2. Provisions adopted within the framework of a compulsory national health-care scheme with the object of refusing insured persons the right to be supplied, at the expense of the insurance institution, with specifically named medicinal preparations are compatible with Article 30 of the Treaty if the determination of the excluded medicinal preparations involves no discrimination regarding the origin of the products and is carried out on the basis of objective and verifiable criteria, such as the existence on the market of other, less expensive products having the same therapeutic effect, the fact that the preparations in question are freely marketed without the need for any medical prescription, or are products excluded from reimbursement for reasons of a pharmaco-therapeutic nature justified by the protection of public health, and provided that it is possible to amend the lists whenever compliance with the specified criteria so requires.

3. Article 36 of the Treaty relates to measures of a non-economic nature. That provision cannot therefore justify a measure whose primary objective is budgetary, inasmuch as it is intended to reduce the operating costs of a sickness insurance scheme.

4. Article 34 of the Treaty concerns national measures which have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a Member State and its export trade in such a way as to provide a particular advantage for national production or for the domestic market of the State in question.

5. Article 5 of the Treaty and Directives 65/65 and 75/319 regarding proprietary medicinal products do not preclude provisions adopted within the framework of a compulsory national health-care insurance scheme with the object of denying insured persons the right to be supplied, at the expense of the insurance institution, with specifically named medicinal preparations. The system in question does not concern access to the market within the meaning of the two directives cited, since the validity of the authorizations granted by application of those directives is not called in question.

In Case 238/82

REFERENCE to the Court under Article 177 of the EEC Treaty by the President of the Arrondissementsrechtbank [District Court], The Hague, for a preliminary ruling in the proceedings pending before that court between

DUPHAR BV AND OTHERS

and

THE NETHERLANDS STATE, in the person of the Minister van Volksgezondheid en Milieuhygiëne [Minister of Health and the Environment]

for a preliminary ruling on the interpretation of Articles 3, 5, 30, 34, 36, 85 and 86 of the Treaty and 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 (Official Journal, English Special Edition 1965-66, p. 20) and of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal 1975, L 147, p. 13),

THE COURT

composed of: J. Mertens de Wilmars, President, T. Koopmans, K. Bahlmann and Y. Galmot (Presidents of Chambers), P. Pescatore, Lord Mackenzie Stuart, A. O'Keeffe, G. Bosco, O. Due, U. Everling and C. Kakouris, Judges,

Advocate General: G. F. Mancini
Registrar: J. A. Pompe, Deputy Registrar

gives the following

JUDGMENT

Facts and Issues

The facts of the case, the course of the procedure and the written observations submitted pursuant to Article 20 of the Protocol on the Statute of the Court of Justice of the European Economic Community may be summarized as follows:

I — Facts and written procedure

Facts

In order to enable savings to be made in the supply of medicinal preparations charged to the Ziekenfondsverzekering [sickness insurance fund], the Netherlands Minister for Health and the Environment issued on 22 July 1982 the Besluit Farmaceutische Hulp Ziekenfondsverzekering [Sickness Insurance Fund (Provision of Medicinal Preparations) Order]. That order contains a list of medicinal preparations and medical dressings which may not be supplied to persons under the sickness insurance scheme or may be supplied to them only if certain conditions are satisfied.

The order prohibits the supply of certain medicinal preparations and medical dressings to persons insured under the sickness insurance scheme, namely:

(a) the medical preparations listed in Annex 1 to the Order which must not be supplied in view of their price and the existence of alternative products which are less costly and serve the same purpose;

(b) the so-called over-the-counter medicinal preparations listed in Annex 2 to the order;

(c) the medicinal preparations listed in Annex 4, the supply of which is subject to certain conditions and requires prior authorization by the sickness insurance fund. These medicinal preparations may be supplied "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" (Article 3 of the order).

The applicable Netherlands legislation

The legal basis of the order is Article 10 of the Verstrekkingenbesluit Ziekenfondsverzekering [Sickness Insurance Fund (Supply) Order]. By virtue of that article, the Minister for Public Health may decide:

(a) that certain medicinal preparations and medicinal dressings specified by him may not be supplied;

(b) what medicinal preparations may be supplied only subject to certain conditions determined by him.

The Verstrekkingenbesluit Ziekenfondsverzekering is based on the Ziekenfondswet [Law on the Sickness Fund]. That law lays down the rules applicable to compulsory sickness insurance for certain categories of persons. Those persons are entitled to benefits (in kind) for the purpose of medical treatment. The nature, content and scope of the benefits are laid down in or by virtue of regulations issued by the public administration. Entitlement to the insurance is conditional upon payment of a contribution which is a percentage of the insured's wages, determined by the Minister, half being paid by the insured and half by the employer. The contribution for old people's sickness insurance is determined by the Minister each year.

The contributions are paid into the Algemene Kas [general fund] or the Fonds Bejaardenverzekering [old people's insurance fund] which make payments to the sickness funds by way of reimbursement for the benefits supplied to the persons insured. It appears from the file on this case that the State also pays substantial sums each year into the Algemene Kas and the Fonds Bejaardenverzekering.

In view of considerable deficits in the budgets of the sickness funds the government decided to reorganize the system of benefits and to alter the list of medicinal preparations which may be supplied by means of the contested order.

