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ESCOP Section

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Regulatory assessment of herbal medicinal products on a European level: The Herbal Medicinal Products Working Party (HMPWP)

According to the European legislative framework on medicinal products, herbal medicinal products in principle require a pre-marketing approval granted by the competent authority like all other medicinal products. However, herbal medicinal products in most cases contain well-known ingredients such as extracts, which have a long-term use in phytotherapy, and may therefore prove their effectiveness and safety on the basis of published scientific literature. Furthermore, due to their multi-component character, the active ingredients of herbal medicinal products, e.g. the extracts, show certain particularities during their manufacturing process and quality control. Although for herbal medicinal products the same requirements for marketing authorisation apply as for chemical products, besides a guideline related to the quality particular guidance taking into account the special characteristics of herbal medicinal products was lacking for a long time.

In order to create a forum for exchange of experience in the field of herbal medicinal products and to provide guidance for authorities and applicants regarding the assessment of herbal medicinal products, an ad-hoc working group was founded at the European Agency for the Evaluation of Medicinal Products (EMEA) in 1997. This group – meanwhile having received the status of a permanent working party of the EMEA – is 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. One of the main tasks of the working group is to develop new guidance and common criteria for interpretation how to adequately prove quality, safety and efficacy of herbal medicinal products. Particular reference is made to new scientific data and the well-established medicinal use of herbal medicinal products which may apply for marketing authorisation by bibliographic applications making use of scientific literature and e.g. WHO and ESCOP monographs. Further tasks are the establishment and regular update of a common understanding of existing legislation and guidelines, e.g. to discuss existing guidelines on quality, safety and efficacy and to develop further guidance in this field.

During the past few years, the Herbal Medicinal Products Working Party (HMPWP) has finalised many documents, e.g. the revision of the Note for Guidance on Quality of Herbal Medicinal Products as well as a Note for Guidance on Specifications, both published after adoption by the Committee on Proprietary Medicinal Products (CPMP) on the EMEA website. The working group finalised further documents, e.g. on the assessment of fixed combinations, on non-clinical testing of herbal drug preparations and on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin. Further documents have been drafted and released for consultation such as a paper on the evidence of safety and efficacy required for well-established herbal medicinal products as well as eight draft proposals for so-called core data on various commonly used medicinal plants and their preparations which were based on monographs on the medicinal use of these plants as proposed by ESCOP. In its March 2002 meeting, the HMPWP re-elected Dr. Konstantin Keller, Federal Institute for Drugs and Medical Devices, Germany, as chairman and elected Dr. Heribert Pittner, Federal Ministry of Social Security and Generations, Austria, as vice-chairman for a term of three years.

For the near future, the further discussion of guidelines on safety and efficacy, e.g. the assessment of further ESCOP monographs and preparation of core data is planned as well as the discussion of various quality and pharmacovigilance issues. Further details as well as all working documents can be obtained from the EMEA website (www.emea.eu.int) through a specific window for the documents of the HMPWP.

ESCOP has prepared detailed comments on the recently published draft core data and – on the basis of ESCOP's evaluation of scientific literature – has proposed an extension of e.g. the sections on indications, dosage forms and pharmacological properties. When further draft core data become available in the near future, ESCOP will take the opportunity to submit suggestions and thus support the work of the HMPWP in establishing common criteria for the assessment of herbal medicinal products.

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