JUDGMENT OF THE COURT
19 March 1991 *

In Case C-249/88,

Commission of the European Communities, represented by Christine Berardis-Kayser, a member of its Legal Department, acting as Agent, with an address for service in Luxembourg in the office of Guido Berardis, a member of the Legal Department, Wagner Centre, Kirchberg,

applicant,

v

Kingdom of Belgium, represented by Róbert Hoebaer, Director of Administration in the Ministry of Foreign Affairs, Foreign Trade and Co-operation and Development, assisted by Leo Vanderbeke, General Inspector at the Ministry for Economic Affairs, and Fernand Clapuyt, Director at the Institut National d'Assurance Maladie-Invalidité (National Sickness and Invalidity Insurance Institute), acting as Agent, with an address for service in Luxembourg at the Belgian Embassy, 4 Rue des Girondins,

defendant,

APPLICATION for a declaration that:

— by laying down criteria for determining the maximum prices of pharmaceutical products which refer to factors peculiar to the Belgian market and do not permit account to be taken of the specific cost components of imported products;

— by freezing the prices of pharmaceutical products at a level so low that the marketing of certain imported products is impossible or unprofitable;

* Language of the case: French.

— by not permitting the pharmaceutical undertakings concerned to know the criteria on which the decisions fixing the maximum prices of their products or adjusting those prices are based;

— by adopting decisions to allow or not to allow reimbursement on the basis of reasons connected with criteria which are not themselves objective or verifiable;

— by refusing to allow reimbursement of certain pharmaceutical products unless the prices of the products are reduced;

— by placing imported pharmaceutical products, whose prices are frozen, at a disadvantage by the conclusion of programme contracts which permit price rises subject to conditions which can be satisfied only by domestic products;

— by favouring, as regards approval for reimbursement, domestic pharmaceutical products, which benefit from programme contracts, whereas imported products cannot so benefit, the Kingdom of Belgium has failed to fulfil its obligations under Article 30 of the EEC Treaty,

THE COURT,

composed of: O. Due, President, G. F. Mancini, T. F. O'Higgins, J. C. Moitinho de Almeida, G. C. Rodríguez Iglesias and M. Díez de Velasco (Presidents of Chambers), Sir Gordon Slynn, C. N. Kakouris, R. Joliet, F. A. Schockweiler, F. Grévisse, M. Zuleeg and P. J. G. Kapteyn, Judges,

Advocate General: G. Tesauro,
Registrar: J. A. Pompe, Deputy Registrar,

having regard to the Report for the Hearing,

after hearing oral argument on behalf of the parties at the hearing on 4 December 1990 at which the Commission was represented by Hervé Lehman, a national official seconded to the Commission, acting as Agent, and the Kingdom of Belgium by Robert Hoebaer,

after hearing the Opinion of the Advocate General at the sitting on 30 January 1991,

gives the following

Judgment

1 By application lodged at the Court Registry on 9 September 1988, the Commission of the European Communities brought an action under Article 169 of the EEC Treaty for a declaration that:

— by laying down criteria for determining the maximum prices of pharmaceutical products which refer to factors peculiar to the Belgian market and do not permit account to be taken of the specific cost components of imported products;

— by freezing the prices of pharmaceutical products at a level so low that the marketing of certain imported products is impossible or unprofitable;

— by not permitting the pharmaceutical undertakings concerned to know the criteria on which the decisions fixing the maximum prices of their products or adjusting those prices are based;

— by adopting decisions to allow or not to allow reimbursement on the basis of reasons connected with criteria which are not themselves objective or verifiable;

— by refusing to allow reimbursement of certain pharmaceutical products unless the prices of the products are reduced;

— by placing imported pharmaceutical products, whose prices are frozen, at a disadvantage by the conclusion of programme contracts which permit price rises subject to conditions which can be satisfied only by domestic products;

— by favouring, as regards approval for reimbursement, domestic pharmaceutical products which benefit from programme contracts, whereas imported products cannot so benefit,

the Kingdom of Belgium has failed to fulfil its obligations under Article 30 of the EEC Treaty.

