

EDITORIAL

Scientific Evaluation of Herbal Medicinal Products by the HMPC

On 31 May/1 June and on 21/22 July 2005, the Committee on Herbal Medicinal Products (HMPC), which was founded in September 2004, met for the 5th and the 6th time, respectively, at the offices of the European Agency for the Evaluation of Medicinal Products (EMA). A number of guidance documents has been elaborated by the Committee's drafting groups on organisational matters, on quality and on safety and efficacy. As far as finalised by the Committee, these documents have been made available on the EMA website for public consultation (www.ema.eu.int).

The revised *Guideline on quality of herbal medicinal products/traditional herbal medicinal products (CPMP/QWP/2819/00 Rev 1)* updates an existing *Note for Guidance on quality of herbal medicinal products*, now including traditional herbal medicinal products as well. According to the draft, all general principles of quality also apply to traditional herbal medicinal products. Regarding e.g. stability testing, the recommendations given in the existing guideline have not been changed. Another revised draft, the *Guideline on specifications: Test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (CPMP/QWP/2820/00 Rev 1)*, also updates an existing *Note for Guidance* by introducing new definitions and clarifications as well as by including traditional herbal medicinal products according to Directive 2004/24/EC. As the scope of this Directive also covers herbal products, which may additionally contain vitamins or minerals, specific aspects linked to such mixtures are described. Regarding quality standards and consumer safety, a further *Draft public statement on Good Agricultural and Collection Practice for starting materials of herbal origin (EMA/HMPC/246816/2005)* has been published which is based on the existing Points to Consider on Good Agricultural and Collection Practice. It is intended to be used as a basis for the establishment of an appropriate quality assurance system and addresses specific concerns of growing, collecting and primary processing of medicinal plant material.

In order to enable consistent preparation of two different types of monographs within the Committee

(well-established medicinal use as well as traditional use), two documents describing the procedure for the preparation of Community monographs have been published (*EMA/HMPC/182352/2005* and *EMA/HMPC/182320/2005*, respectively). Like e.g. in ESCOP monographs, a structure according to a summary of product characteristics is recommended. Regarding therapeutic indications for herbal medicinal products with a well-established medicinal use, a standard statement "herbal medicinal product..." is proposed, followed by a specific statement, e.g. "for the treatment of...", "for the symptomatic treatment of...", "for the prevention of...", etc. The indications for traditional herbal medicinal products are introduced by "herbal medicinal product traditionally used..." together with a statement that the product is a traditional herbal medicinal product for use in specified indications exclusively based on long-standing use. Further paragraphs include information on posology and method of administration, contraindications, warnings, undesirable effects and further risk information, if required, as well as pharmacological properties for well-established medicinal use products. The latter information is not required for traditional herbal medicinal products unless such data are relevant for the safe use of the product.

The preparation of monographs for individual plant preparations has already started, e.g. on *Valerianae radix*, *Lini semen* and *Plantaginis ovatae testa*. Rapporteurs were appointed for further plants for which bibliographic references had been made available by ESCOP during the past years for assessment and compilation of core-data by the former Working Party.

From the scientific point of view, a new *Draft guideline on the clinical assessment of fixed combinations of herbal substances/ herbal preparations (EMA/HMPC/166326/2005)* seems to be most interesting. It is intended to provide guidance on how to structure the clinical documentation of fixed-combination products, and is applicable for well-established medicinal use as well as for traditional herbal medicinal products. Well-established fixed-combination products must be based on valid therapeutic principles, for traditional herbal

medicinal products; however, the fixed combination must be plausible. In the latter case, considerations related to safety will become more critical because due to the overall assessment of benefits and risks, because scientific evidence on efficacy is not required for traditional herbal medicinal products. Regarding well-established herbal medicinal products, the draft guideline mentions potential advantages of fixed combinations, e.g. an improvement of the benefit-risk-ratio due to an improved safety profile, a higher level of efficacy as compared to the single substances, or a simplification of therapy, but also certain disadvantages e.g. the problem to meet the needs of each individual patient.

Regarding the risk assessment of some herbal preparations, the Committee published a *Draft public statement on “CPMP list of herbal drugs with serious*

risks, dated 1992” (EMEA/HMPC/246736/2005) stating that this list which represents a useful source of information on plants which may have risks, should be published as such. It contains a number of plants for which serious risks but no accepted benefit exists from the health authorities’ point of view, e.g. *Teucrium chamaedrys* or *Rubia tinctorum*, and lists furthermore drugs with toxic principles where a more detailed discussion on the benefit-risk ratio seems to be necessary, e.g. some pyrrolizidinalkaloid-containing herbal drugs.

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