REPORT FOR THE HEARING
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.

I. Introduction

1. By an order dated 3 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.

II. Legal background

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 referred to as the "Directive"), referred to in Point 9 of Chapter XIII of Annex II to the EEA Agreement.

3. Article 1 of the Directive reads:

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

4. Article 2 of the Directive reads:

> *"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:*
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> 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.*
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> 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*

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

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."*

5. Article 3 of the Directive reads:

"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."*

6. Article 4 of the Directive reads:

"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."

7. In Point 16 of Chapter XIII of Annex II to the EEA Agreement, the Contracting Parties have taken note, as a non-binding act, of the Commission Communication on the compatibility with Article 30 of the [EC] Treaty of Measures taken by Member States relating to price control and reimbursement of medicinal products[2]. Under Article 8(3) (a) EEA, medicinal products are subject to the general provisions of the EEA Agreement.

III. Facts and Procedure

8. 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% and those for which the cost price was 3000 Icelandic crowns or higher, the price was to be lowered by 2.65%.

9. 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.

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[2] OJ No. C 310, 4.12.1986, p. 7.

10. 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. This measure can be seen as a part of efforts to prevent an increase in State expenditure on pharmaceuticals.

11. 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.

12. The relevant national provisions are the Pharmaceutical Act No. 93/1994 (*Lyfjalög*), hereinafter "the Pharmaceutical Act", in particular Article 1 (1) and Chapter XIV and the Rules No. 501/1996 relating to determination of prices of pharmaceuticals (*Reglugerð um ákvörðun lyfjaverðs*), hereinafter "the Rules".

13. The objective of the Pharmaceutical Act is described in Article 1:

> *"The objective of this Act is to ensure that the people of Iceland are provided with an adequate supply of necessary pharmaceuticals by the most efficient means of distribution on the basis of fair and equitable competition and in accordance with the rules which apply within the European Economic Area. With regard to trade in pharmaceuticals it shall always be kept in mind that the distribution of pharmaceuticals is an integral part of health services and those employed in the distribution of pharmaceuticals shall work with other professions of the health services towards fulfilling public health service objectives. It is, furthermore, the objective of this Act to ensure as far as possible the quality and safety of pharmaceuticals and pharmaceutical services, counter excessive use of pharmaceuticals and keep their costs to the minimum.*
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> *The Minister of Health and Social Security supervises the implementation of this Act. At the Ministry of Health and Social Security, the Director of Pharmaceutical Affairs is responsible for administering pharmaceutical matters on behalf of the Minister. The Director shall be educated as a pharmacist and may not have vested personal interests in the manufacturing, importation, or distribution of pharmaceuticals. The Director of Pharmaceutical Affairs, the National Centre for Hygiene, Food Control and Environmental Protection, the Director General of Health, the State Drug Inspectorate, the Pharmaceutical Pricing Committee, the Committee on Pharmaceuticals and the Chief Veterinary Officer advise the Minister on the implementation of this Act."*

14. The following provisions regarding prices of pharmaceuticals are laid down in Chapter XIV of the Act:

15. Article 39 reads:

"The pricing of all non-prescription medicines is without restriction. The Pharmaceutical Pricing Committee determines the pricing of non-prescription pharmaceuticals for animals, cf. Article 40."

16. Article 40 reads:

"The Pharmaceutical Pricing Committee determines the maximum wholesale and retail price both of prescription pharmaceuticals and all pharmaceuticals for animals.

Importers and manufacturers of pharmaceuticals as well as their agents shall seek the approval of the Pharmaceuticals Pricing Committee as to maximum wholesale prices and all price changes on prescription pharmaceuticals and veterinary pharmaceuticals.

The Committee shall be comprised of three members appointed by the Ministry of Health and Social Security for the term of his office, of which one shall be nominated by the Supreme Court of Iceland. The Minister appoints the Chairman. Alternates shall be appointed in the same manner. When the maximum wholesale prices for pharmaceuticals are on the agenda, the representative of the organisation of pharmaceutical wholesalers takes a seat on the Committee and when the maximum retail prices for pharmaceuticals are on the agenda the representative appointed by the pharmacy owners' organisation takes a seat on the Committee. When comments from the State Social Security Institute regarding prices for pharmaceuticals are on the agenda, the representative of the Institute takes a seat on the Committee. When the maximum retail price for pharmaceuticals for animals is on the agenda, the representative of the organisation of veterinarians takes a seat on the committee and the Chief Veterinary Officer is also consulted. If during the conduct of the committee's work there is a tie vote, the chairman casts the deciding vote.

