JUDGMENT OF THE COURT

12 July 2001 (1)

(Freedom to provide services - Articles 59 of the EC Treaty (now, after amendment, Article 49 EC) and 60 of the EC Treaty (now Article 50 EC) -

Sickness insurance - System providing benefits in kind - System of agreements - Hospital treatment costs incurred in another Member State - Prior authorisation - Criteria - Justification)

In Case C-157/99,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Arrondissementsrechtbank te Roermond (Netherlands) for a preliminary ruling in the proceedings pending before that court between

B.S.M. Geraets-Smits

and

Stichting Ziekenfonds VGZ

and between

H.T.M. Peerbooms

and

Stichting CZ Groep Zorgverzekeringen,

on the interpretation of Articles 59 of the EC Treaty (now, after amendment, Article 49 EC) and 60 of the EC Treaty (now Article 50 EC),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, C. Gulmann, A. La Pergola (Rapporteur), M. Wathelet and V. Skouris (Presidents of Chambers), D.A.O. Edward, J.-P. Puissochet, P. Jann, L. Sevón, R. Schintgen and F. Macken, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,

Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

- Stichting CZ Groep Zorgverzekeringen, by E.P.H. Verdeuzeldonk, acting as Agent,

- the Netherlands Government, by M.A. Fierstra, acting as Agent,

- the Belgian Government, by A. Snoecx, acting as Agent,

- the Danish Government, by J. Molde, acting as Agent,

- the German Government, by W.-D. Plessing and C.-D. Quassowski, acting as Agents,

- the French Government, by K. Rispal-Bellanger and C. Bergeot, acting as Agents,

- the Irish Government, by M.A. Buckley, acting as Agent, assisted by D. Barniville, BL,

- the Portuguese Government, by L. Fernandes and P. Borges, acting as Agents,

- the Finnish Government, by T. Pynnä and E. Bygglin, acting as Agents,

- the Swedish Government, by L. Nordling, acting as Agent,

- the United Kingdom Government, by M. Ewing, acting as Agent, assisted by S. Moore, Barrister,

- the Icelandic Government, by E. Gunnarsson and V. Hauksdóttir, acting as Agents,

- the Norwegian Government, by H. Seland, acting as Agent,

- the Commission of the European Communities, by P. Hillenkamp, P.J. Kuijper and H.M.H. Speyart, acting as Agents,

having regard to the Report for the Hearing,

after hearing the observations of Stichting Ziekenfonds VGZ, represented by H.G. Sevenster, J.K. de Pree and E.H. Pijnacker Hordijk, advocaten; Stichting CZ Groep Zorgverzekeringen, represented by E.P.H. Verdeuzeldonk; of the Netherlands Government, represented by M.A. Fierstra; of the Danish Government, represented by J. Molde; of the German Government, represented by W.-D. Plessing; of the French Government, represented by C. Bergeot; of the Irish Government, represented by D. Barniville; of the Austrian Government, represented by G. Hesse, acting as Agent; of the Finnish Government, represented by E. Bygglin; of the Swedish Government, represented by A. Kruse, acting as Agent; of the United Kingdom Government, represented by E. Ewing, assisted by S. Moore; of the Icelandic Government, represented by E. Gunnarsson; and of the Commission, represented by H.H. Speyart, at the hearing on 4 April 2000,

after hearing the Opinion of the Advocate General at the sitting on 18 May 2000,

gives the following

Judgment

1. By order of 28 April 1999, received at the Court on 30 April 1999, the Arrondissementsrechtbank te Roermond (District Court, Roermond) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article234 EC) two questions on the interpretation of Article 59 of the EC Treaty (now, after amendment, Article 49 EC) and Article 60 of the Treaty (now Article 50 EC).

2. The two questions have been raised in proceedings between Mrs Geraets-Smits and Stichting Ziekenfonds VGZ ('Stichting VGZ') and between Mr Peerbooms and Stichting CZ Groep Zorgverzekeringen ('Stichting CZ') concerning the reimbursement of hospital treatment costs incurred in Germany and Austria respectively.

National legal framework

3. In the Netherlands, the sickness insurance scheme is based principally on the Ziekenfondswet of 15 October 1964 (Law on Sickness Funds, *Staatsblad* 1964, No 392, as subsequently amended, 'the ZFW'), the Algemene Wet Bijzondere Ziektekosten of 14 December 1967 (Law on general insurance for special sickness costs, *Staatsblad* 1967, No 617, as subsequently amended, 'the AWBZ') and the Wet op de toegang tot ziektekostenverzekeringen (Law on access to sickness insurance, 'the WTZ'). Both the ZFW and the AWBZ establish a system of benefits in kind under which an insured person is entitled not to reimbursement of costs incurred for medical treatment but to free

treatment. Both laws are based on a system of agreements made between sickness funds and providers of health care. The WTZ, on the other hand, establishes a system under which insured persons are reimbursed costs and is not based on a system of agreements.

4.

Under Articles 2 to 4 of the ZFW, workers whose annual income does not exceed an amount determined by law (NLG 60 750 in 1997), persons treated as such and persons in receipt of social benefits and dependent members of their families living with them in the same household are compulsorily and automatically insured under that law.

5.

Article 5(1) of the ZFW provides that any person coming within its scope who wishes to claim entitlement under that law must register with a sickness fund operating in the municipality in which he resides.

6.

Article 8 of the ZFW provides:

'1. An insured person shall be entitled to benefits in the form of necessary medical care, provided that he is not entitled to such care under the Algemene Wet Bijzondere Ziektekosten ... Sickness funds shall ensure that any insured person registered with them is able to rely on that right.