It appears from the documents before the Court that, of the medicinal preparations manufactured in the Netherlands, approximately 20% are consumed in the Netherlands, and approximately 80% are exported, about half of them to other Member States of the EEC.

Roughly 80% of the medicinal preparations consumed in the Netherlands are imported, most of them from other Member States of the EEC.

Of the medicinal preparations consumed in the Netherlands, at least 70% are supplied under the sickness insurance scheme.

Applicable Community legislation

The Council has adopted a number of directives concerning medicinal preparations in order to remove barriers to trade in proprietary medicinal products within the Community.

Directive 65/65, already referred to, provides for approximation of provisions laid down by law, regulation or administrative action relating to authorization for the marketing of proprietary medicinal products (Articles 3 to 12) and the labelling thereof (Articles 13 to 20).

Directive 75/319, also previously mentioned, takes a further step towards the elimination of the barriers to trade existing within the Community, in particular by means of provisions relating to the applications for authorizations provided for in the first directive and the examination of those applications. Moreover, it provides that special authorization is required for the manufacture of proprietary medicinal products and the importation thereof from non-member countries.

The directives thus regulate access to the market, from the point of view of the protection of public health, by imposing the requirement that an authorization must be issued by the authorities, and lay down the conditions subject to which the authorizations are to be granted. No other conditions may be imposed regarding the grant of authorizations. If the product conforms to the prescribed criteria, the authorization may not, by virtue of Article 21 of Directive 65/65, be withheld for reasons connected, for example, with its price, repayment by the sickness insurance fund or other additional grounds.

Procedure and questions submitted for a preliminary ruling

Duphar BV and 22 other pharmaceutical companies considered themselves adverseley affected by that order and brought an action before the Arrondissementsrechtbank, The Hague, against the Netherlands State for the adoption of an interim measure prohibiting the implementation of the order. They put forward arguments based on national law and on Community law.

The President of the Arrondissementsrechtbank, The Hague, asked the Court to give a preliminary ruling on five questions relating to Articles 3, 5, 30, 34, 36, 85 and 86 of the Treaty in conjunction with certain provisions of Council Directives 65/65 and 75/319.

Those questions are, in substance, as follows:

"(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?

(c) If so, must those provisions be construed as set out above?

(d) 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?

(e) If so, must those provisions be construed as set out above?"

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted by the plaintiffs in the main proceedings, represented by W. Alexander and B. H. Ter Kuile, of the Bar of The Hague, by the Netherlands State, represented by F. Italianer, Secretary General, Ministry of Foreign Affairs, acting as Agent, by the Danish Government, represented by L. Mikaelsen, Legal Adviser, acting as Agent, by the Italian Government, represented by O. Fiumara, Avvocato dello Stato, acting as Agent, and by the Commission of the European Communities, represented by R. Wägenbaur, Legal Adviser, acting as Agent, assisted by T. van Rijn, a member of its Legal Department.

Upon 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.

II — Observations submitted to the Court

The *plaintiffs in the main proceedings* state that by virtue of the case-law of the Court any rules adopted by Member States governing trade which are capable directly or indirectly, actually or potentially, of hindering intra-Community trade must be regarded as measures having an effect equivalent to a quantitative restriction prohibited by Article 30 of the Treaty (Case 8/74 *Dassonville* [1974] ECR 837, Joined Cases 88 to 90/75 *SADAM* [1976] ECR 323 and Case 82/77 *Van Tiggele* [1978] ECR 25). The prohibition contained in Article 30 of the Treaty also applies to measures which, although not restricting the freedom to import, unilaterally hinder in any way sales on the national market. A measure adopted by the national authorities which withholds from persons insured under the sickness insurance scheme — who account for more than 70% of consumption — entitlement to the supply of a specifically listed medicinal product coming from another Member State, certainly falls within the prohibition laid down in Article 30 of the Treaty. Such a measure does not escape that prohibition merely because an identical measure has been adopted regarding a proprietary medicinal preparation of national origin, even if the two measures derive from a single decision and were both adopted on the basis of the same objective criteria.

As regards the "rule of reason", it is laid down in the decisions of the Court that obstacles to intra-Community trade may be permitted where the following conditions are satisfied:

(1) no Community rules exist;

(2) the obstacles must be the result of disparities between national laws regarding the marketing of a product;

(3) imperative grounds must exist relating *inter alia* to the effectiveness of fiscal controls, the protection of public health, the fairness of commercial transactions or the protection of the consumer; and

(4) those imperatives must render the obstacles necessary.

According to the plaintiffs in the main proceedings the withholding of insured persons' entitlement to the medicinal preparations listed in Annex 1 to the order is not made necessary by mandatory requirements relating to the protection of public health or other matters referred to above. The protection of public health is not assured since the physician issuing the prescription is denied in advance any possibility of considering either the price or the benefit when choosing a medicinal preparation for the treatment required.

Even if it is considered that the concern to achieve savings in the cost of health care justifies certain restrictions on the fundamental principle of the free movement of goods within the Community, a prohibition of supply affecting 70% of consumers is excessive, that is to say unnecessary. According to Duphar BV and the other plaintiffs in the main proceedings, that objective may be attained by measures which have fewer repercussions on the functioning of the common market and competition.

