purchase in a pharmacy in another Member State must be regarded as offering guarantees equivalent to those resulting from prescription of the medicinal product by a doctor and its sale by a pharmacy in the Member State into which the medicinal product is imported by a private individual, since the conditions governing access to and the exercise of the professions of doctor and pharmacist have been the subject of Community directives.

2. Where a Member State relies on the provisions in 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, among which feature the right to respect for private life and, as one of its aspects, the right to the protection of medical confidentiality. Those rights do not, however, 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. Objectives which may justify such restrictions include the protection of public health and human life.

It is therefore permissible for a Member State to control, for the purposes of protecting public health, the importation by private individuals of medicinal products which are supplied only on prescription in its territory, provided those controls are carried out in such a way as to meet the requirements arising from the protection of fundamental rights.

REPORT FOR THE HEARING
in Case C-62/90 *

I — Facts and pre-litigation procedure

Paragraph 73(1) of the Gesetz zur Neuordnung des Arzneimittelrechts (German law making new provision with respect to medicinal products, hereinafter the 'AMG') of 24 August 1976 (BGBl. I, p. 2445) provides as follows:

'Medicinal products subject to approval or registration may be imported into the territory covered by this Law — except in

* Language of the case: French.

duty-free areas other than the island of Helgoland — only if they are approved or registered for marketing within that territory or 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, a veterinary surgeon or a pharmacist;

...'

However, subparagraphs (2) and (3) of Paragraph 73, as drafted prior to the adoption of the Law of 11 April 1990 amending the AMG (BGBl. I, p. 717), provided as follows:

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

1. are intended in specific cases for use in small quantities for the treatment of certain animals in connection with animal shows, competitions or similar occasions;

2. are intended to meet the needs of scientific and research establishments and are necessary for scientific purposes;

3. are transported across the territory covered by this Law under customs supervision or are re-exported after passing through a customs warehouse or a warehouse under customs control;

4. are intended for the use of a foreign head of state or his entourage when staying in the territory covered by this Law;

5. are intended for the personal use or consumption of members of diplomatic missions or consular representatives established in the territory covered by this Law or for officials of international organizations which have their seat within that territory and for members of their families, provided such persons are neither German nationals nor permanently resident within the territory covered by this Law;

6. are imported by travellers in quantities which do not exceed such use or consumption as is normally appropriate during travel;

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

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

9. are sent as samples to the competent Federal authorities for approval or inspection of consignments;

10. are acquired by the Federal or Land authorities in the course of international trade.

(3) By derogation from subparagraph (1), finished medicinal products which are not approved or registered for marketing within the territory covered by this Law or which have not been exempted from approval or registration may be imported into that territory if they are intended for pharmacies. Such products may be obtained by pharmacies only in small quantities, if specially ordered by individuals and solely in the ordinary course of business.'

The Commission's attention was drawn to those provisions in Case C-215/87 concerning a request to the Court by the Hessisches Finanzgericht pursuant to Article 177 of the EEC Treaty for a preliminary ruling in the proceedings pending before that court between Heinz Schumacher and the Hauptzollamt Frankfurt/Main-Ost on the interpretation of Articles 30 and 36 of the EEC Treaty (judgment in Case 215/87 *Schumacher* v *Hauptzollamt am Main-Ost* [1989] ECR 617).

The Commission takes the view, as it stated in its answer to Written Question No 2640/85 by Mr Rogalla, a Member of the European Parliament (OJ 1986 C 182, p. 44), that the importation of medicines by individuals for their personal needs must be free from restrictions provided they have been properly prescribed or dispensed in another Member State. It 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 Articles 30 and 36 of the EEC Treaty and that the Federal Republic of Germany has consequently failed to fulfil its obligations under the Treaty.

For those reasons, by letter of 22 February 1988 it requested the German Government in accordance with Article 169 of the EEC Treaty to submit its observations.

On 17 June 1988 the German Government replied that the prohibition imposed on the importation of medicinal products by individuals was indissociable from its system of distribution for such products which was designed to ensure safety in that sector and that it could not be replaced by less restrictive provisions without detracting from the effectiveness of the system. The German Government added that it had taken into account the interest of individuals in so far as imports were authorized, under Paragraph 73(2), in cases that were considered justified and that in the absence of recognition at Community level of authorizations to market the products, wider possibilities of importation by individuals would enable the system of authorization to be circumvented thereby increasing the risks for public health.

