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ESCOP Section

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Traditional Herbal Medicinal Products: An update

At an earlier stage (1), we reported on the development of a new European Directive on traditional herbal medicinal products. This Directive will amend the existing European Directive 2001/83/EC which provides the basic requirements for marketing authorization of a medicinal product including the proof of quality, safety and efficacy. In addition to the existing system, the new provisions, which will probably form Articles 16a to 16h of the existing Directive, will introduce a simplified registration procedure for traditional herbal medicinal products which are harmless and of proven quality and whose efficacy is based on tradition and experience instead of clinical trials or reference to bibliographies. In any case, however, the applicant is obliged to present data on manufacture and quality control of the product in order to demonstrate an appropriate quality. For this new group of products, the applicant must present evidence on the traditional use of the product as well as a review of safety data together with an expert report unless the respective herbal substance is included in a specific list to be set up on a European level.

Following the debates in the European Parliament in November 2002, an amended proposal was adopted by the European Commission in April 2003. In this proposal, the European Commission adopted several important modifications:

- The competence of the new Committee for Herbal Medicinal Products will be extended including in particular the arbitration procedure for these products in the European decentralised marketing authorization system.
- Apart from herbal substances, the scope of the Directive and the option to use the simplified registration procedure will also comprise combinations of herbals with non-herbal ingredients. Thus, these products might contain vitamins or minerals or other substances with a mode of action that must be " ancillary" to that of the herbal active ingredients.
- Regarding the period of tradition, as a rule 30 years of use must be documented in total and at least 15 years in the Community. However, in terms of products coming from outside the Community and not being able to demonstrate these 15 years, the new Committee shall be empowered to analyse whether the available information on the use is sufficient.
- The statement on the label and in the leaflet which indicates the traditional use of the product will be re-worded without a disclaimer and state that safety and efficacy of the product rely exclusively on information obtained from its long-term use and experience instead of saying that clinical data is lacking. The same applies for the requirements on advertising.

Besides these developments on traditional herbal medicinal products, which are appreciated because they contribute to harmonization of the legislative framework for these products, it should be kept in mind that there are many authorized herbal medicinal products in the European market with a so-called "well-established medicinal use" demonstrating their safety and efficacy by bibliographic data according to the existing European Directives. Thus, the provisions of the new Directive for traditional medicinal products are applicable only for those products which do not fulfill the criteria stipulated by Directive 2001/83/EC. Monographs such as those compiled by ESCOP, however, represent a summary of the available evidence taking into account all available scientific literature on pharmacological and clinical studies and therefore being suitable for bibliographic applications. For this reason, it is of vital importance that the "well-established medicinal use" category for herbal medicinal products remain a basis for marketing authorizations in accordance with Directive 2001/83/EC, including the statements laid down in ESCOP monographs as an example for bibliographic data. The option of the "traditional use" category should therefore only apply to products for which "well-established medicinal use" as defined in the Directive cannot be demonstrated.

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Co-chairperson of the ESCOP Scientific Committee

(1) Phytomedicine 2002; 9 (6): 572.
(2) Amended proposal for a Directive of the European Parliament and of the Council amending the Directive 2001/83/EC as regards traditional herbal medicinal products, COM (2003) 161 final. 2002/0008 (COD). 9 April 2003.

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