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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 23-24 September 2004

The inaugural meeting of the Committee on Herbal Medicinal Products took place on 23 September in the presence of major contributors to the development and adoption of Directive 2004/24/EC as referred to in the press release of 27 September.

<http://www.emea.eu.int/Press%20Office/presshome.htm>

The composition of the Committee is available on the EMEA website.

<http://www.emea.eu.int/htms/general/contacts/HMPC.html>

Under the chairmanship of the newly elected chairman, Dr Keller, the Committee on Herbal Medicinal Products discussed on 23 and 24 September a number of topics, mostly related to the organisation of the Committee and the prioritisation of its tasks.

Organisation of the Committee

The Committee discussed the rules of procedure of the HMPC. Once adopted, these rules of procedure will be made publicly available. The Committee also took note of the EMEA Policy on the handling of conflicts of interests and the EMEA Code of Conduct that guarantee the impartiality and independence of Committee members, alternates and experts.

Dates for meetings in 2005 were agreed and are presented in annex.

The Committee had a first discussion on the appointment of co-opted members to complement the scientific expertise available in the Committee through members and alternates. Members were invited to express their views on the specific scientific areas that most require additional expertise.

The Committee held a preliminary discussion on the future development at the EMEA of a procedure to ensure an appropriate coordination between the scientific committees of the Agency as referred to in both Regulation (EC) No 726/2004 and Directive 2004/24/EC. Various aspects of the coordination were considered and further discussion will be required to identify the requirements of the Committee in this respect.

<http://pharmacos.eudra.org/F2/eudralex/vol-1/home.htm>

The Committee reviewed the 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' (EMEA/18442/04) under public consultation until 8 December. <http://www.emea.eu.int/pdfs/general/direct/pr/6281804en.pdf>

The Committee concluded that all features of the procedure might not be relevant to the entire work of the Committee, especially during the transitional period until October 2005 when pressure is high that the Committee delivers a great number of guidance documents in a short timeframe. Further discussion is expected in November 2004.

Working methodology and priorities

The Committee reviewed a number of points of interpretation of Directive 2004/24/EC based on feedback received from the European Commission.

An initial debate was held by the Committee on the prioritisation of its future tasks, with a preliminary discussion on how to find a suitable working methodology, allowing the Committee to address many of the priorities emerging at the level of the Member States and those arising directly from Directive 2004/24/EC.

The Committee will aim at targeting the most urgent tasks amongst which stand:

- 1- preparatory work for the establishment of the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products;
- 2- preparation of draft Community herbal monographs for herbal medicinal products with a well-established use;
- 3- preparatory work in the area of procedures to be established in relation to the adoption by the Committee after October 2005 of opinions at the request of either Member States or the Committee for Medicinal Products for Human Use;
- 4- clarification on the requirements related to the content of a dossier for a registration application;

Examples of areas where clarification is necessary include:

- the format and content of the bibliographic review of safety data and expert report required as part of the documentation supporting an application for registration
 - the bibliography or expert evidence on the medicinal use throughout a period of at least 30 years (format and type of evidence) to support a registration application
 - demonstration that the pharmacological effects or the efficacy are made plausible on the basis of long-standing use and experience
- 5- clarification on the status of guidance prepared by the Herbal Medicinal Products Working Party (HMPWP) between 1997 and 2004.

The Committee decided to set up three temporary working groups to review available guidance, prepare for their update if deemed necessary and identify missing parts of guidance in the light of the above-mentioned priority tasks, in the following fields:

- Quality
- Safety and Efficacy
- Organisational matters.

These groups will report during the next plenary meeting scheduled for 11-12 November 2004, during which the Committee aims to define next steps in the preparation of key guidance documents.

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HMPC Meeting dates in 2005

27-28 January

22-23 March

31 May - 1 June

21-22 July

19-20 September

22-23 November