JUDGMENT OF THE COURT
8 April 1992 *

In Case C-62/90,

Commission of the European Communities, represented by Jörn Sack, Legal Adviser, assisted by Renate Kubicki, a national official on secondment to the Commission, acting as Agents, with an address for service in Luxembourg at the Chambers of Roberto Hayder, a representative of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Federal Republic of Germany, represented initially by Ernst Röder, Ministerialrat at the Federal Ministry for Economic Affairs, and Gerhard Leibrock, Oberregierungsrat in the same Ministry, subsequently by Ernst Röder alone, acting as Agents, with an address for service in Luxembourg at the Embassy of the Federal Republic of Germany, 20-22 Avenue Emile Reuter,

defendant,

APPLICATION for a declaration that, by prohibiting individuals, subject to the exceptions provided for in indents 6 and 6a of Paragraph 73(2) of the Law on Medicinal Products (Gesetz zur Neuordnung des Arzneimittelrechts, Arzneimittelgesetz) of 24 August 1976, as most recently amended by the Law of 11 April 1990, from importing, in quantities not exceeding normal personal needs, medicinal products which, available only on prescription in the Federal Republic of Germany, have been prescribed by a doctor and purchased in a pharmacy in another Member State, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty,

* Language of the case: German.

THE COURT,

composed of: O. Due, President, R. Joliet, F. A. Schockweiler, F. Grévisse and P. J. G. Kapteyn (Presidents of Chambers), G. F. Mancini, C. N. Kakouris, J. C. Moitinho de Almeida, G. C. Rodríguez Iglesias, M. Díez de Velasco and M. Zuleeg, Judges,

Advocate General: F. G. Jacobs,
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 January 1992,

after hearing the Opinion of the Advocate General at the sitting on 13 March 1992,

gives the following

Judgment

1 By application lodged at the Court Registry on 12 March 1990, the Commission of the European Communities brought an action under Article 169 of the EEC Treaty seeking, in its claims, as finally formulated, a declaration that, by prohibiting individuals, subject to the exceptions provided for in indent 6 and 6a of Paragraph 73(2) of the Law of 24 August 1976 on medicinal products (Arzneimittelgesetz, hereinafter referred to as 'the AMG', BGBl. I, p. 2445), as amended by the Law of 11 April 1990 (BGBl. I, p. 717), from importing, in quantities not exceeding normal personal needs, medicinal products which, available only on prescription in the Federal Republic of Germany, have been prescribed by a doctor in a purchased in a pharmacy in another Member State, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty.

2 Paragraph 73(1) of the AMG, as amended by the Law of 11 April 1990, provides:

'Medicinal products subject to approval or registration may be imported into the territory covered by this Law — except in duty-free areas other than the Island of Heligoland — only if they are approved or registered for marketing within that territory or if they are exempt from approval or registration and,

1. where the product is imported from a Member State of the European Communities, the recipient is a pharmaceutical undertaking, a wholesaler, veterinary surgeon or a pharmacist;

...'

3 However, subparagraph (2) of the same paragraph states:

'(2) Subparagraph (1) shall not apply to medicinal products which:

...

6. are imported upon entry into the territory covered by this Law in a quantity corresponding to normal personal needs;

6a. are available without medical prescription, may be put on the market in the country of origin and are obtained in a Member State of the European Communities in a quantity corresponding to normal personal needs;

7. are imported in vehicles intended for use and consumption exclusively by the persons carried in those vehicles;

8. are intended for use and consumption on sea-going vessels and are consumed on board such vessels;

...'

4 The Commission, which takes the view that the importation by private persons, for their personal needs, of medicinal products properly prescribed and supplied in another Member State should not be subject to restrictions (answer to written question No 2640/85 by Mr Rogalla, a member of the European Parliament, OJ 1986 C 182, p. 44), considers that the German legislation, in so far as it does not authorize such importation except in cases which are far more narrowly defined, is contrary to the provisions of Articles 30 and 36 of the EEC Treaty.

5 It accordingly decided to initiate the infringement procedure under Article 169 of the Treaty against the Federal Republic of Germany for failure to comply with its obligations under the Treaty. After giving formal notice to the Federal Republic of Germany to submit its observations, it issued a reasoned opinion on 23 November 1988. Since it considered that the reply by the German Government was unsatisfactory, it then brought the present action, although, in its reply, and then in its written answer to the questions put to it by the Court, it narrowed the scope of its claims.

6 Its claims now cover only the importation by individuals, for their personal needs, of medicinal products available on prescription in the Federal Republic of Germany, prescribed by a doctor in another Member State and purchased in a pharmacy in another Member State. However, the Commission stated, in reply to the questions put to it by the Court, that it was not its intention to limit the action solely to the dispatch of such medicinal products by post.

7 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the procedure and the pleas and arguments of the parties, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

8 It should first be noted that, as maintained by the Commission and admitted by the Federal Republic of Germany, the prohibition on the importation by individuals of medicinal products, subject to the exceptions set out in the Law, constitutes, as the Court has consistently held, a measure having an effect equivalent to a restriction on imports.