2. The nature, content and extent of the benefits shall be defined by or pursuant to a Royal Decree, it being understood that they shall in any event include medical assistance, the extent of which remains to be defined, and also the care and treatment provided in categories of institutions to be defined. Furthermore, thegrant of a benefit may be conditional on a financial contribution by the insured person; this contribution need not be the same for all insured persons.

...'

7.

The Verstrekkingenbesluit Ziekenfondsverzedering of 4 January 1966 (Decree on sickness insurance benefits in kind, *Staatsblad* 1966, No 3, as subsequently amended, 'the Verstrekkingenbesluit') implements Article 8(2) of the ZFW.

8.

The Verstrekkingenbesluit thus determines entitlement to benefits and the extent of such benefits for various categories of care, including in particular the categories 'medical and surgical assistance' and 'in-patient hospital treatment'.

9.

Article 2(3) of the Verstrekkingenbesluit provides that entitlement to benefit cannot be claimed unless the insured person, in the light of his needs and with a view to effective therapy, has no reasonable choice other than to seek a benefit of that nature, content and extent.

10.

Under Article 3 of the Verstrekkingenbesluit, the category of medical and surgical care is to include care provided by a general practitioner and a specialist, 'the extent [of which] shall be determined in accordance with what is normal in the professional circles concerned'.

11.

As regards in-patient hospital treatment, Articles 12 and 13 of the Verstrekkingenbesluit provide, first, that such treatment may involve, *inter alia*, medical, surgical and obstetric examination, treatment and care and, second, that there must be evidence that hospital treatment is justified. The Besluit ziekenhuisverpleging ziekenfondsverzekering of 6 February 1969 (Decree on care provided in hospitals under sickness insurance, *Staatscourant* 1969, No 50), determines the cases in which evidence justifying hospital treatment is established.

12.

The ZFW is applied by sickness funds, which are legal persons approved by the Minister in accordance with Article 34 of the ZFW. The Ziekenfondsraad is responsible for advising and informing the Minister concerned and with overseeing the management and administration of the sickness funds. Where a complaint is lodged against a sickness fund decision concerning entitlement to a benefit, the sickness fund is required to obtain the opinion of the Ziekenfondsraad before reaching a decision on the complaint.

13.

The ZFW provides for the establishment of a system of agreements, the principal features of which are as follows.

14.

Article 44(1) of the ZFW provides that the sickness funds are to 'enter into agreements with persons and establishments offering one or more forms of care, as referred to in the Royal Decree adopted to implement Article 8'.

15.

Article 44(3) of the ZFW provides that such agreements are to include at least provisions concerning the nature and extent of the parties' mutual obligations and rights, the categories of care to be provided, the quality and effectiveness of the care and supervision of compliance with the terms of the agreement, including supervision of the benefits provided or to be provided and the accuracy of the amounts charged for those benefits, and also an obligation to communicate the information necessary for that supervision.

16.

The agreements do not, however, apply to the scales of charges for health care. These are governed exclusively by the Wet tarieven gezondheidszorg (Law on the scales of charges for health care). According to the explanations provided by the Netherlands Government, however, that does not mean that agreements on costs cannot be entered into between the sickness funds and care providers. All the factors which influence the level of costs and hospital budgets can form the subject of an agreement between the parties.

17.

The sickness funds are free to enter into agreements with any care provider, subject to a twofold reservation. First, it follows from Article 47 of the ZFW that any sickness fund 'is required to enter into an agreement ... with any establishment in the area in which it operates or which the population of that area regularly attend'. Second, agreements can only be entered into with establishments which are duly authorised to provide the care in question or with persons lawfully authorised to do so.

18.

Article 8a of the ZFW provides:

'1. An establishment providing services such as those referred to in Article 8 must be authorised to do so.

2. A Royal Decree may provide that an establishment belonging to a category to be defined by Royal Decree is to be regarded as authorised for the purposes of this Law. ...'

19.

It follows from Article 8c(a) of the ZFW that approval of an establishment operating hospitals must be refused if that establishment does not meet the requirements of the Wet ziekenhuisvoorzieningen (Law on hospital equipment) on distribution and needs. That law, its implementing directives (in particular the directive based on Article 3 of the law, *Staatscourant* 1987, No 248) and also the district plans determine in greater detail the national needs in relation to various categories of hospitals and their distribution between the various regions defined within the Netherlands for health purposes.

20.

As regards the specific implementation of the right to benefits, Article 9 of the ZFW provides:

'1. Save as provided for in the Royal Decree referred to in Article 8, an insured person wishing to claim entitlement to a benefit shall apply to a person or an establishment with whom or with which the sickness insurance fund with which he is registered has entered into an agreement for that purpose, subject to the provisions of paragraph 4.

2. The insured person may choose from among the persons and establishments mentioned in paragraph 1, subject to the provisions of paragraph 5 and the provision regarding conveyance by ambulance, as laid down in the Wet ambulancevervoer ((Law on conveyance by ambulance), *Staatsblad* 1967, No 369).

3. [repealed]

4. A sickness insurance fund may, by way of derogation from paragraphs 1 and 2 hereof, authorise an insured person, for the purpose of claiming entitlement to a benefit, to apply to another person or establishment in the Netherlands where this is necessary for his medical treatment. The Minister may determine the cases and circumstances in which an insured person may be granted authorisation, in claiming entitlement to a benefit, to apply to a person or an establishment outside the Netherlands.

...'

21.

