OPINION OF MR ADVOCATE GENERAL MANCINI DELIVERED ON 14 SEPTEMBER 1983 [1]

Mr President,
Members of the Court,

1. This request for a preliminary ruling requires the Court to interpret the principles of the EEC Treaty which govern the movement of goods. The Court must: (a) establish whether rules whereby a Member State does not allow insured persons to be reimbursed by the competent social-security authority for certain national and imported medicinal preparations are compatible with Article 30 *et seq.;* and, if they are held to be incompatible, (b) to ascertain whether those rules may be regarded as lawful in so far as they fulfil imperative requirements such as the protection of health or other general interests of considerable importance.

First, the facts. By ministerial order of 22 July 1982 ("Besluit Farmaceutische Hulp Ziekenfondsverzekering" [Sickness Insurance Fund (Provision of Medicinal Preparations) Order]), the Netherlands Minister for Health issued a list of medicinal preparations and medical dressings to which insured persons are not entitled in any circumstances or else only if certain conditions are satisfied. That order was challenged by Duphar BV, Amsterdam, and 22 other Netherlands pharmaceutical undertakings which import medicinal products. They requested the Arrondissementsrechtbank [District Court], The Hague, to defer the entry into force of the order or at least of those of its provisions which prevent insured persons from being supplied with certain preparations. However, they reserved the right subsequently to bring an action regarding the substance of the case and at that time to contest the lawfulness of the measure in question.

In the proceedings between the plaintiff companies and the Netherlands State in the person of the Minister who issued the order, the court stayed the proceedings and requested the Court of Justice for a preliminary ruling under Article 177 of the EEC Treaty on the following questions:

(a) Must Community law, as laid down in Articles 30, 34 and 36 of the EEC Treaty, be construed as meaning that those articles prevent a Member State from introducing, with a view to making savings in the field of the supply of medicinal preparations to persons insured under sickness insurance schemes, unilateral provisions under which insured persons are deprived of a right to be supplied with specific named medicinal preparations and dressings?

(b) Must Community law, as laid down in Article 5 of the EEC Treaty in conjunction with Article 21 read with Articles 11, 12 and 5 of Directive 65/65 and Article 32 read with Articles 28 and 31 of Directive 75/319, be construed as meaning that those provisions have direct effect? If so, must those provisions be construed as set out above?

(c) Must Community law, as laid down in Article 3 (f) in conjunction with Articles 85 and 86 of the EEC Treaty, be construed as meaning that those provisions have direct effect? If so, must those provisions be construed as set out above?

2. These questions raise problems of legal policy and interpretation which I unhesitatingly describe as crucial.

1 — Translated from the Italian.

However, before dealing with them I think it is appropriate to consider, at least in outline, their context, that is to say the Netherlands legislation in the matter of pharmaceutical assistance.

In addition to the 1982 order to which I have referred, there are essentially two pieces of legislation to be considered in that connection: the Law of 15 October 1964 on the Sickness Insurance Fund (Ziekenfondswet), and the Decree of 4 January 1966 governing the benefits relating thereto. The former provides for compulsory insurance for employees and for old people with an income below a specified ceiling, whereas it provides for "voluntary" insurance for all other persons (self-employed persons and the like) whose income does not exceed a specified level. The insured persons are entitled to reimbursement of medical expenses but it is the responsibility of the administration, and in particular of the Minister for Health who makes orders in that behalf, to determine the nature, the form and the scope of the benefits under the scheme. Entitlement to the benefits is conditional upon payment of contributions the amount of which is commensurate with the income of the insured persons. The contributions are paid to the General Fund (Algemene Kas) in the case of employees and to a special old-age insurance fund (Fonds Bejaardenverzekering) in the case of old people. Both those funds, to which the State also pays considerable amounts each year, then pass on the proceeds to the sickness insurance fund which reimburses insured persons' medical expenses.

