OPINION OF MR ADVOCATE GENERAL TESAURO
delivered on 26 January 1989 *

Mr President,
Members of the Court,

1. The facts giving rise to the proceedings for a preliminary ruling with which the Court is concerned today relate to a trip made by Mr Schumacher, a German national, as a tourist in France in 1983. At that time, the 'unfortunate' (or 'deliberate'?) idea occurred to him of having mailed to his address in the Federal Republic of Germany a package containing a pharmaceutical product purchased in a pharmacy in Strasbourg, essentially comprising an extract of artichoke. If instead of choosing that method of despatch he had followed the example of thousands of tourists and simply imported the product directly by putting it into his pocket, he would not have fallen foul of the German customs authorities. In fact, since that day Mr Schumacher has been locked in a struggle with the customs authorities of his country which, relying on the law amending the law on medicines (the 'AMG'), rejected his application to have the medicinal preparation released into free circulation, on the ground that to do so would infringe the prohibition of imports laid down in that law. To save time I shall not recount the other episodes of this amusing tale, in which I suspect that, as often happens in proceedings in which questions are referred to this Court, the protagonist's role is played by the god Mercury rather than by the goddess Hygeia: it appears from the file on the case that the product is sold in Germany at around four times the price charged in France . . . I therefore refer the Court to the Report for the Hearing and shall confine myself to reciting the question submitted by the Hessische Finanzgericht:

'Is Paragraph 73(1) of the Gesetz zur Neuordnung des Arzneimittelrechts of 24 August 1976 (*Bundesgesetzblatt* I, 1976, p. 2445 *et seq.*) compatible with Article 30 of the EEC Treaty in so far as it generally prohibits the importation by private individuals of medicines from Member States?'

2. Needless to say, a question in those terms must be reformulated since, in proceedings for a preliminary ruling, the Court has no jurisdiction to rule as to the compatibility of national provisions with Community law. On the basis of a consistent line of decisions of the Court, from which it follows that, where questions are improperly formulated, the Court's decision may set out criteria enabling the national court to decide the case before it, I propose that the national court be deemed to have asked essentially whether Articles 30 and 36 of the EEC Treaty must be interpreted as preventing a Member State from prohibiting private individuals from importing for their own consumption medicinal preparations which are authorized

* Original language Italian

and sold without a medical prescription on its own territory, where those products have been purchased in a pharmacy in another Member State.

3. One thing appears to me to be beyond doubt: the prohibition of imports of medicinal preparations by a private individual is a measure having an effect equivalent to a restriction of imports and as such is caught by Article 30 (the *Dassonville* case). That fact is not contested by the German and Danish Governments which, like the French Government and the Commission, have submitted observations to the Court.

4. The whole problem boils down to deciding whether the prohibition in question may be allowed under Article 36, in particular on the ground that it is justified for reasons of protection of health.

5. Two radically different views have been advanced on that point: on the one hand, the German and Danish Governments maintain that Article 36 is applicable to this case and, on the other, the French Government and the Commission forcefully deny this.

6. Let me say straight away that I fully share the latter view. I would add with the same immediacy that in the present case I consider it superfluous to rebut in detail the arguments put forward in defence of the German rules. Those arguments essentially amount to no more than an assertion that the prohibition in question must be accepted because it forms an integral part of the distribution system for pharmaceutical products; as such, it is the only suitable way of meeting the requirements of protection of health and could not be changed or replaced by alternative means of control; indeed, notwithstanding the need to safeguard the unity of the Community internal market, it is inconceivable that the German rules should be changed.

That argument is without foundation.

7. To demonstrate that fact, let us return, in the first place, to the *facts* of the case pending before the national court. It is common ground that the medicinal preparation in question is on open sale in pharmacies in Germany, that is to say without the need for a prescription. It is also uncontested that the product was sold by a pharmacist in France. It is similarly clear that if Mr Schumacher had himself carried the medicinal preparation from Strasbourg to his place of residence he would not have been browbeaten by the German rules, since the seventh indent of Paragraph 73(2) of the AMG expressly provides that the prohibition laid down in Paragraph 73(1) 'does not apply where the products are carried in vehicles and are intended exclusively for use or consumption by persons carried in such vehicles'.

8. We now come to the *legal assessment.* I do not think it is necessary to undertake a detailed examination of the previous cases of the Court, the only purpose of which would be to show something which, after the judgment of 20 May 1976 in Case 104/775 *De Pijper* [1976] ECR 613, is superabundantly evident: as Community law stands at present, pharmaceutical preparations are included among the products to

which the principle of free movement of goods applies. Of course, that assertion must immediately be tempered by a reservation: 'subject to compliance with certain conditions'. And that is obvious if it is borne in mind that a pharmaceutical product for which free movement is considered is neither a nutcracker nor a corkscrew and that *ex natura rerum* in addition to, or even instead of, producing the desired therapeutic effects, the supply of a medicinal preparation may in fact cause considerable damage to human health.

For those reasons the Community legislature has progressively drawn up a system of rules whose purpose, as is apparent from the fifth recital in the preamble to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (75/319/EEC, Official Journal L 147, 9.6.1975, p. 13), is the *'free movement of proprietary medicinal products'*.