The Minister exercised the powers conferred on him by the final sentence of Article 9(4) of the ZFW in adopting the Regeling hulp in het buitenland ziekenfondsverzekering of 30 June 1988 (Regulation on care provided abroad under the sickness insurance rules, *Staatscourant* 1988, No 123, 'the Rhbz'). Article 1 of the Rhbz provides:

'A sickness insurance fund may authorise an insured person claiming entitlement to a benefit to apply to a person or establishment outside the Netherlands in those cases in which the sickness insurance fund shall determine that such action is necessary for the health care of the insured person.'

22.

The national court states that, under the case-law of the Centrale Raad van Beroep (Netherlands appellate court in social security matters) on applications for authorisation to receive medical treatment abroad funded under the ZFW, two conditions must be satisfied here.

23.

First, the treatment in question must be capable of being regarded as a qualifying benefit within the meaning of Article 8 of the ZFW and of the Verstrekkingenbesluit. As stated above, the relevant test under Article 3 of the Verstrekkingenbesluit is whether the proposed treatment is regarded as 'normal in the professional circles concerned' (decision of the Centrale Raad van Beroepof 23 May 1995, RZA 1995, No 126). For example, as regards a particular type of treatment in Germany, the Centrale Raad van Beroep has held that 'the basis [for the treatment] is not (yet) sufficiently recognised in scientific circles and, according to current thinking in the Netherlands, is regarded as experimental' (decision of 19 December 1997, RZA 1998, No 48). It is thus clear from the case-law that in practice reference is made to the views prevailing within professional circles in the Netherlands in order to determine whether treatment can be held to be normal and not experimental.

24.

Second, it must be determined whether the treatment is necessary for the medical treatment of the insured person within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz. The national court states that in practice it is necessary to take into account the methods of treatment available in the Netherlands (see, in particular, the decision of the Centrale Raad van Beroep of 13 December 1994, RZA 1995, No 53) and to ascertain whether adequate treatment can be available without undue delay in the Netherlands.

The main proceedings

The Geraets-Smits case

25.

Mrs Geraets-Smits suffers from Parkinson's disease. By letter of 5 September 1996, she requested Stichting VGZ to reimburse the costs of care received at the Elena-Klinik in Kassel in Germany for specific, multidisciplinary treatment of that disease. That method involves, *inter alia*, examinations and treatment to determine the ideal medical treatment, physiotherapy and ergotherapy and socio-psychological support.

26.

By decisions of 30 September and 28 October 1996, Stichting VGZ informed Mrs Geraets-Smits that the costs of the treatment would not be refunded under the ZFW. The reasons stated were that satisfactory and adequate treatment for Parkinson's disease was available in the Netherlands, that the specific clinical treatment provided at the Elena-Klinik

provided no additional advantage and that there was therefore no medical necessity justifying treatment in that clinic.

27.

Mrs Geraets-Smits sought the opinion of the Ziekenfondsraad on 14 November 1996. On 7 April 1997, the Ziekenfondsraad issued an opinion stating that it regarded the decision of Stichting VGZ refusing her request as proper.

28.

Mrs Geraets-Smits then lodged an appeal with the Arrondissementsrechtbank te Roermond against the decision of 30 September 1996. She claims, in substance, that the specific clinical treatment provided in Germany has a number of advantages over the 'symptomatic' approach used in the Netherlands, whereby the various manifestations of the disease are treated individually, on a symptom-by-symptom basis.

29.

In its examination, the Arrondissementsrechtbank finds that the decision refusing to reimburse Mrs Geraets-Smits's costs was based, first, on the fact that the specific clinical method is not regarded as normal treatment within the professional circles concerned and is therefore not one of the benefits covered by Article 8 of the ZFW. Should the treatment, or part of it, none the less be regarded as normal, the refusal is based, second, on the consideration that, since satisfactory and adequate treatment was available in the Netherlands at an establishment having contractual arrangements with the sickness insurance fund, the treatment in Kassel was not necessary within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz.

30.

The national court appointed a neurologist as an expert witness. In the report which he filed on 3 February 1998, the expert concluded that there was no clinical or scientific evidence that the specific clinical approach was more appropriate and that therefore there was no strictly medical justification for the treatment received by Mrs Geraets-Smits in Germany.

The Peerbooms case

31.

Mr Peerbooms fell into a coma following a road accident on 10 December 1996. He was taken to hospital in the Netherlands and then transferred in a vegetative state to the University Clinic in Innsbruck in Austria on 22 February 1997.

32.

The Innsbruck clinic gave Mr Peerbooms special intensive therapy using neurostimulation. In the Netherlands, that technique is used only experimentally at two medical centres and patients over the age of 25 years are not allowed to undergo this therapy. It is therefore common ground that if Mr Peerbooms, who was born in 1961, had remained in the Netherlands, he would not have been able to receive such treatment.

33.

By letter of 24 February 1997, Mr Peerbooms's neurologist requested Stichting CZ to pay the costs of the treatment at the University Clinic in Innsbruck.

34.

That request was rejected by decision of 26 February 1997, delivered after consideration of the opinion of the medical consultant, on the ground that adequate treatment could have been obtained in the Netherlands from a care provider and/or an establishment with which Stichting CZ had entered into an agreement.

35.

Mr Peerbooms's neurologist repeated his request, which was again refused on 5 March 1997. The complaint lodged against those decisions was rejected by Stichting CZ on 12 June 1997.

36.

In the meantime, Mr Peerbooms came out of his coma. He was able to leave the Innsbruck clinic on 20 June 1997 and was transferred to the clinic in Hoensbroeck (Netherlands) to continue his rehabilitation.