The Committee shall monitor the purchase and manufacturing prices of pharmaceuticals and the wholesale and retail pricing of pharmaceuticals and make price determinations based on its observations. The Committee is, furthermore, responsible for the publication of a price schedule which shows the maximum prices of prescription pharmaceuticals and all pharmaceuticals for animals.

The costs of the Committee's work, including remuneration of committee members is paid by the State Treasury."

17. Article 41 reads:

"The Minister, after receiving proposals from the State Social Security Institute, determines the participation of social security in pharmaceutical costs of health insured persons in accordance with the existing Social Security Act and the annual budget."

18. For further implementation of the Act, Rules No. 501/1996 relating to determination of prices of pharmaceuticals have been enacted. Pursuant to their Article 1, they apply to pricing of prescription pharmaceuticals and all pharmaceuticals for animals for wholesale and retail sale. Article 2 concerns how the prices of pharmaceuticals are determined. The Article provides *inter alia* that the Pharmaceutical Pricing Committee determines the maximum wholesale and retail prices of prescription pharmaceuticals. Article 4 concerns applications for wholesale prices, stipulating *inter alia* that the holders of a marketing authorization for proprietary medicinal products or their agents are to apply to the Pharmaceutical Pricing Committee for a maximum wholesale price and any proposed price increases for prescription pharmaceuticals, and that they are to use a designated form for this purpose. Applicants must also furnish the Committee with adequate information. The Pharmaceutical Pricing Committee is to ensure, as a rule, that an application for a maximum wholesale price is decided upon within 90 days from receipt of an adequately completed application. Article 5 concerns the determination of a wholesale price and provides that, when general decisions regarding maximum wholesale prices are taken, the representative of the organization of pharmaceutical wholesalers or pharmaceutical producers, as the case may be, are to take a seat on the Committee. When individual applications for pricing submitted by individual companies are considered, a representative of the holder of a marketing authorization is entitled to take a seat on the Committee in the place of the representatives of the organizations referred to above. Article 7 provides *inter alia* that the Pharmaceutical Pricing Committee is to monitor the purchase and manufacturing prices of pharmaceuticals and the wholesale and retail pricing of pharmaceuticals in the country and compare them to comparable prices in other countries. Article 8 concerns changes in and the review of prices. Article 8 states *inter alia* that the Pharmaceutical Pricing Committee and/or interested parties may ask for a review of previously-determined maximum wholesale and retail prices, when changed circumstances or new information so warrant. When the Committee considers such changes, representatives of the relevant interested party shall take a seat on the Committee.

19. Reykjavík City Court has decided to submit a Request for an Advisory Opinion to the EFTA Court. The order 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.

IV. Questions

20. The following questions were referred to the EFTA Court:

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

V. Written observations

21. Pursuant to Article 20 of the Statute of the EFTA Court and Article 97 of the Rules of Procedure, written observations have been received from:

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

- the Government of Norway, represented by Morten Goller, Office of the Attorney General, acting as Agent;

- 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.

Federation of Icelandic Trade

22. The *plaintiff* submits that a decision of the Pharmaceutical Pricing Committee is an administrative measure intended to control the prices of medicinal products for human use and is therefore covered by Article 1 of the Directive.

23. Concerning the intention of the Directive, reference is made to the Preamble. The main goal of the Directive is to achieve transparency in the criteria on which competent authorities base their decisions on prices. National pricing measures must be harmonized to prevent potential restrictions or distortions in trade of medicinal products.

24. The plaintiff states that Article 1(1) of the Directive applies regardless of whether the measures are laid down by law, regulation or administrative action. It must be considered that the Directive prescribes in Articles 2 to 5 the methods the Member States may follow when making price decisions.

25. In Iceland, all marketing of prescription pharmaceuticals is subject to prior approval of the pharmaceutical prices and all price increases are subject to

approval by a public authority. The Pharmaceutical Pricing Committee is thus the competent authority within the meaning of Articles 2 and 3 of the Directive.

26. Furthermore, the Plaintiff considers that the Directive lists exhaustively in Articles 2 to 5 all national measures for controlling prices of medicinal products. The case at hand is not covered by Articles 4, 5, 6 and 7 of the Directive. A decision such as the one in dispute must be considered in light of Article 2 (2) of the Directive.

