JUDGMENT OF THE COURT (Sixth Chamber)

27 November 2001 *

In Case C-424/99,

Commission of the European Communities, represented by J.C. Schieferer, acting as Agent, with an address for service in Luxembourg,

applicant,

v

Republic of Austria, represented by C. Pesendorfer, acting as Agent, with an address for service in Luxembourg,

defendant,

APPLICATION for a declaration that, by not adopting or by not communicating to the Commission within the prescribed period 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

* Language of the case: German.

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 Republic of Austria has failed to fulfil its obligations under the EC Treaty,

THE COURT (Sixth Chamber),

composed of: N. Colneric, President of the Second Chamber, acting for the President of the Sixth Chamber, C. Gulmann, R. Schintgen, V. Skouris (Rapporteur) and J. N. Cunha Rodrigues, Judges,

Advocate General: A. Tizzano,
Registrar: H. A. Rühl, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 28 March 2001, at which the Commission was represented by J.C. Schieferer and the Republic of Austria by H. Dossi, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 31 May 2001,

gives the following

Judgment

1 By an application lodged at the Court Registry on 29 October 1999 the Commission of the European Communities brought an action under Article 226 EC for a declaration that, by not adopting or by not communicating to the Commission within the prescribed period 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) (hereinafter 'the directive'), the Republic of Austria has failed to fulfil its obligations under the EC Treaty.

Legal framework

Community legislation

2 Article 1(1) of the directive provides:

'Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the price 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.'

3 Article 6 of the directive provides:

'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.

...'

4 Under Article 11(1) of the directive the Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with the directive by 31 December 1989 at the latest. The directive had to be transposed in Austria by 1 January 1995 at the latest, the date of entry of that Member State into the European Community.

5 Moreover, Article 11(2) of the directive provides that '[b]efore the date referred to in paragraph 1, Member States shall communicate to the Commission the texts of any laws, regulations or administrative provisions relating to the pricing of medicinal products, the profitability of manufacturers of medicinal products and the coverage of medicinal products by the national health insurance system. Amendments and modifications to these laws, regulations or administrative provisions shall be communicated to the Commission forthwith.'

National legislation

6 Under Paragraphs 116 and 122(1) of the Allgemeines Sozialversicherungsgesetz (General law on social security, hereinafter 'the ASVG') every insured person has the right to claim, for himself and for the members of his family, sickness benefits. Under Paragraph 133 of the ASVG those benefits include, *inter alia*, adequate and appropriate medical treatment including the requisite medicinal products.

7 Under Paragraph 350 of the ASVG the cost of a medicinal product prescribed by an approved doctor, that is to say a doctor who has signed an agreement with the social security institution to which the patient is affiliated, may be borne by the health scheme if the product appears on the register of medicinal products published by the Hauptverband der österreichischen Sozialversicherungsträger (Principal Federation of Austrian Social Security Institutions, hereinafter 'the Federation'). The cost of a medicinal product not on the register may nevertheless be borne by the scheme if the principal doctor or the supervising doctor of the competent social security institution agrees that it is necessary and appropriate for the patient, in view of his condition, in which case prior authorisation must be given by that doctor. In the case of medicinal products prescribed by a non-approved doctor, whether or not they are on the list, such authorisation is always required.

8 Paragraphs 31(3)(12) and 133(2) of the ASVG provide that the Federation is to publish a register indicating the medicinal products which may be prescribed generally or subject to certain conditions and which will be reimbursed by the social security institutions without requiring the usual authorisation of the principal doctor or the supervisory doctor (hereinafter 'the Register').

9 Paragraph 133(2) of the ASVG, which forms the basis for a decision to include a medicinal product on the register, states that medical treatment, including the prescription of medicinal products, must be adequate and appropriate. However, it must not exceed what is necessary.

