

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws of the Member States on medicinal products and laying down additional provisions on homeopathic medicinal products

COM(90) 72 final — SYN 251

(Submitted by the Commission on 23 March 1990)

(90/C 108/05)

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,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

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;

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

Whereas the provisions of Council Directive 65/65/EEC⁽¹⁾ and the Second Directive 75/319/EEC⁽²⁾, as last amended by Directive 89/341/EEC⁽³⁾, 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, therefore, it is appropriate to recognize certain national homeopathic traditions without imposing them throughout the Community)

Whereas even if homeopathic remedies 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 remedies with a clear indication of their homeopathic character and with sufficient guarantees of their quality and safety;

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

Whereas, having regard to the particular characteristics of these medicinal products, such as their very low content of active principles and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is appropriate to provide a simplified registration system for those traditional homeopathic medicinal products which are placed on the market without specific therapeutic indications in a preparation which does not present a risk for the patient;

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

⁽¹⁾ OJ No 22, 9. 2. 1965, p. 369/65.

⁽²⁾ OJ No L 147, 9. 6. 1975, p. 13.

⁽³⁾ OJ No L 142, 25. 5. 1989, p. 11.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope

Article 1

For the purposes of this Directive 'homeopathic medicinal product' shall mean any medicinal product prepared in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the official pharmacopoeia of a Member State.

Homeopathic preparations are produced from products, substances or compositions called homeopathic stocks by successive dilutions.

Article 2

1. The provisions of this Directive shall apply to industrially prepared 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 of Directive 65/65/EEC.

2. The medicinal products referred to in paragraph 1 must be identified by the inclusion on their labels in clearly legible form of the words 'homeopathic medicinal product'.

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 measures of supervision 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 effect mentioned 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.

Article 5

The 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 mentioned 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 marketed within the Community are registered or authorized in accordance with the provisions of Articles 7, 8 and 9. Each Member State shall take registrations and authorizations previously granted by another Member State into due consideration.

2. A Member State may refrain from establishing any system of registration or authorization for homeopathic medicinal products. A Member State applying this provision shall inform the Commission thereof. The Member State concerned shall allow the use in its territory of homeopathic medicinal products registered or authorized by other Member States in accordance with Articles 7, 8 and 9.

Article 7

1. Homeopathic medicinal products shall be subject to a simplified registration procedure if they satisfy all of the following conditions:

- they are administered orally or externally,
- they are marketed without any specific therapeutic indication, whether on the labelling of the product or in any accompanying product information,
- there is a sufficient degree of dilution to guarantee the safety of the preparation; in particular, the preparation shall contain less than one part per million of any active principle which is subject to the requirement of a medical prescription.

2. In addition to the clear mention of the words 'homeopathic medicinal product', the labelling and packaging of the homeopathic medicinal products referred to in paragraph 1 shall consist of the following information and no other information:

- the scientific name of the stock followed by the degree of dilution, using the symbols used in the official pharmacopoeia of the Community,

- name and address of the person responsible for marketing, and of the manufacturer,
- method of administration,
- expiry date, in plain language,
- special storage precautions, if any,
- manufacturer's batch number,
- registration number.

3. The criteria and rules of procedure provided for in Articles 5 to 12 of Directive 65/65/EEC shall apply to the simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic effect.

Article 8

An application for a simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch consistency of the products concerned:

- scientific name of the homeopathic stock, together with a mention of the various routes of administration, pharmaceutical forms and dilutions to be registered,
- dossier describing how the stock is obtained and controlled, and justifying its homeopathic nature, on the basis of an adequate homeopathic bibliography,
- manufacturing and control file for each pharmaceutical form and a description of the method of dilution,
- manufacturing authorization for the preparations concerned,

- copies of any registrations or authorizations obtained for the same preparations in other Member States,
- one or more specimens or mock-ups of the sales presentation of the preparations to be registered.

Article 9

1. Homeopathic medicinal products other than those referred to in Article 7 shall be authorized and labelled in accordance with the provisions of Articles 5 to 21 of Directive 65/65/EEC and Articles 1 to 7 of Directive 75/319/EEC, including the provisions concerning proof of therapeutic effect.

2. A Member State may lay down specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic medicinal products other than those referred to in Article 7. In this case, before the date referred to in Article 10 (1) the Member State concerned shall notify the Commission of the specific rules in force.

CHAPTER IV

Final provisions

Article 10

1. Member States shall take the measures necessary to comply with this Directive by 31 December 1992. They shall inform the Commission thereof forthwith.

The provisions adopted pursuant to the first subparagraph shall make express reference to this Directive.

2. Applications for registration or for marketing authorization for products covered by this Directive lodged after the date set out in paragraph 1 shall comply with the provisions of this Directive.

Article 11

This Directive is addressed to the Member States.