2 It is clear from the terms in which the Commission's allegations are framed and from the file that those allegations concern three aspects of the rules governing price determination and approval for reimbursement of medicinal products in Belgium, namely:

— the rules for fixing the prices of proprietary pharmaceuticals and other medicinal products by the Minister for Economic Affairs under the Law of 9 July 1975 introducing a system of prices for proprietary pharmaceuticals and other medicinal products (*Moniteur Belge*, 30.7.1975, p. 9328);

— the rules on approval for reimbursement by the Institut National d'Assurance Maladie-Invalidité (National SIckness and Invalidity Insurance Institute) of pharmaceutical supplies laid down in the Royal Decree of 2 September 1980 (*Moniteur Belge* of 30.9.1980, p. 11107);

— and, finally, the system of programme contracts in the pharmaceutical sector introduced by the Royal Decree of 31 December 1983 (*Moniteur Belge* of 21.1.1984, p. 850).

3 Reference is made to the Report for the Hearing for a fuller account of the course of the procedure, both at the pre-litigation stage and after the action was brought, together with the pleas in law and arguments of the parties, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

The fixing of the maximum prices of pharmaceutical products

4 Pursuant to Article 2 of the Law of 9 July 1975, mentioned above, the Minister for Economic Affairs may 'fix the maximum prices for proprietary pharmaceuticals and other medicinal products in general, and for each proprietary pharmaceutical or other medicinal product in particular', having regard to criteria determined, on

the basis of Article 3 of that law, by a royal decree of 11 December 1975 (*Moniteur Belge* of 16.12.1975, p. 15989).

5 According to the Commission, the legislation and the manner in which it is implemented impede imports of pharmaceutical products, first, because the criteria adopted in the Royal Decree of 11 December 1975, mentioned above, refer at least in part to factors peculiar to the Belgian market and do not permit account to be taken of the specific cost components of imported products, secondly because the prices are fixed at a level so low that the marketing of imported products is often not profitable, and lastly because the ministerial decisions do not enable the undertakings concerned to know the criteria on which the decisions have been taken.

6 Before examining these various allegations, it should be recalled that, when the Commission requests the Court to declare that a State has failed to fulfil its obligations under the Treaty, it is for the Commission itself to adduce evidence of the alleged infringement (judgment in Case 141/87 *Commission* v *Italy* [1989] ECR 943).

The criteria listed in the Royal Decree of 11 December 1975

7 As is stated in Article 2(3)(c), (d) and (e) of Commission Directive 70/50/EEC of 22 December 1969, based on the provisions of Article 33(7) of the EEC Treaty, on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (Official Journal English Special Edition 1970 (I), p. 17), Article 30 of the Treaty precludes, *inter alia*, national price controls which fix price components differently for domestic products and for imported products, to the detriment of the latter, preclude any increase in the price of the imported product corresponding to the supplementary costs and charges inherent in importation, or fix the prices of products solely on the basis of the cost price or the quality of domestic products at such a level as to create a hindrance to importation. That interpretation of Article 30 has been confirmed by the well-established case-law of the Court and, in particular, by the judgment in Case 56/87 *Commission* v *Italy* [1988] ECR 2919, paragraphs 6 and 7.

8 It is true that Article 3 of the Royal Decree of 11 December 1975 mentions criteria such as 'investment and employment', 'market and competitive conditions and effect on exports', 'socio-economic and technical and scientific interests of the community' which directly concern national undertakings and which, if taken into consideration on a systematic or priority basis, would enable the products of those undertakings to be placed at an advantage in the fixing of prices.

9 However, the decree in question includes other criteria which concern all undertakings without distinction and certain criteria, such as the 'ex-producer or ex-importer price components', 'cost of the factors of production, importation or distribution', 'selling costs', which enable in particular account to be taken of the specific cost components of imported pharmaceutical products (judgment in Case C-347/88 *Commission* v *Greece* [1990] ECR I-4747, paragraph 73).

10 In any event it is not apparent from the documents before the Court that, in the exercise of the powers conferred on him by the Law of 9 July 1975, the Minister for Economic Affairs gave priority to the criteria concerning Belgian undertakings and neglected or underestimated the value of the criteria concerning undertakings from the other Member States, thus placing the latter at a disadvantage. Although the Commission asserts that no allowance was made for 'monetary fluctuations', it adduces in support of that assertion no evidence that the Belgian Minister failed to take account of exchange parities in determining prices.

11 In those circumstances the Commission's first allegation must be rejected.

The level of prices resulting from the application of the Belgian legislation

12 The Commission criticizes the Belgian Government for fixing the prices of imported pharmaceutical products at a level too low for them to be remunerative. It emerges from the Commission's pleadings and from its arguments on this point that this is clearly an essential argument in support of its action for a declaration that the defendant has failed to fulfil its obligations under the Treaty.