10 The procedure for inclusion of a medicinal product in the register is governed by the provisions of the Verfahrensordnung für die Erstellung des Heilmittelverzeichnisses gemäß § 31 Abs. 3 Z 12 ASVG (Procedure for the compilation of the register of medicinal products under Paragraph 31(3), No 12 of the ASVG) (*Soziale Sicherheit* No 11/98, of 27 November 1998, p. 853, Amtliche Verlautbarung No 104/1998, hereinafter 'the VOHMV').

11 Under the VOHMV the medicinal products proposed for inclusion in the register are examined by the bureau of the federation. The result of the examination is submitted, by way of a proposal for a recommendation, to the small technical advisory board and communicated to the pharmaceutical company from which the medicinal products proposed originate (Paragraph 2(2) of the VOHMV). The small technical advisory board then examines the proposals in accordance with its rules of procedure and issues a recommendation (Paragraph 2(3)(a) of the VOHMV).

12 If the pharmaceutical company does not accept the rejection of its proposal for the inclusion of a medicinal product, with the alteration in the prescribing conditions or with the removal of a product from the register of medicinal products, it may within a period of six weeks lodge a written complaint with the Federation (Paragraph 2(4)(a) of the VOHMV). That complaint comes before the small technical advisory board. If its recommendation is not in favour of the applicant, it must submit the complaint, accompanied by any new information and its observations, to the main technical advisory board (Paragraph 2(4)(b) of the VOHMV). That board considers whether the recommendation of the small technical advisory board is reasonable and may alter it (Article 2(5) of the VOHMV).

13 The Federation has to decide within a period of 80 days whether and under what conditions a proposal may be accepted (Paragraph 2(7)(a) of the VOHMV). That period may be extended by 60 days when the Federation's workload is exceptionally high, that is, more than 100 proposals for the entry of medicinal products have been presented to it within the same three-month period. The Federation cannot, however, invoke that provision more than three times in two years (Paragraph 2(7)(b) of the VOHMV).

Pre-litigation procedure

14 On 25 May 1998 the Commission sent a letter of formal notice to the Republic of Austria informing it that its national legislation was considered to be contrary to the directive in three respects. First, the period of 90 days within which a decision had be taken on a request for inclusion of a medicinal product on the 'positive list', provided for in Article 6(1) of the directive, had not been observed. Secondly, the statement of reasons for refusal of a request for inclusion of a medicinal product on the register was either non-existent or erroneous, which was contrary to the first sentence of Article 6(2) of the directive. Finally, contrary to the provisions of the second sentence of Article 6(2) of the directive, national legislation provided for no remedies against such a refusal.

15 By letter of 27 July 1998 the Austrian Government replied that Article 6 of the directive was not applicable in Austria because any medicinal product could be reimbursed under the legislation. According to the Government, the register was merely a working instrument inasmuch as patients could be prescribed any medicinal product irrespective of whether it was included in that register once the legal conditions were satisfied.

16 Judging that reply to be inadequate, the Commission addressed to the Republic of Austria a reasoned opinion by letter of 30 December 1998, requesting it to comply with that opinion within two months of its notification.

17 In its reply of 3 March 1999 the Austrian Government maintained its position. However, on the inadequacy of the statement of reasons for refusals that Government stated that new procedural rules had been adopted and attached to its letter a copy of the VOHMV.

18 It was against that background that the Commission brought the present action.

Substance

19 As a preliminary point it should first be stated that, according to settled case-law, the application must be based on the same grounds and arguments as the reasoned opinion (see, in particular, Case 290/87 *Commission* v *Netherlands* [1989] ECR 3083, paragraph 8).

20 Yet it appears that the reasoned opinion of 30 December 1998 does not allege that the Republic of Austria did not communicate to the Commission the laws, regulations and administrative provisions necessary to comply with the directive, with the result that on this point the action is inadmissible.

21 Secondly, it should be pointed out that the Commission stated in its application that it was abandoning its allegation concerning the obligation under Article 6(2) of the directive to state reasons for decisions rejecting applications for inclusion in the register since Paragraph 2(3)(b) of the VOHMV henceforth provides that the Federation must give written reasons for its decisions.

