COUNCIL DIRECTIVE

of 21 December 1988

relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

(89/105/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 marketing authorizations for proprietary medicinal products issued pursuant to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4), as last amended by Directive 87/21/EEC (5), may be refused only for reasons relating to the quality, safety or efficacy of the proprietary medicinal products concerned;

Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products; whereas such measures include direct and indirect controls on the prices of medicinal products as a consequence of the inadequacy or absence of competition in the medicinal products market and limitations on the range of products covered by national health insurance systems;

Whereas the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; whereas, however, such measures should also be intended to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends;

Whereas disparities in such measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products;

Whereas the objective of this Directive is to obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States; whereas this information should be public;

Whereas, as a first step towards the removal of these disparites, it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto; whereas, however, these requirements do not effect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products; whereas these requirements also do not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive;

Whereas the further harmonization of such measures must take place progressively,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive.

2. The definition of 'medicinal products' laid down in Article 1 of Directive 65/65/EEC shall apply to this Directive.

3. Nothing in this Directive shall permit the marketing of a proprietary medicinal product in respect of which the authorization provided for in Article 3 of Directive 65/65/EEC has not been issued.

(1) OJ No C 17, 23. 1. 1987, p. 6 and OJ No C 129, 18. 5. 1988, p. 14.
(2) OJ No C 94, 11. 4. 1988, p. 62 and OJ No C 326, 19. 12. 1988.
(3) OJ No C 319, 30. 11. 1987, p. 47.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 15, 17. 1. 1987, p. 36.

Article 2

The following provisions shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product:

1. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed.

2. Should the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria. In addition, the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

3. At least once a year, the competent authorities shall publish in an appropriate publication, and communicate to the Commission, a list of the medicinal products the price of which has been fixed during the relevant period, together with the prices which may be charged for such products.

Article 3

Without prejudice to Article 4, the following provisions shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities:

1. Member States shall ensure that a decision is adopted on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization to increase the price of a medicinal product and communicated to the applicant within 90 days of its receipt. The applicant shall furnish the competent authorities with adequate information including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information.

   In case of an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the period.

   In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to apply in full the price increase requested.

2. Should the competent authorities decide not to permit the whole or part of the price increase requested, the decision shall contain a statement of reasons based on objective and verifiable criteria and the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

3. At least once a year, the competent authorities shall publish in an appropriate publication and communicate to the Commission, a list of the medicinal products for which price increases have been granted during the relevant period, together with the new price which may be charged for such products.

Article 4

1. In the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. Within 90 days of the start of this review, the competent authorities shall announce what increases or decreases in prices are being made, if any.

2. In exceptional cases, a person who is the holder of a marketing authorization for a medicinal product may apply for a derogation from a price freeze if this is justified by particular reasons. The application shall contain an adequate statement of these reasons. Member States shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. Should the derogation be granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Should there be an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the initial period.

Article 5

Where a Member State adopts a system of direct or indirect controls on the profitability of persons responsible for placing medicinal products on the market, the Member State concerned shall publish the following information in an appropriate publication and communicate it to the Commission:

(a) the method or methods used in the Member State concerned to define profitability: return on sales and/or return on capital;

(b) the range of target profit currently permitted to persons responsible for placing medicinal products on the market in the Member State concerned;

(c) the criteria according to which target rates of profit are accorded to an individual responsible for placing medicinal products on the market, together with the criteria according to which they will be allowed to retain profits above their given targets in the Member State concerned;

(d) the maximum percentage profit which any person responsible for placing medicinal products on the market is allowed to retain above his target in the Member State concerned.

This information shall be updated once a year or when significant changes are made.

Where, in addition to operating a system of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products which are excluded from the scope of the profit control scheme, Articles 2, 3 and 4 shall, where relevant, apply to such price controls. However, the said Articles shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.

Article 6

The following provisions shall apply if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list of medicinal products covered by the national health insurance system.

1. Member States shall ensure that a decision on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorization to include a medicinal product in the list of medicinal products covered by the health insurance systems is adopted and communicated to the applicant within 90 days of its receipt. Where an application under this Article may be made before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, or where a decision on the price of a medicinal product and a decision on its inclusion within the list of products covered by the health insurance system are taken after a single administrative procedure, the time limit shall be extended for a further 90 days. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the time limit shall be suspended and the competent authorities shall forthwith notify the applicant of what detailed additional information is required.

   Where a Member State does not permit an application to be made under this Article before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, the Member State concerned shall ensure that the overall period of time taken by the two procedures does not exceed 180 days. This time limit may be extended in accordance with Article 2 or suspended in accordance with the provisions of the preceding subparagraph.

2. Any decision not to include a medicinal product in the list of products covered by the health insurance system shall contain a statement of reasons based upon objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of the remedies available to him under the laws in force and of the time limits allowed for applying for such remedies.

3. Before the date referred to in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists.

4. Within one year of the date referred to in in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission a complete list of the products covered by their health insurance system, together with their prices fixed by the national competent authorities. This information shall be updated at least once every year.

5. Any decision to exclude a product from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

6. Any decision to exclude a category of medicinal products from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication.

Article 7

The following provisions shall apply if the competent authorities of a Member State are empowered to adopt

decisions to exclude individual or categories of medicinal products from the coverage of its national health insurance system (negative lists).

1. Any decision to exclude a category of medicinal products from the coverage of the national health insurance system shall contain a statement of reasons based upon objective and verifiable criteria and be published in an appropriate publication.

2. Before the date referred to in Article 11 (1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to exclude an individual medicinal product from the coverage of the national health insurance system.

3. Any decision to exclude an individual medicinal product from the coverage of the national health insurance system shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time limits allowed for applying for such remedies.

4. Within one year of the date referred to in Article 11 (1), the competent authorities shall publish in an appropriate publication and communicate to the Commission a list of the individual medicinal products which have been excluded from the scope of its health insurance system. This information shall be updated at least every six months.

Article 8

1. Before the date referred to in Article 11 (1), Member States shall communicate to the Commission any criteria concerning the therapeutic classification of medicinal products which are used by the competent authorities for the purposes of the national social security system.

2. Before the date referred to in Article 11 (1), Member States shall communicate to the Commission any criteria which are used by the competent authorities in verifying the fairness and transparency of the prices charged for transfers within a group of companies of active principles or intermediate products used in the manufacture of medicinal products or finished medicinal products.

Article 9

1. In the light of experience, the Commission shall, not later than two years after the date referred to in Article 11 (1), submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to, or distortions of, the free movement of proprietary medicinal products, so as to bring this sector closer into line within the normal conditions of the internal market.

2. The Council shall decide on the Commission proposal not later than one year after its submission.

Article 10

1. A Committee called the 'Consultative Committee for the implementation of Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems' shall be set up and attached to the Commission.

2. The tasks of the committee shall be to examine any question relating to the application of this Directive which is brought up by the Commission or at the request of a Member State.

3. The committee shall consist of one representative from each Member State. There shall be one deputy for each representative. This deputy shall be entitled to participate in meetings of the committee.

4. A representative of the Commission shall chair the committee.

5. The committee shall adopt its rules of procedure.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1989 at the latest. They shall forthwith inform the Commission thereof.

2. Before the date referred to in paragraph 1, Member States shall communicate to the Commission the texts of any laws, regulations or administrative provisions relating to the pricing of medicinal products, the profitability of manufacturers of medicinal products and the coverage of medicinal products by the national health insurance system. Amendments and modifications to these laws, regulations or administrative provisions shall be communicated to the Commission forthwith.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1988.

For the Council
The President
V. PAPANDREOU