WHO guideline on Good Sourcing Practices (expected end of 2003)

- Contribution to quality (specifications) related aspects of the review of applications for orphan-drug designation carried out by COMP (with whom a formal collaboration has been established).
  Action: HMPWP to provide quality comments on herbal medicinal products' specifications, upon request from COMP Secretariat

2. Safety-related guidance documents

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.

- CPMP List of herbal drugs with serious risks dated October 1992
  Action: HMPWP to carry out a revision/update of the List according to the strategy adopted by CPMP in September 2003

- HMPWP Position paper on pulegone containing herbal medicinal products
  Action: AR to be prepared by Rapporteur and discussed by HMPWP

- HMPWP Position paper on menthofuran containing herbal medicinal products
  Action: AR to be prepared by Rapporteur and discussed by HMPWP

- HMPWP Position paper on Quassin *(Quassia amara)* containing herbal medicinal products
  Action: to be prepared by Rapporteur and discussed by HMPWP

- HMPWP Position paper on Hypericine *(Hypericum perforatum)* containing herbal medicinal products
  Action: to be prepared by Rapporteur and discussed by HMPWP

- Note for guidance on non-clinical testing of herbal drug preparations with long-term marketing experience - guidance to facilitate mutual recognition and use of bibliographic data (EMEA/HMPWG/11/99)
  Action: Document to be updated after publication of final CPMP Note for guidance on the non - clinical documentation of medicinal products with well-established use (CPMP/SWP/799/95)

3. Pharmacovigilance related issues

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.

The HMPWP will address relevant pharmacovigilance issues relevant to herbal medicinal products, in particular those under review by the PhVWP.

4. Efficacy-related guidance documents

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.

- Core-data following assessment of ESCOP monographs
  Action: Preparation of core-data according to agreed timetable. Release on the EMEA Website of draft core-data for consultation and of final core-data for information. Status Report on core-data and assessment reports prepared by the HMPWP to be updated constantly according to progress.

- SOP "Recording of core-data for herbal drugs/products"
  Action: Constant update of the document taking into account experiences gathered during drafting core-data

IV. ICH Guidelines and activities

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.
N/A

V. EU Regulatory Activities

Guidelines should be classified in the following order: guidelines to be finalised after consultation period, guidelines to be released for consultation, New Topic/CP to be prepared.

- Proposal for a Directive of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use
  Action: HMPWP to prepare for the implementation of the directive

- Proposal for a future EU List (database) of herbal substances, preparations and combinations with traditional indications
  Action: HMPWP to prepare proposals for the possible format of such list, on the IT requirements for EU database and to reflect on future content of this list in anticipation of coming into force of new directive

- Updated draft Points to consider on the Evidence of Safety and Efficacy required for Well-established Herbal Medicinal Products in Bibliographic applications (EMEA/HMPWP/23/99).
  Action: Document to be updated. Update of the document following progress on the Directive on traditional herbal medicinal products and taking into account CPMP guidance documents.

- Draft concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs (EMEA/HMPWP/1156/03)
  Action: Document to be updated following receipt of comments from Interested Parties. Update of the document following progress on the Directive on traditional herbal medicinal products

- Draft Well-Established use Justification Template for Applicants in the Centralised Procedure (EMEA/H/34646/02)
  Action: HMPWP to follow up ORGAM discussions

- Draft Advisory note to Assessors in addressing Well-Established Use for bibliographical applications in the Centralised Procedure (EMEA/H/34647/01)
  Action: HMPWP to follow up ORGAM discussions

- Draft EC Directive on Food supplements
  Action: HMPWP to monitor the consequences for herbal products after of the Directive entered into force

VI. Activities with external parties

1. European Pharmacopoeia

- The Working party will collaborate with Eur. Ph. on the Procedure for the "Certification of suitability to the monographs of the European Pharmacopoeia" for herbal substances and herbal preparations, whenever necessary.

- The HMPWP will provide comments on monographs issued by the European Pharmacopoeia, which are related to herbal medicinal products.

2. **Interested Parties** (e.g. Learned Societies, Public health Stake Holders -Public health professionals, Patients' organisations-, Pharmaceutical Industry Representatives)

- The HMPWP will hold its annual Hearing with European Interested Parties at the last meeting of each year (AESGP, EFPIA, EHPM, EGA, ESCOP, Europam, SEE, GA, CPEM, EHPA, ECPM**,** PGEU, BEUC, EFNMU, IAPO – See list in Annex 1).
- The HMPWP will review the scope and format for the organisation of such hearings in order to improve its impact in terms of transparency, better exchange of information and implementation of decisions.
- The HMPWP will monitor the publication in identified scientific journals of final documents from the working party.

3. Interaction with scientific community

Interaction with scientific community will be initiated as necessary with regard to arising scientific issues and guidelines.

4. Interaction with WHO

- Investigation is to be sought on the possibility to get the participation of a permanent observer from WHO

- Co-operation with WHO Traditional Medicine (TRM), Department of Essential drugs & Medicines Policy (EDM)
  Action: On request of WHO, HMPWP will comment on draft WHO documents making reference to EU scientific guidelines and legislation

- WHO Training program for competent authorities in developing countries
  Action: On request of WHO, HMPWP will contribute by referring WHO to experts from EU Member states

VII. Organisational matters

1. List of adopted organisational documents (e.g. mandate, template, SOP)
   - Mandate for the Herbal Medicinal Products Working Party (EMEA/HMPWP/4/99)

2. List of organisational documents to be developed in the forthcoming 2 years.
   - Development of several **databases** as foreseen in the future directive on traditional herbal medicinal products

3. List of proposed scientific guidelines for the next work programme/work plan.
   - See section III.

European Interested Parties / Annual hearing of the HMPWP

Industry Associations

AESGP, European Proprietary Medicines Manufacturers' Association

EFPIA, European Federation of Pharmaceutical Industries and Associations

EHPM, European Federation of Associations of Health Product Manufacturers

EGA, European Generic medicines Association

Scientific Societies

ESCOP, European Scientific Cooperative on Phytotherapy

Europam, European Herb Growers Association

S.E.E., European Society of Ethnopharmacology

G.A., Society for Medicinal Plant Research

Healthcare professional and Consumers Organisations

CPEM, Standing Committee of European Doctors

EHPA, European Herbal Practitioners Association

PGEU, Pharmaceutical Group of the European Union

BEUC, Bureau Européen des Unions de Consommateurs

EFNMU, European Federation of Natural Medicine Users

ECPM, European Council of Doctors for Plurality in Medicine

IAPO, International Alliance of Patients Organisations