27. In accordance with the objective of the Directive, the public authorities are obliged to publish in advance all requirements for applications for prices for medicinal products. The Plaintiff considers this understanding of the Directive to be in full conformity with the case law of the Court of Justice of the European Communities (ECJ).[3]

28. The Plaintiff submits that the disputed decision of the Pharmaceutical Pricing Committee is an onerous decision, of the type for which public authorities are obliged to state reasons, pursuant to the case law of the ECJ.[4]

29. The decision itself was not at all reasoned. The criteria that the prices of pharmaceuticals were too high in Iceland and that it was likely that expenditure would far exceed its limits unless measures were taken were presented after the dispute arose. The Plaintiff contests that these criteria may be seen as legitimate criteria on which the disputed decision may be based.

30. Concerning these criteria, the Plaintiff points to the price differences between individual Member States of the European Union. Furthermore, it is unclear whether important factors have been considered, such as increased longevity of the population and increase in the population of elderly people which, it is commonly accepted, increases pharmaceutical cost. It is further not clear whether the calculations include to some extent newer and more expensive pharmaceuticals, or the economizing which results from better and improved medical treatment in other areas of the health care system.

31. The Plaintiff submits that, when making its disputed decision, the Pharmaceutical Pricing Committee has not taken into account objective criteria relating to the composition of prices, such as turnover of pharmaceuticals, transport expenses, storage etc., and other criteria which are directly related to the composition of prices of pharmaceuticals. The criteria used by the authority cannot be considered objective within the meaning of the Directive.

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3 See e.g. Case C-222/86 *Union nationale entraîneurs et cadres techniques professionnels du football (Unectef)* v *Georges Heylens and others* [1987] ECR 4097; Case C-249/88 *Commission of the European Communities* v *Kingdom of Belgium* [1991] ECR I-1275.

4 See footnote 3.

32. Furthermore, the plaintiff states that the disputed decision is a measure having equivalent effect to quantitative restrictions on imports under Article 11 EEA. In his view, the lack of transparency constitutes a breach of this provision. Reference is made to an opinion of an Advocate General of the ECJ.[5]

33. The effect of the decision of the Pharmaceutical Pricing Committee is to reduce importers' income of a considerable share of pharmaceuticals and may cause importers to stop importing expensive pharmaceuticals and/or marketing new ones, as the low mark-up does not grant satisfactory profit and imports will not be profitable. It has also to be considered that the decision of the Pharmaceutical Pricing Committee was based on a wholesale mark-up which was at a minimum. According to the case law of the ECJ, a measure having equivalent effect to a quantitative restriction is present when imported products cannot be sold at a reasonable price.[6]

34. The possibility for individual importers to apply to the Pharmaceutical Pricing Committee for increases in the price of pharmaceuticals does not change the conclusion that the disputed decision is unlawful. The Plaintiff submits that it is contrary to the rules of the parties' being entitled to an objective assessment to require them to apply for permission for a price increase from the same entity that has decided that the price of the product concerned is to be decreased, in accordance with instructions from public authorities.

35. The Plaintiff points out that neither the Directive nor the Icelandic legislation contains a provision which provides that the relevant authority may decrease previously-decided prices of pharmaceuticals by way of unilateral decision. It is irrelevant whether the decision is a general decision regarding all pharmaceuticals in a particular price category or a specific decision. The effects of the decision are the same, i.e. the rights of parties concerned granted by the provisions of the Directive are adversely affected.

36. If this was not so, public authorities could easily avoid their obligation to provide a statement of reasons for a rejection of an application for a certain price if they could first authorize marketing of a pharmaceutical and then, by a review of the accepted price, decrease the price without having to comply with the requirements regarding a statement of reasons and ensure that parties concerned were aware of their right to remedies.

37. With regard to the foregoing, the Plaintiff proposes the following answers to the questions referred to the EFTA Court:

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5 See footnote 3 and Opinion of Mr. Advocate General Tesauro delivered on 30 January 1991 in Case C-249/88 *Commission of the European Communities* v *Kingdom of Belgium* [1991] ECR I-1275.

6 See footnote 3 and Case 181/82 *Roussel Laboratoria BV and others* v *État néerlandais* [1983] ECR 3849.

"1(a) This part of the question must be answered in the affirmative. A decision of the Pharmaceutical Pricing Committee, such as the one at issue in the main proceedings, must be considered to be an administrative measure intended to control the pricing of medicinal products, within the meaning of Article 1 of Directive 89/105/EEC and is thus, as such, covered by the provisions of the Directive.

1 (b) This part of the question must be answered in the negative. A unilateral decision by a competent authority such as the one at issue in the main proceedings is not in conformity with the provisions of Council Directive 89/105/EEC.