By virtue of the powers vested in him by that law, in 1966 the Minister for Health issued the order concerning benefits, which is the second source of law which must be considered. Article 10 confers upon him a further power, namely the power to direct that certain medicinal preparations and medical dressings are not to be supplied to insured persons or else are to be supplied to insured persons or else are to be supplied to them only on certain conditions. And it was on the basis of that provision that 16 years later the order giving rise to the present proceedings was issued. It lists in various annexes the products not qualifying for reimbursement. Annex I lists the medicinal preparations which may not be supplied by reason of their price; Annex 2 lists those which do not qualify for reimbursement because they are not on sale in pharmacies; Annex 4 lists those for which reimbursement is possible only "if it may reasonably be assumed that if the preparations in question are not supplied this will have an unacceptably harmful effect on the outcome of the treatment and only if and in so far as the sickness insurance fund shall have given its consent on application by or on behalf of the insured person".

3. The national court therefore asks this Court whether or not the effect of those annexes is compatible with Articles 30 and 34 of the Treaty.

As is well known Article 30 prohibits two kinds of measures: "quantitative restrictions on imports" and "measures having equivalent effect". According to the plaintiff undertakings, the rules to be considered here belong to the second category which, as the Court has held, embraces "all trading rules" which are capable of "hindering, directly or indirectly, actually or potentially, intra-Community trade" (judgment of 11 July 1974 in Case 8/74 *Dassonville* [1974] ECR 837). The salient feature of this broad definition consists, I believe, in the

importance attributed to the *effect of the measure on patterns of trade between Member States.* In other words, it is sufficient if there is a causal relationship between a national measure concerning certain products and the volume of the imports thereof for the measure to be caught by the prohibition contained in Article 30.

If that is correct, the first question to be asked is whether the disputed measures have an appreciable impact on the importation of medicinal products into the Netherlands. I think that they do and my opinion is based not only on logical inferences but also on empirical observations. As regards the inferences which I draw, the Court has been informed that in the Netherlands the trade in medicinal preparations is based preponderantly (80%) on foreign products: the Netherlands market is therefore one in which no rule capable of affecting the consumers' choice can fail ultimately to be reflected in the volume of imports. Moreover, both quantitatively and qualitatively, the likelihood that the rules in question will influence the public could not be greater. The products charged to the sickness insurance fund in fact account for 70% of the total products consumed; and it seems obvious to me that, faced with a choice between medicinal products for which reimbursement is available and those for which he must pay himself, the average insured person (and indeed the average doctor) will choose the former, or at least will choose it in the many cases in which the two medicinal preparations in question are of equal therapeutic effect.

The empirical data to which I have referred are contained in the graphs produced by Duphar BV. They give the sales curve for a number of imported medicinal products after the entry into force of the 1982 order and show very clearly that the provisions of that order constitute a real obstacle to intra-Community trade. The sales of a large proportion of the medicinal preparations listed in the three annexes to the order — and in particular those distributed through outlets other than pharmacies (Annex 2) — have in fact decreased.

The Netherlands Government is aware of all this. It therefore chooses another ground on which to do battle. It contends that the measures contained in the 1982 order are not of equivalent effect because they do nothing more than express decisions adopted by the State in its capacity of consumer. An individual is free to choose the products which best suit him as regards price and quality, so why should the State not enjoy the same freedom in its role as a buyer on the market? It is clear that the position of the State is in all essential respects similar to that of an individual. The sickness insurance fund is a public body. The State finances it, at least in part, and regulates its functioning and its spending policy with the public interest in mind.

Let me say straight away that I find this argument attractive but far-fetched. In particular, I think it is arbitrary to place the State and individuals on the same footing, above all if it is borne in mind that the decisions of the State take the form of authoritative measures and have far-reaching effects on the patterns of trade. It should be added that citizens enjoy no genuine power of self-determi-

nation as a counterpart to the enormous power of the State. To say that individuals are free to buy medical products which do not qualify for reimbursement is hypocritical. As I have pointed out, the truth is that they do not buy them or that they purchase them to a lesser extent and that, in view of the peculiar character of the Netherlands market, this reduction of consumption cannot fail to have repercussions on imports. Both terms of the equation which the Court is asked to accept are thus false and that equation will not therefore serve to conceal the fact that the rules in question have an effect equivalent to a quantitative restriction.

