European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11-12 November 2004

The Chairman welcomed to the Committee on Herbal Medicinal Products the newly appointed member from Hungary Pharm. Zsuzsanna Biró-Sándor and alternate from Norway Pharm. Gro Fossum as well as the European Commission representative Dr Birka Lehmann. The Committee noted the appointment of an alternate member for Denmark Pharm. Kristine Hvolby. Information about the HMPC composition is published on the EMEA website.
http://www.emea.eu.int/htms/general/contacts/HMPC.html

The Committee adopted its rules of procedure, available publicly on the EMEA website.
http://www.emea.eu.int/pdfs/human/hmpc/13980004en.pdf

The HMPC further discussed the co-option of members with a view to complementing the scientific expertise available in the Committee. The Committee adopted a procedure for the nomination and appointment of three co-opted members in the following fields:

- clinical pharmacology (covering expertise in methodology)
- paediatric medicines
- toxicology.

The Committee agreed to consider the appointment of two additional co-opted members in the course of 2005, following further investigation of the Committee's needs in terms of expertise in traditional medicines including Traditional Chinese Medicine.

Meeting dates for 2006 were provisionally agreed and are presented in Annex.

The Committee discussed the "European Medicines Agency Road Map to 2010: Preparing the Ground for the Future" and proposed some amendments to the document in order to better reflect the competence of the Committee on Herbal Medicinal Products into the Agency's new responsibilities.
http://www.emea.eu.int/htms/hotpress/mb9216004.htm

The Committee discussed the set up of a list of parties with an interest at European level in herbal (traditional) medicinal products, with whom to establish contacts as foreseen in the above-mentioned rules of procedure. The Committee had a preliminary discussion on relevant criteria for the selection of such parties. Whilst it still needs to refine these criteria, the Committee invites any organisation (Association, Federation, Council, etc..) to express their willingness to be regarded as an interested party to the HMPC. It is worth noting that EU representativity is an essential criterion for any organisation considering to come forward.
Responses to this invitation for the identification of interested parties to the HMPC should be addressed to hmpc.secretariat@emea.eu.int.

The Committee is considering means to *actively* communicate about its activities. This will be further discussed after the list of the above-referred interested parties has been established.

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In relation to the establishment of an EMEA procedure to ensure appropriate coordination between scientific committees of the Agency, the Committee agreed on several means to exchange information with the CHMP Quality Working Party.

The Committee was informed about ongoing discussions at EU level about products containing herbal substances and preparations and so called borderline products (e.g. cosmetics and food supplements apart from herbal medicinal products).
The Committee took note of the publication by the European Food Safety Authority (EFSA) of the document "Botanicals and botanical preparations widely used as food supplements and related products: coherent and comprehensive risk assessment and consumer information approaches".
http://www.efsa.eu.int/science/sc_commitee/sc_documents/616/scdoc_advice03_botanicals_en1.pdf

Outcome of drafting group meetings

Concerning its working methodology, the Committee supported continuation of the work by drafting groups during meetings scheduled prior to the start of the plenary session.

Results from the first meeting of the drafting groups can be summarised as follows:

The **drafting group on organisational matters** listed the obligations of the Committee laid down in the pharmaceutical legislation. The Committee agreed to a number of priority tasks derived from the provisions of Title IV of Regulation (EC) 726/2004 that entered into force in May 2004 and from the provisions of Directive 2001/83/EC as amended. This includes setting up procedures for providing a scientific opinion and advice to the Member States and European Institutions on any questions relating to herbal medicinal products.

As far as advising undertakings on the conduct of tests and trials necessary to demonstrate the quality, safety and efficacy of herbal medicinal products, the Committee agreed to prepare as much guidance documents as possible for publication on the EMEA website. However should a specific request be received -not addressed in such general guidance-, the Agency would reply, acting through its scientific committees within their respective remits and after ensuring appropriate coordination.

A number of templates and forms will be developed to support the Committee's tasks arising from provisions of Directive 2001/83/EC as amended, including Standard Operating Procedures for the drafting of the List of herbal substances, preparations and combinations thereof and establishment of Community herbal monographs.

Following recommendations from the **drafting group on quality**, the Committee discussed options for the release by the Committee of guidance on quality. It was agreed to build on the guidance documents developed by the Herbal Medicinal Products Working Party (HMPWP). From the preliminary analysis carried out by the drafting group, it seems that no fundamental changes are expected to be required in the published guidelines. However, it was acknowledged that the Committee would need to verify whether they provide sufficient guidance to applicants for traditional use registration on the quality requirements to be met. Clarification on certain provisions and their interpretation might be helpful to applicants, especially when considering complex traditional combination products.

The **drafting group on safety and efficacy** highlighted the preparation of guidance to applicants for the preparation of traditional use registration applications as a key task. The Committee preliminary discussed several scientific questions in relation to some of Directive 2004/24/EC's requirements. Upon finalisation of the Committee's opinion, these scientific issues will be made known to future applicants in the format of either specific guidelines or in a general Questions & Answers document depending on the extend of the matter.

Requirements where the Committee's interpretation is expected are for example those concerning vitamins and minerals in traditional herbal medicinal products, data to demonstrate 30 years of medicinal use, data on plausibility of pharmacological effects, safety data, etc... Practical guidance would also be needed concerning corresponding products, external use and combination products as referred to in Directive 2004/24/EC.
http://pharmacos.eudra.org/F2/eudralex/vol-1/DIR_2004_24/DIR_2004_24_EN.pdf

Existing guidance from the HMPWP on the level of evidence to demonstrate the safety and efficacy of herbal medicinal products will be revisited with a view to releasing the Committee's conclusions on the borderline between herbal medicinal products with a well-established use and traditional herbal medicinal products.

For further information, please contact:

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HMPC Meeting dates in 2006

10-11-12 January
7-8-9 March
10-11-12 May
11-12-13 July
5-6-7 September
24-25-26 October

