COUNCIL DIRECTIVE

of 3 May 1989

extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens

(89/342/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Hacing 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 products within the Community;

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

Whereas Directive 65/65/EEC (4), as last amended by Directive 87/21/EEC (5), and Second Directive 75/319/EEC (6), as last amended by Directive 83/570/EEC (7), on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, although appropriate, are inadequate for immunological medicinal products consisting of vaccines, toxins or serums and allergens;

Whereas, in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (8), the Commission is required to submit proposals to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of immunological medicinal products before 22 December 1987;

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

Whereas the Commission should be empowered to adopt any necessary changes in the requirements for the testing of proprietary medicinal products set out in the Annex to Council Directive 75/318/EEC of 20 May 1975 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 proprietary medicinal products (9), as last amended by Directive 87/19/EEC (10), to take account of the special nature of immunological medicinal products 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 Proprietary Medicinal Products Sector, thus ensuring greater quality, safety and efficacy,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. In derogation from Article 34 of Directive 75/319/EEC, and subject to the provisions of this Directive, Directives 65/65/EEC and 75/319/EEC shall apply to immunological medicinal products for human use consisting of vaccines, toxins or serums and allergen products.

2. For the purposes of this Directive, the following definitions shall apply:

— 'allergen product' shall mean any product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent,

— vaccines, toxins and serums shall have the meaning assigned to them in the Annex to Directive 75/319/EEC.

Article 2

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

(1) OJ No C 36, 8. 2. 1988, p. 25.
(2) OJ No C 290, 14. 11. 1988, p. 131; OJ No C 120, 16. 5. 1989.
(3) OJ No C 208, 8. 8. 1988, p. 64.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 15, 17. 1. 1987, p. 36.
(6) OJ No L 147, 9. 6. 1975, p. 13.
(7) OJ No L 332, 28. 11. 1983, p. 1.
(8) OJ No L 15, 17. 1. 1987, p. 38.
(9) OJ No L 147, 9. 6. 1975, p. 1.
(10) OJ No L 15, 17. 1. 1987, p. 31.