37.

Mr Peerbooms lodged an appeal before the Arrondissementsrechtbank te Roermond against Stichting CZ's decision of 12 June 1997 rejecting his complaint.

38.

According to the explanations provided by that court, Stichting CZ's refusal was based, first, on the fact that, owing to the experimental nature of therapy using neurostimulation

and the absence of scientific evidence of its effectiveness, that type of treatment was not regarded as normal within the professional circles concerned nor, consequently, as a benefit qualifying for reimbursement under Article 8 of the ZFW. Should that treatment none the less be held to be normal, the refusal was based, second, on the consideration that, since satisfactory and adequate treatment was available without undue delay in the Netherlands at an establishment with which the sickness insurance fund had contractual arrangements, the treatment at Innsbruck was not necessary within the meaning of Article 9(4) of the ZFW and Article 1 of the Rhbz.

39.

The neurologist appointed as an expert witness by the Arrondissementsrechtbank concluded in his report submitted on 12 May 1998 that appropriate and adequate treatment, such as that provided to Mr Peerbooms in Innsbruck, was not available in the Netherlands owing to his age and that he would not have been able to receive adequate therapy in another hospital centre in the Netherlands. The neurologist advising Stichting CZ stated in reply that that method of treatment was experimental and had not so far been approved in scientific circles. However, the court expert stated in a further report filed on 31 August 1998 that he stood by his conclusions.

Questions referred to the Court

40.

By order of 28 April 1999, the Arrondissementsrechtbank te Roermond decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. (a) Must Articles 59 and 60 of the EC Treaty be interpreted as meaning that a provision such as Article 9(4) of the ZFW in conjunction with Article 1 of the Rhbz is inconsistent with those Treaty provisions where the national rules cited provide that a person insured under the sickness insurance fund requires prior authorisation from the sickness insurance fund in order to claim his entitlement to benefits from a person or establishment outside the Netherlands?

(b) What is the answer to Question 1(a) where the authorisation referred to therein is refused or does not apply, because the relevant treatment in the other Member State is not regarded "as normal in professional circles" and thus is deemed not to constitute a benefit within the meaning of Article 8 of the ZFW? Does it make any difference in that connection whether regard is had solely to the conceptions ofNetherlands professional circles and whether national or international scientific yardsticks are applied and, if so, in what respect? Is it also relevant whether the relevant treatment is reimbursed under the social security system provided for under the law of that other Member State?

(c) What is the answer to Question 1(a) where the treatment abroad is deemed to be normal and therefore to constitute a benefit but the requisite authorisation is refused on the ground that timely and adequate care can be obtained from a contracted Netherlands care provider and treatment abroad is therefore not necessary for the health care of the person concerned?

2. If the requirement to obtain authorisation constitutes a barrier to the freedom to provide services enshrined in Articles 59 and 60 of the EC Treaty, are the overriding reasons in the general interest relied on by the defendants ... sufficient in order for the barrier to be regarded as justified?'

41.

The national court observes that, although the requirements relating to the approval of hospital establishments provided for in the ZFW do not appear to preclude approval of foreign establishments, for example those in border areas, it can be inferred from those requirements, and in particular from the principle of the geographical distribution governing approval, that it is essentially establishments in the Netherlands which will be approved.

42.

The national court goes on to state that particular attention must be paid to what is actually meant by 'normal' treatment where it is a matter of deciding whether or not Netherlands sickness insurance funds should authorise the assumption of costs of treatment provided outside the Netherlands. If the sickness insurance funds have regard solely to what is considered normal within Netherlands professional circles, that may mean that certain methods of treatment, which are none the less generally accepted in other Member States and for which reimbursement is made because professional circles in those Member States hold views different from those prevailing in the Netherlands, will not be regarded as benefits covered by the ZFW, so that authorisation will have to be refused.

The questions referred to the Court

43.

By its two questions, which fall to be dealt with together, the national court is asking essentially whether Articles 59 and 60 of the Treaty are to be interpreted as precluding legislation of a Member State, such as the legislation at issue in the main proceedings, which makes the assumption of the costs of care provided in a hospital establishment in another Member State conditional upon prior authorisation by the sickness insurance fund with which the insured person isregistered, that authorisation being granted only in so far as the following two conditions are satisfied. First, the proposed treatment must be among the benefits for which the sickness insurance scheme of the first Member State assumes responsibility, which means that the treatment must be regarded as 'normal in the professional circles concerned'. Second, the treatment abroad must be necessary in terms of the medical condition of the person concerned, which supposes that adequate care cannot be provided without undue delay by a care provider which has entered into an agreement with a sickness insurance fund in the first Member State.

The power of the Member States to arrange their social security systems and the obligation to comply with Community law in exercising that power

44.

In order to answer the questions as thus reformulated, it should be remembered at the outset that, according to settled case-law, Community law does not detract from the power of the Member States to organise their social security systems (Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16, Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 27, and Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 17).

45.

In the absence of harmonisation at Community level, it is therefore for the legislation of each Member State to determine, first, the conditions concerning the right or duty to be insured with a social security scheme (Case 110/79 *Coonan* [1980] ECR 1445, paragraph 12, Case C-349/87 *Paraschi* [1991] ECR I-4501, paragraph 15, and *Kohll*, paragraph 18) and, second, the conditions for entitlement to benefits (Joined Cases C-4/95 and C-5/95 *Stöber and Piosa Pereira* [1997] ECR I-511, paragraph 36, and *Kohll*, paragraph 18).

46.