9. But whilst it is certainly true that, without doubt, the principle of free movement of medicinal preparations continues to be subject to certain exceptions, justified by Article 36 — a provision which must incontestably be narrowly interpreted — in the present case the facts are such that the contention of the two governments (of Germany and Denmark) that justification for the prohibition of imports is to be found in the requirement of the protection of health does not stand up to an analysis properly based on the aims pursued by Articles 30 and 36, which adopts as a criterion of assessment not the exception to the rule, that is to say the permitted restrictions to freedom of movement, but rather the rule itself, namely that of free movement.

And it seems to me that that conclusion may be arrived at without even having to rely upon a previous decision of the the Court (the *De Pijper* judgment) regarding 'proportionality'. In other words, having regard to the state of advancement — albeit incomplete but nevertheless not to be underestimated — of the harmonization of the national laws on medicinal preparations, I am of the opinion that in the present case the powers still available to the Member State of importation have been reduced to the minimum.

10. And in fact, although it might appear justifiable for the authorities of a Member State, relying on doubts as to the innocuousness of a medicinal preparation produced in another Member State whose release into circulation has not, for the sake of argument, been authorized in either the first or the second State, to invoke reasons of protection of health under Article 36 to control the importation into its own territory of that preparation, the facts of the case pending before the national court are such as to render recourse to Article 36 unjustified. And the Hessische Finanzgericht in my opinion reacted correctly when, in the order for reference, it expressly emphasized the fact that it had strong doubts as to whether Paragraph 73 of the AMG was compatible with Article 36 of the EEC Treaty.

11. The true position is extremely simple: as Community law stands at the moment in this area, four years before the achievement of the great single market, in the circumstances described by the national court there is no scope for the Court to uphold, either objectively or subjectively, arguments relating to the protection of health so as to suspend the operation of the prohibition laid down in Article 30 of the EEC Treaty. The reason for this is simple: since the medicinal preparation in question is authorized in both the Member States involved, all the

requirements concerning the protection of health have already been taken into account in the State of exportation and that must be sufficient for the State of importation.

12. *Objectively*: the same product is sold in pharmacies without the need for a medical prescription in the country into which importation is sought. Any person residing there may therefore purchase unlimited quantities of it for himself, for the members of his family, for his neighbours, for his colleagues. Is that not the best proof of the fact that the Member State in question, by authorizing its sale — what is more without prescription — has recognized that the medicinal preparation is harmless? In those circumstances the defence of the prohibition of imports of the product appears very weak. That applies *a fortiori* in view of the fact that, on the basis of the first and second Council directives approximating the provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (65/65/EEC and 75/319/EEC), the release on to the market of a Member State of a medicinal preparation must be preceded by a prior authorization issued by the competent authorities, which highlights *ad abundiantam* the differing treatment accorded to the sale of a medicinal preparation on the one hand and a corkscrew on the other.

The issue of authorization for release on to the market presupposes compliance with extremely rigorous procedural requirements and every Member State is required, under Article 3 of the first directive to which I have just referred, to withhold such authorization where it is found that the proprietary medicinal preparation is harmful under normal conditions of use. Moreover, the Community legislature included, among the conditions laid down in Article 9 *et seq.* of the second directive, machinery enabling the producer of a medicinal preparation authorized for release on to the market of a Member State to have the Committee on Medicinal Preparations determine whether the product fulfils the requirements laid down for the issue of authorization in other Member States. And at that time those Member States have an opportunity to oppose the grant of authorization for their territory.

It therefore seems more than a little hazardous to contend that a medicinal preparation of which the marketing is legally authorized both in the Member State of exportation and in that of importation and for which, moreover, no prescription is necessary, might give rise in the latter State to such a danger to public health as to justify a prohibition of imports. And that applies, I repeat, regardless of any considerations — which frankly appear to me to be superfluous in this case — regarding failure to observe the principle of proportionality.

Furthermore, as I pointed out earlier and as also became clear at today's hearing, the German legislature itself permits imports of medicinal preparations by private individuals in the course of a journey where the quantity does not exceed that required for personal use (sixth indent of Paragraph 73(2)) and, where passage through customs is by vehicle, without limit as to quantity if the medicinal preparations are intended for the consumption of the passengers (ibid., seventh indent). In those circumstances, the question remains unanswered whether there is a difference between imports of that kind and the situation with which these proceedings are concerned where a product

is imported by post for personal use, in which the possibilities of verifying the quantity, origin and consignee are certainly greater.

13. *Subjectively*: the Commission is in my opinion quite right to draw attention to the importance to this case of the Council directive concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy (85/432/EEC, Official Journal L 253, 24.9.1985, p. 34) and the Council directive concerning mutual recognition of diplomas, certificates and other qualifications in pharmacy (84/433, ibid., p. 37). Without burdening the Court with a detailed description of the provisions of those directives, I must nevertheless emphasize in essence that the Member States gave a commitment to recognize the qualifications of pharmacists in other Member States and to allow them to participate in the 'supply of medicinal products in pharmacies open to the public'. It follows that the argument based on the alleged need to ensure that the sale of medicinal preparations should be controlled on the national market by pharmacists of the Member State of importation is manifestly unfounded. Once the Member States recognize the professional qualifications of pharmacists of other Member States, they no longer have any basis for claiming, without contradicting themselves, that the health of their population must be protected by ensuring that pharmaceutical products are sold by their own pharmacists.

14. In conclusion, I propose that the Court state in reply to the question from the national court that Articles 30 and 36 of the EEC Treaty prevent a Member State from prohibiting private individuals from importing for their own consumption medicinal preparations authorized and sold without a prescription on its own territory, where such medicinal preparations have been purchased in a pharmacy in another Member State.