



Contents lists available at ScienceDirect

Phytomedicine

journal homepage: www.elsevier.de/phytomed

Editorial

ESCOP's role in defining a scientific foundation for herbal medicinal products

ESCOP, the European Scientific Cooperative on Phytotherapy, was founded as an umbrella organisation representing national phytotherapy or plant-based medicine associations across Europe, with the scope of strengthening the scientific status of herbal medicinal products and of supporting harmonisation of their regulatory status on a European level.

The Scientific Committee of ESCOP was established with the aim of compiling monographs on the medicinal use of individual plant drugs, primarily of those having European or national pharmacopoeia monographs which provide definitions and quality criteria. ESCOP monographs represent proposals for European monographs summarising the medicinal uses (efficacy) of plant drugs, beginning with its first series of publications in 1990. The current editions have the format of two books published in 2003 and in 2009 (*European Scientific Cooperative on Phytotherapy, 2003, 2009*). According to the earlier recommendation of the European Committee for Proprietary Medicinal Products (CPMP), the format adopted for the ESCOP texts is that of a "Summary of Product Characteristics" in accordance with the respective EU legislation. Since establishment of the European Medicines Agency (EMA, now EMA), ESCOP has formally submitted its monographs to EMA's Committees responsible for herbal medicinal products, who attributed a high scientific standard to them and considered them as an important part of the basis for a marketing authorization.

ESCOP monographs represent a comprehensive source of scientific information on herbal medicinal products which may be used by manufacturers, health authorities, universities, researchers, health professionals and numerous others. The consolidated effort of the academic members in the Scientific Committee, where each delegate is specialised in various aspects of medicinal plant science, provides relevant information for both prescribers and consumers. Each one of the fully referenced monographs includes information summarised under the following main headings: definition, constituents, clinical particulars (i.e. therapeutic indications, dosages, method and duration of administration, but also contraindications, special warnings and precautions, interactions and other clinical information), and pharmacological properties. The latter sub-heading is further subdivided into pharmacodynamic properties (*in vitro* and *in vivo*), clinical studies, pharmacokinetic properties as well as pre-clinical and clinical safety data. Each monograph thus provides comprehensive scientific information of relevance for assessing clinical efficacy, pharmacological effects, side effects and a safety profile of a herbal medicinal product, including its major constituents.

It should appear evident to ESCOP's readers that not each and every paper of the sometimes overwhelming amount of literature data published on an individual medicinal plant can be integrated into an ESCOP monograph. Therefore ESCOP carefully selects the most relevant papers, taking into account in particular recent findings and publications supporting the medicinal use of a herbal product. Negative or contradicting results and critical papers are of course thoroughly discussed. However, not all published pharmacological papers can be relevant for an ESCOP monograph, but rather those related to the assessment of safety and efficacy are considered most important. In case a broad spectrum of clinical studies of good quality is available, the monograph focuses mainly on this data and may omit e.g. the citation of certain *in vitro* studies of lower relevance, in order to provide evidence of efficacy clearly arranged and easily readable. Furthermore, a certain cut-off date has to be set, up to which the published results are integrated into a monograph because an additional timeframe is needed to finalise, supervise and edit a monograph and to prepare it for printing. Thus it is understandable that a certain lag time exists between the literature cut-off date and the publication date and that certain papers which have appeared within this period can no longer be incorporated into a finalized monograph.

The ESCOP monograph on *Capsici fructus* can serve as an example demonstrating how such a selection may operate: In this monograph "topical use" is proposed for the indications "relief of muscle pain; treatment of pain from osteoarthritis and rheumatoid arthritis; treatment of neuralgias; treatment of pruritus of different aetiology". As a consequence of being selective, studies on the underlying molecular mechanisms are mentioned only briefly as a summary in the final ESCOP monograph, and studies on internal or intravesical use as well as data on the intra-operative instillation of capsaicin were not included in the monograph. Due to the defined cut-off date for each monograph which was mid of 2008 for *Capsici fructus*, three important more recent studies could so far not be included in the finalised text published in 2009 (Barry et al., 2008; Simpson et al., 2008; Backonja et al., 2008). The latter shortcoming will be less likely to occur, if the cut-off date is closer to the effective publication date. This, however, will be possible in future once ESCOP monographs and revisions will appear as online publications.

Besides clinical studies, also older traditional information which can still be considered part of a historical scientific basis, is addressed and intentionally included for medicinal plants that have mainly or only "traditional" claims. Such information on a traditional use is important particularly in case the herbal substance is

described in an European or national pharmacopoeia. With regard to data on combinations, in principle such studies are not taken into consideration. In ESCOP monographs, the compilation of pharmacological studies focusses on those studies which relate to the indication for the respective single herbal drug.

In preparing drafts, the ESCOP Scientific Committee incorporates the views, knowledge and experience from different EU nationalities and from different scientific and professional backgrounds, such as medical doctors, phytochemists, pharmacognosists, pharmacologists, toxicologists, pharmacists, botanists and regulatory affairs specialists. The Committee also involves external experts into the preparation of a monograph and for discussion and critical evaluation of the data from available literature. These external experts mostly come from universities, but also from companies. In spite these experts from industry have a broad knowledge and experience on medicinal plants and their preparations and are considered extremely valuable contributors, this situation may have given rise to the idea that ESCOP monographs might not be free from influence of industry. However, all available knowledge on a herbal drug and all pharmacological and clinical data presented by each external expert is extensively discussed in a critical manner within the Committee. Finally, this leads to a scientifically sound evaluation of data and a balanced monograph.

Further guidance and criticism on the draft monographs is provided by the ESCOP Board of Supervising Editors, a panel of distinguished and eminent academic experts in the field of phytotherapy and medicinal plant research. They receive a pre-final draft monograph for a last critical check-up and send their comments to the Scientific Committee for a final discussion before the monograph is released for final editing and publication by ESCOP.

As a consequence and as expressed by the subtitle of the published books, the monographs provide “*the scientific foundation for herbal medicinal products*”. The purpose is to present a comprehensive overview and relevant information from a variety of studies

carried out on single herbal drugs and their preparations. However, the monographs do not necessarily aim to present a fully systematic and complete overview of all available literature. This is also due to the fact that literature sometimes provides a variety of data not arising from consistent and systematic investigations. In principle and for scientific reasons, completeness may always be desired. However, for a manageable text “less can sometimes be more!”

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