4. But the Netherlands Government has another, much better card up its sleeve: even if it is admitted that the rules in question are incompatible with Article 30, they should nevertheless, it claims, be acknowledged to be lawful by virtue of Article 36. It is clear that they are justified on the ground of protection of health. Moreover, being applicable to both national and imported products, they satisfy the requirement of non-discrimination which that article makes a prerequisite for such justification.

What is to be said of these arguments? Over the second there can be no dispute. The argument based on the protection of health is problematical but is based on data and figures which it would be absurd to dismiss out of hand. According to the Netherlands Government there were in 1981, that is to say in the year before the contested order was issued, more than 9.5 million people covered by compulsory and voluntary insurance. The contributions paid to the Algemene Kas amounted to 8 200 million guilders and the cost of reimbursements for medicinal products was 8 900 million. The total debit balance was 700 million, to which must be added the minor but nevertheless significant deficits of the Fonds Bejaardenversekering and of the voluntary insurance scheme. In 1982, it would appear, that shortfall increased by around 200 million, and because the crisis prevailing within the Community shows no signs of receding it is to be feared that it will become a permanent feature, with obvious risks for the operation of a service essential to society and, in particular, to the weakest social groups.

In a situation of that kind, I think it is impossible to deny that Member States have a power of intervention and that, at least as a general proposition, the safeguards provided by Article 36 must be extended to the measures adopted by them. I am well aware that this argument is open to objections but, in view of the seriousness of the preoccupations underlying it, none of the objections seems strong enough to cast any doubt upon the result which I believe must be reached.

This applies, for example, to the objection which I shall describe as relating to the "indirect purpose" of the measures. The Netherlands rules, it is said, are only indirectly concerned with the protection of health; intended as they are to restore the finances of the social security bodies, their most salient feature — which is of primary importance as regards their legal classification — is the economic policy objective which they seek to achieve. That is indeed more or less the actual position. The

consequences of this are, however, of little weight. Article 36 refers to justification on the basis of a number of specific grounds or purposes which must underlie the internal measures. It does not, however, say that, in order to operate as grounds of exemption, those purposes must be pursued in a direct fashion. Neither does it say that if a measure has several objectives, only one of which constitutes a ground of justification, that measure must be regarded as unjustified. To read all that into the article, without any basis in logic or in its wording, is tantamount to reducing its scope, which is purely and simply to render lawful national measures intended to protect health or achieve the other important objectives referred to therein.

But, it may be retorted, that is an extensive interpretation to which Article 36 is not amenable. The Court has on several occasions emphasized the "exceptional" nature of that provision with respect to the principle of the free movement of goods and has added that that fact is to be taken into account when the provision is being interpreted (cf. judgment of 25 January 1977 in Case 46/76 *Bauhuis* v *Netherlands* [1977] ECR 5 and 12 October 1978 in Case 13/78 *Eggers* [1978] ECR 1935). To this I could reply that an exceptional provision is amenable not to an analogical interpretation but to an extensive interpretation, since the latter serves only to identify the intention of the legislature when the wording is unclear or is capable of having a number of meanings. I, however, do not do so because I do not believe that mine is an extensive interpretation.

In fact, if I may repeat myself, my interpretation derives from a linear judgment and, I am convinced, one which is true to the letter of the provision in question. When it refers to the "grounds" of a particular set of national rules, Article 36 clearly intends to refer to the basic considerations — such as the protection of health — which inspire those rules. The fact that those considerations are accompanied by others which are not relevant to that article is immaterial, as is the fact that the relevant considerations inspire the contested rules indirectly — albeit not too remotely — rather than in an immediate or direct fashion. There is only one feature which those considerations must display if the ground of justification is to be operative: they must have had a decisive influence on the choices made by the national legislature. And nobody called upon to interpret the Netherlands measures could seriously doubt that this applies to those measures, in so far as they are plainly intended to promote a policy of "austerity".