1 (c) This part of the question must be answered in the negative. The fact that it was possible to apply for price increases for particular pharmaceuticals, despite the general decision to decrease wholesale prices, does not affect the answer to the question.

With reference to the answer to the first question, [the plaintiff] considers that there is no need for the EFTA Court to answer [the second question] from the Reykjavík City Court."

The Government of Iceland

38. The *defendant*, the Government of Iceland, is of the opinion that the Directive does not regulate the pricing itself of pharmaceutical products. Therefore, the Member States are free to adopt measures to control public health expenditure on medicinal products if these measures are not contrary to the general principles of the EEA Agreement, including the four freedoms.

39. Referring to the Preamble to the Directive, as well as to its purpose and an explanatory document, the Government of Iceland submits that Article 2 and Article 3 of the Directive were to apply only in case of single medicinal products but not generally. The case at hand concerns a general wholesale price decrease of all prescribed pharmaceuticals above a certain price limit. Therefore, Article 2 and Article 3 of the Directive should not apply.

40. The Government of Iceland states that, by its wording, Article 4 of the Directive does not cover a situation of a general price decrease. In case of a price decrease without a prior price freeze, undertakings are protected by Article 3 and all efforts to interpret Article 4 as covering such a situation would deprive undertakings of the protection of Article 3. This would be contrary to the aim of the Directive.

41. Furthermore, undertakings are also protected by Article 11 EEA if the official interference with prices in pharmaceuticals is regarded as constituting a measure equivalent to a quantitative restriction.

42. Should the Directive be found applicable by the EFTA Court, the Government of Iceland submits, with reference to the Preamble to and Article 4 of the Directive, that the Member States have in any case the right to control prices of medicinal products *inter alia* by decreasing allowable prices.

43. Concerning the question whether the decision is compatible with Article 11 EEA, the Government of Iceland emphasizes that the decision was based on a special study showing that the drug prices in Iceland were 20% to 117% above the average wholesale prices in Denmark, Sweden and Norway.

44. Referring to the case law of the ECJ, the Government of Iceland argues that a price control system does not in itself constitute a measure having an equivalent effect to a quantitative restriction.[7] According to that case law, it is for the plaintiff to establish that the prices approved by the competent authorities do not enable those products to be sold at a reasonable profit due to the structure and amount of production costs and the expenses and charges relating to import, or that the sale of imported products becomes impossible as a result of the price decision.[8]

45. In the case at hand, the plaintiff has not provided the competent authorities or the EFTA Court with such an analysis.

46. The Government of Iceland suggests answering the questions as follows:

> *"1.a The provisions of the Directive are not applicable to the situation referred to in the question.*
>
> *1.b The decision referred to is not in contradiction to the Directive, since its provisions do not apply to the situation at hand.*
>
> *1.c Since the provisions of the Directive do not apply to the situation, the question needs not be answered.*
>
> *2.a Since the Directive is not applicable to such a decision, the question needs not be answered.*
>
> *2.b Since the Directive not applicable to such a decision, the questions needs not be answered."*

The Government of the Netherlands

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7 See footnote 6.

8 See footnote 3.

47. In the opinion of the *Government of the Netherlands*, the objective of the Directive is modest. Reference is made to the Preamble and to the main objective of the Directive, which is transparency. The goal of the Directive does not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. Furthermore, there is no effect on price-setting nor on determination of social security schemes in the Member States.

48. It is submitted that the decision of the Pharmaceutical Pricing Committee is a general decision because it relates to all pharmaceutical products. Accordingly, the decision does not fall within the ambit of Article 2 of the Directive, but is covered by Article 4 of the Directive.

49. According to the Government of the Netherlands, the wording of Article 4 of the Directive does not preclude this provision covering decisions imposing general price reductions as well as general price decisions containing the fixing of prices at their present level. The scope of Article 4 of the Directive would be very limited if it was only to apply to a price freeze in the strictest sense. The competent authorities would be able to achieve a similar result by refusing permission for a price increase under Article 3.

50. In many States, the determination of maximum prices for pharmaceutical products may concern both products in general and products in particular.

51. The Government of the Netherlands states that Article 4 of the Directive does not preclude a unilateral decision. It would seriously affect national policies on price-setting for pharmaceuticals if such a decision were to be made dependent on an application.

52. The possibility under Article 4(2), under which 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, has no bearing on the answers to question 1 a and 1 b.

