COUNCIL DIRECTIVE 92/73/EEC

of 22 September 1992

widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas differences currently existing between the provisions laid down by law, regulation or administrative action in the Member States may hinder trade in homeopathic medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products;

Whereas the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health;

Whereas, despite considerable differences in the status of alternative medicines in the Member States, patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products;

Whereas the anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products;

Whereas the provisions of Directive 65/65/EEC (4) and the Second Directive 75/319/EEC (5), are not always appropriate for homeopathic medicinal products;

Whereas homeopathic medicine is officially recognized in certain Member States but is only tolerated in other Member States;

Whereas, even if homeopathic medicinal products are not always officially recognized, they are nevertheless prescribed and used in all Member States;

Whereas it is desirable in the first instance to provide users of these medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

Whereas the rules relating to the manufacture, control and inspection of homeopathic medicinal products must be harmonized to permit the circulation throughout the Community of medicinal products which are safe and of good quality;

Whereas, having regard to the particular characteristics of these medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient;

Whereas, however, the usual rules governing the authorization to market medicinal products should be applied to homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; whereas, in particular, those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

Article 1

1. For the purposes of this Directive, 'homeopathic medicinal product' shall mean any medicinal product

(1) OJ No C 108, 1. 5. 1990, p. 10 and OJ No C 244, 19. 9. 1991, p. 8.
(2) OJ No C 183, 15. 7. 1991, p. 322 and OJ No C 241, 21. 9. 1992.
(3) OJ No C 332, 31. 12. 1990, p. 29.
(4) OJ No 22, 9. 2. 1965, p. 369/65. Directive as last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).
(5) OJ No L 147, 9. 6. 1975, p. 13. Directive as last amended by Directive 89/341/EEC (OJ No L 142, 25. 5. 1989, p. 11).

prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

2. A homeopathic medicinal product may also contain a number of principles.

Article 2

1. The provisions of this Directive shall apply to homeopathic medicinal products for human use, to the exclusion of homeopathic medicinal products prepared in accordance with a magistral or an officinal formula as defined in Article 1 (4) and (5) of Directive 65/65/EEC and of homeopathic medicinal products which satisfy the criteria laid down in Article 2 (4) of the said Directive.

2. The medicinal products referred to in paragraph 1 shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter IV of Directive 75/319/EEC shall apply to the manufacture, control, import and export of homeopathic medicinal products.

Article 4

The supervision measures and the sanctions provided for in Chapter V of Directive 75/319/EEC shall apply to homeopathic medicinal products, together with Articles 31 and 32 of the same Directive.

However, the proof of therapeutic efficacy referred to in Article 28 (1) (b) of the same Directive shall not be required for homeopathic medicinal products registered in accordance with Article 7 of this Directive or, where appropriate, admitted in accordance with Article 6 (2).

Article 5

Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and marketed within the Community, and in particular the information referred to in Articles 30 and 33 of Directive 75/319/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorized in accordance with Articles 7, 8 and 9. Each Member State shall take due account of registrations and authorizations previously granted by another Member State.

2. A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic medicinal products referred to in Article 7. A Member State applying this provision shall inform the Commission accordingly. The Member State concerned shall, by 31 December 1995 at the latest, allow the use in its territory of homeopathic medicinal products registered by other Member States in accordance with Articles 7 and 8.

3. Advertising of the homeopathic medicinal products referred to in paragraph 2 of this Article and in Article 7 (1) shall be subject to the provisions of Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use [1], with the exception of Article 2 (1) of that Directive.

However, only the information specified in Article 7 (2) may be used in the advertising of such medicinal products.

Moreover, each Member State may prohibit in its territory any advertising of the homeopathic medicinal products referred to in paragraph 2 and in Article 7 (1).

Article 7

1. Only homeopathic medicinal products which satisfy all of the following conditions may be subject to a special, simplified registration procedure:

— they are administered orally of externally,

— no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto,

— there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.

[1] OJ No L 113, 30. 4. 1992, p. 13.