Taking formal note of the fact that the German Government did not intend to amend its legislation, the Commission issued a reasoned opinion on 23 November 1988 stating that, by prohibiting the importation

by individuals of medicinal products intended for their personal use, the Federal Republic of Germany had failed to fulfil its obligations under Article 30 of the EEC Treaty, and it requested the Federal Republic to adopt the measures needed to comply with the reasoned opinion within two months.

By letter of 25 January 1989 the German Government replied that the prohibition imposed on the importation of medicinal products by individuals was justified on grounds of public health, which it was the German Government's task to safeguard, and that it could not be abolished without calling in question the fundamental principle that medicinal products are to be prescribed by doctors and without disregarding the role of pharmacists in dispensing such products.

By letter of 15 November 1989 the German Government notified the Commission of its draft law amending the AMG and, in particular, authorizing the importation of medicinal products by individuals, to the extent provided for by the Court in its judgment of 7 March 1989 in *Schumacher*.

Paragraph 41 of the aforesaid Law of 11 April 1990 amending the AMG amended indent 6 of Paragraph 73(2) of the AMG and added indents 2a and 6a thereto. It follows from those provisions that Paragraph 73(1) is applicable only to medicinal products which:

'2. a are required in small quantities by a pharmaceutical undertaking as samples for experimental or analytical purposes,

...

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

6. a are available without a 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,

...'.

II — Procedure before the Court and forms of order sought by the parties

1. By an application lodged at the Court Registry on 12 March 1990 the Commission brought an action against the Federal Republic of Germany before the Court pursuant to the second paragraph of Article 169 of the EEC Treaty for failure to fulfil its obligations.

2. Following the adoption of the aforesaid Law of 11 April 1990 amending Paragraph 73 of the AMG, the Commission stated in its reply that it was limiting the subject-matter of its application accordingly.

3. In the latest version of its application, the *Commission* claims that the Court should:

(i) declare that, by prohibiting individuals — except in the cases referred to in indents 6 and 6a of Paragraph 73(2) of the AMG — from importing for their personal use medicinal products purchased in a pharmacy in another Member State, where such products are not permitted in the Federal Republic of Germany or are available only on prescription, and in the latter case even when the products have been prescribed by a doctor established in the Member State of exportation, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty;

(ii) order the Federal Republic of Germany to pay the costs.

4. The *Federal Republic of Germany* contends that the Court should:

(i) dismiss the Commission's application;

(ii) order the Commission to pay the costs.

5. On hearing the Report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

III — Submissions and arguments of the parties

A — The *Commission* points out first of all that a degree of harmonization has already been achieved in the field of medicinal products as a result of the directives adopted by the Council, in particular Directive 65/65/EEC of 26 January 1965 (OJ English Special Edition 1965-1966, p. 20) and Directive 75/319/EEC of 20 May 1975 (OJ 1975 L 147, p. 13), on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as most recently amended by Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11), and that full harmonization will be achieved between now and 1992. In particular, Article 3 of Directive 65/65 of 26 January 1965 provides that no medicinal product may be placed on the market without an authorization issued in accordance with a specific procedure and under specific conditions, and that the labelling of the product and the leaflet for users must contain the information specified by that article, including certain information drafted in the language of the country in which the product is marketed; those requirements have been incorporated in Articles 21, 10 and 11 of the AMG.

Next, the Commission points out that the restriction on imports of medicinal products provided for by the first indent of Paragraph 73(1) of the AMG constitutes a measure having equivalent effect within the meaning of Article 30 of the Treaty, according to the Court's judgment of 7 March 1989 in *Schumacher.*

Since in that judgment the Court held to be incompatible with Articles 30 and 36 of the EEC Treaty the prohibition of imports of medicinal products authorized and dispensed without medical prescription in the Member State of importation, which are purchased in a pharmacy in another Member State, the Commission considers

that the position must be the same where the medicinal product is not freely on sale in the Member State of importation or is available there only on prescription.

