COUNCIL DIRECTIVE

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

(90/677/EEC)

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 disparities in the provisions laid down by law, regulation or administrative action by Member States may hinder trade in immunological veterinary medicinal products within the Community;

Whereas the essential aim of any rules governing the production, distribution or use of veterinary medicinal products must be to ensure a high level of protection of public health;

Whereas the provisions of Directive 81/851/EEC (4) as last amended by Directive 90/676/EEC (5), although appropriate, are not adequate for veterinary medicinal products used in order to produce active immunity, to diagnose the state of immunity or to produce passive immunity (immunological veterinary medicinal products);

Whereas in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national provisions relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (6), the Commission is required to submit proposals to harmonize the conditions for authorizing the manufacture and placing on the market of immunological veterinary medicinal products;

Whereas, before an authorization to market an immunological veterinary medicinal product can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency;

Whereas the competent authorities should also be empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal disease;

Whereas changes will be required to the requirements for the testing of veterinary medicinal products laid down in Annex I to Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (7), as amended by Directive 87/20/EEC (8), to take account of the special nature of immunological veterinary medicinal products; whereas the Commission should be empowered to adopt the necessary changes in close cooperation with the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, thus ensuring greater quality, safety and effectiveness,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Subject to the provisions of this Directive, Directive 81/851/EEC shall apply to immunological veterinary medicinal products.

2. For the purposes of this Directive 'immunological veterinary medicinal product' means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.

3. This Directive and Directive 81/851/EEC shall not apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

4. Member States may provide that this Directive does not apply to non-activated immunological veterinary medicinal products of the type referred to in paragraph 3.

(1) OJ No C 61, 10. 3. 1989, p. 20 and OJ No C 131, 30. 5. 1990, p. 20.
(2) OJ No C 96, 17. 4. 1990, p. 111 and Decision of 21 November 1990 (not yet published in the Official Journal).
(3) OJ No C 201, 7. 8. 1989, p. 1.
(4) OJ No L 317, 6. 11. 1981, p. 1.
(5) See page 15 of this Official Journal.
(6) OJ No L 15, 17. 1. 1987, p. 38.
(7) OJ No L 317, 6. 11. 1981, p. 16.
(8) OJ No L 15, 17. 1. 1987, p. 34.

Article 2

1. The quantitative particulars of an immunological veterinary medicinal product shall be expressed by mass or by international units or by units of biological activity or by the number of germs or by specific protein content where possible, as appropriate to the product concerned.

2. In respect of immunological veterinary medicinal products, in Directive 81/851/EEC the expression 'qualitative and quantitative composition of the constituents' shall include particulars relating to biological activity or to protein content and the expression 'qualitative and quantitative composition' shall include the composition of the product expressed in terms of the biological activity or of protein content.

3. In any document established in accordance with Directive 81/851/EEC in which the name of an immunological veterinary medicinal product is expressed, the full common or scientific name of the active constituents shall also be included at least once.

Article 3

1. Member States shall take all appropriate measures to ensure that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are completely validated and batch-to-batch consistency is ensured, in accordance with Article 34 of Directive 81/851/EEC.

2. For the purpose of implementing Article 35 of Directive 81/851/EEC, Member States may require persons responsible for placing immunological veterinary medicinal products on the market to submit to the competent authorities copies of all the control reports signed by the qualified person in accordance with Article 30 of Directive 81/851/EEC.

The person responsible for placing immunological veterinary medicinal products on the market shall ensure that an adequate number of representative samples of each batch of finished products is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities on request.

3. Where it considers it necessary, a Member State may require persons responsible for placing immunological veterinary medicinal products on the market to submit samples from the batches of the bulk and/or finished product for examination by a State laboratory or an approved laboratory before entry in free circulation. In the case of a batch manufactured in another Member State, examined by the competent authority of another Member State and declared to be in conformity with national specifications, such a control may be carried out only after the control reports of the batch in question have been examined, after the Commission has been informed, and where the difference in veterinary conditions between the two Member States concerned justifies it. Except where the Commission has been informed that a longer period is necessary to complete the analyses, Member States shall ensure that any such examination is completed within 60 days of receipt of the samples. The person responsible for placing the product on the market shall be notified of the results of the examination within the same time limit. Before 1 January 1992, the Member States shall notify the Commission of the immunological veterinary medicinal products subject to compulsory official control before being placed on the market.

Article 4

In the absence of specific Community legislation concerning the use of immunological veterinary medicinal products for the eradication or control of animal disease, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

(a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals;

(b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

The competent authorities of the Member States shall inform the Commission of all instances in which the provisions of this Article are applied.

Article 5

The amendments which need to be made to the testing requirements for veterinary medicinal products set out in the Annex to Directive 81/852/EEC to take account of the extension of the scope of Directive 81/851/EEC to cover immunological veterinary medicinal products shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

Article 6

1. Member States shall take the necessary measures to comply with this Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

In the event of the amendments referred to in Article 5 not being adopted by 1 January 1991, the date indicated in the first subparagraph shall be put back to one year after the date of adoption of those amendments.

2. When Member States adopt the measures referred to in paragraph 1, 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.

3. Requests for marketing authorization for products covered by this Directive lodged after the date indicated in paragraph 1 must comply with the provisions of this Directive.

4. Within five years of the date indicated in the first subparagraph of paragraph 1, this Directive shall apply to existing immunological veterinary medicinal products.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1990.

For the Council

The President

P. ROMITA