ADVISORY OPINION OF THE COURT
24 November 1998*

(Pricing of pharmaceutical products – general price decrease – price control system)

In Case E-2/98

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by Héraðsdómur Reykjavíkur (Reykjavík City Court) for an Advisory Opinion in the case pending before it between

Federation of Icelandic Trade (*Samtök verslunarinnar - Félag íslenskra stórkaupmanna, FÍS*)

and

The Government of Iceland and the Pharmaceutical Pricing Committee (*Lyfjaverðsnefnd)*

on the interpretation of Council Directive 89/105/EEC of 21 December 1988.

THE COURT,

composed of: Bjørn Haug, President, Thór Vilhjálmsson and Carl Baudenbacher (Judge-Rapporteur), Judges,

Registrar: Gunnar Selvik,

* Language of the Request for an Advisory Opinion: Icelandic.

after considering the written observations submitted on behalf of:

– the plaintiff, represented by Counsel Baldvin Hafsteinsson;

– the defendant, the Government of Iceland, represented by Einar Gunnarsson, Legal Officer in the Ministry of Foreign Affairs, Directorate of External Trade, acting as Agent and assisted by Martin Eyjólfsson, Legal Officer in the Ministry for Foreign Affairs, Directorate of External Trade, and Einar Magnússon, Director of Pharmaceutical Affairs in the Ministry of Health and Social Security of Iceland;

– the Government of Norway, represented by Morten Goller, Office of the Attorney General (Civil Affairs), acting as Agent;

– the Government of the Netherlands, represented by Marc Fierstra and Corinna Wissels, Legal Advisers in the Ministry of Foreign Affairs, acting as Agents;

– the Government of the United Kingdom, represented by John Collins, Treasury Solicitor's Department, acting as Agent and assisted by David Pannick;

– the EFTA Surveillance Authority, represented by Páll Ásgrímsson, Officer, Legal & Executive Affairs, acting as Agent;

– the Commission of the European Communities, represented by Richard Wainwright, Principal Legal Adviser, and Michael Shotter, a national official seconded to the Commission under an arrangement for the exchange of officials, acting as Agents;

having regard to the Report for the Hearing,

after hearing the oral observations of the plaintiff, the Government of Iceland, the Government of Norway, the Government of the Netherlands, the EFTA Surveillance Authority and the Commission of the European Communities at the hearing on 1 October 1998,

gives the following

Advisory Opinion

Facts and procedure

1 By an order dated 4 March 1998 and a request dated 17 April 1998, registered at the Court on 23 April 1998, Héraðsdómur Reykjavíkur (Reykjavík City Court) of Iceland made a Request for an Advisory Opinion in a case brought before it between the Federation of Icelandic Trade and the Government of Iceland and the Pharmaceutical Pricing Committee.

2 The questions submitted by the national court concern the interpretation of Council Directive 89/105/EEC of 21 December 1988, relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems[1] (hereinafter the "Directive"), referred to in Point 9 of Chapter XIII of Annex II to the EEA Agreement.

3 The case before the national court concerns the validity of a decision of the Pharmaceutical Pricing Committee of 22 November 1996. Pursuant to that decision, the maximum wholesale price of pharmaceuticals the cost price of which was equal to or less than 1000 Icelandic crowns was to be increased by 1.77%, while the price of those of which the cost price was 3000 Icelandic crowns or higher was to be lowered by 2.65%.

4 The background for the decision was the result of a comparative study on the wholesale prices of four selected high-selling pharmaceuticals. The wholesale prices in Iceland were found to be higher (20% to 117%) compared to the average wholesale prices in three other Nordic countries. At meetings of the Committee, the plaintiff's representative in the Committee was informed of the Government's objective to economize ISK 250 million in the pharmaceutical field for the year 1997 and of the Committee's proposal for gradually decreasing the mark-up in wholesale pricing.

5 The Committee had estimated that it would lead to an overall reduction in the income of wholesalers of pharmaceuticals amounting to ISK 46 207 754, assuming no changes in the total turnover of pharmaceuticals. This measure was part of efforts to prevent an increase in State expenditure on pharmaceuticals.

6 The plaintiff's claims before the national court are to ask for an annulment of the above decision and for the payment of costs. The defendants ask the national court to reject the plaintiff's claims and to rule on costs in their favour.