As regards the over-the-counter medicinal preparations listed in Annex 2 to the order, the decisive criterion for their inclusion therein is the fact that the products in question may also be obtained elsewhere than in a pharmacy, in other words the criterion is the sales policy of the manufacturer or of the importer of the medicinal preparation in question.

Even though Article 3 (1) of the order does not totally withhold the right to be supplied with the medicinal preparations listed in Annex 4, it imposes very strict conditions upon that right. It should however be noted that the prohibition contained in Article 30 of the Treaty still applies even if the national measure provides for the possibility of exemptions and in fact such exemptions are freely granted (Case 82/77 *Van Tiggele* [1978] ECR 25 and Case 130/80 *Kelderman* [1981] ECR 527).

As regards the incompatibility of the order with Article 34, the plaintiffs in the main proceedings are of the opinion that the order may directly or indirectly hinder the export of medicinal preparations from the Netherlands. The medicinal preparations listed in Annexes 1 and 4 to the order are, in the opinion of the Netherlands authorities, to be regarded as too expensive and must not be prescribed or else must be prescribed only to a limited extent for pharmaco-therapeutic reasons. Those medicinal products are therefore "tainted" in so far as the assessment of the Netherlands authorities is likely indirectly to influence the judgment of the relevant foreign authorities or purchasers. The disappearance of 70% of the Netherlands turnover would in many cases constitute a ground for withdrawal of the product from the market, which might also lead to the discontinuance of exports.

The essential purpose of the order is not to safeguard public health and by its nature it is likely to inhibit the development of the pharmaceutical industry and trade in pharmaceutical products within the Community.

As regards the question whether the order may be justified under Article 36 of the Treaty, the plaintiffs in the main proceedings consider that the costs incurred in the provision of health care are not covered by the protection of the health and life of humans. Control of those costs is an integral part of short-term economic policy and cannot justify departure from the principle of the free movement of goods within the common market (Cases 88 to 90/75 *SADAM,* cited above).

Savings regarding the supply of pharmaceutical products to persons insured under the sickness insurance scheme may be achieved by the adoption of measures which restrict intra-Community trade to

a lesser degree. It cannot be validly claimed that in the absence of measure depriving persons insured under the sickness insurance scheme of the right to specifically listed proprietary medicinal products, the expenses incurred for the provision of pharmaceutical products to persons insured under that insurance scheme would exceed the limits of what might reasonably be required.

Even if the order in question were justifiable by virtue of the first sentence of Article 36, it would be in breach of the second sentence, in so far as it is a means of arbitrary discrimination or a disguised restriction on trade between Member States.

With regard to the second question, the plaintiffs in the main proceedings are of the opinion that the question whether or not Article 5 of the Treaty has direct effect depends on the content and the scope of the provisions of the Treaty or of the rules of secondary Community law, on the basis of which Article 5 of the Treaty is relied upon. The provisions of the two directives cited in the questions submitted for a preliminary ruling fulfil the conditions which, according to the Court of Justice, must be satisfied if a provision of a directive is to have direct effect (Case 51/76 *Verband van Nederlandse Ondernemingen* [1977] ECR 113). Consequently, Article 5 and the provisions of the directives in question have direct effect.

As regards the third question, the order is manifestly in conflict with the spirit of the Community provisions regarding medicinal preparations. The practical consequence of the order is to suspend the authorization to market the medicinal preparations listed in Annexes 1 and 4 to the order. The prohibition laid down in the order regarding the proprietary medicinal preparations listed in Annex 4 is incompatible in particular with Article 12 of Directive 65/65 because the procedural guarantees required by virtue of that provision are not observed in the order.

With regard to the fourth question, the plaintiffs in the main proceedings claim that the question whether or not Article 3 (f) of the EEC Treaty has direct effect depends on the content and the scope of the rules of the Treaty relating to competition, on the basis of which Article 3 (f) of the Treaty is relied upon. In this case, Article 3 (f) has direct effect because Articles 85 and 86 have direct effect (Case 127/73 *SABAM*, [1974] ECR 51).

As regards the fifth question, Community law must be interpreted as meaning that the articles in question prevent a Member State from adopting, with a view to achieving savings regarding the provision of pharmaceutical products to persons insured under the sickness insurance scheme, unilateral provisions disentitling insured persons to the supply of specifically listed medicinal products and medicinal dressings if the effect of the adoption of such provisions is directly or indirectly, actually or potentially, to distort competition in the common market and if those provisions are capable of affecting trade between Member States.

The *defendant in the main proceedings* considers that the first question should be answered in the negative. The purpose of Articles 30 and 34 is the creation of a common market characterized not only by the removal of barriers to trade between Member States but also by the normal functioning of the economy and genuine competition.

Therefore, it is not contrary to the principle of the free movement of goods for an undertaking not to choose an imported product (or a product manufactured in its own country) and to give preference to another product (likewise imported or else manufactured in its own country). Where there is real access to the market, an undertaking has an opportunity to choose. By making its choice on the basis of objective criteria, it ensures the genuine competition sought by the Treaty and contributes to the functioning of the common market.

In such circumstances, economic decisions of undertakings which are determined by practical and objective considerations do not constitute measures having an equivalent effect within the meaning of Articles 30 and 34 of the Treaty. Such a decision may influence the volume of imports but is not thereby contrary to Article 30 of the Treaty.

