

Case C-372/04

The Queen, on the application of:

Yvonne Watts

v

Bedford Primary Care Trust and Secretary of State for Health

(Reference for a preliminary ruling from the

Court of Appeal (England and Wales) (Civil Division))

(Social security – National health system funded by the State – Medical expenses incurred in another Member State – Articles 48 EC to 50 EC and 152(5) EC – Article 22 of Regulation (EEC) No 1408/71)

Summary of the Judgment

1. *Social security for migrant workers – Health insurance – Services in kind supplied in another Member State – Second subparagraph of Article 22(2) of Regulation No 1408/71*

(Council Regulation No 1408/71, Art. 22(2) second subpara.)

2. *Freedom to provide services – Services – Meaning*

(Art. 49 EC)

3. *Freedom to provide services – Restrictions*

(Art. 49 EC)

4. *Freedom to provide services – Restrictions*

(Art. 49 EC)

5. *Social security for migrant workers – Health insurance – Services in kind supplied in another Member State – Article 22(1)(c)(i) of Regulation No 1408/71*

(Council Regulation No 1408/71, Art. 22(1)(c)(i))

6. *Freedom to provide services – Restrictions*

(Art. 49 EC)

7. *Freedom to provide services – Social security for migrant workers – Health insurance – Services in kind supplied in another Member State – Article 22 of Regulation No 1408/71*

(Arts 49 EC and 152(5) EC; Council Regulation No 1408/71, Art. 22)

1. The second subparagraph of Article 22(2) of Regulation No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Regulation No 118/97, must be interpreted as meaning that, in order to be entitled to refuse to grant the authorisation to go to the territory of another Member State to receive treatment referred to in Article 22(1)(c)(i) of that regulation on the ground that there is a waiting time for hospital treatment in the Member State of residence, the competent institution is required to establish that that time does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be.

(see paras 63, 79, operative part 1)

2. Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration, there being no need to determine whether the provision of hospital treatment within the national health service with which that person is registered is in itself a service within the meaning of the Treaty provisions on the freedom to provide services.

The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply. It has already been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service.

(see paras 89, 123, operative part 2)

3. Article 49 EC must be interpreted as meaning that it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the grant of prior authorisation by the competent institution.

A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

(see paras 113, 119-120, 123, operative part 2)

4. Article 49 EC must be interpreted as meaning that where the legislation of the competent Member State provides that hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question limited, if necessary, to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Regulation No 118/97, on behalf of the competent institution pursuant to the legislation of that Member State.

(see para. 143, operative part 3)

5. Article 22(1)(c)(i) of Regulation No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Regulation No 118/97, must be interpreted as meaning that the right which it confers on the patient authorised by the competent institution to go to another Member State and there receive treatment appropriate to his state of health relates exclusively to the expenditure connected with the healthcare received by that patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to his stay in the hospital.

The purpose of that provision is not to settle the question of ancillary costs, such as the cost of travel and any accommodation other than in the hospital itself.

(see paras 138, 143, operative part 3)

6. Article 49 EC must be interpreted as meaning that a patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled to seek from the competent institution reimbursement of the ancillary costs associated with that cross-border movement for medical purposes provided that the legislation of the competent Member State imposes a corresponding obligation on the national system to reimburse in respect of treatment provided in a local hospital covered by that system.

(see para. 143, operative part 3)

7. The obligation of the competent institution under both Article 22 of Regulation No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Regulation No 118/97, and Article 49 EC to authorise a patient registered with a national health service to obtain, at that institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period having regard to an

objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC, according to which Community action in the field of public health is to respect fully the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Article 152(5) EC does not exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their national systems of social security. It does not follow that this undermines their sovereign powers in the field.

Furthermore, the requirements arising from Article 49 EC and Article 22 of Regulation No 1408/71 are not to be interpreted as imposing on the Member States an obligation to reimburse the cost of hospital treatment in other Member States without reference to any budgetary consideration but, on the contrary, are based on the need to balance the objective of the free movement of patients against overriding national objectives relating to management of the available hospital capacity, control of health expenditure and financial balance of social security systems.

(see paras 145-148, operative part 4)

JUDGMENT OF THE COURT (Grand Chamber)

16 May 2006 (*)

(Social security – National health system funded by the State – Medical expenses incurred in another Member State – Articles 48 EC to 50 EC and 152(5) EC – Article 22 of Regulation (EEC) No 1408/71)

In Case C-372/04,

REFERENCE for a preliminary ruling under Article 234 EC from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by order of 12 July 2004, received at the Court on 27 August 2004, in the proceedings

The Queen, on the application of:

Yvonne Watts

v

Bedford Primary Care Trust,

Secretary of State for Health,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmermans and A. Rosas, Presidents of Chambers, R. Schintgen, N. Colneric, K. Lenaerts (Rapporteur), J. Klučka, U. Lõhmus, E. Levits and A. Ó Caoimh, Judges,

Advocate General: L.A. Geelhoed,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 4 October 2005,

after considering the observations submitted on behalf of:

- Mrs Watts, by R. Gordon QC and J. Hyam, Barrister,
- the United Kingdom Government, by E. O'Neill and S. Nwaokolo, acting as Agents, D. Lloyd-Jones QC, D. Wyatt QC and S. Lee, Barrister,
- the Belgian Government, by M. Wimmer, acting as Agent,
- the Spanish Government, by E. Braquehais Conesa and J.M. Rodríguez Cárcamo, acting as Agents,
- the French Government, by G. de Bergues and C. Bergeot-Nunes, acting as Agents,

- Ireland, by D. O’Hagan, acting as Agent, and N. Travers BL,
- the Maltese Government, by S. Camilleri, acting as Agent, and S. Mifsud, avukat,
- the Polish Government, by P. Sadowy, acting as Agent,
- the Finnish Government, by T. Pynnä, acting as Agent,
- the Swedish Government, by K. Norman and A. Kruse, acting as Agents,
- the Commission of the European Communities, by D. Martin and N. Yerrell, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 15 December 2005,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 48 EC to 50 EC and Article 152(5) EC, as well as Article 22 of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1; ‘Regulation No 1408/71’).

2 The reference was made in the course of proceedings arising from the refusal of Bedford Primary Care Trust (‘Bedford PCT’) to reimburse the cost of hospital treatment received in France by Mrs Watts, who resides in the United Kingdom.

Legal context

Community law

3 Article 22 of Regulation No 1408/71, entitled ‘Stay outside the competent State – Return to or transfer of residence to another Member State during sickness or maternity – Need to go to another Member State in order to receive appropriate treatment’, states:

‘1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:

...

(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition,

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay ... in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

...

2. ...

The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of his disease.

...'

4 As is apparent from Decision No 153 (94/604/EC) of the Administrative Commission of the European Communities on Social Security for Migrant Workers of 7 October 1993 on the model forms necessary for the application of Council Regulations (EEC) No 1408/71 and (EEC) No 574/72 (E 001, E 103 to E 127) (OJ 1994 L 244, p. 22), Form E 112 is the certificate necessary for the application of Article 22(1)(c)(i) of Regulation No 1408/71.

National law

5 The National Health Service Act 1977 ('the NHS Act') states that the Secretary of State for Health is required to provide a National Health Service in England and Wales.