7 The relevant national provisions are the Pharmaceutical Act No. 93/1994 (*Lyfjalög* – hereinafter the "Pharmaceutical Act"), in particular Article 1(1) and

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1 OJ No. L 40, 11.2.1989, p. 8.

Chapter XIV and the Rules No. 501/1996 relating to determination of prices of pharmaceuticals (*Reglugerð um ákvörðun lyfjaverðs* – hereinafter the "Rules"). Before the national court the plaintiff submits that Article 8 of the Rules, which confer power on the public authority to ask, on its own motion, for an amendment of previously-determined pharmaceutical prices, confers power on the authority in excess of what is stipulated in the Pharmaceutical Act. The plaintiff further submits that Article 8 of the Rules contravenes Article 2 of the Directive, which provides that the public authority must accept or reject a certain price proposed by the applicant. The plaintiff considers it necessary that a provision of the Directive provide for the possibility of an independent review of a decision.

Questions

8 Considering that it was necessary to interpret provisions of the EEA Agreement in order to reach a decision and pursuant to Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, Héraðsdómur Reykjavíkur submitted a request to the EFTA Court for an Advisory Opinion on the following questions:

1.a Does Council Directive 89/105/EEC, in particular Articles 2 and 3, apply to circumstances where a competent authority, empowered to approve the maximum prices of pharmaceuticals, decides, on its own motion, to decrease by 2.65% the wholesale prices of all prescribed pharmaceuticals which are subject to provisions regarding marketing authorization following the approval by a competent authority of a certain price, and which are subject to provisions regarding authority to increase prices, following the approval thereof by a competent authority, and which cost more than 3000 Icelandic crowns, for the purpose of lowering the prices of pharmaceuticals to the public in accordance with prices in neighbouring countries and to reduce State expenditure on pharmaceuticals?

b. Is such a unilateral decision by a competent authority in conformity with Council Directive 89/105/EEC?

c. Does it affect the answer to the question if it is possible to apply for price increases for particular products despite the general decision to decrease wholesale prices?

2.a Is Article 2(2) of Council Directive 89/105/EEC to be interpreted to the effect that a unilateral decision by a competent authority, such as the one referred to in question 1, amounts to a rejection by the

authority for marketing of a pharmaceutical product at a particular price?

b. If so, and if it is possible to apply for a price increase for particular products despite the general decision to decrease wholesale prices, does this affect the requirements for the reasoning by the competent authority, the information regarding legal measures available to the wholesaler and the time-limits available?

9 The order of Héraðsdómur Reykjavíkur was appealed to the Supreme Court of Iceland under a summary procedure pursuant to Article 1(3) of Act No. 21/1994 regarding requests to the EFTA Court for an advisory opinion on the interpretation of the EEA Agreement. By a judgment of 1 April 1998, the Supreme Court upheld the order.

10 Reference is made to the Report for the Hearing for a more complete account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

Findings of the Court

11 Before the specific questions referred to the Court are addressed, a general discussion of the aim and purpose of the Directive may be helpful. As acknowledged in the Preamble to the Directive, measures of an economic nature on the marketing of medicinal products, including direct and indirect controls on the prices of medicinal products, have the primary objective of promoting public health, but such measures, or disparities between such measures between Contracting Parties, may hinder or distort intra-EEA trade in medicinal products and thereby affect the common market.

12 More recently, positive measures have been taken to further harmonization. The Directive in question is such a measure, but it has a limited objective. Its aim is only to ensure transparency and grant certain procedural guarantees to all participants in the pharmaceutical market. These procedural guarantees are intended to ensure that all concerned may verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto within the meaning of Article 30 EC and Article 11 EEA. While distortive measures have been challenged under Article 30 EC, which corresponds to Article 11 EEA (Case C-249/88 *Commission* v *Belgium* [1991] ECR I-1275), there is nothing that indicates that Article 11 EEA would apply in the circumstances of this case. The Directive lays down a series of requirements in Articles 1 to 5, the relevance of which depends on the system in place in each of the Contracting Parties and the nature of the measure.

13 In light of the background to the Directive, it is clear that it is only a first step towards the removal of disparities between the national pricing arrangements which may hinder or distort trade between Contracting Parties in medicinal products. The Directive does not affect the price-setting policies of the Contracting Parties. Therefore, under the Directive, a Contracting Party is free to adopt measures to control public health expenditure on medicinal products, provided that those measures are in line with the transparency requirements of the Directive.