In its view, if it is clear that medicinal products purchased abroad without medical prescription are intended exclusively for personal needs, it is unnecessary to raise the question whether those products are also authorized in Germany.

The Commission considers that every citizen is at liberty to select the medical treatment which he undergoes, as well as the Member State in which he wishes to consult a doctor or purchase medicinal products. Although the Member States may regulate the market in medicinal products on their territory, they may not interfere with the private choices of their nationals or, in particular, restrict on grounds of public health imports of medicinal products intended for personal use. There is an obligation to protect public health only in relation to society as a whole, that is to say towards persons who are unaware of the risk they incur. The State has a special duty of protection only if it has refused to authorize the marketing of a medicinal product on account of the gravity of its secondary effects on health. In all other cases in which a medicinal product has not been authorized, either on economic grounds or because the authorization procedure has not been completed, the patient's freedom of choice must take precedence. Moreover, the AGM recognizes that freedom since in Paragraphs 40 and 41 it allows the experimental use of unauthorized medicinal products on consenting patients. The same considerations should apply with regard to the importation of such products, provided they are imported through pharmacies in the ordinary course of business or by travellers for their own purposes.

According to the Commission, in view of the degree of harmonization already achieved in this sector, a medicinal product authorized in one Member State cannot endanger the health of nationals of another Member State. Any differences in the accompanying leaflets and in the wording of information intended for patients may be resolved by the doctor's intervention in the case of medicinal products available only on prescription or by the pharmacist's intervention in other cases. Furthermore, in practice, those who purchase medicinal products in another country frequently possess an adequate knowledge of that country's language, or at least have links with that country which preclude any risk of misuse. Finally, since a medicinal product freely on sale may be imported even if the leaflet is not drafted in the language of the purchaser, the same must hold true in the case of medicinal products available only on prescription.

The Commission also maintains that the purchase of a medicinal product in another Member State in no way precludes medical supervision. That is normally ensured, as in the case of medicinal products purchased domestically, where they are prescribed by a doctor of the State in question. Supervision may be ensured by means of regular consultations or, in emergencies, by telephone, where — a situation which very seldom arises in practice — it is a doctor from another Member State who makes out the prescription. In the case of a product sold

over the counter, medical supervision is unnecessary.

According to the Commission, the purchase of a medicinal product in another Member State does not affect the pharmacist's advisory role either. If the product is available only on prescription, the pharmacist's task is limited to ensuring that the product is properly dispensed. In other cases, the pharmacist discharges his advisory role, either at the time of purchase or, if necessary, in writing.

The Commission points out that the use of a single prescription more than once in order to obtain medicinal products can easily be prevented if it is stamped by the pharmacist, which is the current practice in the Member States. In that regard, the Commission observes that the German Government has been unable to provide any firm evidence of the abuses which, it alleges, occur in other Member States.

Finally, the Commission considers that, contrary to the German Government's contention, it is quite possible to supervise the quantity of medicinal products purchased by an individual. The quantity is limited by the medical prescription in the case of products available only on prescription. It can easily be supervised in other cases, since medicinal products are liable to an import tax. Furthermore, it is possible to determine whether the imports are intended for personal use, the onus of proof always being borne by the recipient. The right to privacy in no way prevents a citizen who decides to import medicinal products from being subjected to the usual and necessary controls and from being required, in particular, to provide information regarding the content and intended use of the imported product. The Commission points out, in that regard, that the fact that unauthorized medicinal products may be purchased through pharmacies, pursuant to Paragraph 73(3) of the AMG, demonstrates that the prohibition on importation by individuals is designed to protect the interests of German pharmacists and not the health of the public.

B — The *Federal Republic of Germany* points out first of all that Article 36 of the EEC Treaty remains applicable since, as the Commission acknowledges, the harmonization of the rules relating to medicinal products has not yet been fully achieved at Community level, particularly as regards important matters such as the mutual recognition of marketing authorizations, the labelling of finished medicinal products, accompanying leaflets and the requirement of a prescription for the dispensation of medicinal products. Since the process of harmonization is incomplete, the Member States are still free to adopt rules which they consider to be most appropriate for the protection of public health. The Federal Republic points out in that regard that the Commission concedes, in particular, that the sales monopoly conferred on pharmacists by German law is in conformity with the Treaty.