Whether the register is a 'positive list' for the purposes of Article 6 of the directive

22 The Austrian Government claims at the outset that Article 6 of the directive is not applicable in Austria, with the result that the Commission cannot require implementation of the obligations laid down therein. Since that provision is not applicable it is clear that the allegations against the Republic of Austria concerning non-observance of the period for examining applications for inclusion and the absence of judicial remedies must be rejected.

23 The Government maintains that it is clear from the terms of Article 6 of the directive that a list of medicinal products constitutes a 'positive list' only where authorisation by the social security system of prescription of a medicinal product is dependent upon its inclusion in the list. However, under the Austrian system, although medicinal products not appearing in the register may be reimbursed, where the patient has obtained authorisation, those appearing on it may not be reimbursable if they are not necessary and appropriate to the patient's condition.

24 Thus, the register kept by the Federation is in no way an exhaustive catalogue of the medicinal products covered by the sickness insurance scheme but constitutes a

working tool for the use of doctors enabling them to determine the medicinal products whose cost is borne by the social security system without prior authorisation.

25 More generally, the Austrian Government claims that in this action the Commission is seeking to interfere in the organisation of national systems of social security, which come within the sole competence of the Member States.

26 On the latter point 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 Austrian 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.

27 As to the argument that the register kept by the Federation under Paragraph 133(2) of the ASVG cannot be classified as a 'positive list' under Article 6 of the directive, it should be stated that that provision precludes such argument.

28 Under the Austrian legislation, the cost of medicinal products included on the register is automatically borne by the scheme as a matter of principle, whereas the medicinal products not included in that register are not, unless authorised by the principal doctor or supervising doctor.

29 Yet it is clear from Article 6 of the directive that that provision is intended to apply where inclusion of a medicinal product on a list means that its cost will automatically be reimbursed or borne by the scheme. Thus, the fact that in a Member State there is a register and not a 'positive list' and that the cost of medicinal products not included on the register may likewise be borne there by the scheme if the medicinal product prescribed by the doctor is necessary for the condition affecting the patient in no way detracts from the sole determining factor, namely the fact that inclusion of a medicinal product on the register normally means that its cost will automatically be borne by the scheme.

30 That interpretation is, moreover, corroborated by the purpose of the directive which, under 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 health insurance systems complies with the requirements of the directive.

31 On that point it should be stated that, as the Austrian Government acknowledged at the hearing, the register enables the competent authorities to reduce the expenditure of the Austrian social security system, inasmuch as the pharmaceutical companies are generally required to agree to lower prices in consideration for the inclusion on the register of one of their medicinal products since that inclusion means that the cost will automatically be borne by the scheme. Under those conditions inclusion of a medicinal product in that register thus constitutes a measure intended to control prices.

32 Accordingly, the register may be regarded as a positive list within the meaning of Article 6 of the directive, with the result that it is appropriate to ascertain whether that provision was correctly transposed into Austrian law.

The period of 180 days within which the Federation has to decide on applications for inclusion on the register of medicinal products

33 The Commission maintains that the period of 180 days, referred to in Paragraph 2(7)(a) of the VOHMV, within which the Federation has to decide on applications for inclusion of medicinal products on the register is incompatible with the period of 90 days referred to in Article 6(1) of the directive.

34 The Austrian Government replies that, under Article 6(1) of the directive, where — as in Austria — a decision is made both on inclusion in the register of a medicinal product and on its price, the period may be extended by 90 days. Accordingly, the Austrian legislation is in conformity with that provision.

35 In that connection, it has been consistently held that it is incumbent upon the Commission to prove the allegation that an obligation has not been fulfilled and to place before the Court the information needed to enable it to determine whether that obligation has not been fulfilled (see, *inter alia*, Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 102).

36 However, the Commission has been unable to demonstrate the inexactitude of the Austrian Government's assertion that, where an application for inclusion of a medicinal product in the register is lodged, the competent authorities have to decide within the 180 day period both on inclusion of a medicinal product on the register and on its price.