53. The Government of the Netherlands suggests answering the questions as follows:

> *"[Q]uestion 1.a should be answered in the negative. (…)*
>
> *[Q]uestion 1.b should (…) be answered in the affirmative. (…)*
>
> *Question 1.c (…) has no bearing on the answers suggested by the Netherlands Government to questions 1.a and1.b.*
>
> *In view of the reply suggested to the first question, it is not necessary to deal with the second question."*

The Government of Norway

54. *The Government of Norway* argues that a literal interpretation of Article 1 would apparently imply that any measure to control prices of medicinal products is covered by the Directive. The Government of Norway argues against this kind of interpretation of Article 1 of the Directive and states that the decision is not covered by the scope of the Directive. Articles 2 to 7 of the Directive only concern the various procedural requirements with which national measures must comply. If a measure falls outside the scope of these provisions, Article 1 of the Directive, which only refers to these provisions, does not in itself answer the question of which procedural rules apply, if any.

55. Consequently, States are free to employ methods of regulating prices other than those described in the Directive, subject to the limitations of Article 11 EEA. No specific procedural requirements apply to such methods.

56. The Government of Norway argues that none of the provisions of the Directive directly regulates a situation where the competent authority unilaterally decides to impose a general decrease in prices. It follows from the wording of Articles 2 and 3 that only individual applications related to specific products are concerned. A general decrease in prices like the one in question is not covered by these provisions. The only provision providing rules for a general measure is Article 4, which governs general price freezes.

57. Furthermore, Article 2 applies only where a new product is placed on the market. The contested decision concerns the price of all products currently on the market. In the opinion of the Government of Norway, the contested decision falls outside the scope of Article 2 of the Directive.

58. Following the wording of Article 3 of the Directive, the provision applies only to applications for price increases for individual products in a situation where the marketer wishes to increase the price of a product currently on the market. The contested decision concerns a general decrease in prices, whereas Article 3 concerns applications for increases in the prices of individual products. This distinguishes the contested decision from the measure regulated by Article 3. In the opinion of the Government of Norway, the contested decision falls outside the scope of Article 3.

59. The measure described in Article 4 of the Directive resembles the decision in question in that both are general in scope and have been adopted unilaterally. The difference is that Article 4 applies only to a price freeze, and not to a decision to reduce prices. This distinguishes the contested decision from the measure regulated by Article 4. In the opinion of the Government of Norway, the contested decision falls outside the scope of Article 4.

60. The Government of Norway points out that the question whether a national measure constitutes a quantitative restriction on imports or a measure having equivalent effect thereto must be answered by assessing Article 11 EEA.

61. The object of the Directive is only to ensure that all concerned can verify that national measures do not constitute such restrictions. It is thus of crucial importance that the Directive is not interpreted so as to impose material restrictions on the Member States' freedom to set prices within the limitations of Article 11 EEA.

62. To support this interpretation, reference is made to the Preamble to the Directive. The objective of the Directive is to ensure that all concerned may verify that national measures to control prices are in accordance with Article 11 EEA. The Directive is not intended to define the limits of possible methods of regulating the pricing of pharmaceuticals.

63. Furthermore, it is clearly stated in the Preamble that national policies on price-setting are not affected by the requirements set out in the Directive except in so far as is necessary to attain transparency. The Directive cannot be read as setting out an exhaustive list of possible methods of regulating prices of pharmaceuticals by the Member States. Such a reading would be contrary to the freedom granted to the Member States in the Preamble to the Directive.

64. In addition, the Preamble acknowledges that future harmonization of such measures must take place progressively. This means that the Member States may currently use their discretion in finding the most suitable methods for achieving the overriding goal of controlling public health expenditures and ensuring the availability of adequate supplies of medicinal products at a reasonable cost.

65. The Government of Norway points out that, under Article 7 EEA, the legal effect of a directive is that the Member States are required to adopt national legislation that implements the primary objectives of the directive. In the opinion of the Government of Norway, the relevant Icelandic legal provisions are clearly in conformity with the objectives of the Directive in question here.

66. Alternatively, the Government of Norway states that the Directive may be seen as providing procedural rules for a catalogue of methods for regulating prices more or less by way of exemplification, so that other methods must be treated in the same manner as the method set out in the Directive that they most closely resemble.

67. Should the Directive be found applicable, the Government of Norway states that the measure described in Article 4 is the most comparable of all the measures in the Directive to the one in question. A price freeze will, over time, have the same effect as a general reduction in prices. Given the tendency of

prices and incomes to increase over time, a price freeze will eventually induce a reduction in real prices of pharmaceuticals. Therefore, the decision in question is in many ways comparable to the measure regulated by Article 4.