The Federal Republic also contends that the prohibition on imports laid down by the AMG is not an absolute prohibition and embodies certain mitigating factors of the kind advocated by the Commission.

To begin with, indent 6 of Paragraph 73(2) of the AMG, as amended following the

judgment of 7 March 1989 in *Schumacher*, permits the importation of medicinal products, even where a medical prescription is needed, in a quantity corresponding to normal personal needs, upon entry into the territory covered by the AMG. Secondly, indent 6a of Paragraph 73(2) of the AMG authorizes the importation of medicinal products which are available without a prescription and which are authorized in the Member State of origin in a quantity corresponding to normal personal needs. On those two points the Commission's application is unfounded.

The Federal Republic therefore considers that the Commission's application can relate only to the situation — which very seldom arises in practice — where medicinal products are sent by post since the importation of such products by travellers is authorized under the AMG.

In such a case, it maintains, importation cannot be authorized without restriction, contrary to the Commission's contention, and the restrictions resulting from the AMG are justified in the light of Article 36 of the Treaty since they are necessary for the effective protection of public health and are in keeping with the aim pursued.

First of all the defendant points out that the power conferred on the Member States under Article 36 of the EEC Treaty is not limited to supervising access to a given market. It enables Member States to limit the freedom of individuals, particularly of their own nationals when they are on their territory, in the interests of public health, and to ensure that the rules laid down to that end have been observed. The Federal Republic contends in that regard that to accept that a medicinal product whose consumption is prohibited in a Member State may nevertheless, in the name of freedom of consumption, be freely consumed in that State once it has been imported is tantamount to depriving the prohibition of its effectiveness and subjecting one Member State to the rules enacted by another Member State.

Secondly, the defendant points out that although, in the judgment of 7 March 1989 in *Schumacher*, the medicinal products in question were not regarded as dangerous for public health by the importing Member State which had, as a result, authorized them to be dispensed without a prescription, that is not so in this case which is concerned with medicinal products available only on prescription, that is to say medicinal products in respect of which the importing Member State intends to exercise the powers conferred on it by Article 36 of the Treaty in the interests of public health.

Thirdly, the Federal Republic contends that the Commission's argument restricts to a considerable extent the supervisory role of doctors and the advisory role of pharmacists.

Medical supervision, which is essential where the patient takes a medicinal product which is available only on prescription and which may therefore be dangerous if the prescribed doses are exceeded, requires the doctor to be capable of being reached at all times. That cannot be assured if the doctor resides in another Member State. The defendant regards as unrealistic the

Commission's argument that regular consultations or, in emergencies, contact by telephone alone, are sufficient to ensure constant medical supervision. First of all, the cost of such consultations, which are non-refundable, added to that of sending the medicinal product by post, would nullify any saving which could be made by purchasing a product that is cheaper abroad, which is the only plausible reason for importing it. Secondly, linguistic obstacles would complicate such consultations and especially telephone conversations. Thirdly, the idea of patients being advised over the telephone without being examined by a doctor is particularly disquieting.

The pharmacist's advisory function, which is recognized in Article 1(2) of Council Directive 85/432/EEC of 16 December 1985 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (OJ 1985 L 253, p. 34) is equally essential, particularly in connection with medicinal products which may endanger the patient's health, and plays an important role in practice. It complements the doctor's task since Paragraph 17(8) of the Apothekenbetriebsordnung (Rules on the operation of pharmacies) of 9 January 1987 (BGBl. I, p. 547) provides that pharmacists must prevent any abuse of medicinal products and, if necessary, refuse to dispense such products.

The pharmacist's advisory function entails direct contact with the patient, which is impossible if a product is sent by post in another Member State, whilst that function is particularly necessary precisely in those circumstances in view of the fact that the indications set out on the packaging or in the accompanying leaflet are in a foreign language.

