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.