68. The macro-economic justification for the decision can be seen in the fact that prices of pharmaceuticals in Iceland were excessive compared to those in other Nordic countries. Consequently, the relevant Icelandic provisions and the contested decision are in accordance with Article 4 of the Directive.

69. The Government of Norway proposes that the EFTA Court answer the questions from Reykjavík City Court as follows:

> *"Council Directive 89/105/EEC does not apply to the circumstances set out in question 1a. The decision must thus be viewed as being in conformity with the Directive. For this reason it is unnecessary to address questions 1c, 2a and 2b.*
>
> *Council Directive 89/105/EEC cannot be interpreted to the effect that a unilateral decision by a competent authority, such as the one referred to in question 1a, amounts to a rejection by the authority for marketing of a pharmaceutical product at a particular price. For this reason it is unnecessary to address question 2b."*

The Government of the United Kingdom

70. The *Government of the United Kingdom* also makes reference to the Preamble to the Directive. The Directive does not prohibit Icelandic law from authorising the Committee to take a unilateral decision reducing the price of all relevant pharmaceuticals because the concern of the Directive is transparency. It would be surprising if the Directive were to prohibit a unilateral reduction of prices, when the Directive recognizes that a general price freeze may be imposed.

71. Article 6 of the Directive does not require Member States to adopt a "positive list" system. The purpose of Article 6 is to specify transparency requirements if a Member State decides to adopt such a system. Such a system is not necessarily a practical and less onerous measure than a general reduction of pharmaceutical prices as a means of limiting or restricting State expenditure on pharmaceutical products.

72. The transparency requirements imposed under Articles 2 and 3 do not apply to unilateral decisions to reduce pharmaceutical prices generally because these provisions concern approval of prices and decisions on price increases taken in each case by reference to the circumstances of the specific product. A unilateral reduction of prices is generally not taken by reference to the circumstances of the specific product but by reference to general economic conditions and the impact of pharmaceutical prices on public health.

Furthermore, these provisions concern decisions taken by reference to an application.

73. In the view of the Government of the United Kingdom, the unilateral decision to decrease the wholesale prices of all relevant pharmaceuticals is more closely analogous to a price freeze within the scope of Article 4. Therefore, the transparency requirements which must be satisfied by the Committee in the present case may be no more onerous than those contained in Article 4.

74. The Government of the United Kingdom states that the transparency requirement in Article 4 would not apply if a company was to apply for price increase for particular products. Such a situation is covered by Article 3.

75. Article 2 paragraph 2 does not apply to a unilateral decision by a competent authority to reduce pharmaceutical prices for all products.

76. The Government of the United Kingdom submits that the questions must be answered as follows:

> *"(1) Directive 89/105/EEC does not prohibit Icelandic law from authorising the Committee to take a unilateral decision reducing the price of all relevant pharmaceuticals.*
>
> *(2) The transparency requirements of Article 2 of the Directive do not apply to such a decision.*
>
> *(3) The transparency requirements which must be satisfied by the Committee can be no more onerous than those contained in Article 4:*
>
> *(a) To carry out a periodic review of whether the macro-economic conditions justify the unilateral price reduction;*
>
> *(b) To consider within 90 days (extended by 60 days where appropriate) an application by any particular company for a derogation from the general price reduction and to give a reasoned decision on that application.*
>
> *(4) However, if it is possible for a company to apply for price increases for particular products, despite the general decision to decrease wholesale prices, the transparency requirements in Article 4 would not apply. That is because any such application for a price increase would attract the transparency provisions of Article 3."*

The EFTA Surveillance Authority

77. The *EFTA Surveillance Authority* is of the opinion that medicinal products are governed *inter alia* by Articles 11 and 13 EEA. In light of the wording of the

questions put by the national court, it is not necessary and in fact not possible, on the basis of the facts available to the Authority, to consider the compatibility of the general measure to lower wholesale prices of medicines with Article 11 and 13 EEA.

78. The EFTA Surveillance Authority points out that the decision in dispute is a general one. Furthermore, it is submitted that the decision by the Pharmaceutical Pricing Committee constitutes a "national measure" and that its purpose is to "control the prices of medicinal products". Thus the decision falls under the scope of the Directive.

79. According to the wording of Article 2 and Article 3, certain procedural requirements are triggered only after an application for a certain price or an increase in price of a medicinal product has been submitted to the competent authority.

