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.

2. In respect of immunological products in Directives 65/65/EEC and 75/319/EEC the expressions 'qualitative and quantitative particulars of the constitutents' shall also include particulars relating to biological activity or to protein content and 'qualitative and quantitative composition' shall include the composition of the product expressed in terms of biological activity or of protein content.

3. Whenever the name of an immunological medicinal product is expressed, the common or scientific name of the active constituents shall also be included.

Article 3

In addition to the information referred to in Article 4a of Directive 65/65/EEC the summary of product characteristics referred to in point 9 of the second subparagraph of Article 4 of Directive 65/65/EEC shall contain the following information in respect of immunological products:

— under point 5.4, information regarding any special precautions to be taken by persons handling the immunological medicinal product and persons administering it to patients, together with any precautions to be taken by the patient.

Article 4

1. Member States shall take all appropriate steps to ensure that the manufacturing processes used in the manufacture of immunological products are properly validated and attain batch-to-batch consistency.

2. For the purpose of implementing Article 8 of Directive 65/65/EEC and Article 27 of Directive 75/319/EEC, Member States may require manufacturers of immunological products to submit to a competent authority copies of all the control reports signed by the qualified person in accordance with Article 22 of Directive 75/319/EEC.

3. Where it considers it necessary in the interests of public health, a Member State may require persons responsible for marketing:

— live vaccines,

— immunological medicinal products used in the primary immunization of infants or of other groups at risk,

— immunological medicinal products used in public health immunization programmes,

— new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorization,

to submit samples from each batch of the bulk and/or finished product for examination by a State laboratory or a laboratory designated for that purpose before release on to the market unless, in the case of a batch manufactured in another Member State, the competent authority of another Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. Member States shall ensure that any such examiniation is completed within 60 days of the receipt of the samples.

Article 5

Any amendents which are necesssary in the testing requirements for medicinal products set out in the Annex to Directive 75/318/EEC to take account of the extension of the scope of Directives 65/65/EEC and 75/319/EEC to cover immunological medicinal products shall be adopted in accordance with the procedure laid down in Article 2c of Directive 75/318/EEC.

Article 6

1. Except as provided in paragraph 2, 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.

2. If the amendments to Directive 75/318/EEC referred to in Article 5 have not been adopted by the date referred to in paragraph 1, this Directive shall come into force on the same date as those amendments.

3. Requests for marketing authorizations for products covered by this Directive lodged after the date on which it comes into force must comply with the provisions of this Directive.

4. This Directive shall be progressively extended to existing immunological medicinal products before 31 December 1992.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1989.

For the Council

The President

P. SOLBES