COUNCIL DIRECTIVE 92/74/EEC

of 22 September 1992

widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary 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 veterinary 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 veterinary medicinal products must be to safeguard human and animal health;

Whereas, despite considerable differences in the status of alternative medicines in the Member States, free choice of treatment should be guaranteed, provided all precautions are taken to ensure the quality of products;

Whereas the provisions of Directive 81/851/EEC (4) are not always appropriate for homeopathic veterinary 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 most 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 veterinary 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 specific therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the animal;

Whereas in the light of current knowledge it appears difficult to allow according to a special, simplified registration procedure the marketing of medicinal products intended to be administered to animals whose flesh or products are intended for human consumption; whereas, however, this question should be re-examined during the preparation of the overall report on the application of this Directive which has to be submitted by the Commission not later than 31 December 1995;

Whereas, however, the usual rules governing the authorization to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect; whereas Member States 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 for pet animals and exotic species, 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 veterinary medicinal product' shall mean any veterinary

(1) OJ No C 108, 1. 5. 1990, p. 13.
(2) OJ No C 183, 15. 7. 1991, p. 323 and OJ No C 241, 21. 9. 1992.
(3) OJ No C 332, 31. 12. 1990, p. 32.
(4) OJ No L 317, 6. 11. 1981, p. 1. Directive as amended by Directive 90/676/EEC (OJ No L 373, 31. 12. 1990, p. 15).

medicinal product 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 veterinary medicinal product may also contain a number of principles.

Article 2

1. The provisions of this Directive shall apply to homeopathic medicinal products for veterinary use.

This Directive shall not apply to homeopathic veterinary medicinal products which meet the conditions of Article 4 (4) of Directive 81/851/EEC; however, the withdrawal period referred to in the second subparagraph of that Article 4 (4) shall not apply with regard to homeopathic veterinary medicinal products in which the level of active principles is equal to or less than one part per million.

2. Without prejudice to Article 7 (2), the medicinal products referred to in paragraph 1 shall be identified by the inclusion on their labels, in clearly legible form, of the words 'homeopathic medicinal product for veterinary use'.

3. This Directive shall not apply to immunological homeopathic veterinary medicinal products, which shall be authorized by Member States in accordance with the provisions of Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products (1).

CHAPTER II

Manufacture, control and inspection

Article 3

The provisions of Chapter V of Directive 81/851/EEC shall apply to the manufacture, control, import and export of homeopathic veterinary medicinal products.

Article 4

The supervision measures and the sanctions provided for in Chapter VI of Directive 81/851/EEC shall apply to homeopathic veterinary medicinal products.

However, the proof of therapeutic effect referred to in Article 37 (1) (b) of the same Directive shall not be required for homeopathic veterinary 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 veterinary medicinal products manufactured and marketed within the Community, and in particular the information referred to in Articles 39 and 42 of Directive 81/851/EEC.

CHAPTER III

Placing on the market

Article 6

1. Member States shall ensure that homeopathic veterinary 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 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 veterinary 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 veterinary medicinal products registered by other Member States in accordance with Articles 7 and 8.

Article 7

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

— they are intended for administration to pet animals or exotic species whose flesh or products are not intended for human consumption,

— they are administered by a route described in the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States,

— no specific therapeutic indication appears on the labelling of the veterinary 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 veterinary prescription.

(1) OJ No L 373, 31. 12. 1990, p. 26.

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

2. In addition to the clear mention of the words 'homeopathic veterinary medicinal product without approved therapeutic indications', the labelling and, where appropriate, package insert for the medicinal products referred to in paragraph 1 shall bear the following information and no other information:

— the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used in accordance with Article 1 (1),

— name and address of the person responsible for marketing and, where appropriate, of the manufacturer,

— method of administration and, if necessary, route,

— expiry date, in clear terms (month, year),

— pharmaceutical form,

— contents of the sales presentation,

— special storage precautions, if any,

— target species,

— a special warning if necessary for the medicinal product,

— manufacturer's batch number,

— registration number.

3. The criteria and rules of procedure provided for in Articles 8 to 15 of Directive 81/851/EEC shall apply by analogy to the special, simplified registration procedure for homeopathic veterinary medicinal products, with the exception of the proof of therapeutic effect.

Article 8

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

— scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered,

— dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate homeopathic bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens,

— manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,

— manufacturing authorization for the medicinal products concerned,

— copies of any registrations or authorizations obtained for the same medicinal products in other Member States,

— one or more specimes or mock-ups of the sales presentation of the medicinal products to be registered,

— data concerning the stability of the medicinal product.

Article 9

1. Homeopathic veterinary medicinal products other than those referred to in Article 7 shall be authorized in accordance with the provisions of Articles 5 to 15 of Directive 81/851/EEC, including the provisions concerning proof of therapeutic effect, and labelled in accordance with Articles 43 to 50 of the same Directive.

2. A Member State may introduce or retain in its territory specific rules for the pharmacological and toxicological tests and clinical trials of homeopathic veterinary medicinal products intended for pet animals and exotic species whose flesh or products are not intended for human consumption, other than those referred to in Article 7 (1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.

In this case, 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 1993. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

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

3. Not later than 31 December 1995, the Commission shall present a report to the Council and to the European Parliament concerning the implementation of this Directive.

Article 11

This Directive is addressed to the Member States.

Done at Brussels, 22 September 1992.

For the Council

The President

R. NEEDHAM