JUDGMENT OF THE COURT (Sixth Chamber)

12 June 2003 *

In Case C-229/00,

Commission of the European Communities, represented by I. Koskinen and H. Støvlbæk, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Republic of Finland, represented by T. Pynnä and E. Bygglin, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for a declaration that, by not adopting the laws, regulations and administrative provisions necessary to comply with Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures

* Language of the case: Finnish.

regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8), in particular by not applying the prescribed procedure to decisions determining a category of special cover and, with regard to the prescribed obligations, by not providing the applicant with a sufficient statement of reasons based on objective and verifiable criteria in the case of negative decisions, the Republic of Finland has failed to fulfil its obligations under that directive and in particular Article 6 thereof,

THE COURT (Sixth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, C. Gulmann, V. Skouris, F. Macken (Rapporteur) and J.N. Cunha Rodrigues, Judges,

Advocate General: A. Tizzano,
Registrar: H. von Holstein, Deputy Registrar,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 25 April 2002,

after hearing the Opinion of the Advocate General at the sitting on 11 July 2002,

gives the following

Judgment

1 By application lodged at the Court Registry on 8 June 2000, the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by not adopting the laws, regulations and administrative provisions necessary to comply with 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 (OJ 1989 L 40, p. 8, 'the directive'), in particular by not applying the prescribed procedure to decisions determining a category of special cover and, with regard to the prescribed obligations, by not providing the applicant with a sufficient statement of reasons based on objective and verifiable criteria in the case of negative decisions, the Republic of Finland has failed to fulfil its obligations under that directive and in particular Article 6 thereof.

Law

Community law

2 The sixth recital in the preamble to the directive states that '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'.

3 Article 1(1) of the directive provides that:

'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.'

4 The first and second subparagraphs of Article 2 of the directive provide that:

'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 authorisation. 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.'

5 The first, second and third subparagraphs of Article 6 of the directive provide:

'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 authorisation 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.'

6 It is apparent from Article 11(1) of the directive that the Member States must bring into force the laws, regulations and administrative provisions necessary to comply with the directive by 31 December 1989. The directive should have been transposed in Finland by 1 January 1995, the date of accession of the Republic of Finland to the European Union.

National law

7 It is apparent from Articles 5(a) and 9 of the sairausvakuutuslaki (Finnish law on sickness insurance) as amended in 1993 that, in order for a medicinal product to be covered by the sickness insurance scheme, the holder of a licence to market the medicinal product ('marketing licence') must apply to the lääkkeiden hintalautakunta (Commission for Medicine Prices), stating a reasonable wholesale price which it undertakes to observe. If that wholesale price is accepted by that Commission, the medicinal product concerned is automatically entered on the list of reimbursable products subject to the ordinary scheme of insurance cover, under which 50% of the price over FIM 50 is reimbursed per purchase.

8 Pursuant to Article 23, first subparagraph of the hallintomenettelylaki (Law No 598/1982 on administrative procedures ('Law No 598/1982'), a refusal to enter a medicinal product 'shall contain a clear statement of the rights and obligations of the party concerned or the other factors upon which the decision is based'.

9 The first subparagraph of Article 24 of Law No 598/1982 provides:

'The decision shall contain a statement of the principal facts and the rules and provisions justifying it'.

10 A right of appeal exists from the decisions of the Commission for Medicine Prices to the relevant courts.

11 In addition to the ordinary scheme of insurance cover, there are two schemes of higher-level cover which provide for the following levels of cover:

— 75% of the price over FIM 25 per purchase, where the medicinal product is essential for the treatment of a serious or chronic illness;

— 100% of the price over FIM 25 per purchase where the medicinal product is generic and of equivalent effect to a medicinal product which is essential for the treatment of a serious and chronic illness.

12 The Council of Ministers is to determine by decree those serious and chronic illnesses in respect of which a patient may receive higher-level cover for the cost of medicinal products and is to draw up a general list of the active ingredients used in a medicine to combat those illnesses.

13 Since that decision establishing the list of active ingredients used in medicinal products which may then receive that cover was not adopted pursuant to an individual application, as a matter of Finnish law it is not subject to the provisions of the directive, in particular Article 6(1) thereof. Therefore, that decision does not contain a statement of reasons, the persons concerned have no right to be heard and neither the preparatory documents nor the decree are open to judicial review.