The contested order which lists the supplies available through the sickness funds also of course has repercussions for the persons insured under the health care scheme. In fact, the order determines the rights to which persons insured under the scheme are entitled by virtue of the insurance. Nevertheless, a person insured under the health care scheme still retains his freedom of action, in so far as he wishes to act independently from the economic point of view. The order does not place any obstacle in the way of a person insured under the health care scheme who wishes to purchase an excluded product by paying the price asked for it.

As regards Article 34, the order does not, in the view of the Netherlands State, affect exports in any way.

If it were considered that the contested order should however be regarded as constituting an infrigement of Article 30 of the Treaty, the Netherlands Government is of the opinion that such an infringement is justified. The purpose of the order in question is to ensure health care of the highest possible standard, at acceptable costs. Consequently, the exception recognized in the case-law of the Court regarding the "rule of reason" extends to the public interests involved in this case. Alternatively, the Netherlands Government considers that it is possible to rely upon the exception regarding the protection of public health provided for in Article 36 of the Treaty.

As regards the second and third questions, the purpose of the directives in question is to regulate the marketing of proprietary medicinal products. The rules include the introduction of a system of authorizations and lay down criteria relating to the composition and quality of the products in question. The purpose of the contested order is different. It contains rules for the consumer as regards the list of available benefits and embodies an economic decision taken by or for the benefit of an organization operating within the economy. The freedom to take such economic decisions is not limited by the directives in question. Those directives certainly contribute to defining the range of products on offer from which that organization may choose but, for the rest, it retains its freedom of choice.

In consequence, the directives and the order have different purposes and are not in conflict.

For that reason the directives in question do not prohibit rules such as those referred to by the national court in its judgment making the reference, and therefore the third question should also be answered in the negative.

The Netherlands Government takes the view that, in the circumstances, the Court ought not to consider the direct effect of the articles in question.

As regards the fourth and fifth questions, the Netherlands Government considers that Articles 85 and 86 of the Treaty are not relevant to the assessment of the contested order in the light of Community law. In fact, the order does not constitute an agreement between undertakings affecting trade between States and distorting competition within the common market. Neither can it be validly claimed that the authorities, by adopting the order, are compelling undertakings to act in breach of the provisions in Articles 85 und 86. Moreover, Article 3 (f), which is given more specific expression *inter alinea* in Articles 85 and 86, has no real significance in this case.

The Netherlands Government therefore considers that the fifth question must also be answered in the negative. Accordingly, there is no need to answer the fourth question. If the Court nevertheless considers that it must also examine the fourth question, the Netherlands Government defers entirely to the judgment of the Court regarding the answer to be given to that question.

In its observations the *Danish Government* points out in the first place that schemes for assistance with the provision of medicinal products exist in several Member States, including Denmark. Such systems are manifestly justified by social considerations, because assistance in defraying a patient's expenses makes it possible to ensure that the availability of the appropriate medical treatment is not dependent upon the patient's financial situation. Community law, and in particular Article 30 *et seq.* of the Treaty, imposes certain specific limits to which Member States are subject when drawing up schemes for the provision of assistance regarding the supply of medicinal preparations. It follows, in particular, that the selection of preparations in respect of which assistance may be granted must not depend upon their origin. A public scheme for assistance with the provision of medicinal products is not contrary to Article 30 *et seq.* of the Treaty provided that, in the selection of the proprietary medicinal preparations in respect of which assistance may be granted, account is taken exclusively, on the basis of an objective and fair assessment, of their therapeutic value and of the expenses incurred for normal and necessary medical treatment.

The *Italian Government* considers that Articles 30 and 34 of the Treaty do not prevent a Member State, in its concern to achieve savings regarding the provisions of pharmaceutical products, from introducing unilateral rules which withhold from persons insured under a benefit scheme entitlement to the supply of certain medicinal preparations, provided that the decision to include or exclude a particular product from the scheme is adopted in accordance with objective criteria and does not discriminate between national and imported products. Quantitative restrictions on imports or exports and measures having an equivalent effect are prohibited in so far as they are discriminatory. The provisions at issue, despite having adverse effects on trade in the products in question, affect national and imported products without distinction, on the basis of wholly objective considerations.

Directives 65/65 and 75/319 make it incumbent upon the Member States to amend their provisions regarding authorizations to produce and market

proprietary medicinal preparations, but they impose no obligation with regard to the provisions by virtue of which States or other public bodies defray expenses in respect of benefits in kind supplied to their nationals, unless they are implemented in a manner which is found to affect the marketing of such preparations. The measures in question do not supersede those governing the authorizations for trade in such products, even though they might affect the volume of the product marketed. Even if a product does not appear on the list, it remains on the market and is sold, albeit to a lesser extent, to persons not affected by its exclusion from sickness insurance schemes.

As regards the alleged distortion of competition and the encouragement of concerted practices and underhand dealings, the Italian Government considers that the measures in question do not distort competition. In any event, recourse might be had to Article 85 (3) because there is no doubt that the careful choice made by the national authority contributes to improving production or promoting technical and economic progress.

In its observations on the first question, the *Commission* considers that Article 34 is not applicable. The order in question has no effect on exports of medicinal preparations manufactured in the Netherlands. It is not intended specifically to restrain the flow of exports and does not therefore provide for a difference of treatment as between domestic trade and the export trade.