Nevertheless, the Member States must comply with Community law when exercising that power.

Application to hospital care of the provisions on freedom to provide services

47.

It is first necessary to determine whether the situations at issue in the main proceedings do indeed fall within the ambit of the freedom to provide services provided for in Articles 59 and 60 of the Treaty.

48.

A number of the governments which have submitted written observations to the Court have argued that hospital services cannot constitute an economic activity within the meaning of Article 60 of the Treaty, particularly when they are provided in kind and free of charge under the relevant sickness insurance scheme.

49.

Relying in particular on Case 263/86 *Humbel* [1988] ECR 5365, paragraphs 17 to 19, and Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685, paragraph 18, they argue, in particular, that there is no remuneration within the

meaning of Article 60 of the Treaty where the patient receives care ina hospital infrastructure without having to pay for it himself or where all or part of the amount he pays is reimbursed to him.

50.

Some of those governments also maintain that it follows from Case 293/83 *Gravier* [1985] ECR 593 and Case C-109/92 *Wirth* [1993] ECR I-6447, paragraph 17, that a further condition to be satisfied before a service can constitute an economic activity within the meaning of Article 60 of the Treaty is that the person providing the service must do so with a view to making a profit.

51.

The German Government considers that the structural principles governing the provision of medical care are inherent in the organisation of the social security systems and do not come within the sphere of the fundamental economic freedoms guaranteed by the EC Treaty, since the persons concerned are unable to decide for themselves the content, type and extent of a service and the price they will pay.

52.

None of those arguments can be upheld.

53.

It is settled case-law that medical activities fall within the scope of Article 60 of the Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment (see Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16; *Society for the Protection of Unborn Children Ireland*, paragraph 18, concerning advertising for clinics involved in the deliberate termination of pregnancies; and *Kohll*, paragraphs 29 and 51).

54.

It is also settled case-law that the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement (Case 279/80 *Webb* [1981] ECR 3305, paragraph 10, and *Kohll*, paragraph 20), so that the fact that the national rules at issue in the main proceedings are social security rules cannot exclude application of Articles 59 and 60 of the Treaty (*Kohll*, paragraph 21).

55.

With regard more particularly to the argument that hospital services provided in the context of a sickness insurance scheme providing benefits in kind, such as that governed by the ZFW, should not be classified as services within the meaning of Article 60 of the Treaty, it should be noted that, far from falling under such a scheme, the medical treatment at issue in the main proceedings, which was provided in Member States other than those in which the persons concerned were insured, did lead to the establishments providing the treatment being paid directly by the patients. It must be accepted that a medical service provided in one Member State and paid for by the patient should not cease to fall within the scope of the freedom to provide services guaranteed by the Treaty merely because reimbursement of the costs of the treatment involved is applied for under another Member State's sickness insurance legislation which is essentially of the type which provides for benefits in kind.

56.

Furthermore, the fact that hospital medical treatment is financed directly by the sickness insurance funds on the basis of agreements and pre-set scales of fees is not in any event such as to remove such treatment from the sphere of services within the meaning of Article 60 of the Treaty.

57.

First, it should be borne in mind that Article 60 of the Treaty does not require that the service be paid for by those for whom it is performed (Case 352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, paragraph 16, and Joined Cases C-51/96 and C-191/97 *Deliège* [2000] ECR I-2549, paragraph 56).

58.

Second, Article 60 of the Treaty states that it applies to services normally provided for remuneration and it has been held that, for the purposes of that provision, the essential characteristic of remuneration lies in the fact that it constitutes consideration for the service in question (*Humbel*, paragraph 17). In the present cases, the payments made by the sickness insurance funds under the contractual arrangements provided for by the ZFW, albeit set at a flat rate, are indeed the consideration for the hospital services and unquestionably represent remuneration for the hospital which receives them and which is engaged in an activity of an economic character.

59.

Since the provisions of services at issue in the main proceedings do fall within the scope of the freedom to provide services within the meaning of Articles 59 and 60 of the Treaty, it is necessary to consider whether the rules at issue in the main proceedings place restrictions on that freedom and, if so, whether those restrictions can be objectively justified.

The restrictive effects of the legislation at issue in the main proceedings

60.

It is necessary to determine whether there is a restriction on freedom to provide services within the meaning of Article 59 of the Treaty where the costs of treatment provided in a hospital in another Member State is assumed under the sickness insurance scheme only on condition that the person receiving the treatment obtains prior authorisation, which is granted only if the treatment concerned is covered by the sickness insurance scheme of the Member State in which the patient is insured, which requires that the treatment be 'normal within the professional circles concerned', and where the insured person's sickness fund has decided that his medical treatment requires that he be treated in the hospital establishment concerned, presupposing that adequate timely treatment cannot be provided by a contracted care provider in the Member State in which the patient is insured.

61.

According to settled case-law, Article 59 of the Treaty precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State (Case C-381/93 *Commission* v *France* [1994] ECR I-5145, paragraph 17, and *Kohll*, paragraph 33).

62.

In the present case, while the ZFW does not deprive insured persons of the possibility of using a provider of services established in another Member State, it does nevertheless make reimbursement of the costs incurred in another Member State subject to prior authorisation and provides for such reimbursement to be refused where the two requirements referred to in paragraph 60 above are not satisfied.

63.

As regards the first of those requirements, namely that the proposed treatment must be treatment covered by the ZFW, in other words treatment which can be regarded as 'normal in the professional circles concerned', it is sufficient to point out that by its very essence such a condition is liable to lead to refusals of authorisation. It is only the precise frequency with which authorisation is refused, not refusal itself, that will be determined by the interpretation of 'normal' treatment and 'the professional circles concerned'.