13 The Commission first maintained that the prices of medicinal products in Belgium were lower than in other Member States. The Belgian Government endeavoured to show that assertion to be incorrect. In reply to a written question by the Court, the Commission 'wished to state that it drew no inference in law from the data on the comparative level of prices of pharmaceutical products in the Member States'. The arguments exchanged in this connection may therefore be left out of account.

14 In order to demonstrate the low level of prices of medicinal products in Belgium, the Commission also relies on the trends in the price of certain pharmaceutical products chosen by it for their pertinence, in its view, for the purposes of comparisons over a given period of time. The Belgian Government gives a demonstration to the contrary by referring to other groups of products for the purpose of calculating price trends. Whatever may be their respective merits, neither of those demonstrations has any significance with regard to prices approved in Belgium for imported products.

15 On this specific point, which is the one at issue, the Court has held on several occasions that price control systems applicable to domestic products and imported products alike, although not in themselves constituting measures having an equivalent effect to a quantitative restriction contrary to Article 30 of the Treaty, may nevertheless have such an effect when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products (see in particular the judgment in Case 181/82 *Roussel Laboratoria* v *Netherlands* [1983] ECR 3849, paragraph 17).

16 It should be added that the same applies in the case of a system for fixing the prices of individual products, such as that challenged by the Commission. Even if, on account of the policy followed by the Government of ensuring a moderate level of prices for pharmaceutical products, such a system renders more difficult the marketing both of domestic products and imported products, it is sufficient that the circulation of the latter be impeded for that system to constitute a measure having equivalent effect to a quantitative restriction.

17 Such a hindrance occurs when imported products cannot be sold at a reasonable profit on the market of the State of importation.

18 For the Commission proof that this is the situation in the present case is to be found in the fact that importers have abandoned the marketing of products from other Member States owing to the inadequacy of the prices approved by the Belgian authorities.

19 That factor cannot, alone and in itself, be regarded as proof of the fact that the prices approved for imported pharmaceutical products were too low.

20 As the Belgian Government rightly observes, differences in the price of the same product, from one Member State to another, may be accounted for by the commercial strategy of the manufacturing undertaking, and a hindrance to imports may not be inferred from the mere fact that an undertaking abandons the marketing of a given product on the market of a Member State on the ground that the maximum price imposed on it is inadequate. It may be observed, for example, that, in order to avoid parallel exports, an undertaking may have an interest in not marketing its products in a Member State at a price which it considers to be insufficiently remunerative.

21 It was for the Commission to establish that, in the case of the imported products on which it sought to base its finding of a failure to fulfil Treaty obligations, the prices approved by the Belgian authorities did not enable those products to be sold at a reasonable profit on account of the structure and amount of production costs, and of the expenses and charges relating to importation.

22 In the absence of such analyses, neither the general matters nor the circumstances to which the Commission points suffice to enable its arguments to be upheld.

Reasoning of the ministerial pricing decisions

23 According to the Commission, the decisions adopted by the Minister for Economic Affairs, pursuant to the Law of 9 July 1975, do not disclose to the addressees of those decisions the reasons for which the administration fixed at a given level the maximum price of the product in question, contrary to the requirements of the Court in this matter, as they emerge from the judgment in Case 238/82 *Duphar* [1984] ECR 523.

24 The Kingdom of Belgium states that, following a number of judgments delivered by the Belgian Conseil d'État (Council of State) in 1981, the Minister for Economic Affairs was prompted to alter the reasoning given for pricing decisions and that he no longer refers generally to criteria 1 to 10 of the Royal Decree of 11 December 1975, mentioned above, but has since then specified the precise criterion or criteria on which his decision is based. Moreover, in view of the dialogue which is entered into with the undertakings, the price-fixing procedure, taken as a whole, plainly enables them to know why the Minister has opted for one price rather than another.

25 Although, according to the case-law of the Court, one of the general principles of Community law is that any person must be able to obtain effective judicial review before the national courts of national decisions which may infringe a right conferred by the Treaties, and although that principle requires that the persons concerned must be able to obtain from the administration, prior to their bringing any action, knowledge of the grounds of such decisions (judgments in Case 222/84 *Johnston* v *Chief Constable of the Royal Ulster Constabulary* [1986] ECR 1651, and in Case 222/86 *Unectef* v *Heylens* [1987] ECR 4097), the Commission has not demonstrated, and is it not apparent from the documents before the Court, that the undertakings in question were unable upon request to obtain from the Minister for Economic Affairs the precise reasons for the decisions adopted in the matter of prices, even though in most cases, according to the documents before the Court, the reasons for those decisions were given only in summary form.