Fourthly, the Federal Republic contends that the use of a medicinal product presupposes the ability to understand the indications set out on the packaging and in the accompanying leaflet. To that end, the AMG provides that only medicinal products which also bear indications in German may be imported. That could not be guaranteed if individuals were themselves to import such products. In the absence of complete harmonization in this field, which will only be achieved in 1992, Paragraph 73(3) of the AMG lays down that medicinal products from abroad may be purchased only through pharmacies so as to ensure that the patient is provided with information concerning the exact use of the product. That could not be guaranteed either if the product were freely imported.

The Federal Republic's fifth point is that in order to avoid any abuse of medicinal products on its territory, the German legislation provides that a prescription may only be used once for dispensing a medicinal product (Article 3 of the Regulation of 31 October 1987, BGBl. I, p. 1933, as amended by the Regulation of 20 June 1984, BGBl. I, p. 767, on medicinal products available only on prescription). In its view, the purchase of medicinal products by post would render the legislation inoperative since pharmacists in other Member States would be unable to ascertain whether or not the products had already been dispensed. Furthermore, the Commission has failed to establish that the current practice in the Member States is for the prescription to be stamped by the pharmacist and that, in the absence of harmonization at Community level of the rules governing the sale of medicinal products available only on prescription, such a practice is not guaranteed by law.

Accordingly, since the multiple dispensation of medicinal products is authorized in certain Member States and the pharmacist's stamp may be devoid of any significance, the protection of health pursued by the German authorities would no longer be guaranteed.

The Federal Republic considers in that regard that, contrary to the Commission's contention, patients cannot be allowed to use without proper supervision and in the absence of any guarantees medicinal products which are available only on prescription and entail health risks.

The defendant's sixth point is that it is very difficult in practice to supervise the importation of medicinal products. To begin with, customs officers are unable to determine whether the imported quantities are intended for personal use only. Secondly, in view of the personal nature of the information required for the purposes of customs control, individuals would be entitled to rely on their right to privacy in refusing to communicate such information. Supervision of the kind envisaged by the Commission would not be sufficient to prevent any abuses of medicinal products.

Finally, the Federal Republic maintains that, contrary to the Commission's contention, Paragraph 73(3) of the AMG is intended to guarantee the safety of persons who obtain medicinal products from abroad and not to protect the economic interests of pharmacists because in the final analysis it is the pharmacists who have to bear the costs connected with such an order, since only the transport and telegraph costs can be charged to the patient (Paragraph 8 of the Arzneimittelpreisverordnung (Regulation on the prices of medicinal products) of 14 November 1980, BGBl. I, p. 2147).

IV — Answers by the parties to questions from the Court

A — The Court has put the following questions to the *German Government*:

Question:

(1) Does Paragraph 73(2) of the Arzneimittelgesetz (Law on Medicinal Products) of 24 August 1976 ('the AMG') authorize the importation into the Federal Republic of Germany of medicinal products which have not been approved or registered for marketing in the territory covered by that Law?

Answer:

The German Government replied that, by derogation from Paragraph 73(1) of the AMG, Paragraph 73(2) authorized the importation into the Federal Republic of Germany of medicinal products which had not been approved or registered for marketing in the territory covered by that Law.

Question:

(2) In the event, in particular, of Question 1 being answered in the affirmative, does Paragraph 73(2) of the AMG authorize the importation into the Federal Republic of Germany of medicinal products which may not be marketed in the country of origin?

Answer:

According to the German Government, the answer to this question differs according to the circumstances referred to in Paragraph 73(2) of the AMG. In some cases (for instance those referred to in indents 2, 2a, 4, 5, 6 and 9) a marketing authorization is not required either because it would be contrary to the very purpose of the derogating provision (where the products are intended for research or analysis), or because proof of approval cannot reasonably be required (where the products are intended for the use of foreign delegations, in accordance with diplomatic practice; where the products are imported by individual travellers, having regard to the practical disadvantages).

The German Government points out that in the case of medicinal products imported by individual travellers (indent 6), the legislature has abandoned the requirement that documents should be produced attesting that the product in question is authorized in the country of origin so as to ensure that, in the event of a conflict concerning the provisions applicable in the matter, a traveller undergoing medical treatment is not required to forego either his medicines or the trip.

In the situation referred to in indent 6a, however, such proof is required because, since the product and the patient do not cross the frontier together, it is both possible and reasonable to require production of the documents attesting that the product in question has been authorized.