As regards the applicability of Article 30, the Commission observes that the order is a measure under public law forming part of a sickness insurance scheme regulated and managed in accordance with law and that it falls within the field of application of Article 30.

In view of the high percentage (70%) accounted for by the medicinal preparations prescribed within the framework of the sickness insurance scheme by comparison with the total quantity of medicinal preparations sold in the Netherlands, and by reason of the fact that roughly 80% of all the medicinal products sold in the Netherlands are imported, there can be no doubt that the order in question restricts imports. Consequently, the Commission considers that the order constitutes a measure having an effect equivalent to a quantitative restriction.

As the Court held in its decision in the "Cassis de Dijon" case [1979] ECR 649, the prohibition laid down in Article 30 does not apply to national measures which apply without distinction to national and imported products and which are justified by mandatory requirements relating in particular to the protection of public health, the fairness of commercial transactions and the protection of consumers. According to the Commission, the mandatory requirements which the Court has to date recognized are not of such a nature as to justify the order. In particular, the measure cannot be justified by mandatory requirements relating to the protection of public health, with which the measure has strictly no connection. If the order had not been adopted, public health would in no way have been endangered.

However, the Court has not given an exhaustive list of the mandatory requirements. Although, according to the Commission, it is appropriate to observe caution regarding any extension of the concept of mandatory requirements, it considers that this case is an example of

a mandatory requirement of national policy which the Court should regard as justified within the meaning of Article 30.

The purpose of the measure is to reorganize and improve the financial management of a sickness insurance scheme governed by public law. Although the Commission does not wish to claim that any national measure adopted to improve national finances ought to be permissible under Article 30, it considers that the order in question, which is intended exclusively to improve the financial management of a public sickness insurance scheme, may be regarded as compatible with Article 30 even if it affects trade. The measure applies objectively to medicinal products manufactured in the Netherlands and to imported medicinal products. The products are not treated differently according to their origin. Moreover, no measure has been adopted which is capable of directly affecting the marketing of the products, in the strict sense of the word. The marketing of them remains totally unrestricted, so that anyone may obtain the medicinal preparations in question, if necessary on the basis of a medical prescription. The restriction lies in the fact that the medicinal products appearing on the negative list are not supplied to persons insured under a health-care scheme within the framework of sickness insurance. Otherwise, they may purchase the medicinal preparations in the usual way, if they wish to do so, but without reimbursement.

The Commission concludes therefore that the order in question does not fall within the prohibition imposed by Article 30.

However, if the Court takes the view that Article 30 does apply to the order at issue, the question of the interpretation of Article 36 arises. The Commission is of the opinion that the grounds of justification laid down in Article 36 do not apply in this case.

As regards the second question, the Commission considers that the articles mentioned in the question submitted by the national court contain a clearly-defined obligation which is not subject to any prior conditions and regarding the fulfilment of which the Member States have no margin of discretion. Moreover, fulfilment of the obligation does not require any legal measure to be adopted by the Member States or the Community institutions. Those articles satisfy all the conditions laid down in the decisions of the Court which must be satisfied if a provision of Community law is to have direct effect (Case 41/74 *Van Duyn* [1974] ECR 1337, Case 51/76 *Verbond van Nederlandse Ondernemingen* [1977] ECR 113 and Case 38/77 *Enka* [1977] ECR 2203).

The third question, in the Commission's view, should be answered in the negative. The order in question does not concern access to the market. It in no way affects the freedom of producers to continue to market the medicinal preparations appearing on the negative lists.

With regard to the fourth and fifth questions, the Commission considers that Articles 3 (f) and 5 may be relied upon by individuals before a national court provided that they are so relied upon in conjunction with Articles 85 and 86. As regards Articles 85 and 86, the Commission is of the opinion that they are not applicable to this case because one of the preconditions for the applicability of either article is the existence of an agreement between undertakings, a decision by associations of undertakings, a concerted practice or abuse of a dominant position. The Commission sees no reason for describing the order as constituting any of the foregoing. It considers the order

to be a genuine measure of public law. It would be incompatible with Article 86 only if it upheld the abuse of a dominant position by an undertaking. It is however unlikely that such a situation exists in this case.

III — Oral procedure

At the sitting on 1 June 1983 oral argument was presented by the plaintiffs in the main proceedings, represented by B. H. Ter Kuile and W. Alexander, both of the Hague Bar, the Netherlands Government, represented by A. Bos, acting as Agent, by the Italian Government, represented by O. Fiumara, acting as Agent, and the Commission, represented by its Legal Adviser R. Wägenbaur and R. Fischer, a member of its Legal Department.

The Advocate General delivered his opinion at the sitting on 14 September 1983.

Decision

1 By order dated 16 September 1982, which was received at the Court on 29 September 1982, the President of the Arrondissementsrechtbank [District Court], The Hague, referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty several questions on the interpretation of Articles 3, 5, 30, 34, 36, 85 and 86 of the Treaty and 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 (Official Journal, English Special Edition 1965-66, p. 20) and of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (Official Journal 1975, L 147, p. 13), to enable it to decide whether certain national rules concerning the supply of medicinal preparations and dressings under a sickness insurance scheme were compatible with those provisions.