6 That duty is laid down in sections 1 and 3 of the NHS Act, which are worded as follows:

'Section 1

1. (1) It is the Secretary of State's duty to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement

(a) in the physical and mental health of the people of those countries, and

(b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with this Act.

(2) The services so provided shall be free of charge except in so far as the making and recovery of charges is expressly provided for under any enactment, whenever passed.

...

Section 3

3. (1) It is the Secretary of State's duty to provide throughout England and Wales, to such extent as he considers necessary to meet all reasonable requirements,

- (a) hospital accommodation;
- (b) other accommodation for the purpose of any service provided under this Act;
- (c) medical, dental, nursing and ambulance services;
- (d) such other facilities for the care of expectant and nursing mothers and young children as he considers are appropriate as part of the health service;
- (e) such facilities for the prevention of illness, the care of persons suffering from illness and the aftercare of persons who have suffered from illness as he considers are appropriate as part of the health service;
- (f) such other services as are required for the diagnosis and treatment of illness.'

7 According to the information provided by the order for reference, the National Health Service ('NHS') has the following principal characteristics.

8 Hospital care is provided free of charge by the relevant NHS bodies to all persons ordinarily resident in the United Kingdom, on a non-profit-making basis.

9 Treatment is funded directly by the State, essentially from general taxation revenue which is apportioned by central government between the various Primary Care Trusts ('PCTs') according to the relative needs of the populations of the geographical area covered by them.

10 No employee or employer contributions are payable. No patient co-payments are charged.

11 There are no national lists of medical benefits to be provided.

12 Access to hospital treatment is generally dependent on referral by a general practitioner.

13 As the budget allocated by the government to the NHS is not sufficient to allow for the swift provision of treatment to all patients, regardless of urgency, the NHS makes use of the available resources by setting priorities, which results in some quite lengthy waiting lists for less urgent treatment. NHS bodies determine, within the limits of the budgetary provision made available to them, the weighting of clinical priorities within national guidelines.

14 The waiting lists are intended to ensure the provision of hospital care in accordance with priorities and decisions made by the NHS bodies as to the use of available resources and to maintain fairness between patients who require hospital treatment for differing conditions and with different degrees of urgency.

15 NHS patients are not entitled to receive a specific treatment at a specific time. The type, location and timing of hospital treatment are determined on the basis of clinical priority and the resources of the relevant NHS body, and not the choice of the patient. Decisions of the NHS bodies can be challenged by judicial review, but such challenges usually fail.

16 Given that NHS treatment is provided free of charge, the question of its reimbursement does not arise and is not regulated. Therefore there is no set tariff for reimbursement in United Kingdom legislation.

17 NHS patients are not entitled to obtain hospital treatment in the private sector in England and Wales at the expense of the NHS.

18 PCTs are statutory bodies established under section 16A of the NHS Act, as inserted by section 2 of the Health Act 1999 and amended by the National Health Service Reform and Health Care Professions Act 2002. Their membership is determined in accordance with regulations. Some of their members are appointed by the Secretary of State for Health. The role of PCTs is to manage and deliver healthcare locally, including general medical services. All areas of England are covered by a PCT. In each financial year, the Secretary of State pays the different PCTs an amount, which is subject to a cash limit, designed to cover expenditure on hospital treatment and administration costs.

19 'NHS trusts' are separate legal bodies, which were set up under the National Health Service and Community Care Act 1990. Section 5(1) of that Act, as amended by section 13 of the Health Act 1999, provides that the purpose of the NHS trusts is to provide goods and services within the framework of the NHS. The functions of the trusts are conferred by ministerial order. Nearly all UK hospitals are run by an NHS trust. NHS trusts receive their funding through payments made by PCTs in respect of the treatments and medical services commissioned by them.

20 The relationship between PCTs and NHS trusts is based, by virtue of section 4 of the 1990 Act, on a system of 'NHS contracts', which are not contracts enforceable at law, but which have attached to them a special form of internal arbitration by the Secretary of State. NHS contracts generally record agreement as to the amount of services anticipated and their relative funding.

21 PCTs and NHS trusts are not profit-making bodies. Any budget which is allocated, but not spent, can in some circumstances be carried forward. Otherwise, it must be returned to central government.

22 Patients not ordinarily resident in the United Kingdom may receive medical treatment under the NHS, though in principle not free of charge. The NHS (Charges to Overseas Visitors) Regulations 1989 provide for the making and recovery of charges for NHS treatment provided to overseas visitors. The PCTs are required to provide such treatment unless the patient satisfies any of the exemption criteria in those regulations. Those regulations provide exceptions inter alia for treatment within hospital accident and emergency departments, and to reflect the rights of persons insured in other Member States.

23 The order for reference states that since Regulation No 1408/71 is directly applicable in all Member States there is no legislation implementing it in the United Kingdom. An NHS patient ordinarily resident in the United Kingdom may receive hospital treatment in another Member State pursuant to Article 22(1)(c) of that regulation, in which case reimbursement of the costs associated with that treatment is made in accordance with that regulation directly to the competent institution in the Member State in which the treatment was obtained at the rate of reimbursement applicable in that Member State.

The main proceedings

24 Suffering from arthritis of the hips, Mrs Watts made enquiries of Bedford PCT as to the possibility of her undergoing surgery abroad under the E 112 scheme.

25 On 1 October 2002, she was seen by a UK consultant who informed Bedford PCT by letter of 28 October 2002 that Mrs Watts was as deserving as any of his other patients with severe arthritis, that her mobility was severely hampered and that she was in constant pain. He classified her case as 'routine', which meant a wait of approximately one year for surgery in a local hospital.

26 On 21 November 2002, Bedford PCT informed Mrs Watts of its refusal to issue her with an E 112 form on the ground that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 was not satisfied. It considered that she could receive treatment in a local hospital 'within the government's NHS Plan targets' and therefore 'without undue delay'.

27 On 12 December 2002, Mrs Watts issued proceedings seeking permission to apply for judicial review of that refusal decision.

28 On 22 January 2003, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), heard the application for permission. The court heard that, at the beginning of January 2003, Mrs Watts went to see a consultant in France who told her that her need for surgery was becoming more urgent because of a deterioration in her state of health. The Secretary of State for Health and Bedford PCT therefore suggested that Mrs Watts should be re-examined so that the decision of 21 November 2002 could be reconsidered.

29 On 31 January 2003, Mrs Watts was re-examined by the UK consultant who had examined her in October 2002. He wrote to Bedford PCT on the same day stating that Mrs Watts should now be categorised as a patient requiring surgery 'soon', in an intermediate category between the most urgent cases and the routine cases. That meant that she would be operated on within three or four months, in April or May 2003.

30 On 4 February 2003, Bedford PCT repeated its refusal to issue an E 112 form on the ground that the waiting period for treatment locally had been reduced to three or four months. It repeated its reliance on the NHS Plan targets in concluding that there was no undue delay in Mrs Watts's case.

31 On 7 March 2003, Mrs Watts underwent a hip replacement operation in Abbeville (France). She paid the fees for that surgery, equivalent to GBP 3 900.

32 She continued with her application for permission to apply for judicial review of Bedford PCT's refusal decision, claiming in addition reimbursement of the medical fees incurred in France.

33 On 1 October 2003, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), which had reserved judgment until the delivery of the judgment of the Court of Justice of 13 May 2003 in Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, held that the medical services which Mrs Watts received in France fall within the scope of Article 49 EC notwithstanding the fact that the reimbursement of the costs of the treatment received is applied for under the NHS.