Question:

(3) Following its amendment by the Law of 11 April 1990, does indent 6 of Paragraph 73(2) of the AMG apply to importation in any form and by any means?

Answer:

According to the German Government, indent 6 applies only to a situation in which the patient brings the products with him on his return to the Federal Republic of Germany.

Question:

(4) What is the meaning of the phrase 'normal personal needs' in the same provision?

Answer:

The German Government has pointed out that these are individual needs which are capable of being identified in practice, case by case, according to the patient's disease and the length of his stay. That phrase also covers a quantity taken by way of precaution, that is to say without a particular disease having manifested itself, in order to cover individual needs.

Question:

(5) The German Government is asked to state the reasons why indent 6a was added

by the Law of 11 April 1990 to Article 73(2) of the AMG, as well as to indicate and justify the scope of those new provisions, particularly in relation to indent 6.

Answer:

The German Government stated that indent 6a was added in order to take account of the Court's judgment of 7 March 1989 in *Schumacher*. That legislative amendment is intended to apply to products whose classification as medicinal products is recognized in the Federal Republic of Germany but not in the country of origin, as well as to medicinal products in respect of which approval is not required.

According to the German Government, indent 6a, unlike indent 6, applies to the importation of medicinal products by post. In that case, the product is dispensed without the pharmacist being able to carry out his supervisory and advisory functions. In addition, in the absence of harmonization in this area, the first stage of which is the proposal for a Council directive concerning the legal status of the supply of medicinal products for human use, the conditions governing the dispensation of such products vary appreciably from one Member State to another. Overriding considerations of public health have prompted the German legislature to restrict that possibility of importation to medicinal products which are available without prescription in the Federal Republic of Germany and whose potential harmfulness is therefore limited.

The German Government points out that any person may import by post into the Federal Republic of Germany medicinal products which are available only on prescription, in accordance with the procedure provided for in Paragraph 73(3) of the AMG, that is to say through a pharmacy.

B — The Court has put the following questions to *the Commission*:

(1) The German Government maintains, in paragraph 2 of its defence (page 6), that the infringement proceedings 'can relate only to the dispatch by post of medicinal products available only on prescription'.

Does the Commission agree with that analysis?

Answer:

The Commission stated that the form of order sought in its application should be worded as follows:

The Court is requested to 'declare that, by prohibiting individuals — except in the cases referred to in indents 6 and 6a of Paragraph 73(2) of the AMG — from importing for their personal use medicinal products purchased in a pharmacy in another Member State, where such products are available only on prescription in the Federal Republic of Germany, even when the products have been prescribed by a doctor

established in the Member State of exportation, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty'.

According to the Commission, the application relates only to the dispatch of medicinal products, regardless of the form it takes. Accordingly, it is not limited solely to the dispatch of such products by post.

Question:

(2) The Commission is asked to state precisely what steps, in its view, the Member States can take in order to ensure that medicinal products are imported in accordance with the conditions laid down in the form of order sought in its application and, in particular, in quantities which are not in excess of personal needs.

Answer:

According to the Commission, the Member States acknowledge that the phrase 'quantity corresponding to normal personal needs' covers the quantity of medicinal products needed for a month's treatment, which means the quantity generally prescribed for chronic diseases in boxes of the usual size dispensed in pharmacies.

The Commission considers that the number of boxes dispatched makes it easy to supervise the quantities imported. Such supervision may, if necessary, be tightened by seeking an expert's report or requiring the medical prescription to be produced.

C — The Court has put the following questions to the *Commission* and the *German Government*:

Question:

(1) According to Article 3 of 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, as most recently amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), which applies to this case, 'no proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State'.

The Commission and the Federal Republic of Germany are requested to state what the meaning and scope are, in their view, of the expression 'placed on the market' for the purposes of that provision. Does a medicinal product imported from another Member State always require a marketing authorization? In the importing State? In the State of origin? Does a medicinal product imported exclusively for the importer's personal needs require an authorization in order to be 'placed on the market' in the importing State?

