

EDITORIAL

The first HMPC community herbal monographs

The Committee on Herbal Medicinal Products (HMPC), has released some important new documents for public consultation which can be found on the EMEA website (www.emea.eu.int). Besides several technical guidance documents as well as public statements on the risk assessment of certain herbal substances, the first five draft Community herbal monographs and draft entries to the list of herbal substances, preparations and combinations thereof were adopted during the HMPC meeting in September 2005 and were released for consultation by interested parties until the end of January 2006:

Valerian root

Draft Community herbal monograph (EMEA/HMPC/340719/2005)

Draft entry to the list (EMEA/HMPC/340779/2005)

Linseed

Draft Community herbal monograph (EMEA/HMPC/340849/2005)

Draft entry to the list (EMEA/HMPC/340854/2005)

Ispaghula husk

Draft Community herbal monograph (EMEA/HMPC/340857/2005)

Ispaghula seed

Draft Community herbal monograph (EMEA/HMPC/340861/2005)

Psyllium seed

Draft Community herbal monograph (EMEA/HMPC/340865/2005)

According to the HMPC template for the preparation of monographs, all these draft monographs are structured as “double-track” monographs with headings and respective information on the well-established medicinal use on the left and on the traditional use on the right-hand side. Regarding the drafts on *Ispaghula husk* and *seed* as well as on *Psyllium seed*, however, they only contain information on the well-established medicinal use without a traditional use. For *Valerian root* and *Linseed*, the draft entries to the list correspond to the respective “traditional” columns of the monographs.

ESCOP, the European Scientific Cooperative on Phytotherapy, in principle appreciates these draft

documents because they represent current scientific knowledge and might serve as guidance on harmonized criteria for the evaluation of herbal medicinal products in Europe. From ESCOP’s viewpoint, however, the list of *Valerian* preparations attached to the one or the other area should be extended to further preparations for which a well-established or a traditional use, respectively, can be demonstrated by published literature. In general, many herbal preparations can be attached to both areas, always depending on individual data on indication, strength (including drug-extract ratio) and posology.

Further comments have been submitted on *Valerian root* within the 3-month consultation period, relating to the HMPC’s recommendation to avoid co-medication with other sedatives. In the areas of well-established and traditional use, combinations of Valerian with other herbal sedatives, e.g. Hops or *Passiflora* are commonly used.

In addition it has been suggested to delete or modify the test for valepotriates required by the draft monograph. Such a test is in contrast to the European Pharmacopoeia which does not include a test for valepotriates in *Valeriana radix*. Valepotriates are only relevant for *Valeriana mexicana* and *V. edulis*. Only traces occur in *Valeriana officinalis*, and these substances decompose rapidly.

Regarding the draft Community herbal monographs on *bulk-forming laxatives*, the wording of the therapeutic indications, which are exclusively attached to the well-established medicinal use, is considered very positive. Based on recent scientific knowledge and in accordance with ESCOP monographs, the indications for *Ispaghula husk* do not only cover the treatment of constipation and further conditions for the use of bulk-forming laxatives but also patients to whom an increased daily fibre intake may be advisable, e.g. in **irritable bowel** syndrome or as an adjuvant to diet in hypercholesterolemia.

However, the warnings given with a view to a potential throat obstruction in case the product is taken without a sufficient amount of fluid do not seem to be understandable for the patient/consumer and would prevent him from taking the product. For this reason, an alternative wording has been proposed. Furthermore,

there are some inconsistencies with a view to the posology as compared with the ESCOP monographs on *Ispaghula husk* and *seed*.

Regarding the draft monograph on *Linseed*, it has been suggested to include further indications which are supported by references, also in the area of traditional use. Furthermore, in accordance with scientific data, ESCOP has proposed to delete the recommendation not to use Linseed during pregnancy and lactation.

In the respective meeting reports published by the EMEA, progress of the Committee is reported regarding

the work on further draft monographs such as *Senna leaf* and *Senna fruit*. For the near future, draft monographs for *Barbados Aloes* and *Cape Aloes* as well as for *Frangula bark* are scheduled.

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