64.

As regards the second requirement, namely that provision of hospital treatment in another Member State must be a medical necessity, which will be the case only if adequate treatment cannot be obtained without undue delay in contracted hospitals in the Member State in which the person seeking treatment is insured, this requirement by its very nature will severely limit the circumstances in which such authorisation can be obtained.

65.

The Netherlands Government and the Commission have stressed, however, that it was open to the sickness insurance funds to enter into agreements with hospital establishments outside the Netherlands and that in such a case no prior authorisation would be required in order for the cost of treatment provided by such establishments to be assumed under the ZFW.

66.

Even disregarding the fact that no such possibility is apparent from the provisions of national law to which the Court has been referred, the order for reference points out that in practice, having regard, in particular, to the contracting conditions, it will be mainly hospital establishments in the Netherlands that will strike contractual arrangements with the sickness insurance funds. It must also be recognised that, with the exception of hospitals situated in areas adjoining the Netherlands, it seems unlikely that a significant number of hospitals in other Member States would ever enter into agreements with the Netherlands sickness insurance funds, their prospects of admitting patients insured by those funds remaining uncertain and limited.

67.

It is therefore accepted that in the majority of cases the assumption of costs, under the ZFW, of hospital treatment provided by establishments in Member States other than the Member State in which a person is insured will have to be subject to prior authorisation, as is indeed the case for the treatment at issue in the main proceedings, and that this authorisation will be refused if the two requirements set out in paragraph 60 above are not satisfied.

68.

By comparison, treatment provided in contracted hospitals situated in the Netherlands, which represents the greater part of the hospital treatment provided there to persons covered by the ZFW, is paid for by the sickness insurance funds without any prior authorisation being required.

69.

It follows from the foregoing considerations that rules such as those at issue in the main proceedings deter, or even prevent, insured persons from applying to providers of medical services established in another Member State and constitute, both for insured persons and service providers, a barrier to freedom to provide services (see, to that effect, *Luisi and Carbone*, paragraph 16, Case C-204/90 *Bachmann* [1992] ECR I-249, paragraph 31, and *Kohll*, paragraph 35).

70.

Consequently, it is necessary to examine whether, in so far as they concern medical services provided within a hospital infrastructure, such as those at issue in the main proceedings, such rules can be objectively justified.

71.

In that regard, it is first necessary to determine whether there are overriding reasons which can be accepted as justifying barriers to freedom to provide medical services supplied in the context of a hospital infrastructure, then to determine whether the prior authorisation principle is justifiable in the light of such overriding needs and last to consider whether the conditions governing the grant of prior authorisation can themselves be justified.

Overriding considerations which may be relied on to justify barriers to the exercise of freedom to provide services in the sphere of hospital treatment

72.

As all the governments which have submitted observations to the Court have pointed out, the Court has held that it cannot be excluded that the possible risk of seriously undermining a social security system's financial balance may constitute an overriding reason in the general interest capable of justifying a barrier to the principle of freedom to provide services (*Kohll*, paragraph 41).

73.

The Court has likewise recognised that, as regards the objective of maintaining a balanced medical and hospital service open to all, that objective, even if intrinsically linked to the method of financing the social security system, may also fall within the derogations on grounds of public health under Article 56 of the EC Treaty (now, after amendment, Article 46 EC), in so far as it contributes to the attainment of a high level of health protection (*Kohll*, paragraph 50).

74.

The Court has further held that Article 56 of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival of, the population (*Kohll*, paragraph 51).

75.

It is therefore necessary to determine whether the national rules at issue in the main proceedings can actually be justified in the light of such overriding reasons and, in such a case, in accordance with settled case-law, to make sure that they do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules (Case 205/84*Commission* v *Germany* [1986] ECR 3755, paragraphs 27 and 29; Case C-180/89 *Commission* v *Italy* [1991] ECR I-709, paragraphs 17 and 18; and Case C-106/91 *Ramrath* [1992] ECR I-3351, paragraphs 30 and 31).

The prior authorisation requirement

76.

As regards the prior authorisation requirement to which the ZFW subjects the assumption of the costs of treatment provided in another Member State by a non-contracted care provider, the Court accepts, as all the governments which have submitted observations have argued, that, by comparison with medical services provided by practitioners in their surgeries or at the patient's home, medical services provided in a hospital take place within an infrastructure with, undoubtedly, certain very distinct characteristics. It is thus well known that the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible.

77.

As may be seen, in particular, from the contracting system involved in the main proceedings, this kind of planning therefore broadly meets a variety of concerns.

78.

For one thing, it seeks to achieve the aim of ensuring that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned.

79.

For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage is all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for health care are not unlimited, whatever the mode of funding applied.

80.

From both those perspectives, a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in another Member State must be subject to prior authorisation appears to be a measure which is both necessary and reasonable.

81.

Looking at the system set up by the ZFW, it is clear that, if insured persons were at liberty, regardless of the circumstances, to use the services of hospitals with which their sickness insurance fund had no contractual arrangements, whether they were situated in the Netherlands or in another Member State, all the planning which goes into the contractual system in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke.

82.

Although, for the considerations set out above, Community law does not in principle preclude a system of prior authorisation, the conditions attached to the grant of such authorisation must none the less be justified with regard to the overriding considerations examined and must satisfy the requirement of proportionality referred to in paragraph 75 above.

The condition that the proposed treatment be 'normal'

83.