5. A third objection to my reading of Article 36 might be based on the judgments in *De Peijper* (20 May 1976, Case 104/75 [1976] ECR 613, in particular paragraphs 16 to 18) and *Denkavit Futtermittel* (8 November 1979, Case 251/78 [1979] ECR 3369, in particular paragraph 23). In those judgments it is stated that the provision in question "cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence

[thereof] this burden or expenditure clearly would exceed the limits of what can reasonably be required".

I acknowledge that at first sight those observations appear to be applicable to the 1982 order; but that impression is dispelled as soon as the situations in relation to which those observations were made are closely analysed. In *De Peijper* the contested rules authorized producers of medicinal products and their exclusive concessionaires to withhold from the supervisory authorities documentation concerning medicinal preparations imported or sold and, for that reason, to exercise a *de facto* monopoly on the import and marketing thereof. In *Denkavit* the rules provided for health controls upon importation and allowed the authorities to make exceptions in individual cases. Both disputes, in short, were concerned with practices which were discriminatory, and as such restrictive, but which were also fundamentally of a liberalizing nature (permission to refuse documents, exceptions). Assuming that to be the case, it certainly does not appear correct to derive from those judgments arguments intended to condemn rules which, as in this case, are solely and wholly restrictive in their effect.

Let us admit, however, that that argument is not sufficiently persuasive. The fact nevertheless remains that in *De Peijper* and in *Denkavit* the question was to establish whether certain internal rules intended to reduce costs or simplify procedures were lawful by reason of the fact that they formed part of a system of health controls; whereas in this case the question is one of ascertaining whether Article 36 justifies certain internal rules which, in seeking to satisfy an inescapable requirement, such as the restoration of the finances of the sickness insurance fund, are intended to ensure that the health-care scheme is able to function and thus to protect health. It should be added that in this case the aims of the rule — reduction of the deficit and the protection of health — are of equal importance and that whilst the first may be more conspicuous it is in fact instrumental to the second. It is out of the question not to recognize at this stage that there is an irreducible difference between the two situations, so that the situation with which we are concerned cannot be judged in the same way as the other.

A last argument in favour of the view which I propose may be derived from the interpretative criterion of "effectiveness". In various judgments, but in particular in that of 29 November 1956 in Case 8/55 *Fédération Charbonnière de Belgique* [1954 to 1956] ECR 292, the Court has decided that "the rules laid down by [a] treaty ... presuppose the rules without which that treaty ... would have no meaning or could not reasonably and usefully be applied". That principle should be applied in this case. It cannot be denied that to read Article 36 in such a way as to deprive the State of any power to intervene in order to improve health-care assistance would be tantamount to rendering the exemption on grounds of the "protection of health" largely "useless" — with disastrous effects, I should add, if it is true that no

State exists in which that public service does not cover a large proportion of its citizens and, as I have said, is not essential for the least wealthy among them. On the other hand, an interpretation of the provision with which this case is concerned which acknowledges the importance of the matter of "health" but places too many obstacles in the way of its protection would be manifestly contradictory and, what is worse, deceitful.

6. It has thus been established that the Netherlands measures fulfil the need for protection of the health of humans. But that does not exhaust the issues. The plaintiff undertakings in the main proceedings ask whether that result could not have been achieved by methods involving fewer risks for intra-Community trade, in other words, whether, even if they are covered by Article 36, the methods adopted in the Netherlands are in conformity with the principle of proportionality.

This question is based on firmly established case-law (cf. *inter alia* the judgments of 20 May 1976 in *De Peijper*, cited earlier; of 5 October 1977 in Case 5/77 *Tedeschi* v *Denkavit* [1977] ECR 1555; of 12 July 1979 in Case 153/78 *Commission* v *Federal Republic of Germany* [1979] ECR 2555; and of 8 November 1979 in *Denkavit Futtermittel*, cited earlier) and is therefore certainly legitimate. I do not however believe that the Court can give the conclusive answer which the plaintiffs seek. It is appropriate to bear in mind that this dispute has come before the Court under Article 177 and that means that the Court may appraise the national provisions only in so far as in necessary to enable it to answer the question put by the national court. It is ultimately the responsibility of the national court to establish whether the domestic provisions are in conformity with the principle of proportionality (cf. judgment in *Denkavit Futtermittel*, already cited, and the judgment of 16 December 1980 in Case 27/80 *Fietje* [1980] ECR 3839).