26 It follows from all the foregoing that none of the Commission's allegations concerning the system of fixing the prices of pharmaceutical products is well founded.

Approval of pharmaceutical products for reimbursement by social security

27 The rules on the reimbursement of pharmaceutical supplies are laid down in the Royal Decree of 2 September 1980, mentioned above. In accordance with that decree, the proprietary pharmaceuticals and other pharmaceutical products appearing on the lists drawn up under the conditions determined by the Institut National d'Assurance Maladie-Invalidité may qualify for reimbursement by it.

28 Under Article 3 of that decree, 'to qualify for approval proprietary pharmaceuticals must comply with criteria for approval with regard to composition and price and must present an interest from the social point of view'. The criteria governing composition and dosage are contained in an annex to the decree. To qualify for approval for reimbursement, a product must not only come within a given therapeutic category, but its approval must be of practical 'utility'. Under Article 5 of the decree, the prices for sale to the public of the products whose approval is requested must not exceed a certain percentage of the price of a similar proprietary pharmaceutical. However, proprietary pharmaceuticals with identical active principles and comparable galenic form must be reimbursed under the same conditions.

29 The Commission maintains, on the one hand, that the decisions adopted on approval for reimbursement are not based on objective and verifiable criteria and, on the other hand, that inclusion of the products on the list of products eligible for reimbursement is often made conditional on a reduction in the maximum price determined by the Minister for Economic Affairs, which leads undertakings to forgo marketing them.

30 The Kingdom of Belgium replies, first, that the undertakings became aware of the criteria applied to them as a result of the dialogue established between them and the technical committee on proprietary pharmaceuticals and, secondly, that there is nothing to prohibit a demand for a reduction in price, since it is open to the Government purely and simply to exclude a product from reimbursement. It adds that the rules contested by the Commission were amended by a decree of 20 April 1988 (*Moniteur Belge* of 29 April 1988, p. 6118) which, on the one hand, establishes a procedure for dialogue with the undertakings in question whereby greater transparency can be assured and, on the other hand, prohibits price-reduction recommendations from being made to them.

31 It should be borne in mind that, as the Court has already pointed out in the *Duphar* judgment, mentioned above, although the exclusion of a pharmaceutical product from reimbursement by the social security institutions may result in its complete disappearance from the national market, States must, because of the specific nature of the trade in pharmaceutical products, which is characterized by the coverage to a large extent of their cost by the social security institutions, be permitted to regulate the consumption of such products, particularly in order to promote the financial stability of those institutions, in particular by determining

the products which may be reimbursable. However, decisions in that regard must not discriminate against imported products and must be based on objective criteria that are independent of the origin of the products and verifiable by any importer. The Commission's allegations must be examined in the light of those principles.

32 As regards the criteria applied for approval for reimbursement, it is clear from the documents before the Court, first, that the therapeutic criteria are laid down in annexes, amended from time to time, to the Royal Decree of 2 September 1980. They are therefore accessible to everyone. Secondly, it is clear from the documents before the Court that the undertakings enter into a dialogue with the competent departments whereby they can ascertain the criteria applied in their case and may be prompted, in an appropriate case, to challenge those criteria and to supply the administration with further relevant factors. Given those circumstances, the Commission has not discharged the burden, which falls upon it, of proving that the criteria applied lacked objectivity as such, or in the use made of them, or that the undertakings concerned were unable to carry out any verification.

33 As regards the price to which the reimbursement of pharmaceutical products is made subject — and there is nothing to prevent it from being lower than the maximum price approved under the system of price control — it appears from the documents before the Court that that price is fixed by the administration by means of a comparison with the price of comparable proprietary pharmaceuticals on the market. The few examples given by the Commission do not support the conclusion that it was fixed in an arbitrary manner or, moreover, that an excessively low level was the sole reason which led undertakings to abandon the marketing of their products.

