

ESCOP SECTION

New documents for the assessment of herbal medicinal products

The Herbal Medicinal Products Working Party (HMPWP) was founded at the European Agency for the Evaluation of Medicinal Products (EMA) in 1997 and is nowadays a permanent working party composed of representatives from health authorities of the European Member States, the European Parliament and the European Commission as well as of observers from the European Pharmacopoeia and from the CADREAC countries. At an earlier stage,¹ we reported about the main tasks of the working group regarding the development of new guidance and common criteria for an adequate proof of quality, safety and efficacy of herbal medicinal products. During the past few years, the group has finalised numerous documents in this field. After the new Directive on traditional herbal medicinal products was published in the Official Journal on 30 April 2004 of the European Union and set into force, a new Committee on Herbal Medicinal Products will now be founded which will be responsible for the assessment of all kinds of herbal medicinal products. In particular, the committee will have the task to prepare a draft list of traditional herbal substances, preparations and combinations thereof as well as to establish monographs for traditional and well-established herbal medicinal products. The existing working party consisting of competent experts from Europe is likely to be turned into the new Committee on Herbal Medicinal Products with potential slight changes in its composition and extension to representatives from the new accession countries of the European Union.

In its meeting on 2–3 February 2004, the working party finalised recommendations concerning the use of herbal medicinal products containing methyleugenol and estragole after review of comments which had been submitted by interested parties. After evaluation of mutagenicity and cancerogenicity studies with a 100–1000-fold dose administered to rats, the paper comes to the conclusion that there is no significant risk for

humans resulting from consumption of herbal medicinal products. However, further studies are considered necessary, and the group has expressed its opinion that exposure of estragole or methyleugenol, respectively, to sensitive groups such as children as well as pregnant and breastfeeding women should be minimised.

The following core-data which have been prepared on the basis of ESCOP monographs were finalised after review of the comments which had been submitted, e.g. by ESCOP and other interested parties:

- Salicis cortex (HMPWP/341/03)
- Primulae radix (HMPWP/243/03)
- Thymi herba (HMPWP/343/03)
- Menthae piperitae aetheroleum (HMPWP/1417/02)

Some modifications, e.g. regarding a contra-indication for children under 12 years of age as well as widening the scope of individual core-data to further relevant preparations available in the European market, have been included.

Furthermore, the group finalised the “Concept paper on the implementation of different levels of scientific evidence in core-data” (HMPWP/1156/03) adding a clarification that the grade and level of evidence of particular claims (major, medium and minor claims) relate to minimum requirements. As a consequence it seems clear now that clinical documents corresponding to level Ia or Ib might be used to support indications other than “serious diseases”.

The Standard Operating Procedure on “Recording of core-data for herbal drugs/herbal drug preparations” (SOP/HMPWP/41/01 Rev. 3) was revised in order to include a reference to the “Guideline on excipients in the label and package leaflet of medicinal products for human use” and to the need to put an appropriate warning on the label in case a herbal medicinal product contains alcohol.

The Working Party has prepared a draft position paper on the use of herbal medicinal products containing

¹Phytomedicine 2002;9:673.

Arachis oil and preparations from Soya bean. A potential allergenic risk of soya and peanut proteins based on reports of possible life-threatening type I reactions is discussed. Although the risk of soya and peanut products is considered low after oral consumption, it is proposed to discuss the necessity of label warnings, in particular for medications used in children (e.g. vitamin D preparations). Due to available data on cross-reactions, contra-indications for patients with known allergies to other legumes should also be included. Interested parties had been invited to submit comments on this draft by the end of May 2004.

According to the EMEA press release,² the group had a discussion with the EMEA on timelines and practical arrangements for the establishment of the new Committee in preparation of the implementation of the new Directive. For 2004, four further meetings are scheduled, of which two additional meetings are planned to allow preparatory work for the implementation of the Directive on traditional herbal medicinal products.

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²EMEA Press Release. Meeting of the Working Party on Herbal Medicinal Products. 2–3 February 2004 in London; EMEA/CPMP/HMPWP/533/04.