34 It nevertheless dismissed Mrs Watts's application. Although it found that 'any national authority properly directing itself in accordance with the principles laid down by the [Court], in particular [in Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473] and *Müller-Fauré and van Riet*, would have been bound to conclude in October-November 2002 that the anticipated delay of approximately one year was, on any view, "undue", and thus such as to trigger the claimant's right under Article 49 [EC] to reimbursement of the costs of obtaining more timely treatment in another Member State', it nevertheless held that Mrs Watts had not had to face undue delay after her case was reassessed at the end of January 2003. The court held that a waiting time of between three and four months did not entitle Mrs Watts to have treatment abroad and claim reimbursement of the cost of that treatment from the NHS.

35 Mrs Watts and the Secretary of State for Health appealed against that judgment to the Court of Appeal (England and Wales) (Civil Division). Mrs Watts's appeal was based primarily on the dismissal of her application for reimbursement and on the considerations set out in the judgment at first instance that the waiting time applicable in national law is a relevant factor in applying Article 49 EC and a factor of fundamental importance in the context of Article 22 of Regulation No 1408/71. The Secretary of State for Health's appeal was based essentially on the argument that NHS patients are not entitled to rely on Article 49 EC, so that Mrs Watts's case should be governed exclusively by Article 22 of Regulation No 1408/71.

36 In a decision of 20 February 2004, the referring court states that, given the judgments in *Smits and Peerbooms* and *Müller-Fauré and van Riet*, national health services financed by the State, such as the NHS, fall within the scope of Article 49 EC. It adds, however, that it appears from paragraph 98 of the judgment in *Müller-Fauré and van Riet* that the right, based on that article, to receive treatment abroad is subject to there being a right to obtain treatment in the relevant Member State, which UK patients do not have under the NHS.

37 It is of the view that, since medical treatment is a supply of services within the meaning of Article 49 EC, the national authorities responsible for financing health services may not, in principle, prevent residents from receiving treatment in another Member State unless such a restriction is justified by the need to maintain a balanced medical and hospital service which is available to everyone; such a justification may not, however, be invoked where it would result in undue delay in the provision of treatment to the patient in his Member State of residence.

38 It states that, by virtue of the judgment in Case C-56/01 *Inizan* [2003] ECR I-12403, the concept of undue delay must be interpreted, in line with the second condition in the second subparagraph of Article 22(2) of Regulation No 1408/71, on the basis of clinical

considerations arising in each individual case and not by having regard to normal waiting times and lists based on economic considerations. It asserts, however, that the Court has not yet given a clear answer as to how that concept should be interpreted.

39 It also raises the question, in the light of the *Inizan* judgment, of the relevance of budgetary considerations in the context of a case such as the present dispute in the main proceedings. It asks whether it must be found that a Member State is under an obligation to set aside resources to enable its nationals to receive treatment abroad within a shorter period, at the risk, first, of extending the waiting times for treatment in that Member State of more urgent cases and, second, of affecting the management of resources and the planning of the healthcare system in question.

40 Assuming such an obligation exists, the referring court asks whether the Member State concerned is required to reimburse the cost of treatment received abroad according to the legislation of the host Member State, pursuant to Article 22 of Regulation No 1408/71, or according to its own legislation, pursuant to Article 49 EC. It also asks whether travel and accommodation expenses must be taken into account in such a case.

41 The referring court stresses that a duty to reimburse according to the legislation of the competent Member State would mean, for a system such as the NHS in which healthcare is provided free of charge, a duty to reimburse in full. It considers therefore that if the concept of undue delay is to be assessed without regard to budgetary considerations, the application of Article 49 EC would involve the interference of Community law in the budgetary policy of the Member States in relation to public health, such as to raise questions with regard to Article 152(5) EC.

The questions referred for a preliminary ruling

42 In those circumstances the Court of Appeal (England and Wales) (Civil Division) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(1) Having regard to the nature of the NHS and its position under national law, is Article 49 EC, read in the light of *Geraets-Smits [and Peerbooms]*, *Muller-Fauré [and van Riet]* and *Inizan*, to be interpreted as meaning that in principle persons ordinarily resident in the United Kingdom enjoy an entitlement in EU law to receive hospital treatment in other Member States at the expense of the United Kingdom National Health Service (“the NHS”)?

In particular, on the true interpretation of Article 49 EC:

(a) Is there any distinction between a State-funded national health service such as the NHS and insurance funds such as the Netherlands ZFW scheme, in particular having regard to the fact that the NHS has no fund out of which payment must be made?

(b) Is the NHS obliged to authorise and pay for such treatment in another Member State, notwithstanding that it is not obliged to authorise and pay for such treatment to be carried out privately by a United Kingdom service provider?

(c) Is it relevant if the patient secures the treatment independently of the relevant NHS body, and without prior authorisation or notification?

(2) In answering Question 1, is it material whether hospital treatment provided by the NHS is itself the provision of services within Article 49 EC?

If so, and in the circumstances set out in the statement of facts above, are Articles 48 EC, 49 EC and 50 EC to be interpreted as meaning that in principle:

(a) the provision of hospital treatment by NHS bodies constitutes the provision of services within Article 49 EC;

(b) a patient receiving hospital treatment under the NHS as such exercises a freedom to receive services within Article 49 EC; and

(c) NHS bodies providing hospital treatment are services providers within Articles 48 EC and 50 EC?

(3) If Article 49 EC applies to the NHS, may it or the Secretary of State rely as objective justification for refusing prior authorisation for hospital treatment in another Member State on:

(a) the fact that authorisation would seriously undermine the NHS system of administering medical priorities through waiting lists;

(b) the fact that authorisation would permit patients with less urgent medical needs to gain priority over patients with more urgent medical needs;

(c) the fact that authorisation would have the effect of diverting resources to pay for less urgent treatment for those who are willing to travel abroad, thus adversely affecting others who do not wish or are not able to travel abroad or increasing costs of NHS bodies;

(d) the fact that authorisation may require the United Kingdom to provide additional funding for the NHS budget or to restrict the range of treatments available under the NHS;

(e) the comparative costs of the treatment and the incidental costs thereof in the other Member State?

(4) In determining whether treatment is available “without undue delay” for the purposes of Article 49 EC, to what extent is it necessary or permissible to have regard in particular to the following:

(a) waiting times;

(b) the clinical priority accorded to the treatment by the relevant NHS body;

(c) the management of the provision of hospital care in accordance with priorities aimed at giving best effect to finite resources;

(d) the fact that treatment under the NHS is provided free at the point of delivery;

(e) the individual medical condition of the patient, and the history and probable course of the disease in respect of which that patient seeks treatment?

(5) On the proper interpretation of Article 22(1)(c) of Regulation No 1408/71 and in particular the words “within the time normally necessary for obtaining the treatment in question”:

(a) Are the applicable criteria identical with those applicable in determining questions of “undue delay” for the purposes of Article 49 EC?

(b) If not, to what extent is it necessary or permissible to have regard to the matters set out in Question 4?

(6) In circumstances where a Member State is obliged in EU law to fund the hospital treatment in other Member States of persons ordinarily resident in the first Member State, is the cost of such treatment to be calculated under Article 22 of Regulation No 1408/71 by reference to the legislation of the Member State where the treatment is provided or under Article 49 EC by reference to the legislation of the Member State of residence?

