



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS



CPME/AD/Exec/140602/14/EN/fr

At the request of the CPME Executive Committee (emergency issue), Brussels, 14th June 2002, the CPME adopted the following policy : **Comments on the proposed directive amending the directive 2001/083 instituting a Community code on medicinal products for human use as regards traditional herbal medicinal products** (CPME 2002/060 EN/fr)



**Comments on the proposed directive amending the directive 2001/83
instituting a Community code on medicinal products for human use as regards
traditional herbal medicinal products**

Executive Summary

CPME is very concerned about the proposal to promote a special simplified registration procedure for herbal medicinal products.

The mere long use of a product does not guarantee its safety nor does it say anything about its efficacy either.

Without proper testing it is sure that no information on the efficacy of the product could be given.

The proposed directive emphasises the importance of guaranteeing the quality and safety of herbal medicinal products. CPME underlines that public health and patient safety must be the first consideration of any legislation within this field. The highest quality and safety of medicinal products of whatever type (including the traditional herbal medicinal products) must be guaranteed to protect the health of EU citizen.

CPME is of the opinion that a dossier containing information relating to the results of physic-chemical, biological, microbiological results, must accompany **all** medicinal products. Pharmacological and toxicological tests as well as clinical trials should be carried out on the product proving its quality, safety and efficacy.

CPME urges the European Parliament to amend the proposal by removing mention of a special simplified registration procedure for traditional herbal medicinal products.



Introduction

On 17 January 2002, the European Commission presented a proposal for a directive aimed at adding a specific chapter referring to traditional herbal medicinal products to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

The declared goal of promoting a special simplified registration procedure for these medicinal products is to guarantee a level of harmonisation and, at the same time, to improve the health of European citizens as well as to facilitate the free circulation of these products.

To understand the scope of this proposal, it is appropriate to consider the means suggested to encourage the placing of these products on the market that, until now, has been subject only to national regulations. Such an initiative seems to be, broadly speaking, a suitable opportunity to coordinate procedures at the European level.

Guarantees

In the past, CPME has spoken about the problem of preparations of herbal medicinal products and has already expressed its own opinion on the review of the pharmaceutical legislation.¹

In this proposal there is an emphasis on the importance of guaranteeing amongst other things the quality and safety of medicinal products while recognising that applications for the authorisation to market a medicinal product, must in any case, be accompanied by a dossier containing information and documents relating in particular to the results of physico-chemical, biological, microbiological, pharmacological and toxicological tests and clinical trials carried out on the product and proving its quality, safety and efficacy.

'Competition' and 'health' are not always compatible

Also the European Commission recognises that, *"A significant number of medicinal products, despite their long tradition, do not fulfil the requirements of a well-established medical use with a recognised efficacy and an acceptable level of safety and are not eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted different procedures and provisions. These differences currently existing between the provisions laid down in the Member States may hinder trade in traditional medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products. They may also have an impact on the protection of public health since the necessary guarantees of quality, safety and efficacy are not always given at present."*

¹ In CPME 2001/049



CPME acknowledges these considerations and emphasizes that deliberations of an exclusively economic nature, which are solely aimed at protecting the interests of the small or medium-sized Community businesses, involved in marketing traditional herbal medicinal products, cannot and should not lead to prevarication in the face of the need for rigorous and absolute protection of citizens' health.

Evidence based?

The harmonization of procedures should not be more important than the quality of any medicinal product nor its safety. Efficacy, quality and safety of any pharmaceutical product should be ranked nr.1 and this is equally valid for traditional herbal medicinal products.

In the light of the preceding considerations, the text of the proposal introducing Chapter 2 a on specific provisions applicable to traditional herbal medicinal products arouses therefore well-founded and important concerns.

The requirements specified in article 16c to be fulfilled by the applicant in order to get a simplified registration and thus a marketing authorisation do not guarantee enough the safety and the quality of such products.

The proposed article 16c -1 point c) and 16c- 4 allow a marketing application for a product on the basis only of Community use for thirty years or for 15 years in case there is an additional period of use outside the Community, even though it might possibly have never been subject to scientific tests or trials.

Assuming that the quality and the safety requirement are met on the basis of a time-in-use-system does not protect adequately the interests of the patients/consumers.

Moreover, guaranteeing the quality and the safety of a product purely on the basis of simple experience and long-term use, without having ever tested the product in a proper way is clearly scientifically debatable.

No simplified registration

By proposing the directive it becomes clear that the legislator is concerned about the public health consequences of the traditional herbal medicinal products trade. However instead of setting as the standard an obligation for scientific tests and trials and regulating the registration procedures to be the same as those for all medicinal products for human use, he limits himself to terms of plausibility, about the debatable character of which there are still worrying and well-founded doubts.

Confining ourselves strictly to the principles of guarantees in terms of quality and safety of medicinal products of whatever type (including the traditional herbal medicinal products) we believe that it is required to amend the sections mentioned above.

CPME proposes the removal of the special simplified registration procedure for traditional herbal medicinal products. We must also ask that these products would be required to have adequate documentation about their efficacy and an acceptable safety level.



Even a long tradition of use, without tests and trials, cannot exclude possible well-founded fears concerning the safety, efficacy and toxicity of the product.

The quality of a traditional herbal medicinal product is definitely not certified by its long-term traditional use and therefore, it should not be granted exemption from the obligation to carry out the physico-chemical, biological and microbiological tests on it which are necessary and indispensable.

These are the indispensable presuppositions which, when used, enable good clinical practice for medicine based on the evidence of results to protect the health of citizens, guaranteed at the start by marketing reliable medico-health products.