That matter having been clarified — I believe — it is proper to lay down some guidelines to assist the national court to resolve the problem in a case such as this. The Netherlands measures have in their favour the fact that they are certainly effective. Assuming that reduction of the expenses of the sickness benefit funds is essential, I do not know, at least where the assistance is guaranteed by indirect means, of a more effective method of achieving that aim than disallowing reimbursement for medicinal preparations whose cost appears to be too high, *inter alia* in relation to their therapeutic efficacy. Admittedly, it could be said that there are possibilities less detrimental to the free movement of goods, for example action affecting the income rather than the outgoings of the funds in the form of an increase in contributions. But, let it be said quite candidly, it is doubtful — and indeed highly improbable — in view of the present economic situation in Europe whether proposals of that kind would command any attention.

Thus there are no truly practical alternatives or else such alternatives are difficult to find. There is on the other hand a problem of limits, that is to say limits within which the exception regarding health must operate in order to ensure that the principle of proportionality may be observed. It should be borne in mind that systems such as the Netherlands scheme are delicately

balanced. I have dwelt at length on what is their main characteristic, namely the fact that they pursue numerous objectives. In the abstract, that fact does not mean that the rules in point cannot be justified under Article 36. Specifically, the risk that Article 36 might be called in aid for the purpose of legitimizing what is nothing more than an "austerity" policy or protectionist measures incompatible with the functioning of a common market is serious. All depends therefore on whether the choice of the medicinal preparations for which reimbursement is prohibited was based on objective criteria (very high price, no greater therapeutic efficacy than that of less expensive preparations and so on) which are easily recognizable and susceptible of verification at the request of the traders concerned.

7. There is a last question relating to the matter considered so far which requires to be dealt with before I can go on to other problems. The Netherlands Government, clearly not convinced that the shield provided by Article 36 is sufficient to protect the rules adopted by it, puts forward a further theory in the alternative — with the support, however, of the intervening governments and the Commission. Those rules it asserts, may be regarded as lawful in the light of Article 30 in so far as they satisfy an imperative requirement which it calls upon the Court to recognize. That requirement is the restoration of the finances of the public health-care scheme.

I do not agree, and not only because I am of the opinion that, although tempered by the principle of proportionality, Article 36 is entirely sufficient for that purpose. To add a new imperative requirement to those already acknowledged by the Court (fairness in commercial transactions, protection of consumers, efficacy of fiscal controls, and so on) seems to me to be extremely dangerous, above all because to keep it within the limits now suggested to the Court is impossible or, rather, irrational. Once it is admitted that quantitative restrictions or measures having equivalent effect are lawful if they are motivated by the advisability of reducing expenditure and once it is decided not to found their lawfulness on the grounds of the "protection on health", does it not make very little sense to state that the subject of the cuts must be the outgoings of the sickness insurance fund? Why those in particular and not others? Why not all the items of public or social expenditure which have an adverse effect on the balance of payments?

Article 30 is the most important of the pillars upon which the Community edifice rests. The rule of reason has — how can I put it? — clarified it and, here and there, perhaps even perfected it. A solution such as that suggested to the Court would undermine it and in the long run would destroy it. It is the inescapable duty of this Court vigorously to reject that solution.

8. By the first question the national court also wishes to know whether the rules which it is asked not to apply are in conformity with Article 34 of the Treaty. According to the plaintiff undertakings there is at least a potential conflict between the article and those rules. By massively reducing the sales of national

products not qualifying for reimbursement, assert the plaintiffs, the order of 22 July 1980 affects the structure of production. It is thus likely that there will have to be a reduction in scale, production will be interrupted and exports will decrease and ultimately cease.