14 After the Council of Ministers has adopted that decree, the Kansaneläkelaitos ('Institute for Social Security') is to draw up a list of specialist medicinal products on the market in Finland and already covered by the basic scheme of insurance

cover which contain an active ingredient listed in that decree. That decision, which is published, is not open to judicial review.

Pre-litigation procedure

15 Following the receipt of a complaint, the Commission requested the Finnish Government to provide further information on the administrative procedure for entering medicinal products on the list. Not satisfied with that reply, on 29 May 1998 the Commission sent the Republic of Finland a letter of formal complaint requiring it to comply with the directive, first, by providing that decisions as to the inclusion of a medicinal product in a category qualifying for higher-rate cover comply with the requirements of Article 6 of the directive and, second, by requiring decisions refusing to accept the price of specialist medicinal products to contain a statement of reasons based on objective and verifiable criteria, pursuant to the second subparagraph of Article 2 of the directive, and not the standard wording in the following terms: 'The application is refused because the applicant has not provided detailed reasons such as to enable the proposed wholesale price to be adjudged reasonable.'

16 By letter of 20 July 1998, the Republic of Finland acknowledged that last complaint, stating that the procedure had been amended in that regard, but challenged the assertion that the procedure for determination of the medicinal products qualifying for higher-rate cover fell within the directive.

17 On 17 December 1998, the Commission issued a reasoned opinion in which it reiterated the complaint concerning the decisions establishing the categories of medicinal products qualifying for higher-rate cover and stated, in particular, that the Finnish Government's assertion that negative decisions were accompanied by an adequate statement of reasons was not supported by any law or regulation.

18 By letter of 8 February 1999, the Finnish authorities stated, first, that they had not infringed the first subparagraph of Article 6 of the directive in so far as the decision fixing the medicinal products qualifying for higher-rate cover was taken by the Council of Ministers. Second, they stated that they had remedied the several shortcomings which occurred in practice with regard to the obligation to include in the negative decision the statement of reasons laid down in the second subparagraph of Article 2 of that directive.

19 The Commission therefore brought the present action for a declaration from the Court of a failure to fulfil obligations in the terms set out at paragraph 1 of the present judgment and an order that the defendant pay the costs.

20 The Republic of Finland contends that the Court should dismiss the action as inadmissible or unfounded and order the Commission to pay the costs.

Substance

The complaint concerning the decisions establishing the categories of medicinal products subject to higher-rate cover

21 By its first complaint, the Commission alleges against the Republic of Finland that neither the Council of Ministers' decision nor the subsequent decision of the Institute for Social Security establishing the medicinal products qualifying for the scheme of higher-rate cover comply with the requirements laid down by Article 6 of the directive.

22 In that regard, the Commission criticises the fact that the persons concerned are given no opportunity to argue their point of view during the decision procedure referred to in the preceding paragraph and that, because of that, the competent authorities are under no obligation to give reasons for the inclusion or exclusion of an active ingredient in the scheme of higher-rate cover.

23 Yet Article 6 of the directive concerns not only the entry of a product on the list of specialist medicinal products covered by the national sickness insurance scheme, but also subsequent decisions, failing which it would be easy for the Member States, without infringing the directive, to circumvent the obligations laid down by it and thus to compromise the attainment of its objectives.

24 The Finnish Government claims that the first subparagraph of Article 6 of the directive governs solely the application procedure for the entry on the list of specialist medicinal products reimbursed under the national sickness insurance scheme. The decision of the Council of Ministers concerning the list of active ingredients falling within the scheme of higher-rate cover is not taken in the context of an application within the meaning of that provision.

25 According to that government, the Council of Ministers does not take a decision on an application to enter a medicinal product in the list of medicinal products qualifying for higher-rate cover since, in that regard, it merely establishes by decree a list of illnesses and active ingredients following which the Institute for Social Security draws up the list of medicinal products containing an active ingredient covered by the decree.

26 The Finnish Government concludes from this that that procedure is not covered by the first subparagraph of Article 6 of the directive.

27 In its view, the Council of Ministers' decree on higher-rate cover falls within the scope of the third subparagraph of Article 6 of the directive and not the first.

28 Moreover, the interpretation advocated by the Commission would result in an interference in the establishment of the intervention criteria used in the Finnish sickness insurance scheme, contrary to the purpose of the directive and the case-law of the Court to the effect that, as a matter of Community law, the Member States are free to organise their own social security systems and to adopt provisions intended to govern the consumption of medicinal products in order to promote the financial stability of their health insurance schemes (Case 238/82 *Duphar and Others* [1984] ECR 523).