34 Accordingly, with regard to these two allegations the Commission has not provided proof of the alleged infringement.

The system of programme contracts in the pharmaceutical products sector

35 The Royal Decree of 31 December 1983, mentioned above, permitted the Minister for Economic Affairs and the Minister for Social Security to enter into programme contracts with producers, importers or packagers of pharmaceutical products, entailing commitments with regard, *inter alia*, to investment, research, employment

and exports, in exchange for authorized prices and reimbursement. To take account of those contracts, a royal decree of 14 October 1985 (*Moniteur Belge* of 21 November 1985, p. 17137), amending the Royal Decree of 2 September 1980 on conditions for reimbursement, provided that the prices of pharmaceutical products coming within the terms of a programme contract would, on the one hand, not be subject to the provisions of Article 5 of the latter decree, pursuant to which the price of pharmaceutical products may not exceed, for the purpose of approval for reimbursement, a certain percentage of the price of similar products, and, on the other hand, could not be used as a basis of comparison in determining the basis for reimbursement of products not subject to a programme contract.

36 In the Commission's view, the system of programme contracts is discriminatory and favours national products because only national undertakings can benefit from them and the price advantage has repercussions on approval for reimbursement.

37 The Kingdom of Belgium states that, following the Commission's reasoned opinion of 30 September 1987 (SG (87) 11716), a law of 30 December 1988 (*Moniteur Belge* of 5.1.1989, p. 75) repealed the system of programme contracts. Existing contracts continue until expiry, but are not renewed, and no new contracts are entered into.

38 By permitting price increases to be granted outside the general rules laid down by the Law of 9 July 1975 and by the Royal Decree of 11 December 1975 in return for undertakings on investment, research, employment and exports, the system of programme contracts resulting from the Royal Decree of 31 December 1983 is such as to place imported products at a disadvantage and therefore constitutes a measure having an effect equivalent to a quantitative restriction prohibited by Article 30 of the EEC Treaty (see judgment in *Commission* v *Italy*, cited above).

39 That is all the more true since the pharmaceutical products covered by a programme contract are expressly exempted from the rules laid down in Article 5

of the Royal Decree of 2 September 1980 barring pharmaceutical products from approval for reimbursement where their price exceeds that of similar products by a given percentage, and since they may not, moreover, be used as a basis of comparison for the purposes of approval for reimbursement of other products.

40 Although it is true that the system of programme contracts was repealed by the Law of 30 December 1988, it is not disputed by the Kingdom of Belgium that contracts already entered into continue to be performed until their expiry, which has the effect of perpetuating the infringement.

41 As regards contracts which had already been concluded and which have expired, it should be pointed out that, according to the consistent case-law of the Court, the subject-matter of infringement proceedings under Article 169 of the EEC Treaty is determined in the Commission's reasoned opinion and that, even where the default has been remedied after the time-limit prescribed by the second paragraph of that article, there is still an interest in pursuing the action. That interest may, in particular, be to establish the basis of liability which a Member State may incur, as a result of its default, vis-à-vis other Member States, the Community or private parties (see judgments in Case 39/72 *Commission* v *Italy* [1973] ECR 101 and in Case C-287/87 *Commission* v *Greece* [1990] ECR I-125).

42 It must therefore be held that by introducing, by the Royal Decree of 31 December 1983, a system of programme contracts in the pharmaceutical products sector and by giving preference as regards approval for reimbursement to products benefiting from such contracts, the Kingdom of Belgium has failed to fulfil its obligations under the EEC Treaty.

Costs

43 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. However, the first subparagraph of Article 69(3) provides that the Court may order the parties to bear their own costs in whole or in part if

each party succeeds on some and fails on other heads. Since the Commission has succeeded only on some heads of the form of order which it seeks, the parties should be ordered to bear their own costs.

On those grounds,

THE COURT

hereby:

(1) Declares that, by introducing by the Royal Decree of 31 December 1983, a system of programme contracts in the pharmaceutical products sector and by favouring, as regards approval for reimbursement, products which benefit from such contracts, the Kingdom of Belgium has failed to fulfil its obligations under the EEC Treaty;

(2) Dismisses the remainder of the Commission's application;

(3) Orders the parties to bear their own costs.

Due Mancini O'Higgins Moitinho de Almeida

Rodríguez Iglesias Díez de Velasco Slynn Kakouris

Joliet Schockweiler Grévisse Zuleeg Kapteyn

Delivered in open court in Luxembourg on 19 March 1991.

J.-G. Giraud
Registrar

O. Due
President