As observed above, the rules at issue in the main proceedings subject the grant of authorisation to the condition that the proposed medical or surgical treatment can be regarded as 'normal in the professional circles concerned'.

84.

It should be emphasised at the outset that, under Article 3 of the Verstrekkingenbesluit, this condition applies generally to the assumption of costs, under the ZFW, of all medical and surgical treatment, so that in principle it applies regardless of whether the proposed treatment is to be provided in a contracted establishment or outside such an establishment, within the Netherlands or outside the Netherlands.

85.

With that point in mind, it should also be remembered, as already stated in paragraphs 44 and 45 above, that it is for the legislation of each Member State to organise its national social security system and in particular to determine the conditions governing entitlement to benefits.

86.

The Court has thus held, in particular, that it is not in principle incompatible with Community law for a Member State to establish, with a view to achieving its aim of limiting costs, limitative lists excluding certain products from reimbursement under its social security scheme (*Duphar and Others*, paragraph 17).

87.

The same principle must apply to medical and hospital treatment when it is a matter of determining which treatments will be paid for by the social security system of the Member State concerned. It follows that Community law cannot in principle have the effect of requiring a Member State to extend the list of medical services paid for by its social insurance system: the fact that a particular type of medical treatment is covered or not covered by the sickness insurance schemes of other Member States is irrelevant in this regard.

88.

None the less, as observed in paragraph 46 above, in exercising that power the Member State must not disregard Community law.

89.

Thus it follows from the Court's case-law that the list of medicinal preparations excluded from reimbursement must be drawn up in accordance with Article 30 of the EC Treaty (now, after amendment, Article 28 EC) and that this will be so only where the list is drawn up in accordance with objective criteria, without reference to the origin of the products (*Duphar*, paragraph 21).

90.

It likewise follows from settled case-law that a scheme of prior authorisation cannot legitimise discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom such as that at issue in the main proceedings (see, to that effect, Joined Cases C-358/93 and C-416/93 *Bordessa and Others* [1995] ECR I-361, paragraph 25; Joined Cases C-163/94, C-165/94 and C-250/94 *Sanz de Lera and Others* [1995] ECR I-4821, paragraphs 23 to 28, and Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 37). Therefore, in order for a prior administrative authorisation scheme to be justified even though it derogates from such a fundamental freedom, it must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (*Analir and Others*, paragraph 38). Such a prior administrative authorisation scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings.

91.

The actual system of sickness insurance laid down by the ZFW is not based on a pre-established list of types of treatment issued by the national authorities for which payment will be guaranteed. The Netherlands legislature has enacted a general rule under which the costs of medical treatment will be assumed provided that the treatment is 'normal in the professional circles concerned'. It has therefore left it to the sickness insurance funds, acting where necessary under the supervision of the Ziekenfondsraad and the courts, to determine the types of treatment which actually satisfy that condition.

92.

In the present two cases, it is clear from the arguments submitted to the national court, reflected in part (b) of the first preliminary question, and from the observations submitted to the Court that the expression 'normal in the professional circles concerned' is open to a number of interpretations, depending, in particular, on whether it is considered that regard should be had to what is considered normal only in Netherlands medical circles, which, to judge by the order for reference, seems to be the interpretation favoured by the national court (see paragraph 23 above) or, on the other hand, to what is considered normal according to the state of international medical science and medical standards generally accepted at international level.

93.

In that regard, the Netherlands Government has explained that when a specific treatment constitutes professionally appropriate treatment having a valid scientific basis, it is regarded as a qualifying benefit for the purposes of the ZFW, so that the application of the 'normal' criterion must not have the consequence that only treatment normally available in the Netherlands can qualify for reimbursement. According to the Netherlands Government, professional opinion in the Netherlands is also based on the state of the art and on scientific thinking at international level and depends on whether, in the light of the

state of national and international science, the treatment is regarded as normal treatment. That criterion thus applies, it says, without distinction to the various types of treatment provided in the Netherlands and also to those for which the insured person wishes to go abroad.

94.

Only an interpretation on the basis of what is sufficiently tried and tested by international medical science can be regarded as satisfying the requirements set out in paragraphs 89 and 90 above.

95.

It follows from the those requirements that the institution of a system such as that at issue in the main proceedings, under which the authorisation decision needed to undergo hospital treatment in another Member State is entrusted to the sickness insurance funds, means that the criteria which those funds must apply in reaching that decision must be objective and independent where the providers of treatment are established.

96.

To allow only treatment habitually carried out on national territory and scientific views prevailing in national medical circles to determine what is or is not normal will not offer those guarantees and will make it likely that Netherlands providers of treatment will always be preferred in practice.

97.

If, on the other hand, the condition that treatment must be regarded as 'normal' is extended in such a way that, where treatment is sufficiently tried and tested by international medical science, the authorisation sought under the ZFW cannot be refused on that ground, such a condition, which is objective and applies without distinction to treatment provided in the Netherlands and to treatment provided abroad, is justifiable in view of the need to maintain an adequate, balanced and permanent supply of hospital care on national territory and to ensure the financial stability of the sickness insurance system, so that the restriction of the freedom to provide services of hospitals situated in other Member States which might result from the application of that condition does not infringe Article 59 of the Treaty.

98.

Further, where, as in the present case, a Member State decides that medical or hospital treatment must be sufficiently tried and tested before its cost will be assumed under its social security system, the national authorities called on to decide, for authorisation purposes, whether hospital treatment provided in another Member States satisfies that criterion must take into consideration all the relevant available information, including, in particular, existing scientific literature and studies, the authorised opinions of specialists and the fact that the proposedtreatment is covered or not covered by the sickness insurance system of the Member State in which the treatment is provided.