I am not convinced by that argument. It practically takes for granted the existence of circumstances which in reality are merely hypothetical or apprehended. In short I do not perceive any such relationship — indirect if you like, but nevertheless logical and recognizable — between an internal measure and the effect of hindering exports which is an essential precondition for the prohibition contained in Article 34 to become operative.

9. The second question is intended to establish whether certain provisions of secondary Community law prevent Member States from adopting, in the field of pharmaceutical assistance, rules such as those adopted in the Netherlands. The legislation in question is Directive 65/65 of 6 January 1965 (Official Journal, English Special Edition 1965-66, p. 20) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, and Directive 75/319 of 20 May 1975 (Official Journal L 147, 9 June 1975, p. 13 *et seq.)* dealing with the same subject. In fact, the court making the reference makes the preliminary request that the Court should give a ruling as to their effect. But a ruling of that kind would be superfluous because there is no doubt that those directives do not affect the powers of the Member States in the manner outlined in the question.

As regards Directive 65/65, the provisions to which the national court draws the attention of this Court are Articles 5, 11, 12 and 21. They concern various aspects of the controls to which Member States may subject pharmaceutical products before authorizing their marketing, a matter falling therefore wholly outside the 1982 order which, despite prohibiting reimbursement in respect of certain medicinal preparations, has no effect whatsoever on the marketing thereof. The same may be said of Directive 75/319. That too (and in particular the articles referred to by the national court) merely regulates the controls to which the marketing of medicinal products is subject.

10. In the third and last question, the Arrondissementsrechtbank, The Hague, wishes to know whether rules such as those giving rise to these proceedings are compatible with Articles 3 (f), 85 and 86 of the EEC Treaty. In this case also, the Netherlands court seeks a ruling as to whether those provisions have direct or indirect effect; and in this case too it is so obvious that the question must be answered in the negative that I do not think it serves any purpose for the Court to consider the problem in detail.

Articles 85 and 86 refer to agreements between undertakings which adversely affect trade between the Member States. They cannot therefore be relied upon for the purpose of assessing rules by which such trade is so affected for reasons

which bear no relation to any such agreement. Article 3 (f) merely contemplates, among the activities of the Community, "the institution of a system ensuring that competition in the common market is not distorted". I do not see how this programmatic provision can be compromised by rules like those in question which have a very limited field of application and, moreover, find their justification in an essential interest of the States.

11. In view of all these considerations I suggest that the Court reply as follows to the question submitted by the Arrondissementsrechtbank, The Hague, by order of 16 September 1982 in the case brought by Duphar BV and 22 other Netherlands pharmaceutical undertakings against the Kingdom of the Netherlands:

(a) Articles 30 and 36 of the EEC Treaty must be interpreted as meaning that national rules which exclude reimbursement under a public health-care scheme for certain medicinal products, whether national or imported, are not incompatible with those articles in so far as they constitute measures which, although having an effect equivalent to quantitative restrictions on imports, find their justification in the requirement of the protection of the health of humans. The application of Article 36 is not precluded by the fact that the immediate aim of those measures is to restore the finances of the sickness insurance institutions and only indirectly to protect public health by that means. The choice of the medicinal products for which reimbursement is not available must however be based on objective criteria (such as whether the product is economic or is therapeutically efficacious), which are easily recognizable and capable of verification at the request of the traders concerned;

(b) Article 34 of the EEC Treaty must be interpreted as meaning that national rules such as those described in paragraph (a) do not constitute measures having an effect equivalent to quantitative restrictions on exports;

(c) Articles 5, 11 and 21 of Council Directive 65/65 of 26 January 1965, and 28, 31 and 32 of Council Directive 75/319 of 20 May 1975 must be interpreted as not preventing the adoption by a Member State of measures of the type indicated in paragraph (a);

(d) Articles 3 (f), 85 and 86 of the EEC Treaty must be interpreted as not preventing the adoption by a Member State of measures of the type referred to in paragraph (a).