80. The EFTA Surveillance Authority notes that no such application has been submitted to the Pharmaceutical Pricing Committee in the case at hand. Thus, read in isolation and applying textual interpretation, the circumstances described in the question of the national court fall outside the scope of application of Articles 2 and 3 of the Directive.

81. The limited objective of the Directive, the wording of the relevant provisions and the preparatory documents lead to the conclusion that the rather vague objectives, supplemented by the fact that further harmonization measures were envisaged, restrict the scope for a progressive teleological interpretation based purely on the purpose of the Directive.

82. Consequently, the Authority is of the opinion that, since no individual application for a price or price increase has been submitted to the relevant authority, support in the wording of Articles 2 and 3 of the Directive is lacking as regards the case at hand.

83. The preparatory documents indicate that the intention to introduce procedural requirements, such as an elaborate statement of reasons and indication of available remedies, applies only in relations to price controls on individual medicinal products.

84. The EFTA Surveillance Authority is of the opinion that the provisions of these Articles, which deal with individual administrative decisions, do not apply to a general decision on the lowering of wholesale prices of medicinal products.

85. Concerning Article 4, the EFTA Surveillance Authority argues that this provision *prima facie* seems to cover only the "freezing" of prices at the prevailing price level. General decisions on the lowering of prices which are subsequently fixed at that level seem not to be covered. Nevertheless, the

Authority is of the opinion that the provisions of this Article must be construed to apply also to such general decisions.

86. The intention of the Contracting Parties to the EEA Agreement, by incorporating the transparency Directive into the Agreement, was to provide economic operators with some minimum procedural guarantees *inter alia* 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 and the fixing of a price at a lower level than that prevailing. It would thus seem contrary to the intention of the Contracting Parties for the latter to fall outside the scope of any of the specific provisions of the transparency Directive.

87. Therefore, 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 general decision on the lowering of prices which are *de facto* subsequently fixed at that lower price level must be regarded as amounting to a "price freeze" within the meaning of Article 4 of the Directive. Otherwise, the States 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.

88. The EFTA Surveillance Authority submits that Article 4 would be left without any real practical value should one accept that the States could escape the procedural requirements set out therein simply by opting for the more onerous measure, i.e. the lowering of prices rather than fixing them at a prevailing price level.

89. Regarding letter b of the first question, it will be for the national court to ascertain, basing itself on all the factual circumstances of the case, whether, as a matter of EEA law, the procedural requirements contained in Article 4 of the transparency Directive have been breached and, if so, what consequences that may have under national administrative law.

90. Furthermore, the EFTA Surveillance Authority points out that Article 4(2) of the Directive provides for the possibility of individual applications for price increases of particular products and applies to applications for a derogation from a price freeze within the meaning of the Directive.

91. In light of the discussion and conclusion with regard to the non-applicability of Articles 2 and 3 to the factual circumstances of the case at hand, the EFTA Surveillance Authority considers it unnecessary to give a substantive answer to the second question, as that question is based on the premise that Article 2(2) of the Directive is applicable.

92. The EFTA Surveillance Authority proposes answering the questions as follows:

> *"1.a Circumstances as described in question 1a of the request for an advisory opinion fall within the scope of the Act referred to in point 9 of Chapter XIII of Annex II to the Agreement on the European Economic Area (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).*
>
> *Articles 2 and 3 of the Directive, being provisions dealing with individual administrative decisions, do not apply to a general decision on the lowering of wholesale prices of medicinal products.*
>
> *b. Such a decision is in conformity with the Directive if the procedural requirements set out in Article 4 thereof are observed. Therefore, a review shall take place, at least annually, to ascertain whether the macro-economic conditions justifying the decision are still present.*
>
> *c. The existence of national procedures, whereby it is possible to apply for a price increase for particular products despite a general decision to decrease wholesale prices, as foreseen in Article 4(2) of the Directive, must be regarded as a prerequisite for the conformity of such a general decision with the Directive.*
>
> *2. In view of the answer to the first question there is no need to answer the second question."*

The Commission of the European Communities

93. The *Commission of the European Communities* refers to the aim and purpose of the Directive. The Member States must ensure transparency and accord certain procedural guarantees to all involved in the market in medicinal products whilst remaining free to pursue national pricing policies.

94. The Commission of the European Communities points out that Article 1 of the Directive is drafted in broad terms to cover any national pricing measure. This extensive approach finds confirmation in the motivation set out in the Directive's recitals. These refer to national pricing arrangements for medicinal products in comprehensive and general terms.