Findings of the Court

29 On the Finnish Government's argument alleging an interference in the organisation of the national social security schemes, it is sufficient to state that the action brought by the Commission in no way calls in question the method of financing or the structure of the social security system but seeks solely to secure observance by the Finnish legislation of the requirements laid down in Article 6 of the directive, which, moreover, relate neither to the functioning of the register and the inclusion on it of medicinal products nor to the possibility of having the cost of a medicinal product borne by the scheme (Case C-424/99 *Commission* v *Austria* [2001] ECR I-9285, paragraph 26).

30 On the question whether the Republic of Finland complies with the requirements of Article 6 of the directive, the Finnish Government claims, first, that that

provision does not apply on the ground that the Council of Ministers' decree does not result in a medicinal product being entered on the list of medicinal products qualifying for higher-rate cover, but refers to certain active ingredients.

31 In that regard, Article 6 of the directive applies where a medicinal product is only covered by the sickness insurance scheme after the competent authorities have decided to include it in a positive list of medicinal products covered by that scheme.

32 It is apparent from the description of the Finnish scheme that, even though the Council of Ministers does not directly decide on the inclusion of certain medicinal products in the list of medicinal products qualifying for higher-rate cover, the decision of the Council of Ministers to include certain active ingredients in the scheme of higher-rate cover necessarily has the effect of making specialist medicinal products subject to that scheme where they contain such ingredients and a marketing licence has been issued in respect of them by the competent authorities.

33 Moreover, following that decision of the Council of Ministers, the Institute for Social Security has no discretion and is required to enter on the list of medicinal products qualifying for higher-rate cover all those medicinal products containing an active ingredient referred to in that decision, in respect of which a marketing licence has been issued and whose wholesale price has been approved.

34 It follows that the Council of Ministers' decision constitutes a bundle of individual decisions on the inclusion of certain medicinal products in one of the social security schemes, so as to bring it within the provisions of Article 6 of the directive.

35 Second, the Finnish Government challenges the applicability of the first subparagraph of Article 6 of the directive on the ground that, unlike that for the purposes of ordinary cover, the decision to include a medicinal product in the list of medicinal products qualifying for higher-rate cover is not taken in response to an application by the person concerned.

36 The first subparagraph of Article 6 of the directive only applies to schemes in which the persons concerned lodge an application for inclusion in a list.

37 In that regard, the purpose of the directive, according to Article 1 thereof, is to ensure that any national measure to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national sickness insurance systems complies with the requirements of that directive (*Commission* v *Austria*, cited above, paragraph 30).

38 The decisions pursuant to which certain medicinal products qualify for higher-rate cover constitute a means of determining the extent of the range of medicinal products covered by the sickness insurance scheme and likely to be used in the treatment of such or such an illness.

39 Moreover, according to the sixth recital in the preamble to the directive, ensuring the effectiveness of the directive also requires that the persons concerned can verify that the official entry of medicinal products on the list corresponds to objective criteria and that there is no discrimination between national medicinal products and those from other Member States.

40 However, those objectives would be compromised if, as the Finnish Government claims, a Member State were able to introduce a dual procedure for the

establishment of a list of medicinal products qualifying for higher-rate reimbursement, one pursuant to the obligations laid down by the first subparagraph of Article 6 of the directive, the other being exempt in part from those obligations and, in part, not complying with the objectives laid down by that directive.

41 Therefore, a declaration of failure to fulfil obligations must be made in respect of the first complaint.

The complaint concerning the statement of reasons for decisions refusing to accept the price of medicinal products

42 By its second complaint, the Commission alleges a failure on the part of the Republic of Finland to ensure that the competent Finnish authority provides a statement of reasons for decisions refusing to accept the prices of medicinal products, contrary to the directive. Moreover, the grounds of those decisions, where they are given, are not based on objective and verifiable criteria. According to the Commission, a comparison between Articles 23 and 24 of Law No 598/1982 and the provisions of the directive seems to show that the latter are stricter than the Finnish legislation with regard to the obligation to state reasons.

43 The Finnish Government raises a plea of inadmissibility against that complaint on the ground that, during the pre-litigation procedure, the Commission challenged solely the practice adopted by the competent authority, which had been remedied, and not the compatibility of the Finnish legislation with the directive.