In each case:

(a) What is the precise extent of the obligation to pay or reimburse the cost, in particular where, as in the case of the United Kingdom, hospital treatment is provided to patients free at the point of delivery and there is no nationally set tariff for reimbursement of patients for the cost of treatment?

(b) Is the obligation limited to the actual cost of providing the same or equivalent treatment in the first Member State?

(c) Does it include an obligation to meet travel and accommodation costs?

(7) Are Article 49 EC and Article 22 of Regulation No 1408/71 to be interpreted as imposing an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, are these requirements compatible with the Member States’ responsibility for the organisation and delivery of health services and medical care, as recognised under Article 152(5) EC?’

The questions

Preliminary considerations

43 By its questions, the referring court seeks clarification of the scope both of the EC Treaty provisions on the freedom to provide services and of Article 22 of Regulation No 1408/71.

44 As the Commission of the European Communities suggested in its written observations, it is necessary to rule first on the request for interpretation of Article 22 of Regulation No 1408/71.

45 It is not in dispute, according to the order for reference, that Mrs Watts sought authorisation under an E 112 form to go to another Member State to receive treatment there appropriate to her condition at the expense of the NHS, pursuant to Article 22(1)(c)(i) of Regulation No 1408/71. It is also clear from that order that Bedford PCT, with which Mrs

Watts was registered, refused her that authorisation on the ground that she did not satisfy the conditions laid down by Article 22(2) of that regulation.

46 The applicability of Article 22 to the present case does not, however, preclude it from also falling within the scope of Article 49 EC.

47 The fact that a national measure may be consistent with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty (Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 25).

48 It should further be noted that the purpose of Article 22(1)(c)(i) of Regulation No 1408/71 is to confer a right to the services in kind provided, on behalf of the competent institution, by the institution of the place where the treatment is provided, in accordance with the provisions of the legislation of the Member State in which the services are provided as if the person concerned were registered with that institution (see *Inizan*, paragraph 20). The applicability of Article 22 of Regulation No 1408/71 to the situation in question does not mean that the person concerned may not simultaneously have the right under Article 49 EC to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22 (see to that effect Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraphs 37 to 53).

49 In the light of the foregoing, an answer should be given first of all to the request for interpretation of Article 22 of Regulation No 1408/71, which is the subject of the fifth question, then to the requests for interpretation of the provisions on the freedom to supply services set out in the first four questions, and lastly to the sixth and seventh questions, which jointly relate to Article 49 EC and Article 22 of Regulation No 1408/71.

50 It should be noted, as the Commission points out, that the present case exclusively concerns medical services supplied by hospitals and requiring the admission of the person concerned as an inpatient to the hospital in which those services are supplied.

The fifth question

51 By this question, the referring court asks essentially whether the criteria for the interpretation of the phrase 'within the time normally necessary for obtaining the treatment in question' in the second subparagraph of Article 22(2) of Regulation No 1408/71 are the same as those used to define the term 'without undue delay' in the context of Article 49 EC.

52 Referring at this stage to the fourth question, the referring court also asks whether, in interpreting the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, it is necessary or permissible to take account of the factors set out in the fourth question, namely the existence of waiting times, the clinical priorities defined by the competent NHS body, the management of the supply of hospital care in accordance with priorities intended to give best effect to finite resources, the fact that treatment under the NHS is provided free of charge and the individual medical condition of the patient and the history and probable course of his illness.

53 It should be noted as a preliminary point that, in the context of the general objectives of the Treaty, Article 22 of Regulation No 1408/71 is one of a number of measures designed to allow a patient covered by the legislation of one Member State to enjoy, under the conditions which it specifies, benefits in kind in the other Member States, whatever the national institution with which he is registered and whatever the place of his residence (see to that effect Case C-156/01 *Van der Duin and ANOZ Zorgverzekeringen* [2003] ECR I-7045, paragraph 50, and Case C-145/03 *Keller* [2005] ECR I-2529, paragraph 45).

54 By guaranteeing in paragraph (1)(c)(i) that a patient covered by the legislation of one Member State who has been authorised may have access to treatment in the other Member States on reimbursement conditions as favourable as those enjoyed by persons covered by the legislation of those States, and by stating in the second subparagraph of paragraph (2) that the competent national institution may not refuse such authorisation where the two conditions referred to in that provision are satisfied, Article 22 of Regulation No 1408/71 helps to facilitate the free movement of patients and, to the same extent, the provision of cross-border medical services between Member States (see to that effect *Vanbraekel*, paragraph 32; *Inizan*, paragraph 21; and *Keller*, paragraph 46).

55 The second subparagraph of Article 22(2) of Regulation No 1408/71 lays down two conditions which, if both satisfied, render mandatory grant by the competent institution, regardless of the Member State to which it belongs, of the prior authorisation to which that provision refers (see *Inizan*, paragraph 37).

56 To satisfy the first condition the treatment in question must be among the benefits provided for by the legislation of the Member State on whose territory the person resides. It does not appear that in the main proceedings the refusal to assume the costs of the treatment was based on the failure to comply with that first condition.

57 The second condition is satisfied only where the treatment which the patient plans to undergo in a Member State other than that in the territory of which he resides cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of his disease.

58 That second condition is clearly in issue in the dispute in the main proceedings, as is shown by both the wording of the fifth question and the terms in which the competent body informed Mrs Watts of its refusal to issue an E 112 form (see paragraphs 26 and 30 of the present judgment).

59 As Mrs Watts, the French and Belgian Governments and the Commission pointed out in their written observations, the Court gave an interpretation in paragraphs 45 and 46 of the judgment in *Inizan* of the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, adopting the interpretation it had given for the term 'undue delay' in *Smits and Peerbooms* (paragraphs 103 and 104) and *Müller-Fauré and van Riet* (paragraphs 89 and 90) concerning the assessment of the compatibility with Article 49 EC of a national provision making the assumption of the cost of hospital treatment planned in another Member State subject to a requirement that that treatment be necessary.

60 Indeed, as Advocate General Geelhoed observed in point 101 of his Opinion, there is no reason which seriously justifies different interpretations depending on whether the context

is Article 22 of Regulation No 1408/71 or Article 49 EC, since in both cases the question is, as the Belgian Government pointed out in its written observations, whether the hospital treatment required by the patient's medical condition can be provided on the territory of his Member State of residence within an acceptable time which ensures its usefulness and efficacy.

61 In paragraph 45 of *Inizan* the Court thus held, referring by analogy to paragraph 103 of *Smits and Peerbooms* and paragraph 89 of *Müller-Fauré and van Riet*, that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is not satisfied whenever it is apparent that treatment which is the same or equally effective for the patient can be obtained without undue delay in his Member State of residence.

62 Basing its decision on paragraph 104 of *Smits and Peerbooms* and paragraph 90 of *Müller-Fauré and van Riet*, the Court held that, in order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case, taking due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (*Inizan*, paragraph 46).

63 In paragraph 92 of *Müller-Fauré and van Riet* the Court also pointed out that, in determining whether a treatment which is the same or equally effective for the patient is available without undue delay from an establishment on the territory of the Member State of residence, the competent institution cannot base its decision exclusively on the existence of waiting lists on that territory without taking account of the specific circumstances of the patient's medical condition.