9 It is therefore necessary to consider whether such a prohibition can be justified under Article 36 of the Treaty.

10 On the one hand, the Court has consistently held that, the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure and in particular how strict the checks to be carried out are to be. On the other hand, Article 36 remains applicable where harmonization of national legislation in the field of the manufacture and marketing of proprietory medicinal products has not been fully achieved (judgments of 7 March 1989 in Case 215/87 *Schumacher* v *Hauptzollamt Frankfurt am Main-Ost* [1989] ECR 617, paragraph 15, and in Case C-347/89 *Freistaat Bayern* v *Eurim-Pharm GmbH* [1991] ECR I-1747, paragraph 26).

11 However, it follows from Article 36 that national rules or practices having, or likely to have, a restrictive effect on the importation of pharmaceutical products is compatible with the Treaty only to the extent that they are necessary for the effective protection of health and life of humans. National rules or practices cannot benefit from the derogation provided for in Article 36 if the health and life of humans can be protected just as effectively by measures which are less restrictive of intra-Community trade.

12 The Commission maintains that the prohibition on importation contained in the German legislation is not necessary for the effective protection of the health and life of humans. It argues essentially that the prescription of a medicinal product by a doctor in the exporting Member State and the dispensing of that product by a pharmacist in that State ensures a protection of public health and human life which is comparable to that provided in the Member State of importation. It notes also that the fact that the medicinal product is used in a Member State other than that in which it was purchased neither prevents the prescribing doctor from continuing medical supervision of the patient nor the pharmacist in the exporting Member State from advising the person purchasing the medicinal product.

13 The Federal Republic of Germany submits, on the other hand, that the prohibition of imports imposed by its legislation, which in practice now involves only the dispatch of medicinal products by post, is essential in order to guarantee effective protection of the health and life of humans. It states that medicinal products for which a prescription is required pose a danger to public health and cannot be used in complete safety if they are purchased in another Member State. The use of a foreign language on the label and in the directions-for-use leaflet, together with the remoteness of the doctor who prescribed the medicinal product and of the pharmacist who sold it, thus give rise to a danger that the imported medicinal product might be incorrectly used by the purchaser and thus imperil his health.

14 In that regard it should first be pointed out that, in order to eliminate obstacles to trade in pharmaceutical products without prejudice to the essential aim of safeguarding public health, Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), in the version in force prior to Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11), provided that no proprietary medicinal products may be placed on the market of a Member State unless an authorization had been issued by the competent authority of that Member State on the basis of an application giving details of the constituents of the product, its use, its effects and the control methods employed by the manufacturer. That same directive requires Member States to refuse or revoke the authorization if the proprietary medicinal product is harmful in the normal conditions of use, or its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant or the controls provided have not been carried out.

15 Since the Commission's action for failure to fulfil Treaty obligations is confined to proprietary medicinal products authorized in both the exporting and importing Member States, the products which are the subject of the present case cannot, in the light of the above provisions of the directive, be regarded as imperilling public health in the normal conditions of use.

16 Secondly, it should be pointed out that the conditions of access to the medical profession and the conduct of the profession were the subject of Council Directive 75/362/EEC of 16 June 1975 concerning the initial recognition of diplomas, certificates and other evidence of formal qualifications in medicine, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services, and of Council Directive 75/363/EEC of 16 June 1975 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of activities of doctors (OJ 1975 L 167, pp. 1 and 14), as most recently amended by Council Directive 89/594/EEC of 30 October 1989 (OJ 1989 L 341, p. 19). As far as the conditions of access to the profession of pharmacist, and the conduct of that profession, are concerned, that was the subject of Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy, and of Council Directive 85/433/EEC of 16 September 1985 concerning the initial recognition of diplomas, certificates and other evidence of formal qualification in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (OJ 1975 L 253, pp. 34 and 37 respectively).

17 The Court has held, in its judgment in *Schumacher*, cited above, paragraph 20, that the purchase of a medicinal preparation in a pharmacy in another Member State provides a guarantee equivalent to that which would arise from sale of the preparation by a pharmacy in a Member State into which the medicinal preparation is imported by a private individual, and that that conclusion is all the more compelling inasmuch as the conditions for access to the profession of pharmacist and the conditions for exercise of that profession regulated in Council Directives 85/342 and 85/433, cited above.

18 Similarly, it must be held that, in the light of the harmonization achieved by Directives 75/362 and 72/363, as amended, with respect to the conditions for

access to the medical profession and the conditions for the exercise of that profession, the prescription of a medicinal product by a doctor in another Member State must be regarded as providing a guarantee equivalent to that which would result from the prescription of a medicinal product by a doctor in the importing State.

19 Contrary to what is maintained by the German Government, the fact that the doctor who prescribed the medicinal product or the pharmacist who sold it are established in a Member State other than that in which the medicinal product is used does not prevent those practitioners from supervising the use of the imported medicinal product, where appropriate with the aid of a colleague established in the importing Member State.