14 With its first question, the national court essentially seeks to know whether a unilateral decision to decrease the wholesale prices of pharmaceuticals falls under the scope of the Directive and, if so, whether such a unilateral decision is in conformity with the requirements of the Directive. In particular, the national court makes reference to Articles 2 and 3 of the Directive. Although the national court did not specifically raise the question whether Article 4 of the Directive could be the relevant provision for the case at hand, the EFTA Court finds it appropriate to consider this provision as well for the purpose of providing an answer to the questions referred to it.

15 Articles 1 to 4 of the Directive read:

"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.

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.*
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> *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."*

16 The *plaintiff* submits that Articles 2 and 3 of the Directive are relevant to a system of direct price control, i.e. regulated prices, whereas situations pertaining to competitive pricing are dealt with under Articles 4 and 5 of the Directive. The plaintiff submits that, by choosing direct control, like the Government of Iceland has done, a selection of specific measures and criteria that are distinct for that type of pricing environment has been made, to the exclusion of others. Consequently, Articles 4 and 5 of the Directive, which apply to a competitive pricing environment and are typically general measures, are not applicable to the situation at hand.

17 The *Government of the Netherlands*, the *EFTA Surveillance Authority* and the *Commission of the European Communities* are all of the opinion that Article 4 should be applied in this case. The provisions of this Article must be construed to apply not only to the "freezing" of prices at the prevailing level, but also to decisions to lower maximum wholesale prices generally. At the oral hearing, the *Government of Iceland* argued that the decision only affected one factor in determining prices, i.e. the wholesale mark-up, and could not be seen as constituting a price freeze.

18 The *Court* finds that the submissions of the plaintiff summarized in paragraph 16 above cannot be accepted. As the Commission of the European Communities has pointed out, the distinction between Articles 2 and 3 on the one hand and Articles 4 and 5 on the other lies in the different measures to control prices these

provisions assume, which, in the case of Articles 2 and 3, are individual decisions aimed at individual medicinal products, whereas Articles 4 and 5 concern general measures affecting all or at least a number of products. Regarding the plaintiff's distinction based on the competitiveness of the market in a particular Contracting Party, it is sufficient to recall that the aim of the Directive is to ensure transparency regarding national measures for controlling prices of medicinal products, but not to have further effects on the pricing-control policies of the Contracting Parties, which rely primarily upon free competition to determine the prices of medicinal products.

19 Based on Articles 2 and 3 of the Directive, decisions on prices are taken following an application by a marketing authorization holder. Articles 2 and 3 do not provide for procedural and transparency requirements when a previously-approved price is unilaterally reduced at a later stage by a general measure. The provisions of Articles 2 and 3, which deal with individual administrative decisions, do not apply to a general decision on the lowering of wholesale prices of medicinal products.

20 It was the intention of the Contracting Parties to the EEA Agreement, by incorporating the Directive into the Agreement, to provide economic operators with some minimum procedural guarantees *inter alia*, undoubtedly, in the event of a price freeze. From the perspective of the economic operators, a price freeze at the prevailing price level is a less burdensome measure than a general price cut followed by a *de facto* fixing of a price at a lower level than the one hitherto prevailing. It would thus be contrary to the intention of the Contracting Parties and the aim of the Directive for the latter scenario to fall outside the scope of any of the specific provisions of the Directive.

21 The Court finds support for this interpretation of the scope of Article 4 in Article 4(1), which provides that the authorities, after a period of price freeze and on the basis of macro-economic considerations, may decide to increase or decrease the frozen prices. The authorities must be able to decide upon a general increase or decrease of individually fixed prices without a preceding period of price freeze.

22 On these grounds, and based on a contextual interpretation of the Directive, the Court finds that the words "price freeze" within the meaning of Article 4 cannot be interpreted so narrowly that they only cover a *status quo* of the prevailing price level. A decision on the general decrease in wholesale prices must be regarded as amounting to a "price freeze" within the meaning of Article 4 of the Directive. This interpretation is supported by the fact that otherwise the Contracting Parties might easily circumvent their obligations to provide minimum procedural guarantees under Article 4 simply by adopting general pricing decisions containing modest or minor price cuts instead of freezing prices at the prevailing level.

