



Utilising potential: changing HMPC monographs

Background

Monographs compiled by the European Medicines Agency's (EMA) Committee on Herbal Medicinal Products (HMPC) include ones on traditional herbal medicinal products (traditional use (TU)) as laid down in Directive 2004/24/EC and those that fulfil the criteria for "well-established medicinal use" (WEU) as defined by Directive 2001/83/EC. The HMPC updates the monographs in the event of any changes in the state of knowledge or when new monographs are added.

Strategic evaluation

The database, that serves as an important HMP marketing authorisation and registration procedures in Europe, is augmented by new monographs and monograph amendments, and their interaction with the changing market and the further development of dosage forms. It is important that marketing authorisation holders and manufacturers of phytopharmaceuticals keep an eye on the HMPC monographs and evaluate their implications, in order to harness potential and detect effects on the product portfolio at an early stage.

THMPs – just old hat?

The pool of HMPC monographs has now become so extensive (169 monographs) that interesting new developments and positioning can still be achieved, if the creative possibilities are utilised in a constructive manner. Even monographs that are allegedly redundant in terms of indication are gaining value, given the growing need for international commercialisation. The pool is being supplemented by new plants as well, however, including the current draft monograph on rock rose (*Cistus*) for the indication "*relief of cough associated with cold*".

Pharmacopoeial monographs have not yet been compiled for some of the drugs in the HMPC pool, such as willowherb (*Epilobium*), ironwort (*Sideritis*) or cranberry. Although these are not yet available "off the shelf", anyone who has a genuine interest in these products will not regard this as being an obstacle, but will recognise the creative potential and opportunities that this situation can offer.

Monograph updates – new possibilities

The recently published draft update to the monograph on ginger root, for example, promises highly interesting possibilities for this popular drug, with two new indications: "*... relief of minor articular pain*" and "*... relief of symptoms of common cold*". Another example is the recent broadening of the indication for pelargonium root to include children aged 3 - 5 years (previously indicated for children aged 6 years or older).

With more than 30 years of successful experience in this field, we offer comprehensive advice on the development of new phytopharmaceuticals, from research and scientific advice to galenic and analytical development, dossier preparation and electronic submission.

Your contacts at PhytoLab:



Medical Affairs:
DR. HARTWIG SIEVERS
Phone +49 9163 88-154
hartwig.sievers@phytolab.de



Regulatory Affairs:
ANKE STEUBER
Phone +49 9163 88-446
anke.steuber@phytolab.de