2 The questions were raised in an action brought against the Netherlands State by 23 pharmaceutical undertakings for the adoption of an interim decision declaring that Articles 2 and 3 of the Besluit Farmaceutische Hulp Ziekenfondsverzekering [Sickness Insurance Fund (Provision of Medicinal Preparations) Order] 1982 (Staatscourant No 139 of 23 July 1982) and the annexes thereto were inoperative since they were incompatible with Community law and in particular with Articles 3, 5, 30, 34, 36, 85 and 86 of the Treaty and Directives 65/65 and 75/319, cited above.

3 The order is intended to enhance the quality of pharmaco-therapeutical services and to eliminate the considerable deficit of the Netherlands health-care scheme. To that end, Article 2 provides that persons insured under the compulsory health-care scheme are no longer to be entitled to be supplied with the medicinal preparations and health products exhaustively listed in Annex 1 and 2 to the order, and Article 3 provides that they are not to be entitled to be supplied with the medicinal preparations listed in Annex 4 to the order except with the prior authorization of the sickness fund, which is to be granted 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.

4 According to the explanatory memorandum to the order in question, the exclusion of products as a result of their being listed in the annexes thereto is justified by considerations relating specifically to each annex. The exclusion of the medical preparations listed in Annex 1 is based on their price and the fact that, in the view of the central medico-pharmaceutical committee, there are in each case other medicinal preparations which have the same therapeutic effect but whose price is lower. The products listed in Annex 2 are excluded because they are over-the-counter products which can be marketed otherwise than through a pharmacist. The exclusion of the medicinal preparations listed in Annex 4 is justified by the fact that, in the view of the abovementioned central medico-pharmaceutical committee they must, for reasons described as being "of a pharmaco-therapeutical nature", be prescribed only in very specific cases.

5 Considering that the decision in the case turned on the interpretation of various rules of Community law, the President of the Arrondissementsrechtbank referred the following questions to the Court for a preliminary ruling:

"(a) Must Community law, 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, 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?

(c) If so, must those provisions be construed as set out in subparagraph (a) above?

(d) Must Community law, laid down in Article 3 (f) in conjunction with Articles 85 and 86 of the EEC Treaty, be construed as set out in subparagraph (a) above?"

I — The first question

6 The first question seeks in substance to ascertain whether the prohibition of measures having an effect equivalent to quantitative restrictions on imports (Article 30) and on exports (Article 34) applies to measures (of the type described above) whereby a Member State, with a view to achieving economies regarding compulsory health-care insurance, prevents specifically named medicinal preparations and dressings from being supplied to persons insured under the scheme. The national court also wishes to know whether, if that part of the question is answered in the affirmative, Article 36 of the Treaty allows an exception to that prohibition.

7 For the purpose of answering the first question, it is appropriate to consider how Articles 30, 34 and 36 of the Treaty are to be interpreted in relation to the particular features of the national legislation in question.

A — The interpretation of Articles 30 and 36 of the Treaty

8 The plaintiffs in the main proceedings propose that Article 30 should be interpreted as meaning that rules such as those with which this case is concerned constitute a measure having an effect equivalent to a quantitative restriction on imports because they restrict intra-Community trade and make it impossible for the suppliers of certain imported medicinal preparations to sell them on the market in question since the proportion of the total consumption of medicinal preparations charged to the sickness funds amounts to 70%.

9 The plaintiffs in the main proceedings argue that such a measure does not escape the prohibition contained in Article 30 merely because it applies without distinction to national and imported products. According to previous decisions of the Court, even measures which apply without distinction to national products and those imported from other Member States but give rise to obstacles to intra-Community trade do not escape the prohibition of measures having equivalent effect unless:

(a) no Community rules exist;

(b) the obstacles are the result of disparities between national laws regarding the marketing of a product;

(c) imperative grounds exist relating *inter alia* to the effectiveness of fiscal controls, the protection of public health, the fairness of commercial transactions or the protection of the consumer; and

(d) those imperatives render the obstacles necessary.

10 According to the plaintiffs in the main proceedings those conditions are not satisfied in any of the three cases in which medicinal preparations are excluded by the annexes to the contested order. As regards exclusion of medicinal preparations by reason of their price (Annex 1) they claim that even if the concern to achieve economies in the costs of health care justifies certain restrictions upon the fundamental rule of the free movement of goods, a national measure which entails such a wide-ranging prohibition is excessive. The desired aim could be attained by measures which did not affect the functioning of the common market and competition to such an extent. As regards the over-the-counter products (Annex 2), they deny that any of the imperative reasons accepted by the previous decisions of the Court exist, in particular the justification based on the protection of public health. As regards medicinal preparations excluded for reasons described as "pharmaco-therapeutical" (Annex 4), they also deny that the conditions mentioned above are satisfied, contending in particular that the obstacle is not the result of any disparity between national laws on the marketing of the products in question.

11 The Netherlands State, the defendant in the main proceedings, submits that the prohibition contained in Article 30 cannot extend to measures of the type with which the main proceedings are concerned. It considers in the first place that there is no question of any obstacle to intra-Community trade. Where a public authority finances by far the greater part of the consumption of medicinal preparations and other health-care products, it is in the position of an economic operator and accordingly is, like any other such operator, entitled to make a choice and to choose among the preparations on the market, giving preference to one rather than to another. Where, as in this case, the national authority made its decision on the basis of objective considerations inspired by the concern to safeguard the quality of the care, there can be no question of obstacles to trade between Member States.