37 It is true that, at the hearing before the Court, the Commission alleged that the Austrian legislation was incompatible with the directive on the ground that Paragraph 2(7)(b) of the VOHMV authorises the competent authorities to extend the period of 180 days by a further period of 60 days where the Federation has an unusually heavy workload.

38 However, under Article 42(2) of the Rules of Procedure, that plea is inadmissible because during the written procedure the Commission merely alleged the incompatibility of the period of 180 days but never, except at the hearing, called in question the possibility of extending that period by a further period of 60 days. The Commission could already have raised this plea in its application, since in its reply to the reasoned opinion the Republic of Austria appended the text of the VOHMV, which clearly mentions, at Paragraph 2(7)(b), that possibility of extension.

Appeal procedures against the decisions concerning applications for inclusion of medicinal products on the register

39 The Commission claims that the Austrian legislation does not provide for any genuine judicial protection, contrary to the requirements of Article 6(2) of the directive which provides that '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'.

40 In fact, in the Commission's view, neither the complaint against the first recommendation of the small technical advisory board provided for in Paragraph 2(4)(a) of the VOHMV, nor, where the opinion of that board is again negative, the application for inclusion which may be submitted to the main technical

advisory board, can be described as appeals since that 'remedy' lies not before the courts but before the administrative authorities.

41 The Austrian Government contends that remedies do in fact exist inasmuch as both the small technical advisory board and the main technical advisory board comprise technicians and professionals who are independent of the social security institutions and are appointed, some for a limited period and others without limit of time.

42 In response to that it should be stated that appeals to independent experts cannot be equated with the remedies mentioned in the directive. In fact, under Article 6(2) of the directive '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'. It necessarily follows that the applicant concerned must be able to avail itself of remedies ensuring effective legal protection.

43 On any test, the remedy provided for in Paragraph 2(4) and (5) of the VOHMV, whether exercised before the small technical advisory board or the main one, lies before supervisory bodies made up of experts belonging to the Federation itself, and thus to an administrative authority and not to genuine judicial bodies.

44 Moreover, since both the small technical advisory board and the main one can issue only recommendations they have no decision-making power, which rests with the Federation.

45 The requirement of judicial review reflects a general principle of Community law stemming from the constitutional traditions common to the Member States and enshrined in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (Case 222/84 *Johnston* [1986] ECR 1651, paragraph 18; Case C-97/91 *Oleificio Borelli* v *Commission* [1992] ECR I-6313, paragraph 14, Case C-1/99 *Kofisa Italia* [2001] ECR I-207, paragraph 46, and Case C-226/99 *Siples* [2001] ECR I-277, paragraph 17).

46 The Commission's action must therefore be held well founded on that point and the failure to comply with the provisions of the directive confirmed.

47 It follows from those considerations that, by not adopting within the prescribed period the laws, regulations and administrative provisions necessary to comply with the second sentence of Article 6(2) of the directive, the Republic of Austria has failed to fulfil its obligations under that article. The remainder of the action is dismissed.

Costs

48 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been asked for in the successful party's pleadings. However, under the first subparagraph of Article 69(3) the Court may order that the parties bear their own costs if each party succeeds on some and fails on other heads. Since the Commission and the Republic of Austria have each been unsuccessful in part, they must be ordered to bear their own costs.

On those grounds,

THE COURT (Sixth Chamber)

hereby:

1. **Declares that, by not adopting within the prescribed period the laws, regulations and administrative provisions necessary to comply with the second sentence of Article 6(2) 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, the Republic of Austria has failed to fulfil its obligations under that article;**

2. **Dismisses the remainder of the application;**

3. **Orders the parties to bear their own costs.**

Colneric Gulmann Schintgen

Skouris Cunha Rodrigues

Delivered in open court in Luxembourg on 27 November 2001.

R. Grass F. Macken

Registrar President of the Sixth Chamber