64 That point made in relation to Article 49 EC may be extended to Article 22 of Regulation No 1408/71, given the matters set out in paragraphs 59 and 60 of the present judgment.

65 It should be noted in this connection that Article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ 2004 L 166, p. 1), which is intended to replace Article 22 of Regulation No 1408/71, lays down a duty to grant the authorisation in question in particular where the treatment cannot be given in the Member State of residence 'within a time-limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness'.

66 It is in the light of those points that the factors should be set out to which the referring court should have regard amongst those identified in the fourth question in order to determine whether the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is satisfied or not.

67 Where the demand for hospital treatment is constantly rising, primarily as a consequence of medical progress and increased life expectancy, and the supply is necessarily limited by budgetary constraints, it cannot be denied that the national authorities responsible for managing the supply of such treatment are entitled, if they consider it necessary, to

institute a system of waiting lists in order to manage the supply of that treatment and to set priorities on the basis of the available resources and capacities.

68 As is clear from the wording of the second subparagraph of Article 22(2) of Regulation No 1408/71, and pursuant to the case-law set out in paragraphs 62 and 63 of the present judgment, in order to be entitled to refuse the authorisation referred to in Article 22(1)(c) of that regulation on the ground of waiting time, the competent institution must however establish that the waiting time, arising from objectives relating to the planning and management of the supply of hospital care pursued by the national authorities on the basis of generally predetermined clinical priorities, within which the hospital treatment required by the patient's state of health may be obtained in an establishment forming part of the national system in question, does not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the authorisation is sought.

69 Furthermore, as the Commission points out and as Advocate General Geelhoed observed in point 86 of his Opinion, the setting of waiting times should be done flexibly and dynamically, so that the period initially notified to the person concerned may be reconsidered in the light of any deterioration in his state of health occurring after the first request for authorisation.

70 If the waiting time arising from the general planning objectives does not exceed a medically acceptable waiting time within the meaning of paragraph 68 of the present judgment, the competent institution is entitled to find that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is not satisfied and to refuse to grant the authorisation sought by the person concerned under Article 22(1)(c)(i) of that regulation.

71 That is because if patients covered by a national health service such as that in issue in the main proceedings had to be authorised to go to another Member State to receive there, at the expense of the competent institution, hospital treatment which the hospitals covered by that service are able to supply within a medically acceptable period within the meaning of paragraph 68 of the present judgment merely because treatment which is the same or equally effective is available more quickly in that other Member State, the resulting patient migration would be liable to put at risk the competent Member State's planning and rationalisation efforts in the vital healthcare sector so as to avoid the problems of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage (see to that effect *Smits and Peerbooms*, paragraph 106, and *Müller-Fauré and van Riet*, paragraph 91).

72 In the situation opposite to that referred to in paragraph 70 of the present judgment, however, the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 must be regarded as satisfied.

73 The fact that the cost of the hospital treatment envisaged in another Member State may be higher than it would have been had it been provided in a hospital covered by the national system in question cannot in such a case be a legitimate ground for refusing authorisation.

74 In such a situation, the fact that the grant of the authorisation sought would oblige a national health service such as that in issue in the main proceedings, which is characterised by free hospital treatment provided within its own establishments, to establish a financial mechanism so as to enable that service to satisfy the request for reimbursement from the institution of the host Member State and relating to the benefits in kind provided by that institution to the patient in question is also not a legitimate ground for refusing authorisation (see to that effect *Müller-Fauré and van Riet*, paragraph 105).

75 Contrary to the fears expressed by the United Kingdom Government in its written observations, the interpretation of the time referred to in the second subparagraph of Article 22(2) of Regulation No 1408/71, set out in paragraphs 59 to 72 of the present judgment, is not liable to undermine the national competent authorities' power to manage the available hospital capacity in their territory by the use of waiting lists, provided that the existence of such lists does not prevent the taking account in each individual case of the medical circumstances and the clinical needs of the person concerned when he requests authorisation to receive hospital treatment in another Member State at the expense of the system with which he is registered.

76 Furthermore, the effect of such an interpretation is to preclude the national competent authorities from refusing to grant the authorisation sought by a patient whose case, in the light of an objective medical assessment, was sufficiently urgent to justify obtaining treatment in another Member State within a shorter period than that which would result from waiting lists reflecting general planning and management objectives, and within which the person concerned may hope to obtain the treatment in question in a local hospital covered by the national health service. It does not undermine, by contrast, the right of those authorities to withhold authorisation where there is no urgency arising from the clinical condition of the patient in question such as to make the waiting time arising from such objectives appear unreasonable in the light of that condition.

77 That interpretation is also not liable to lead to an exodus of patients who, having sufficient resources for that purpose, might seek to go to another Member State to obtain the hospital treatment at the subsequent expense of the national health service with which they are registered, regardless of medical need, within a shorter time than that within which that treatment can be provided to them in a national establishment covered by that service. It preserves the right of the competent institution to refuse the authorisation necessary for the assumption of the cost of the hospital treatment to be obtained in another Member State in the absence of particular circumstances justifying the view that the waiting time imposed on the person concerned exceeds the medically acceptable period in his particular case.

78 In the main proceedings, it is for the referring court to determine whether the waiting time invoked by the competent body of the NHS, and based on the planning objectives pursued by the United Kingdom authorities, in order to refuse the initial application for authorisation and the renewed request exceeded a medically acceptable period in the light of the patient's particular condition and clinical needs at those respective times.

79 In the light of the foregoing, the answer to the fifth question must be that the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that, in order to be entitled to refuse to grant the authorisation referred to in Article 22(1)(c)(i) of that regulation on the ground that there is a waiting time for hospital treatment, the competent institution is required to establish that that time does not exceed the period which is

acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be.

The first four questions

80 By the first four questions, which it is convenient to consider together, the referring court asks essentially whether and in what circumstances an NHS patient is entitled under Article 49 EC to receive hospital treatment in another Member State at the expense of that national service.

81 The first question asks whether, given the particular characteristics of the NHS, a person residing in the United Kingdom is entitled under that article to receive hospital treatment in a Member State other than the United Kingdom at the expense of the NHS. As part of that question, the referring court asks in particular whether, in interpreting Article 49 EC in such a context, account should be taken, first, of the fact that there is no fund available to NHS bodies out of which such treatment may be paid for, and, second, of the fact that there is no duty on the NHS to pay for hospital treatment received by an NHS patient in a private hospital in England or Wales. It also asks whether the failure to request authorisation or notify the competent NHS body in advance has a bearing on the interpretation of Article 49 EC.

82 By the second question, the referring court asks whether, in order to answer the first question, it is necessary to determine whether hospital treatment provided by the NHS constitutes services within the meaning of Article 49 EC.

83 By the third question, it asks, on the assumption that that provision is applicable, whether a series of factors which it lists may validly be relied upon by the national competent authorities in refusing to grant the prior authorisation necessary in order for the NHS to assume the costs of hospital treatment to be obtained in another Member State.

84 The fourth question, which coincides with the third, asks which factors may or must be taken into account in determining whether the hospital treatment required by the patient's state of health may be provided without undue delay in an NHS establishment and whether, consequently, the authorisation sought by that patient for reimbursement of the cost of treatment to be obtained in another Member State may be refused by the competent institution.

85 In order to answer those questions, it is first necessary to determine whether Article 49 EC applies to facts such as those in issue in the main proceedings.