95. The Directive should, therefore, be interpreted as applying to a unilateral decision of a pricing authority of the type taken by the Pharmaceutical Pricing Committee on 22 November 1996.

96. In the opinion of the Commission, it is appropriate to distinguish the provisions covering individual measures to control prices (Articles 2 and 3) from those covering general measures (Articles 4 and 5).

97. Only Article 4 can apply in the circumstances because the decision in question is of a general nature, introducing a price cut to all prescribed pharmaceuticals of a particular category. Moreover, the objectives underlying the price cut are also general in nature, namely to reduce the prices of pharmaceuticals to the public and State expenditure on pharmaceuticals.

98. The procedural differences between Articles 2 and 3 and Article 4 are based on the fact that, in the situations covered by the Articles 2 and 3, the applicant challenges individual administrative decisions, whilst in cases under Article 4 he seeks an exemption from a general administrative measure.

99. Following this approach, the Commission argues that it is not appropriate to apply Articles 2 and 3 to the circumstances in question. This position is confirmed by the practical impossibility of envisaging Article 2 operating as a procedure for a bundle of individual and product-specific measures. In this regard, it is to be borne in mind that in both Articles 2 and 3 the decision on the price is taken following an application by a marketing authorization holder. Articles 2 and 3 do not provide for a procedure if an already-fixed price is unilaterally reduced at a later stage by a general measure.

100. The Commission considers that “price freeze” should be given a broader interpretation within the context of Article 4, to mean a fixing of prices at a certain level, be that at the level applying at the time the freeze is introduced, or at a higher or lower level.

101. It would not be consistent to adopt a strict interpretation of “price freeze”: this would exclude the type of price cut in question from the ambit of Article 4. The wording of Article 4(1) may be taken in support of the interpretation that in this context a “freeze” may also encompass a decrease in prices, as it is implicit in that wording that any such increase or decrease is then subsumed in the “freeze”. In the present circumstances, it must be borne in mind that, due to the operation of the national pricing arrangements, a “price freeze” in its more standard meaning was effectively already in place before the decision of 22 November 1996. In the absence of authority to increase prices following an individual application, prices were already frozen. Moreover, any decision rejecting such an application as part of a general policy of freezing prices at existing levels would not fall under Article 4, but under Article 3 of the Directive. Therefore, in the present circumstances, there would be no need for a general decision imposing a price freeze in the standard sense, whereas the only type of unilateral general measure within the meaning of Article 4 would be one fixing a general increase or decrease in prices.

102. Should it nevertheless be concluded that a narrow interpretation must be given to the notion of "price freeze" in Article 4, the Commission submits in the alternative that the procedural and transparency requirements there laid down should in any case apply by analogy to the national measure. Articles 2-7 of the Directive cannot be seen as setting out an exhaustive list of national measures, thereby excluding and rendering illegal any other national price control measure not explicitly foreseen in the Directive.

103. Concerning the question whether such a unilateral decision is in conformity with the Directive 89/105/EEC, it should be appreciated that the conformity in question is conformity with the procedural and transparency requirements laid down in Article 4 of the Directive. The taking of the pricing decision itself and the substance of that decision, forming as they do part of national policies on price-setting should not as such be affected, in so far as the procedural and transparency requirements are met. A unilateral decision will therefore be in conformity with the Directive if the procedural and transparency requirements laid down by Article 4 are met.

104. Question 1c concerns the relevance of the existence of the possibility of applying for price increases for particular products in derogation from a general decision to decrease wholesale prices. As such, this is closely linked to the answer to Question 1b, since the possibility of applying in exceptional circumstances for a derogation from the general measure is one of the procedural principles explicitly foreseen in Article 4(2) of Directive 89/105/EEC. The existence or non-existence of such a possibility is therefore relevant in applying the answer to Question 1b.

105. The Commission proposes that the reply to the questions submitted by Reykjavík City Court should be as follows:

> *"1(a) Council Directive 89/105/EEC, in particular Article 4, applies 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.*
>
> *1(b) Such a unilateral 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.*

1(c) The answer to the question is affected by the possibility of applying for price increases for particular products in derogation from a general decision to decrease wholesale prices, since this is one of the procedural principles explicitly foreseen in Article 4(2) of Council Directive 89/105/EEC.

2(a) Article 2(2) of Council Directive 89/105/EEC is not 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.

2(b) Given the answer to Question 2a, there is no need to answer Question 2b."

Carl Baudenbacher
Judge Rapporteur