20 The doctor or pharmacist from the other Member State can, moreover, when supplying the medicinal product, make up for any inadequacies in the label or directions for use which may arise in particular from their being written in a language other than that of the patient.

21 The Federal Republic of Germany puts forward two additional arguments. On the one hand, it would not be possible to ensure at the frontier that medicinal products were imported in quantities not exceeding personal needs without intruding on personal privacy and, in particular, on the right to the protection of medical confidentiality. On the other hand, since not all Member States require a pharmacist's stamp on the medical prescription, and since, even where such an obligation exists it is not always respected, it would be impossible to ensure health protection as effective as that guaranteed by the German legislation under which a prescription can be used only once in order to obtain medicinal products.

22 The Commission contends, on the one hand, that the right to medical confidentiality cannot prevent checks from being made on the quantities of medicinal products imported. It contends, on the other hand, that it is current practice in the

Member States for the pharmacist to stamp the prescription, a practice vehicle makes it possible to check the quantity of medicines supplied under one and the same prescription. Furthermore, the German Government has not been able to provide any specific evidence of the abuses alleged to arise from a failure to comply with this practice in certain Member States.

23 The right to respect for private life and, as one of its aspects, the right to the protection of medical confidentiality constitute fundamental rights protected by the legal order of the Community (see judgment in Case 136/79 *National Panasonic* v *Commission* [1980] ECR 2033). As the Court held in its judgment in Case 260/89 *Elleniki Radiophonia Tileorassi* v *Dimiotiki Etaivia Pliroforissis and Others* [1991] ECR 2925, paragraph 43, where a Member State relies on the provisions of the Treaty in order to justify national rules which are likely to obstruct the exercise of a freedom guaranteed by the Treaty, such justification, provided for by Community law, is to be interpreted in the light of the general principles of law and in particular of fundamental rights. Those rights, however, do not constitute unfettered prerogatives and may be restricted, provided that the restrictions in fact correspond to objectives of general interest pursued by the Community and that they do not constitute, with regard to the objectives pursued, a disproportionate and intolerable interference which infringes upon the very substance of the rights guaranteed (judgment in Case 265/87 *Hermann Schräder HS Kraftfutter GmbH & Co KG* v *Hauptzollamt Gronau* [1989] ECR 2237, paragraph 15). Objectives which may justify such restrictions include the protection of public health and human life.

24 In those circumstances, it is permissible for the competent authorities of the Member States to control, for the purposes of protecting public health, the importation of medicinal products which are supplied only on prescription in the importing Member State. Such controls must, however, be carried out in such a way as to meet the requirements arising from the protection of fundamental rights, as set out above.

25 The German Government has, however, failed to adduce in support of its two arguments any evidence to show that it would be impossible for it to adopt control measures meeting what the German authorities consider to be the requirements of

the protection of public health and human life and without unduly impairing medical confidentiality. Its arguments must therefore be rejected.

26 It should also be noted that in Paragraph 73(2) (indents 6, 7 and 8) of the AMG, the German legislature provided that the prohibition on importation was not applicable to medicinal products imported, upon the entry of individuals into the territory covered by the AMG, in quantities not exceeding normal personal needs and to medicinal products imported in vehicles or on board vessels and intended exclusively for use or consumption by the persons transported in those vehicles or on those vessels. The German legislature itself therefore did not consider it necessary to subject the imports mentioned in Paragraph 73(2) of the AMG, although such imports present equivalent difficulties, in terms of control, to a prohibition such as that at issue in the present case.

27 It must therefore be concluded that, by prohibiting individuals, subject to the exceptions provided for in indent 6 and 6a of Paragraph 73(2) of the Law on Medicinal Products (Arzneimittelgesetz) of 24 August 1976, as most recently amended by the Law of 11 April 1990, from importing, in quantities not exceeding normal personal needs, medicinal products which, available only on prescription in the Federal Republic of Germany, have been prescribed by a doctor and purchased in a pharmacy in another Member State, the Federal Republic of Germany has failed to fulfil its obligations and Article 30 et seq. of the Treaty.

Costs

28 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since the defendant has been unsuccessful, it must be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. **Declares that, by prohibiting individuals, subject to the exceptions provided for in indent 6 and 6a of Paragraph 73(2) of the Law on Medicinal Products (Arzneimittelgesetz) of 24 August 1976, as most recently amended by the Law of 11 April 1990, from importing, in quantities not exceeding normal personal needs, medicinal products which, available only on prescription in the Federal Republic of Germany, have been prescribed by a doctor and purchased in a pharmacy in another Member State, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 et seq. of the Treaty;**

2. **Orders the defendant to pay the costs.**

Due Joliet Schockweiler Grévisse

Kapteyn Mancini Kakouris Moitinho de Almeida

Rodríguez Iglesias Díez de Velasco Zuleeg

Delivered in open court in Luxembourg on 8 April 1992.

J.-G. Giraud
Registrar

O. Due
President