12 The defendant in the main proceedings adds that, even if measures of the type in question could be regarded as capable of hindering trade, they nevertheless do not constitute measures having an effect equivalent to quantitative restrictions prohibited by Article 30. Those measures, which apply without distinction to national and imported products, were adopted for imperative reasons — in this case the rationalization, and therefore the continuation, of a national health-care scheme — which, by virtue of the judgment of the Court of 20 February 1979 (Case 120/79 *Rewe* [1979] ECR 649), justify obstacles of that kind so that they escape the prohibition contained in Article 30. Finally, the defendant in the main proceedings claims, in the alternative, that even if the measures in question were to be regarded as measures having an effect equivalent to quantitative restrictions they would fall within the exception provided for in Article 36 of the Treaty as restrictions justified on the grounds of the protection of health.

13 The Commission considers that the order in question constitutes a measure having an effect equivalent to a quantitative restriction. It points out however that, in its judgment of 20 February 1979 (cited above), the Court did not give an exhaustive list of the imperative requirements which might justify a national measure affecting the volume of imports. It considers that the order, which is intended to rationalize the financial management of a sickness insurance scheme, could be regarded as compatible with Article 30 even if it affected trade. The measure applies objectively to medicinal preparations manufactured in the Netherlands and to imported medicinal preparations.

The products are not treated differently according to their origin. Moreover, no measure capable of directly affecting the marketing of the products in the strict sense has been adopted. Such marketing remains wholly unrestricted, so that anyone can obtain the medicinal preparations in question, if necessary on the basis of a prescription. However, if the Court should decide that the contested measures are incompatible with Article 30 of the Treaty, the Commission considers that the grounds of justification set out in Article 36 do not apply in this case.

14 The Danish Government observes that it does not consider national rules which, for social reasons and on the basis of objective criteria, provide for a public scheme for assistance with the provision of pharmaceutical preparations is contrary to Article 30 *et seq.* of the Treaty, provided that, in the selection of the proprietary medicinal preparations in respect of which assistance may be granted, account is taken exclusively, on the basis of an objective and fair assessment, of their therapeutic value and of the expenses incurred for normal and necessary medical treatment.

15 In order to determine the scope of the prohibition contained in Article 30 of the Treaty in relation to national measures of the type in question, it should, in the first place, be noted that the rules whose compatibility with national law is to be considered by the national court display the particular feature that, in principle, they provide for reimbursement, to a substantial percentage of the population, of the price paid for all medicinal preparations which may be prescribed to patients by an approved doctor. In that respect they are different from the legislation of other Member States which draw up a restrictive list of the medicinal preparations or like products in respect of which reimbursement is permitted. That is why the Netherlands rules, with a view to attaining their objective of reducing costs, set out limitative lists excluding preparations.

16 Although it is not possible, contrary to the contention of the defendant in the main proceedings, to equate the competent authority of a Member State which, within the framework of a health-care insurance scheme financed by contributions from the insured persons and by financing from the public authorities, draws up rules governing and limiting reimbursement of the costs of health care, with an economic operator who in each case freely chooses

the goods which he acquires on the market, it must be recognized that Community law does not detract from the powers of Member States to organize their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical preparations in order to promote the financial stability of their health-care insurance schemes.

17 Likewise, it must be recognized that in a scheme which — like that in force in the Netherlands — is based on the principle of reimbursement in respect of all medicinal preparations which may be prescribed, it is not in principle incompatible with Community law for the Member State concerned, with a view to achieving its aim of limiting costs, to prepare limitative lists excluding certain products from the reimbursement scheme.

18 Even if measures such as the provisions in question do not relate directly to the importation of medicinal preparations from other Member States, the fact cannot be overlooked that, depending on the manner of their application and the use made of them, they may affect the possibilities of marketing the preparations and, to that extent, they may indirectly influence the possibilities of importation.

19 In that connection it should be borne in mind that 80% of the medicinal preparations consumed in the Netherlands are imported and that the proportion thereof charged to the public insurance schemes amounts in all to 70%. It follows that, where reimbursement by the insurance authority is excluded in respect of a medicinal preparation, purchases of that preparation fall and consequently there is a risk that the preparation in question will be totally eliminated from the national market.

20 However, in view of the special nature, in that respect, of the trade in pharmaceutical products, namely the fact that social security institutions are substituted for consumers as regards responsibility for the payment of medical expenses, legislation of the type in question cannot in itself be regarded as constituting a restriction on the freedom to import guaranteed by Article 30 of the Treaty if certain conditions are satisfied.

21 In that regard it must be stressed that for such legislation to be in conformity with the Treaty the choice of the medicinal preparations to be excluded must

be free of any discrimination to the detriment of imported medicinal preparations. To that end, the exclusionary lists must be drawn up in accordance with objective criteria, without reference to the origin of the products, and must be verifiable by any importer. If those conditions are fulfilled, an importer may secure access to the Netherlands market provided that he is in a position to market a product which, whilst having the same therapeutic value, offers a price advantage over some other product available on the market. Such rules would in no way detract from the freedom to market any product meeting that requirement, which relates not to the nature of the product but only to its price.

