# COUNCIL DIRECTIVE

## 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

(87/22/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

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

Whereas high-technology medicinal products requiring lengthy periods of costly research will continue to be developed in Europe only if they benefit from a favourable regulatory environment, particularly identical conditions governing their placing on the market throughout the Community ;

Whereas Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4), as last amended by Directive 83/570/EEC (5), makes provision for certain procedures for coordinating national decisions relating to the placing on the market of proprietary medicinal products for human use ; whereas pharmaceutical undertakings may, according to these provisions, request a Member State to take due account of an authorization already issued by another Member State ;

Whereas Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (6) makes provision for a procedure for coordinating national decisions relating to veterinary medicinal products ;

Whereas, however, these procedures are not sufficient to open up to high-technology medicinal products the large Community-wide single market they require ;

Whereas, in this technically advanced sector, the scientific expertise available to each of the national authorities is not always sufficient to resolve problems posed by high-technology medicinal products ;

Whereas it is consequently important to provide for a Community mechanism for concertation, prior to any national decision relating to a high-technology medicinal product, with a view to arriving at uniform decisions throughout the Community ;

Whereas it is desirable to extend this Community concertation to immunological products and substitutes for blood constituents developed by means of new biotechnological processes, and to new products based on radioisotopes, the development of which in Europe can only take place if a sufficiently large and homogeneous market exists ;

Whereas the need for the adoption of new technical rules applying to high-technology medicinal products or for the amendment of existing rules must be examined during a preliminary concertation between the Member States and the Commission within the competent Committees so as not to endanger the advance of pharmaceutical research whilst at the same time ensuring optimum protection of public health within the Community,

HAS ADOPTED THIS DIRECTIVE :

*Article 1*

Before taking a decision on a marketing authorization or on the withdrawal or, subject to Article 4 (2), suspension of a marketing authorization in respect of the medicinal products listed in the Annex, Member States' authorities shall, in accordance with Articles 2, 3 and 4, refer the matter for an opinion to the Committees referred to in Article 8 of Directive 75/319/EEC and Article 16 of Directive 81/851/EEC.

*Article 2*

1. As soon as they receive an application for marketing authorization relating to a medicinal product referred to in the Annex (Lists A and B), the competent authorities shall, at the request of the person responsible for placing the product on the market, bring the matter before either

(1) OJ No C 293, 5. 11. 1984, p. 1.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 147, 9. 6. 1975, p. 13.
(5) OJ No L 332, 28. 11. 1983, p. 1.
(6) OJ No L 317, 6. 11. 1981, p. 1.

the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, in accordance with their competence, for an opinion. Any such request shall be submitted in writing to the competent authorities concerned at the same time as the application for marketing authorization and a copy shall be sent to the Committee concerned.

2. As soon as they receive an application for marketing authorization relating to a medicinal product developed by means of new biotechnological processes and referred to in List A in the Annex, the competent authorities shall be required to bring the matter before the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, in accordance with their competence, for an opinion.

3. Paragraph 2 shall not apply if, when submitting the application for marketing authorization, the applicant certifies to the competent authorities of the Member State concerned that :

(i) neither he nor any other natural or legal person with whom he is connected has, during the preceding five years, applied for authorization to place a product containing the same active principle(s) on the market of another Member State ; and

(ii) neither he nor any other natural or legal person with whom he is connected intends, within the five years following the date of the application, to seek authorization to place a product containing the same active principle(s) on the market of another Member State.

In this case, the competent authorities shall notify the appropriate Committee of the application and forward to it a summary of product characteristics as described in Article 4a of Directive 65/65/EEC (1), as last amended by Directive 87/21/EEC (2) or an equivalent document provided by the applicant if a proprietary medicinal product referred to in the second paragraph of Article 34 of Directive 75/319/EEC or a veterinary medicinal product is involved.

If, within five years of the first application, one or more subsequent applications for authorization to place a product containing the same active principle derived from the same route of synthesis on the market are made to the competent authorities of the other Member States by the person responsible for placing the original product on the market or with his consent, that person shall forthwith in form the competent authorities of the Member State to whom the first application was made and the matter shall be brought before the appropriate Committee for an opinion.

(1) OJ No 22, 9. 2. 1965, p. 369/65.
(2) See page 36 of this Official Journal.

4. Where the Committee has, in accordance with this Directive, issued a favourable opinion on the placing on the market of a high-technology medicinal product, the competent authorities shall refer the matter to the Committee for a new opinion before deciding on the withdrawal or, subject to Article 4 (2), suspension of the marketing authorization for the medicinal product in question.

5. The competent authorities or the Commission may also consult the Committee for Proprietary Medicinal Products on any technical question concerning the proprietary medicinal products referred to in the second paragraph of Article 34 of Directive 75/319/EEC.

6. The competent authorities or the Commission may also consult the Committee for Veterinary Medicinal Products on any technical question concerning the veterinary medicinal products referred to in the second and third indents of Article 2 (2) of Directive 81/851/EEC.

*Article 3*

1. The representative of the Member State which initiated the procedure referred to in Article 2 shall act as rapporteur and shall provide all information relevant to the evaluation of the medicinal product. Information thus disclosed shall strictly confidential.

2. The person responsible for placing the medicinal product in question on the market shall immediately be informed of the referral to the Committee. He may, at this own request, provide the Committee with oral or written explanations.

3. When placing the matter before the Committee, the Member State concerned shall ensure that the person responsible for placing the medicinal product on the market transmits to all the members of the Committee an identical summary of the dossier consisting of the summary of the product characteristics together with the reports of the analytical, pharmaco-toxicological and clinical experts.

In addition, a complete and updated copy of the dossier for the application for marketing authorization lodged with the Member State or Member States concerned shall be transmitted to the Committee by the person responsible for placing the product on the market, who shall certify that all the dossiers submitted to the competent authorities and to the Committee in respect of the medicinal product in question are identical.

4. All available evaluation reports and drug-monitoring reports relating to the same medicinal product shall be forwarded to the Committee by the authorities of the Member States and by the person responsible for placing the product in question on the market.