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ESCOP SECTION

The New Committee for Herbal Medicinal Products—HMPC

On 30 April 2004, Directive 2004/24/EC on traditional herbal medicinal products was published in the Official Journal of the European Union and entered into force on the same day. Besides the option of a simplified registration procedure for traditional herbal medicinal products, which has to be implemented into national laws, the Directive has established a Committee for Herbal Medicinal Products which is part of the EMEA, the European Agency responsible for the evaluation of medicinal products. One of the main tasks of the new Committee will be the preparation of Community herbal monographs for herbal medicinal products in the area of the "well-established medicinal use" as well as the preparation to establish such monographs for traditional herbal medicinal products. Furthermore, the Committee will prepare a draft list of herbal substances, preparations and combinations thereof which will be eligible for a simplified registration procedure without the need to submit own data on safety and duration of traditional use.

According to the Directive, each Member State of the European Union shall appoint for a 3-year term one member and one alternate to the Committee, the term of office may be renewed. The alternates represent and vote for the members in their absence. All of them are chosen for their role and experience in the evaluation of herbal medicinal products. Furthermore, five additional members with specific scientific competence may be co-opted to the Committee, with the same term of office as the members.

On 23 and 24 September 2004, the inaugural meeting of the new Committee HMPC was held at the EMEA in London. At the meeting, Dr. Konstantin Keller (Germany) was elected as chairman and Dr. Heribert Pittner (Austria) as vice-chairman. Dr. Keller was the chairman of the Herbal Medicinal Products Working Party (HMPWP) between 1997 and 2004, Dr. Pittner was vice-chairman between 2002 and 2004. Dr. Pittner is also member of the Committee for Medicinal Products for Human Use (CHMP) at the EMEA.

In its future meetings the HMPC, besides its legal task to prepare monographs as well as the traditional list, is expected to prepare further guidance on quality, safety and efficacy of herbal medicinal products, based on the results elaborated so far by the HMPWP. During the last two meetings of the HMPWP, a number of documents have been drafted either as a final version or as a draft, which shall briefly be described as follows:

In its meeting on 1–2 April 2004, the HMPWP finalised the position statement on chamomilla-containing herbal medicinal products (EMEA/HMPWP/345/03). In spite of several comments which had been submitted, a sentence was included that some cases of anaphylactic shock or asthma have been reported for chamomilla-containing products.

A draft position paper on the use of herbal medicinal products containing pulegone and menthofuran (EMEA/HMPWP/52/04) was prepared which comes to the conclusion that for peppermint oil or mint oil no certain cases of toxicity have been reported and therefore no immediate actions are proposed, but alerted pharmacovigilance of these substances is recommended. The group furthermore regarded a limit for menthofuran in the monograph for mint oil of the European Pharmacopoeia appropriate. The use of pennyroyal oil (*Mentha pulegium* L. or *Hedeoma pulegoides* (L.) Pers) should be discouraged. This draft was open for comments until the end of August 2004.

The last meeting of the HMPWP took place on 3–4 June 2004. In this meeting, the position paper on the allergenic potency of herbal medicinal products containing soya or peanut protein (EMEA/HMPWP/37/04) was finalised. The allergenic potential of soya and peanut products orally used is regarded to be low due to the low protein content; however, specific information is considered to be necessary for oil preparations of soya and peanut which might contain traces of proteins. For this reason, the position paper recommends specific wordings for contraindications and side effects for products containing soya oil, peanut oil or soya lecithin.

The working party agreed on the "Position statement on the concomitant use of laxative bulk producers with medicinal products against diarrhoea"—(EMEA/HMPWP/60/04). In this statement, the group recommends to include a statement on the risk of interaction of bulk-forming laxatives with drugs known to inhibit gastrointestinal propulsive motility. Psyllium seed, Ispaghula seed, Ispaghula husk and Linseed belong to the group of bulk-forming laxatives. Unfortunately, this

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position paper was published without prior consultation of the interested parties, e.g. ESCOP.

The HMPWP furthermore updated its "Compilation of general quality questions answered by the HMPWP" (EMEA/HMPWP/18123/00) to include recommendations on an appropriate declaration of extracts in finished herbal medicinal products. Taking into consideration the three categories of the European Pharmacopoeia (standardised extracts, quantified extracts and other extracts), different options for the declaration of extracts are listed.

In the press release of the last meeting of the HMPWP, it was stated that the group would not be in a position to finalise a number of draft guidance documents released for consultation. It would be up to the new Committee to decide on the outcome of these documents. The working party documents published so far as final versions or as drafts as well as the press release from the inaugural meeting of the HMPC together with a list of the HMPC members can be found on the EMEA website www.emea.eu.int in the section "Human Medicines" in a specific window "Herbal Medicinal Products".

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