22 The answer to the first question should therefore be that provisions adopted within the framework of a compulsory national health-care scheme with the object of refusing insured persons the right to be supplied, at the expense of the insurance institution, with specifically named preparations are compatible with Article 30 of the Treaty if the determination of the excluded medicinal preparations involves no discrimination regarding the origin of the products and is carried out on the basis of objective and verifiable criteria, such as the existence on the market of other, less expensive products having the same therapeutic effect, the fact that the preparations in question are freely marketed without the need for any medical prescription, or are products excluded from reimbursement for reasons of a pharmaco-therapeutic nature justified by the protection of public health, and provided that it is possible to amend the lists whenever compliance with the specified criteria so requires.

23 If the national court should find that the measure whose compatibility with Community law it is called upon to consider does not meet the conditions to which such conformity is subject, it should be borne in mind with regard to the application of Article 36 of the Treaty, as the Court has held on many occasions (for example the judgment of 19 December 1961 in Case 7/61 *Commission* v *Italy* [1961] ECR 317), that Article 36 relates to measures of a non-economic nature. That provision cannot therefore justify a measure whose primary objective is budgetary inasmuch as it is intended to reduce the operating costs of a sickness insurance scheme.

B — The interpretation of Article 34 of the Treaty

24 The first question also seeks to ascertain whether Article 34 of the Treaty must be interpreted as meaning that it precludes national rules of the type in question. The plaintiffs in the main proceedings maintain that the contested order constitutes a measure having an effect equivalent to a quantitative restriction on exports within the meaning of that article.

25 As the Court has already stated in its judgment of 8 November 1979 (Case 15/79 *Groenveld* [1979] ECR 3409), Article 34 concerns national measures which have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a Member State and its export trade in such a way as to provide a particular advantage for national production or for the domestic market of the State in question.

26 That part of the first question must therefore be answered in the negative.

II — The second and third questions

27 The second and third questions submitted by the President of the Arrondissementsrechtbank seek essentially to ascertain whether the provisions of Article 5 of the Treaty in conjunction with the provisions of Articles 5, 11, 12 and 21 of Council Directive 65/65 of 26 January 1965 and the provisions of Article 32 in conjunction with the provisions of Articles 28 and 31 of Council Directive 75/319 of 20 May 1975 have direct effect (second question) and, if so, whether they preclude rules of the kind at issue in this case (third question).

28 As the Commission has rightly contended, the order in question does not concern access to the market within the meaning of the two directives cited, since the validity of the authorizations granted by application of those directives is not called in question. New products brought onto the Netherlands market may be granted authorization as soon as they satisfy the prescribed conditions. The third question must therefore be answered in the negative. In view of those considerations, the second question becomes devoid of purpose.

III — The fourth and fifth questions

29 In his fourth and fifth questions, the President of the Arrondissementsrechtbank asks whether the provisions of Article 3 (f), combined with those of Articles 85 and 86 of the Treaty, have direct effect and preclude rules of the kind at issue in this case.

30 Articles 85 and 86 of the Treaty form part of the competition rules "applicable to undertakings" and therefore are not relevant to an assessment of the question whether the legislation of the type at issue in the main proceedings is in conformity with Community law.

Costs

31 The costs incurred by the Government of the Kingdom of Denmark, the Government of the Italian Republic and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. As these proceedings are, so far as the parties to the main proceedings are concerned, in the nature of a step in the matter for that court, the decision on costs is a matter for that court.

On those grounds,

THE COURT

in reply to the questions submitted to it by the President of the Arrondissementsrechtbank, The Hague, by order of 16 December 1982, hereby rules:

1. **Provisions adopted within the framework of a compulsory national health-care scheme with the object of refusing insured persons the right to be supplied, at the expense of the insurance institution, with specifically named medicinal preparations are compatible with Article 30 of the Treaty if the determination of the excluded medicinal preparations involves no discrimination regarding the origin of the**

products and was carried out on the basis of objective and verifiable criteria, such as the existence on the market of other, less expensive products having the same therapeutic effect, the fact that the preparations in question are freely marketed without the need for any medical prescription, or are products excluded from reimbursement for reasons of a pharmaco-therapeutic nature justified by the protection of public health, and provided that it is possible to amend the lists whenever compliance with the specified criteria so requires.

2. Article 36 of the EEC Treaty cannot justify a measure whose primary objective is budgetary inasmuch as it is intended to reduce operating costs of a sickness insurance scheme.

3. Article 34 of the Treaty does not preclude a system of the kind described in the order making the reference.

4. Article 5 of the Treaty and the provisions of Council Directives 65/65 of 26 January 1965 (Official Journal, English Special Edition 1965-66, p. 20) and 75/319 of 20 May 1975 (Official Journal 1975, L 147, p. 1) do not preclude such a system.

5. Articles 85 and 86 of the Treaty are not relevant to the question whether legislation of the type at issue in the main proceedings is in conformity with Community law.

	Mertens de Wilmars	Koopmans	Bahlmann
Galmot	Pescatore	Mackenzie Stuart	O'Keeffe
Bosco	Due	Everling	Kakouris

Delivered in open court in Luxembourg on 7 February 1984.

P. Heim
Registrar

J. Mertens de Wilmars
President