Answer:

(a) According to the *Commission*, 'placing on the market' is an action performed by the 'person responsible' referred to in

Article 4 of the directive, who is generally the manufacturer. It follows that medicinal products sold to a pharmacy are 'placed on the market' within the meaning of the directive. That is the case, *a fortiori*, where such products are dispensed to the public by a pharmacist. A medicinal product authorized and dispensed in a pharmacy in a Member State is therefore properly 'placed on the market' within the meaning of the directive even if it is subsequently employed, strictly for personal use, in another Member State.

It would be otherwise only if the product were supplied in that other Member State without a marketing authorization, either directly by the 'person responsible' or in a manner equivalent thereto.

The Commission points out that a different interpretation would have an unfavourable impact on the freedom to import other products for personal needs (foodstuffs containing additives which are not authorized in the importing Member State; plant health products which are not authorized in that country).

(b) According to the *German Government*, although 'placing on the market' normally covers the first supply of a product by the manufacturer (or importer) either to a wholesaler or to a retailer or else directly to the consumer, it must be borne in mind that in the case of medicinal products marketing is subject to a national authorization and applies only to the domestic market.

The German Government points out that, according to Paragraph 4(17) of the AMG, 'placing on the market' means the establishment of stocks with a view to sale or another form of disposal, actual sale, offering for sale or disposal to others; consequently, any disposal of a medicinal product after it has been supplied for the first time must be regarded as marketing.

It follows, in its view, that the importation of a medicinal product by a traveller, in accordance with indent 6 of Paragraph 73(2) of the AMG, does not constitute marketing unless the product is resold to a third party. However, importation by post, which is permitted by indent 6a of Paragraph 73(2) of the AMG, constitutes marketing since the product is supplied only when the packet is handed over.

The German Government considers that individual imports of medicinal products are not governed by Community law and that the rules of Paragraph 73(2) of the AMG, which are necessary for the protection of public health and meet practical requirements and international standards, fall within the scope of the powers conferred on the Member States by Articles 30 and 36 of the EEC Treaty.

Question:

(2) The Commission states in paragraph 3 (page 5) of its reply that 'a State is under no obligation to prevent a person from knowingly incurring in connection with his personal use a risk which may be considered minimal' and that 'there is an obligation to protect public health only in relation to society as a whole, that is to say towards persons who, as a rule, are unaware of the risk they incur'.

The Federal Republic of Germany states in page 7 of its rejoinder that it 'firmly rejects' the Commission's argument and maintains, instead, that 'the State must prevent its citizens from incurring such risks'.

In the event of the provisions of Article 36 of the EEC Treaty on the 'protection of health and life of humans' being applicable, can the Commission and the Federal Republic of Germany specify the consequences which may follow, for the purposes of the application of those provisions, from the fact that the infringement proceedings relate only to the importation by individuals of medicinal products intended for their personal use?

Answer:

(a) The *Commission* considers that a Member State may, on the basis of Article 36 of the Treaty, prohibit persons residing within its territory from carrying out certain dangerous acts, even against their will, but it must also comply with the principle of proportionality.

The Commission maintains that in the case of authorized medicinal products which are prescribed by a doctor and sold in pharmacies in one of the Member States, the dangers for public health are very small.

It points out that the German legislation allows certain risks to be incurred by persons moving or residing within its territory since it authorizes medicinal products to be freely imported either by travellers or for clinical tests.

It also points out that the prohibition at issue could jeopardize the health of certain persons (in a situation where a person settling in the Federal Republic of Germany undergoes treatment based on medicinal products which are not authorized in that country).

According to the Commission, the German legislation does not comply with the principle of proportionality.

(b) According to the *German Government*, Article 36 of the EEC Treaty justifies action on the part of a Member State where its nationals are unable to assess to a sufficient extent the health risks which they incur and where those risks may adversely affect third parties. That is the case where a person receives a medicinal product by post from abroad if he is unable to understand all the information set out in the accompanying leaflet and is consequently unaware of the contra-indications and secondary effects. The smaller the doctor's role and that of the pharmacist, the greater the danger. Hence not only does the patient incur a risk himself but he may also, depending on the effects of the product, endanger the lives of third parties (road accidents or accidents at work).

F. Grévisse
Judge-Rapporteur