86 It should be noted in that regard that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services (see, inter alia, Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685, paragraph 18, and *Kohll*, paragraph 29), there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment (*Vanbraekel*, paragraph 41; *Smits and Peerbooms*, paragraph 53; *Müller-Fauré and van Riet*, paragraph 38; and *Inizan*, paragraph 16).

87 It has also been held that the freedom to provide services includes the freedom for the recipients of services, including persons in need of medical treatment, to go to another Member State in order to receive those services there (see Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16).

88 It should be noted as regards the main proceedings that the establishment in another Member State in which Mrs Watts received treatment was paid by her directly.

89 The fact that reimbursement of the hospital treatment in question is subsequently sought from a national health service such as that in question in the main proceedings does not mean that the rules on the freedom to provide services guaranteed by the Treaty do not apply (see to that effect *Smits and Peerbooms*, paragraph 55, and *Müller-Fauré and van Riet*, paragraph 39). It has already been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service (see *Müller-Fauré and van Riet*, paragraph 103).

90 It must therefore be found that Article 49 EC applies where a patient such as Mrs Watts receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates.

91 It must therefore be found that a situation such as that which gave rise to the dispute in the main proceedings, in which a person whose state of health necessitates hospital treatment goes to another Member State and there receives the treatment in question for consideration, falls within the scope of the Treaty provisions on the freedom to provide services, there being no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is in itself a service within the meaning of those provisions.

92 Whilst it is not in dispute that Community law does not detract from the power of the Member States to organise their social security systems, and that, in the absence of harmonisation at Community level, it is for the legislation of each Member State to determine the conditions in which social security benefits are granted, when exercising that power Member States must comply with Community law, in particular the provisions on the freedom to provide services (see, inter alia, *Smits and Peerbooms*, paragraphs 44 to 46; *Müller-Fauré and van Riet*, paragraph 100; and *Inizan*, paragraph 17). Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.

93 It is therefore necessary to ascertain whether there is any such restriction in a case such as that in issue in the main proceedings.

94 It should be noted in this connection that according to well-established case-law, Article 49 EC 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 a Member State (Case C-381/93 *Commission v France* [1994] ECR I-5145, paragraph 17; *Kohll*, paragraph 33; and *Smits and Peerbooms*, paragraph 61).

95 In the present case it is clear from the decision of 20 February 2004 of the referring court and from the order for reference, in particular the third question, that, whilst NHS patients are free to go to a hospital in another Member State, they cannot have treatment in such an establishment at the NHS's expense without prior authorisation.

96 It is true, as the United Kingdom, Spanish, Maltese and Finnish Governments and Ireland submit, that an NHS patient cannot choose when and where the hospital treatment required by his state of health will be provided under the NHS. However, it is not in dispute that the corollary of the Secretary of State's duty under sections 1 and 3 of the NHS Act (see paragraph 6 of the present judgment) is the right to obtain treatment available under the NHS free of charge in NHS hospitals without having to seek prior authorisation.

97 Thus whereas according to the decision of 20 February 2004 and the order for reference prior authorisation is a prerequisite for the NHS to assume the costs of hospital treatment available in another Member State, the receipt of free NHS treatment does not depend on such authorisation, only the means of receiving that treatment being subject to a prior decision by the national competent authorities.

98 It must therefore be found that the system of prior authorisation referred to in paragraph 95 of the present judgment deters, or even prevents, the patients concerned from applying to providers of hospital services established in another Member State and constitutes, both for those patients and for service providers, an obstacle to the freedom to provide services (see to that effect *Smits and Peerbooms*, paragraph 69, and *Müller-Fauré and van Riet*, paragraph 44).

99 That conclusion is not undermined by the fact, referred to in Question 1(b), that the NHS is not obliged to authorise and assume the cost of hospital treatment provided to patients in private non-NHS hospitals in England and Wales.

100 In applying the case-law set out in paragraph 94 of the present judgment, the conditions for the NHS's assuming the cost of hospital treatment to be obtained in another Member State should not be compared to the situation in national law of hospital treatment received by patients in private local hospitals. On the contrary, the comparison should be made with the conditions in which the NHS provides such services in its hospitals.

101 Since the existence of a restriction on the freedom to provide services has been established, and before ruling on whether an NHS patient is entitled under Article 49 EC to receive hospital medical treatment in another Member State at the expense of the national service concerned without such a restriction, it is necessary to examine whether that restriction can be objectively justified.

102 As was done in a large number of the observations submitted to the Court, it is necessary to recall in this regard the overriding considerations capable of justifying obstacles to the freedom to provide hospital medical services.

103 The Court has already held that it is possible for the risk of seriously undermining the financial balance of a social security system to constitute an overriding reason in the general interest capable of justifying an obstacle to the freedom to provide services (*Kohll*, paragraph 41; *Smits and Peerbooms*, paragraph 72; and *Müller-Fauré and van Riet*, paragraph 73).

104 The Court has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within the derogations on grounds of public health under Article 46 EC in so far as it contributes to the attainment of a high level of health protection (*Kohll*, paragraph 50; *Smits and Peerbooms*, paragraph 73; and *Müller-Fauré and van Riet*, paragraph 67).

105 The Court has also held that Article 46 EC 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; *Smits and Peerbooms*, paragraph 74; and *Müller-Fauré and van Riet*, paragraph 67).

106 It is therefore necessary to determine whether the restriction at issue can in fact be justified in the light of such overriding reasons, and if such is the case to make sure, in accordance with settled case-law, that it does not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules (see *Smits and Peerbooms*, paragraph 75, and the case-law cited).

107 As regards hospital medical services, the Court has already made the following observations in paragraphs 76 to 80 of *Smits and Peerbooms*.

108 It is well known that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities 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, generally designed to satisfy various needs, must be possible.

109 For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. 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 would be 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 healthcare are not unlimited, whatever the mode of funding applied.

110 From those two points of view, the requirement that the assumption of costs by the national system of hospital treatment provided in another Member State be subject to prior authorisation appears to be a measure which is both necessary and reasonable.

111 As regards specifically the Netherlands system of health insurance, in issue in the cases giving rise to the *Smits and Peerbooms* judgment, the Court acknowledged in paragraph 81 thereof that, if patients were at liberty, regardless of the circumstances, to use the services of hospitals with which their health insurance fund had no agreement, whether those hospitals were situated in the Netherlands or in another Member State, all the planning which goes into the system of agreements in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke.

112 Those observations, expressed in relation to a system of social security based on a system of agreements between the public health insurance funds and the suppliers of hospital services, which permit, in the name of overriding planning objectives, limits to be placed on the right of patients to resort at the expense of the national system with which they are

registered to hospital treatment not provided by that system, may be adopted in respect of a national health system such as the NHS.

113 In the light of the foregoing, and in answer to Question 1(c), Community law, in particular Article 49 EC, does not therefore preclude the right of a patient to receive hospital treatment in another Member State at the expense of the system with which he is registered from being subject to prior authorisation.

114 Nevertheless, the conditions attached to the grant of such authorisation must be justified in the light of the overriding considerations mentioned above and must satisfy the requirement of proportionality referred to in paragraph 106 of the present judgment (see to that effect *Smits and Peerbooms*, paragraph 82, and *Müller-Fauré and van Riet*, paragraph 83).