The condition concerning the necessity of the proposed treatment

99.

Under the rules at issue in the main proceedings, the grant of authorisation allowing assumption of the costs of a medical service provided abroad is subject to a second condition, namely that it be proved that the insured person's medical treatment requires that service.

100.

As the national court states, it follows from the wording of Article 9(4) of the ZFW and Article 1 of the Rhbz that in principle that condition applies irrespective whether the request for authorisation relates to treatment in an establishment located in the Netherlands with which the sickness insurance fund has no contractual arrangements or in an establishment located in another Member State.

101.

As regards the provision of hospital treatment outside the Netherlands, the national court states, however, that in practice this condition often appears to be interpreted as meaning that the provision of such treatment is not to be authorised unless it appears that appropriate treatment cannot be provided without undue delay in the Netherlands. No distinction is therefore drawn in this respect between whether the treatment could be provided by a contracted establishment or by a non-contracted establishment.

102.

The Netherlands Government explains that the legislation at issue in the main proceedings does not compel refusal of a request for authorisation if the treatment sought

is available in the Netherlands. Under Article 9(4) of the ZFW, read in conjunction with Article 1 of the Rhbz, authorisation must be refused only where the treatment required by the insured person's state of health is available from contracted providers of treatment. The Netherlands Government points out that the sickness insurance funds appear, however, to regard a care provider's country of establishment as a relevant factor, an interpretation which it considers inappropriate.

103.

In view of what is stated in paragraph 90 above, it can be concluded that the condition concerning the necessity of the treatment, laid down by the rules at issue in the main proceedings, can be justified under Article 59 of the Treaty, provided that the condition is construed to the effect that authorisation to receive treatment in another Member State may be refused on that ground only if the same or equally effective treatment can be obtained without undue delay from an establishment with which the insured person's sickness insurance fund has contractual arrangements.

104.

Furthermore, in order to determine whether equally effective treatment can be obtained without undue delay from an establishment having contractualarrangements with the insured person's fund, the national authorities are required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought but also of his past record.

105.

Such a condition can allow an adequate, balanced and permanent supply of high-quality hospital treatment to be maintained on the national territory and the financial stability of the sickness insurance system to be assured.

106.

Were large numbers of insured persons to decide to be treated in other Member States even when the hospitals having contractual arrangements with their sickness insurance funds offer adequate identical or equivalent treatment, the consequent outflow of patients would be liable to put at risk the very principle of having contractual arrangements with hospitals and, consequently, undermine all the planning and rationalisation carried out in this vital sector in an effort to avoid the phenomena of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage.

107.

However, once it is clear that treatment covered by the national insurance system cannot be provided by a contracted establishment, it is not acceptable that national hospitals not having any contractual arrangements with the insured person's sickness insurance fund be given priority over hospitals in other Member States. Once such treatment is ex hypothesi provided outside the planning framework established by the ZFW, such priority would exceed what is necessary for meeting the overriding requirements referred to in paragraph 105 above.

108.

In view of all the foregoing considerations, the answer to be given to the national court must be that Articles 59 and 60 of the Treaty do not preclude legislation of a Member State, such as that at issue in the main proceedings, which makes the assumption of the costs of treatment provided in a hospital located in another Member State subject to prior authorisation from the insured person's sickness insurance fund and the grant of such authorisation subject to the condition that (i) the treatment must be regarded as 'normal in the professional circles concerned', a criterion also applied in determining whether hospital treatment provided on national territory is covered, and (ii) the insured person's medical treatment must require that treatment. However, that applies only in so far as

- the requirement that the treatment must be regarded as 'normal' is construed to the effect that authorisation cannot be refused on that ground where it appears that the treatment concerned is sufficiently tried and tested by international medical science, and

- authorisation can be refused on the ground of lack of medical necessity only if the same or equally effective treatment can be obtained without undue delay at an establishment having a contractual arrangement with the insured person's sickness insurance fund.

Costs

109.

The costs incurred by the Netherlands, Belgian, Danish, German, French, Irish, Austrian, Portuguese, Finnish, Swedish, United Kingdom, Icelandic and Norwegian Governments, and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Arrondissementsrechtbank te Roermond by order of 28 April 1999, hereby rules:

Article 59 of the EC Treaty (now, after amendment, Article 49 EC) and Article 60 of the EC Treaty (now Article 50 EC) do not preclude legislation of a Member State, such as that at issue in the main proceedings, which makes the assumption of the costs of treatment provided in a hospital located in another Member State subject to prior authorisation from the insured person's sickness insurance fund and the grant of such authorisation subject to the condition that (i) the treatment must be regarded as 'normal in the professional circles concerned', a criterion also applied in determining whether hospital treatment provided on national territory is covered, and (ii) the insured person's medical treatment must require that treatment. However, that applies only in so far as

- the requirement that the treatment must be regarded as 'normal' is construed to the effect that authorisation cannot be refused on that ground where it appears that the treatment concerned is sufficiently tried and tested by international medical science, and

- authorisation can be refused on the ground of lack of medical necessity only if the same or equally effective treatment can be obtained without undue delay at an establishment having a contractual arrangement with the insured person's sickness insurance fund.

Rodríguez Iglesias Gulmann La Pergola

Wathelet Skouris Edward

Puissochet Jann Sevón

Schintgen Macken

Delivered in open court in Luxembourg on 12 July 2001.

R. Grass

G.C. Rodríguez Iglesias

Registrar

President

1: Language of the case: Dutch.