23 In answer to question 1a of the referring court, the EFTA Court finds that Article 4 of the Directive applies to a situation where a competent authority, empowered

to approve the maximum prices of prescribed pharmaceuticals, decides, on its own motion, to decrease by 2.65% the maximum wholesale prices of all pharmaceuticals the cost price of which is more than 3000 Icelandic crowns, for the purpose of lowering the prices of pharmaceuticals to the public in accordance with prices in neighbouring countries and to reduce State expenditure on pharmaceuticals.

24 Concerning question 1(b), the *Court* notes the following: in principle, a unilateral decision by a competent authority to lower wholesale prices is in conformity with the Directive in so far as it meets the requirements laid down in Article 4. The Article does not stipulate any specific points to be taken into account at the time of the decision on price freeze or, for that matter, the lowering of prices. It only requires the State in question to carry out a certain review later as further set out in the provision.

25 With question 1(c), the national court inquires whether the possibility of applyinf for price increases for particular products despite the general decision to decrease wholesale prices affects the answer to questions 1(a) and 1(b).

26 In the view of the *plaintiff* and the *Government of the Netherlands*, the fact that it was possible to apply for a price increase for particular pharmaceuticals despite the general decision to decrease wholesale prices does not affect the answer to the first question. The *EFTA Surveillance Authority* and the *Commission of the European Communities* are of the opinion that the possibility of a price increase in a situation of a general price decrease is one of the procedural principles explicitly foreseen in Article 4(2) of the Directive. Consequently, the existence or non-existence of such a possibility is relevant for the application of the answer to question 1(b). The *Government of the United Kingdom* argues that, in such a situation, the transparency requirements in Article 4 of the Directive would not apply. That is because any such application for a price increase would attract the transparency provisions of Article 3.

27 The *Government of Iceland* has contended that, despite the decision of 22 November 1996, all wholesalers are, in principle, free to submit individual applications for price adjustments. The Government of Iceland argues that it is in the interest of economic operators that Article 3 applies to such applications, rather than the narrower provisions of Article 4.

28 The *Court* notes that Article 4(2) of the Directive provides for the possibility of submitting individual applications for price increases for particular products and that the provision applies to applications for a derogation from a price freeze within the meaning of the Directive. As long as the general price decision is in effect, Article 4 must be seen as taking priority over Article 3. In the case of a general measure to lower the maximum wholesale price of certain categories of medicinal products, the requirements under Article 4(2) of the Directive must be fulfilled, *inter alia* that a reasoned decision must be given on all applications. On the other hand, an exception may only be applied for in exceptional

circumstances and only where particular reasons may justify a derogation from the general price decision. With regard to the latter conditions, the Court notes that Article 4 establishes minimum requirements. Thus, national law may set out less restrictive requirements with respect to the conditions under which individual derogations may be granted.

29 In light of the discussion and conclusion with regard to the non-applicability of Articles 2 and 3 of the Directive to the case at hand, it is not necessary to answer the second question, as that question is based on the premise that Article 2(2) of the Directive is applicable.

Costs

30 The costs incurred by the Government of the Kingdom of Norway, the EFTA Surveillance Authority and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by Héraðsdómur Reykjavíkur by the order of 4 March 1998, hereby gives the following Advisory Opinion:

1 Article 4 of Council Directive 89/105/EEC applies to circumstances where a competent authority, empowered to approve the maximum prices of prescription pharmaceuticals, decides, on its own motion, to decrease the maximum wholesale prices of all pharmaceuticals the cost price of which is over a specific amount, for the purpose of lowering the prices of pharmaceuticals to the public in accordance with prices in neighbouring countries and to reduce State expenditure on pharmaceuticals. Articles 2 and 3 of Council Directive 89/105/EEC do not apply to such general measures.

2 Such a general decision by a competent authority is in conformity with Council Directive 89/105/EEC in so far as it meets the procedural and transparency requirements laid down in Article 4.

3 It is a requirement of Article 4(2) of Council Directive 89/105/EEC that the holder of a marketing authorization for a medicinal product may apply for a derogation from a general decision to decrease wholesale prices. The existence of such a possibility must therefore be ensured in order for national measures to be in conformity with Article 4 of the Directive.

Bjørn Haug Thór Vilhjálmsson Carl Baudenbacher

Delivered in open court in Luxembourg on 24 November 1998.

Gunnar Selvik
Registrar

Bjørn Haug
President