115 It is settled case-law that a system 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 *Smits and Peerbooms*, paragraph 90, and *Müller-Fauré and van Riet*, paragraph 84, and the case-law cited in those paragraphs).

116 Thus, in order for a system of prior authorisation to be justified even though it derogates from a fundamental freedom of that kind, 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. Such a system must furthermore 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 (*Smits and Peerbooms*, paragraph 90, and *Müller-Fauré and van Riet*, paragraph 85).

117 To that end, refusals to grant authorisation, or the advice on which such refusals may be based, must refer to the specific provisions on which they are based and be properly reasoned in accordance with them. Likewise, courts or tribunals hearing actions against such refusals must be able, if they consider it necessary for the purpose of carrying out the review which it is incumbent on them to make, to seek the advice of wholly objective and impartial independent experts (see to that effect *Inizan*, paragraph 49).

118 In relation to the dispute in the main proceedings, it should be noted, as does the Commission, that the regulations on the NHS do not set out the criteria for the grant or refusal of the prior authorisation necessary for reimbursement of the cost of hospital treatment provided in another Member State, and therefore do not circumscribe the exercise of the national competent authorities' discretionary power in that context. The lack of a legal framework in that regard also makes it difficult to exercise judicial review of decisions refusing to grant authorisation.

119 It should be noted with regard to the circumstances and factors referred to in the third and fourth questions that, given the findings set out in paragraphs 59 to 77 of the present judgment, a refusal to grant prior authorisation cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in

question an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

120 It follows that, where the delay arising from such waiting lists appears to exceed in the individual case concerned an acceptable period having regard to an objective medical assessment of all the circumstances of the situation and the clinical needs of the person concerned, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the duty to make available specific funds to reimburse the cost of treatment provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

121 As regards the factors mentioned in Questions 1(a) and 3(d), to the findings set out in paragraphs 59 to 77 of the present judgment should be added the point that, although Community law does not detract from the power of the Member States to organise their social security systems and decide the level of resources to be allocated to their operation, the achievement of the fundamental freedoms guaranteed by the Treaty nevertheless inevitably requires Member States to make adjustments to those systems. It does not follow that this undermines their sovereign powers in the field (see *Müller-Fauré and van Riet*, paragraphs 100 and 102).

122 As Advocate General Geelhoed observed in point 88 of his Opinion, it must therefore be found that the need for the Member States to reconcile the principles and broad scheme of their healthcare system with the requirements arising from the Community freedoms entails, on the same basis as the requirements arising from Article 22 of Regulation No 1408/71, a duty on the part of the competent authorities of a national health service, such as the NHS, to provide mechanisms for the reimbursement of the cost of hospital treatment in another Member State to patients to whom that service is not able to provide the treatment required within a medically acceptable period as defined in paragraph 68 of the present judgment.

123 In the light of the foregoing, the answer to the first four questions must be as follows:

- Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration, there being no need to determine whether the provision of hospital treatment within the national health service with which that person is registered is in itself a service within the meaning of the Treaty provisions on the freedom to provide services.
- Article 49 EC must be interpreted as meaning that it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the grant of prior authorisation by the competent institution.
- A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness,

the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

The sixth question

124 By this question, the referring court asks essentially whether the reimbursement which a Member State is required by Community law to provide of the cost of hospital treatment in another Member State should be calculated under Article 22 of Regulation No 1408/71 by reference to the legislation of the Member State in which that treatment was provided (the host Member State), or under Article 49 EC by reference to the legislation of the Member State of residence of the patient (the competent Member State). It also wishes to know whether the fact that the hospital treatment is provided free of charge by the national health service in question and the fact that there is therefore no tariff for reimbursement in the legislation of the competent Member State have any bearing on that question. It also asks whether the obligation to fund hospital treatment provided in the host Member State includes the travel and accommodation costs.

125 It should, first of all, be noted in this regard that the patient who, having requested authorisation under Article 22(1)(c)(i) of Regulation No 1408/71, was granted that authorisation or received a refusal to authorise subsequently held to be unfounded must, according to the express terms of that provision, be entitled to the benefits in kind provided on behalf of the competent institution by the institution of the host Member State, in accordance with the provisions of the legislation of that State, as if he were registered with that institution (see *Vanbraekel*, paragraph 32; *Inizan*, paragraph 20; and *Keller*, paragraph 65).

126 It follows that, in such a case, the rules for reimbursement laid down by the legislation of the host Member State are to be applied, while the competent institution remains responsible for subsequently reimbursing the institution of that State, as provided for in Article 36 of Regulation No 1408/71 (see *Vanbraekel*, paragraph 33).

127 The fact that, because the hospital treatment in the national health service in question is free of charge, the legislation of the competent Member State does not include a tariff for reimbursement does not preclude the application of the provisions of Articles 22(1)(c)(i) and 36 of Regulation No 1408/71. The competent institution's obligation under the system set up by those provisions is to reimburse the institution of the host Member State the costs of the benefits provided by that institution in accordance with the provisions of that State, without there being any need in that regard to refer to any tariff for reimbursement set by the legislation of the competent Member State.

128 Next, it is necessary to consider whether an NHS patient is entitled under Article 49 EC to receive from the competent institution a greater proportion of the cost of hospital treatment received in the host Member State than would be the case under the provisions of the legislation of that State.

129 It should be noted in that connection that the Court has already held that the fact that the legislation of the competent Member State does not guarantee a patient covered by that legislation, who has been authorised to receive hospital treatment in another Member State in accordance with Article 22(1)(c) of Regulation No 1408/71, a level of payment equivalent to that to which he would have been entitled if he had received hospital treatment in the competent Member State is an unjustified restriction of the freedom to provide services within the meaning of Article 49 EC (see *Vanbraekel*, paragraphs 43 to 52).

130 In the light of that case-law, in the context of national rules which, like those in issue in the main proceedings, provide that hospital treatment in establishments belonging to the national health service instituted by those rules is to be free of charge, it must be found that there is no restriction of the freedom to provide services where the patient registered with that service, who was authorised to receive hospital treatment in another Member State pursuant to Article 22(1)(c)(i) of Regulation No 1408/71 or who received a refusal to authorise subsequently held to be unfounded, is entitled to have the cost of that treatment reimbursed in full pursuant to the provisions of the legislation of the host Member State. That patient is not required in such a case to make any financial contribution to the cost of that treatment.

131 By contrast, where the legislation of the host Member State does not provide for the reimbursement in full of the cost of hospital treatment in that State, in order to place the patient in the position he would have been in had the national health service with which he was registered been able to provide him free of charge, within a medically acceptable period, with treatment equivalent to that which he received in the host Member State, the competent institution must in addition reimburse him the difference between the cost, objectively quantified, of that equivalent treatment up to the total amount invoiced for the treatment received in the host Member State and the amount reimbursed by the institution of that State pursuant to the legislation of that State, where the first amount is greater than the second.

132 Contrary to the view taken by Mrs Watts in her written observations, the obligation of the competent institution in all circumstances to cover the full amount of the difference between the cost of the hospital treatment provided in the host Member State and that of the reimbursement by the institution of that Member State under that State's provisions, including where the cost of that treatment is greater than the cost of equivalent treatment in the competent Member State, would afford that patient cover in excess of that to which he is entitled under the national health service with which he is registered.