44 It should be recalled in that regard that, in accordance with settled case-law, the letter of formal notice from the Commission to the Member State, and then the reasoned opinion issued by the Commission, delimit the subject-matter of the

dispute, so that it cannot thereafter be extended. The opportunity for the State concerned to submit its observations, even if it chooses not to avail itself thereof, constitutes an essential guarantee intended by the EC Treaty, adherence to which is an essential formal requirement of the infringement procedure. Consequently, the reasoned opinion and the proceedings brought by the Commission must be based on the same complaints as those set out in the letter of formal notice initiating the pre-litigation procedure (Case C-365/97 *Commission* v *Italy* [1999] ECR I-7773, paragraph 23).

45 Thus, in so far as a judgment declaring that a Member State has failed to fulfil its obligations establishes the basis of liability which that State may incur as a result of its default and constitutes a condition precedent to the bringing of proceedings under Article 228 EC, the Member State must be afforded the opportunity, in the course of the pre-litigation procedure, to refute in their entirety the allegations made against it by the Commission (*Commission* v *Italy*, cited above, paragraph 24).

46 However, that requirement cannot be carried so far as to mean that in every case the statement of complaints in the letter of formal notice, the operative part of the reasoned opinion and the form of order sought in the application must be exactly the same, where the subject-matter of the proceedings has not been extended or altered (*Commission* v *Italy*, cited above, paragraph 25).

47 In the present case, in spite of the summary statement of reasons for the second complaint in the letter of formal notice and the reasoned opinion in which reference is made to a defective practice in respect of the statement of reasons for decisions refusing to accept the price of medicinal products, it is, however, alleged against the Republic of Finland in the operative part of the reasoned opinion that they did not adopt the laws, regulations and administrative provisions necessary to comply with the directive.

48 It follows that the second complaint is admissible.

49 As for the merits, the Commission, on the basis of a few examples of the Finnish system in practice, claims that the statement of reasons for negative decisions does not comply with the provisions of the directive, which require a more detailed statement of reasons than that laid down by Finnish law.

50 In that regard, as the Finnish Government rightly pointed out, first, it is apparent from Articles 23 and 24 of Law No 598/1982 that any administrative decision must contain a statement clearly setting out the rights and obligations of the party concerned and all the factors taken into account and the legislative provisions upon which the decision is based (see, in that regard, paragraphs 8 and 9 hereof).

51 Second, the examples of a failure to state reasons put forward by the Commission do not reveal a practice which infringes the provisions of the directive.

52 Indeed, it is apparent from the data supplied by the Finnish Government, which have not been challenged by the Commission, that whilst, in 1999, 3 266 decisions were taken by the Commission for Medicine Prices, only 133 contained an inadequate statement of reasons.

53 However, generalised failure on the part of the administrative authorities to comply with the directive cannot be inferred from a few defective cases in practice.

54 Accordingly, it cannot but be held that the Commission has not shown how the Finnish practice or legislation was contrary to the provisions of the directive.

55 It is settled case-law that in proceedings under Article 226 EC for failure to fulfil an obligation, it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled and to place before the Court the information needed to enable it to determine whether the obligation has not been fulfilled (see, in particular, Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 102 and Case C-263/99 *Commission* v *Italy* [2001] ECR I-4195, paragraph 27).

56 In those circumstances, it must be held that the second complaint is unfounded.

57 It follows from all the foregoing that, by not adopting the laws, regulations and administrative provisions necessary to comply with the directive as regards the decisions establishing the categories of medicinal products subject to a higher rate of health insurance cover, the Republic of Finland has failed to fulfil its obligations under the first and second subparagraphs of Article 6 of that directive.

Costs

58 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. However, under Article 69(3) of those Rules, the Court may order that the costs be shared or that the parties bear their own costs where each party fails on one or more heads. In this case, since the parties have each been partially unsuccessful, each must be ordered to bear its own costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. Declares that, by not adopting the laws, regulations and administrative provisions necessary to comply with 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 as regards the decisions establishing the categories of medicinal products subject to a higher rate of health insurance cover, the Republic of Finland has failed to fulfil its obligations under the first and second subparagraphs of Article 6 of that directive;

2. Dismisses the remainder of the action;

3. Orders each party to bear its own costs.

Puissochet Gulmann Skouris

Macken Cunha Rodrigues

Delivered in open court in Luxembourg on 12 June 2003.

R. Grass

Registrar

J.-P. Puissochet

President of the Sixth Chamber