133 It should further be noted that in the context of legislation which, like that in the main proceedings, contains, according to the order for reference (see paragraph 22 of the present judgment), rules for calculating the amount of the costs which must in principle be invoiced to particular foreign patients, and recovered from them, for treatment in a hospital covered by the national health service, those rules may be useful reference tools in determining, for the purposes of the calculation referred to in paragraph 131 of the present judgment, the cost in the competent Member State of treatment in a hospital covered by that service, equivalent to that provided to the patient in the host Member State.

134 As regards the travel and accommodation costs, it should be noted in the case of the system of authorisation established by Article 22(1)(c)(i) of Regulation No 1408/71 that that provision confers on the patient the right to receive 'benefits in kind' provided, on behalf of the competent institution, by the institution of the host Member State according to the provisions implemented by that institution.

135 As is confirmed by the second subparagraph of Article 22(2) of Regulation No 1408/71, the sole purpose of Article 22(1)(c)(i) of that regulation is to confer on patients covered by the legislation of one Member State and granted authorisation by the competent institution the right to have access to 'treatment' in another Member State on conditions for reimbursement as favourable as those enjoyed by patients covered by the legislation of that other State (see *Vanbraekel*, paragraph 32, and *Inizan*, paragraph 21).

136 The obligation imposed on the competent institution by Articles 22 and 36 of Regulation No 1408/71 therefore relates exclusively to the expenditure connected with the healthcare received by the patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to the patient's stay in the hospital for the purposes of his treatment.

137 The essential characteristic of 'benefits in kind' within the meaning of Regulation No 1408/71 is that they are 'designed to cover care received by the person concerned' by the direct payment or reimbursement of 'medical expenses' incurred by that patient's state (see, in the context of a statutory scheme of social insurance against the risk of reliance on care, Case C-160/96 *Molenaar* [1998] ECR I-843, paragraphs 32 and 34).

138 Since its purpose is thus not to settle the question of ancillary costs, such as the cost of travel and any accommodation other than in the hospital itself, incurred by a patient authorised by the competent institution to go to another Member State to receive there treatment appropriate to his state of health, Article 22 of Regulation No 1408/71 does not make provision for, but also does not prohibit, the reimbursement of such costs. In those circumstances, it is necessary to consider whether an obligation to reimburse such costs might arise under Article 49 EC (see, by analogy, *Vanbraekel*, paragraph 37).

139 It follows from the case-law cited in paragraph 94 of the present judgment that the legislation of a Member State cannot, without infringing Article 49 EC, exclude reimbursement of the ancillary costs incurred by a patient authorised to go to another Member State to receive there hospital treatment whilst providing for the reimbursement of those costs where the treatment is provided in a hospital covered by the national system in question.

140 By contrast, a Member State is not required under Article 49 EC to lay down a duty on its competent institutions to reimburse the ancillary costs associated with a cross-border movement authorised for medical purposes where there is no such duty in respect of such costs where these arise from movement within the Member State.

141 In those circumstances, it is for the referring court to determine whether the United Kingdom rules provide for the assumption of ancillary costs associated with such movement within the United Kingdom.

142 If that is the case, the patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled, as the Belgian Government stated in its written observations and as Advocate General Geelhoed stated in point 118 of his Opinion, to seek reimbursement of the ancillary costs associated with that cross-border movement for medical purposes subject to the same objective and transparent limits as those set by the competent legislation for the reimbursement of the ancillary costs associated with medical treatment provided in the competent Member State (see to that effect Case C-8/02 *Leichtle* [2004] ECR I-2641, particularly paragraphs 41 to 48).

143 In the light of the foregoing, the answer to the sixth question must be that:

– Article 49 EC must be interpreted as meaning that where the legislation of the competent Member State provides that hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71 on behalf of the competent institution pursuant to the legislation of that Member State.

– Article 22(1)(c)(i) of Regulation No 1408/71 must be interpreted as meaning that the right which it confers on the patient concerned relates exclusively to the expenditure connected with the healthcare received by that patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to his stay in the hospital.

– Article 49 EC must be interpreted as meaning that a patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled to seek from the competent institution reimbursement of the ancillary costs associated with that cross-border movement for medical purposes provided that the legislation of the competent Member State imposes a corresponding obligation on the national system to reimburse in respect of treatment provided in a local hospital covered by that system.

The seventh question

144 By this question, the referring court asks whether Article 49 EC and Article 22 of Regulation No 1408/71 must be interpreted as imposing an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, whether such an obligation is compatible with Article 152(5) EC.

145 It should, first of all, be noted in this regard that, as is clear from the findings set out in relation to the answers to the first six questions, the requirements arising from Article 49 EC and Article 22 of Regulation No 1408/71 are not to be interpreted as imposing on the Member States an obligation to reimburse the cost of hospital treatment in other Member States without reference to any budgetary consideration but, on the contrary, are based on the

need to balance the objective of the free movement of patients against overriding national objectives relating to management of the available hospital capacity, control of health expenditure and financial balance of social security systems.

146 Next, it should be noted that, according to Article 152(5) EC, Community action in the field of public health is to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

147 That provision does not, however, exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their national systems of social security. It does not follow that this undermines their sovereign powers in the field (see to that effect *Müller-Fauré and van Riet*, paragraph 102, and, by analogy, Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419, paragraph 78).

148 In the light of the foregoing, the answer to the seventh question must be that the obligation of the competent institution under both Article 22 of Regulation No 1408/71 and Article 49 EC to authorise a patient registered with a national health service to obtain, at that institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period having regard to an objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC.

Costs

149 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

1. The second subparagraph of Article 22(2) of Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996, must be interpreted as meaning that, in order to be entitled to refuse to grant the authorisation referred to in Article 22(1)(c)(i) of that regulation on the ground that there is a waiting time for hospital treatment, the competent institution is required to establish that that time does not exceed the period which is acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be.

2. Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration, there being no need to determine whether the provision of hospital treatment within the national health service with which that person is registered is in

itself a service within the meaning of the Treaty provisions on the freedom to provide services.

Article 49 EC must be interpreted as meaning that it does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the grant of prior authorisation by the competent institution.

A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State.

3. Article 49 EC must be interpreted as meaning that where the legislation of the competent Member State provides that hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71, as amended and updated by Regulation No 118/97, on behalf of the competent institution pursuant to the legislation of that Member State.

Article 22(1)(c)(i) of Regulation No 1408/71 must be interpreted as meaning that the right which it confers on the patient concerned relates exclusively to the expenditure connected with the healthcare received by that patient in the host Member State, namely, in the case of hospital treatment, the cost of medical services strictly defined and the inextricably linked costs relating to his stay in the hospital.

Article 49 EC must be interpreted as meaning that a patient who was authorised to go to another Member State to receive there hospital treatment or who received a refusal to authorise subsequently held to be unfounded is entitled to seek from the competent institution reimbursement of the ancillary costs associated with that cross-border movement for medical purposes provided that the legislation of the competent Member State imposes a corresponding obligation on the national system to reimburse in respect of treatment provided in a local hospital covered by that system.

4. The obligation of the competent institution under both Article 22 of Regulation No 1408/71, as amended and updated by Regulation No 118/97, and Article 49 EC to authorise a patient registered with a national health service to obtain, at that institution's expense, hospital treatment in another Member State where the waiting time exceeds an acceptable period having regard to an objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC.