

Patient Mobility in the European Union: A Freedom to Choose?

Introduction

A fundamental freedom to receive cross border medical treatment is granted to citizens of the European Union under the internal market provisions of European Community Law.¹ The European Court of Justice has interpreted the extent of, and the limits to, this freedom in a series of rulings,² the most recent and controversial being the ruling delivered in the case of *Yvonne Watts v Bedford Primary Care Trust*,³ in May 2006. Competence in the field of public health is retained by individual Member States who each have the responsibility for organising and delivering health services and medical care.⁴ The European Court of Justice acknowledges 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.⁵ Nevertheless, the Court ruled, in the *Watts* case that this does not exclude the possibility that Member States may be required under European Community law to make adjustments to their social security systems.⁶ An obligation exists under Community law 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.⁷

It is the intention of this paper to examine the implications of this ruling for the National Health Service in the United Kingdom and the extent of, and the barriers which exist to, the freedom to choose to have urgent hospital treatment in another European Union Member State. This paper will also treat the Consultation on the need for Community action on health services,⁸ which was triggered, latterly, by the *Watts* ruling, in order to establish legal certainty for patients and for Member States.

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¹ Article 49 of the European Community Treaty. Joined Cases 286/82 and 26/83 *Luisi and Carbone*.

² Case C-158/96 *Kohll*; Case C-120/95 *Decker*; Case C-368/98 *Vanbraekel*; Case 157/99 *Geraets-Smits and Peerbooms*; Case C-385/99 *Müller-Fauré and van Riet*; Case C-56/01 *Inizan*.

³ Case C-372/04, *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*. Judgment of the Court (Grand Chamber), 16th May 2006. Opinion of Advocate General Geelhoed delivered on 15 December 2005. Reference for a preliminary ruling under Article 234 of the European Community Treaty from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by order of 12 July 2004.

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⁸ Commission Communication, 'Consultation regarding Community action on health services', SEC(2006)1195/4, 26 September 2006.

Yvonne Watts v Bedford Primary Care Trust

The Freedom to Receive Urgent Medical Services in Hospital in the Host Member State

Article 152(5) EC

Open method of Co-ordination

Choice?

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Yvonne Watts v Bedford Primary Care Trust

The case of *Yvonne Watts v Bedford Primary Care Trust*,⁹ a 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 on the Application of Social Security Schemes to Employed Persons, to Self-Employed

⁹ Case C-372/04, *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*. Judgment of the Court (Grand Chamber), 16th May 2006. Opinion of Advocate General Geelhoed delivered on 15 December 2005. Reference for a preliminary ruling under Article 234 of the European Community Treaty from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by order of 12 July 2004.

Persons and to Members of their Families Moving within the Community, as amended and updated by Council Regulation (EC) No. 118/97.¹⁰ This 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.¹¹

Article 22 of Regulation No. 1408/71,

‘1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, ..., 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;

2. The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided 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.’

Form E 112 is the certificate necessary for the application of Article 22(1)(c)(i) of Regulation No. 1408/71.¹²

In the United Kingdom, hospital care is provided free of charge by the relevant National Health Service bodies to all persons ordinarily resident in the United Kingdom, on a non-profit-making basis. 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. Access to hospital treatment is generally dependent on referral by a general practitioner. As the budget allocated by the government to the NHS is not sufficient to allow for the swift provision of

¹⁰ [1997] OJ L28/1.

¹¹ Case C-372/04, paras. 1 and 2 of the judgment.

¹² *Ibid.*, para. 4.

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. 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.¹³

The role of PCTs, which are statutory bodies, 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.¹⁴

19 NHS trusts are separate legal bodies, which were set up under the National Health Service and Community Care Act 1990. NHS trusts receive their funding through payments made by PCTs in respect of the treatments and medical services commissioned by the latter.

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 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.

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

¹³ *Ibid.*, paras. 8, 9, 12, 13 and 15.

¹⁴ 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. *Ibid.*, para. 18.

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.

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 categorized 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 Watt'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 GDP 3900.

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 Watt'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 Watt'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 Watt's case should be governed exclusively by Article 22 of Regulation No. 1408/71.

42The 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*], *Müller-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?

Is so, and in the circumstances set out in the statement of facts above, are Articles 48EC, 49EC and 50EC 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 the 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 49Ec?
- (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?

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.

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 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.

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 possible course of his illness.

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 ..., 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 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,¹⁵ 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 then probable course of his/her illness.

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 ...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

¹⁵ [2004] OJ L166/1

may be reconsidered in the light of any deterioration in his state of health occurring after the first request for authorisation.

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 (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 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. Ruling 1 of the Court (Grand Chamber)

The first four questions

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 ... that the establishment in another Member State in which Mrs Watts received treatment was paid by her directly.

88 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. (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 49EC 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. Ruling 2 paragraph 1 of the Court (Grand Chamber)

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*, paragraph 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 49EC 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).

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).

FREEDOM TO CHOOSE?

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 49EC 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.

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).

PROPORTIONALITY?

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 these 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.

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. Ruling 2 paragraph 2 of the Court (Grand Chamber).

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).

118 In relation to the dispute in the main proceedings, it should be noted, ... 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.

UK NEEDS TO CHANGE HERE – DEFICIENT?

119A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists (intended to enable)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 cause 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. Ruling 2 (paragraph 3) of the Court (Grand Chamber).

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 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) 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. Ruling 2 paragraph 4 of the Court (Grand Chamber).

121 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).

The sixth question: Costs

130 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 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 ... 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.

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.

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 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 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. Ruling 3 paragraphs 1 to 3 of the Court (Grand Chamber).

The seventh question

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. Ruling 4 of the Court (Grand Chamber).

COMMISSION COMMUNICATION REGARDING COMMUNITY ACTION ON HEALTH SERVICES

The European Court of Justice has made clear that Treaty provisions on free movement apply to health services regardless of how they are organised or financed at national level. Many healthcare stakeholders have asked for greater clarity over what Community law means for health services.

The Commission's proposal for a Directive on Services in the Internal Market¹⁶ included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach was not considered appropriate by the European Parliament and by Council, which institutions invited the Commission to develop specific proposals in this area.

¹⁶ COM(2004)2, 13 Jan 2004.

The Commission undertook in its Annual Policy Strategy for 2007 to develop a Community framework for safe, high quality and efficient health services, by reinforcing co-operation between Member States and providing clarity and certainty over the application of Community law to health services and healthcare.¹⁷

At the Health Council of 1 June 2006 ministers adopted a ‘Statement of common values and principles in EU health systems’,¹⁸ which underlined the importance of ‘protecting the values and principles that underpin health systems in the EU’ and called for action: ‘.. ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and enshrining these values and principles in a legal framework in order to ensure legal certainty.’ Community action on health services does not mean harmonising national health or social security systems. The benefits that different health and social security systems provide and their organization remain the responsibility of the Member States, in accordance with the principle of subsidiarity. Nor does Community action mean stepping back from what already exists. Any Community action must respect the principles already established.

The Commission considers that Community action should be founded on two pillars: *Legal certainty*, which citizens as well as national and local health actors currently feel the lack of. There is a need to address the wider application of European Court of Justice rulings regarding Treaty provisions on free movement of patients. The focus is, in particular, on cross-border care; and *Support for Member States* in areas where European action can add value to their national health services. This should enable those responsible for health systems (including social security institutions) to have a clear framework of Community law within which to operate and take advantage of co-operation between health systems where helpful in providing safe, high-quality and efficient health services.

The purpose of the Consultation is to *consult on the issues* to address through Community action on health services, and the *tools to be used for different topics*. Responses to this consultation, focused around the nine specific questions indicated, were invited by 31st January 2007. Responses to this Consultation can be located on the internet.

¹⁷ ‘Boosting trust through action’, COM(2006)122, 14 March 2006. Under the strategic objective of ‘solidarity’, health and safety is considered to be a key priority for 2007.

¹⁸ Council Conclusions on Common values and principles in EU Health Systems, 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006.

The need for Community action on health services

The need for legal certainty

Discussions on using internal market rules to access healthcare provided in other Member States only really began in 1998 after judgments of the European Court of Justice. Until then the Community mechanism enabling patients to receive treatment abroad (other than patients paying for such treatment themselves) was considered to be only Regulation (EC) No. 1408/71 on the co-ordination of social security schemes, which entitles persons for whom a medical treatment becomes necessary during a stay in the territory of another Member State to the same benefits as patients insured in the host Member State, using the European Health Insurance Card. It also ensures assumption of costs for the planned treatment in other Member States, subject to prior authorisation, and deals with the settlement of financial claims between receiving and sending Member States. This framework remains in place.

In 1998, the Court established new principles through its rulings in two cases¹⁹ regarding direct application of the Treaty articles on free movement to the reimbursement of health services provided to patients abroad (patient mobility). In its rulings, the Court made clear that when health services are provided for remuneration, they must be regarded as services within the meaning of the Treaty and thus provisions on the free movement of services apply. The Court also rules that as a result measures making reimbursement of costs incurred in another Member State subject to prior authorisation are barriers to freedom to provide services, although such barriers may be justified by overriding reasons of general interest.

On the basis of these and subsequent cases, the Court's rulings have developed the following principles:

Any non-hospital care to which a person is entitled in their own Member state they may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system;

Any hospital care to which they are entitled in their own Member State they may also seek in any other Member State provided they first have the authorisation of their own

¹⁹ Case C-158/96 *Kohll* and Case C-120/95 *Decker*

system. The authorisation must be given if their system cannot provide them care within a medically acceptable time limit considering their own condition. They will be reimbursed up to at least the level of reimbursement provided by their own system. Two clarifications were provided by the *Watts* judgment on 16 May 2006.

First, some Member States with systems based on integrated public funding and provision of health services had argued that the Treaty provisions on the freedom to provide services did not apply to them: the *Watts* judgment confirmed that they do. Second, some Member States have argued that the requirement in Article 152, paragraph five of the Treaty to ‘*fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care*’ prevented binding obligations under Community law regarding health systems. In the judgment, the Court stated that this provision 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 (EC) No. 1408/71, to make adjustments to their national systems of social security.

The Court’s rulings on these individual cases are clear in themselves, and no pre-condition may be required for the exercise of the rights of patients of patients recognised by the Court. The Commission believes it is necessary to improve clarity to ensure a more general and effective application of the freedoms to receive and provide health services, to address such issues as:

- Whether there are shared values and principles for health services on which citizens can rely throughout the EU and what practical issues need to be clarified for citizens who wish to seek healthcare in other Member States;
- What flexibility Member States have to regulate and plan their own systems without creating unjustified barriers to free movement;
- How to reconcile greater choice in exercising individual entitlements with financial sustainability of health systems overall;
- How to ensure a proper financial compensation mechanism for cross-border healthcare provided by ‘receiving’ health systems;
- How patients or professionals can identify, compare or choose between providers in other countries; and

- The link between health services and related services such as social services and long-term care.

These issues are the focus of this Communication.

This paper is dealing with one aspect of cross-border health care, namely, the use of services in another Member State (ie a patient moving to a healthcare provider in another Member State for treatment). This is what is referred to as patient mobility. (The European Health Insurance Card is intended to cover care that becomes necessary whilst temporarily in another Member State for other reasons.)

Relevance of Community action to overall health system objectives

European action on health services will necessarily also contribute to the wider challenges facing health systems, beyond the specific case of cross-border healthcare.

The cost of healthcare systems to public funds is projected to rise by one or two percent of GDP in most Member States between now and 2050 as a direct result of ageing populations.²⁰ The key to sustainability for health care systems is controlling costs and improving efficiency, alongside prevention and health promotion measures to maximize the number of years of life spent in good health. Ensuring future sustainability of healthcare and social security systems will require efforts to improve efficiency and effectiveness whilst respecting the shared European objectives of universal access to high-quality healthcare on a financially sustainable basis, founded on the principles of equity, equality and solidarity.

Nature and impact of cross-border healthcare

The Consultation is concerned with the economic, social and health impacts of cross-border healthcare for citizens as well as for health and social security systems. This should include the impact on receiving Member States (including appropriate compensation for cross-border healthcare) and smaller Member States, as well as the potential benefits and economies of scale from European co-operation.

Patients generally prefer to be treated near their homes wherever possible, and the current volume of patient mobility is relatively low, estimated at around 1% of overall public expenditure on healthcare. But this figure is very approximate, as most health systems in Europe do not provide the necessary data for an accurate picture. It is clear

²⁰ The impact of ageing on public expenditure: projections for the EU25 Member States on pensions, health care, long-term care, education and unemployment transfers (2004-2050), European Economy Special Report 1/2006, produced by DG ECFIN.

that many more patients are interested in cross-border health care in principle.²¹ But the lack of information about healthcare possibilities in other Member States and the lack of a transparent framework act as a deterrent to seeking care abroad even where it is appropriate to do so.

Advocate General Geelhoed

Question 1: What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

Areas of Possible Community Action

Legal Certainty

Clarity is needed in order to facilitate the general application of Treaty provisions on free movement to health services following the rulings of the European Court of Justice, for citizens as well as for health systems overall.

Possible issues to be addressed and consultation questions:

Minimum information and clarification requirements to enable cross-border healthcare

This could include clarifying procedures and conditions to obtain cross-border healthcare, such as clarification regarding the condition referred to by the Court that authorisation for care abroad must be granted if such care cannot be provided domestically without ‘undue delay’ (though this should focus more on processes for consideration than setting any specific period). It could also include mechanisms through which patients could contest decisions regarding cross-border care (perhaps such as requirements to designate fair appeals procedures and timetables).

Entitlement to healthcare in other Member States is not sufficient unless patients or professional have adequate information to make informed choices about treatments and providers in other Member States.

Question 2: What specific legal clarification and what practical information is required by whom(eg authorities, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

²¹ See the results of the ‘Europe for patients’ project <http://www.europe4patients.org>

Identifying the competent authorities and their responsibilities

Which authority is responsible for ensuring the quality and safety of health services provided to people from other Member States, and whose complaints and compensation system should apply for each type of cross-border health services?

Specific issues to address include continuity of care when a patient is transferred to another Member State to undergo a specific medical intervention and then returned to their own Member State after that intervention.

Question 3: Which issues (eg clinical oversight, financial responsibility) should be the responsibility of which country?

Responsibility for harm caused by healthcare and compensation arising from cross-border healthcare.

An important issue is to be clear about who is responsible for ensuring patient safety in cross-border healthcare; how patients will be compensated when they suffer harm; and if there are errors, whose liability rules apply and how those errors will be followed up. When harm is caused there should be a clear mechanism for appropriate compensation and follow-up to avoid repetition of errors.

Question 4: Who should be responsible for ensuring safety in the case of cross-border health care? If patients suffer harm, how should redress for patients be ensured?

Ensuring a balanced healthcare accessible to all

Although the overall volume of patient mobility is relatively low, the proportion of patient mobility can be higher:

in border regions or popular tourist destinations, where more than half of patients can sometimes be from abroad;

for care outside hospitals, such as dental care. In some of the recently joined Member states, patients from abroad can be a third of the total in some dental clinics. Greater clarity is needed over the possibilities given to the Member State of treatment (ie the 'receiving country') to ensure that treatment from other Member States will not prevent the provision of a balanced healthcare service open to all or undermine the overall sustainability of the health system of the Member State (for example, in terms of organization and delivery of services).

Question 5:

What action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example by means of financial compensation for their treatment in ‘receiving countries)?

Other issues

There should be clarity over ethical issues, and the ability of Member States to take different decisions about what care they consider appropriate to provide, (eg fertility treatment).

Question 6: Are there further issues to be addressed in the specific context of health services regarding the establishment of healthcare providers not already addressed by Community legislation?

Question 7: Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

Support to Member States

A formal framework at EU level is needed to ensure that co-ordinated action between all Member States will be implemented effectively and on a sustained basis in order to bring added value to national health systems.

European networks of centres of reference

Some types of health service require a particular concentration of resources or expertise, for example, for rare diseases. Establishing European networking for centres of reference would help to provide high-quality and cost-effective care, and would thus bring benefits to both patients and healthcare systems as well as helping to promote the highest possible quality of care.

Realising the potential of health innovation

A key challenge for health services is the management of innovation, and ensuring that treatment is provided on the basis of the best scientific evidence. Collaborating on

providing common criteria with a view to establishing such an evidence base at European level will help to spread best practice

A shared evidence base for policy-making

Current mechanisms to ensure efficiency and effectiveness of health services need strengthening in order to eliminate wide variations in Member States in techniques and outcomes. Improving the availability and comparability of healthcare data and indicators can provide the basis for improving healthcare throughout Europe. Some operational mechanism (such as an observatory) may be needed to carry out monitoring and co-operation at European level.

Question 8: In what ways should European action help support the health systems of the Member States and the different actors within them? Are there any areas not identified above?

Tools and instruments for Community action

Options

There are a wide range of possible tools for action at Community level on health services. Legal certainty would be best ensured by a binding legal instrument. This could be a Regulation or a Directive (which could, for example, be based on Article 95 EC), although the appropriate form should be considered taking into account the results of this consultaion. A modernised system of co-ordination of social security systems is also being put in place replacing Regulation 1408/71 and 574/72.²²

A Commission interpretation of case-law (eg an interpretative Communication) could provide additional clarification.

There are also other non-legislative options, including practical co-operation through the High Level Group on health services and medical care. The open method of co-ordination is being used to provide a common framework to support Member States in the reform and development of healthcare and long-term care borne by the social protection system.²³ These can be valuable in taking forward the practical agenda of co-operation between Member states, although they would not be able to provide legal certainty.

²² See COM(2006)16, 31 Jan. 2006.

²³ See COM(2004)304, 20 April 2004.

Any or all of these different types of instruments could be combined in an overall package of Community actions. Ensuring legal certainty seems likely to require at least some elements being dealt with through legislative action. Other issues could be addressed through softer mechanisms such as recommendations, communications or guidelines. Support for practical co-operation between health systems (eg enhanced networking or centres of reference) is also likely to need strengthening to ensure that there are practical structures in place to enable co-operation to work in practice.

Given the constant reform of health services some mechanism for keeping these instruments and rules up to date would also be needed.

Question 9: What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

Commission Legislative and Work Programme 2007²⁴

A strategic initiative is:

A legislative proposal for a Community Framework for safe and efficient health services; legal basis Article 95 of the European Community Treaty. The specific objective is to establish a Community framework for safe, high-quality and efficient health services in order to:

- ensure patient safety wherever healthcare is provided throughout the Community;
- address uncertainties over application of Community law to health services that create obstacles to cross-border healthcare;
- and improve the efficiency and effectiveness of health services throughout the EU.

QUESTIONS AND ANSWERS ON HEALTH SERVICES IN THE EU²⁵

²⁴ COM(2006)629, 24 Oct. 2006.

²⁵ Commission MEMO/06/348, 26 Sept. 2006, available on the Internet at <http://www.europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/348&format=H>

Why is it important to address health services from a European perspective?

Health systems and health policies across the EU are becoming more interconnected than ever in the past. This is due to many factors, including increased movement of patients and professionals around the EU (facilitated by rulings of the European Court of Justice), common public expectations across Europe, dissemination of new medical technologies and techniques through information technology, and the enlargement of the European Union. This increased interconnection raises many health policy issues, including quality and access in cross-border care; information requirements for patients, health professionals and policy-makers; the scope for co-operation on health matters; and how to reconcile national policies with the obligations of the EU's internal market.

Why a specific initiative on health services/

In 2003 health ministers and other stakeholders invited the Commission to explore how legal certainty could be improved following the Court of Justice jurisprudence concerning the right of patients to benefit from medical treatment in another Member State. The Commission's proposal for a Directive on services in the internal market²⁶ included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach was not accepted by the European parliament and the Council. It was felt that specificities of health services were not sufficiently taken into account, in particular their technical complexities, sensitivity for public opinion and major support from public funds. The Commission therefore undertook to explore how best to develop a policy initiative specifically targeting healthcare services as a separate issue.

What is the overall Commission objective in this area?

The basic strategy is to provide two things: legal certainty and support for co-operation between national health systems. The Commission's overall objective is to provide a clear framework addressing the issues raised by the Court of justice rulings enabling patients and those who pay for, provide and regulate health services to have clear and usable options to take advantage of cross-border health services where appropriate. It would facilitate co-operation between health systems, while respecting

²⁶ COM(2004)2, 13 Jan. 2004.

the primary responsibilities of Member States for their healthcare systems and supporting them in working towards core objectives of accessibility, quality and financial sustainability.

The benefits provided by different health systems are determined by Member States. In accordance with Community free movement rules, care to which citizens are entitled in their own Member State they may also seek in another Member State and be reimbursed, subject to certain conditions.

If the European Court of Justice rulings have developed principles concerning patient mobility, why is there a need for further EU action?

The Court's rulings leave many areas of uncertainty about how these principles can be applied in practice by patients, health professionals and Member State regulators.

(Commission consultation (8 points))

How can we achieve legal clarity in this area?

The need here is for clarity regarding the application of Treaty provisions on free movement to health services following the Court of Justice rulings, including the minimum necessary clarity on medical, regulatory and administrative issues that also need to be addressed in order to promote safe, high-quality and efficient health services, whilst respecting the rights of patients and of Member States as already established by the Court. This could cover issues such as the following:

- The terms and conditions according to which health care in another Member State must be authorized and paid for, and the provision of information to patients about treatments available in other Member States;
- Which health authority is responsible for supervising cross-border health care in different circumstances, and ensuring continuity of care;
- Responsibility for any harm caused in cross-border healthcare and compensation arising from such harm;
- Common elements of patient rights.

Ministers at the 'Health' Council of 1 June 2006 adopted a 'Statement of common principles in EU health systems'²⁷ which underlined the importance of 'protecting the values and principles that underpin health systems in the EU' and called in particular

²⁷ Council Conclusions on Common Values and Principles in EU Health Systems, Employment, Social Policy, Health and Consumer affairs Council meeting, Luxembourg, 1-2 June 2006.

for an initiative on health services: ‘ ... ensuring clarity for European citizens about rights and entitlements when they move from one Member State to another and enshrining those values and principles in a legal framework in order to ensure legal certainty’.

The benefits that different health and social security systems provide and their organization remain the responsibility of the Member States, in accordance with the principle of subsidiarity.

Legal certainty would be ensured through a Regulation or a Directive, which could be based on Article 95 EC.

This has been confirmed most recently by the *Watts* judgment of the Court of Justice on 16 May 2006²⁸. In that ruling, the Court made clear that the requirement in Article 152, paragraph five of the Treaty to ‘fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care’, does not exclude the possibility that the Member States may be required under other Treaty provisions, such as article 49EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation (EEC) 1408/71, to make adjustments to their national systems of social security.

COUNCIL Conclusions on Common values and principles in EU Health Systems 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006²⁹

The Council adopted the following conclusions:

1. Notes that European Commission in its amended proposal for a Directive of the European Parliament and of the Council on services in the internal market has decided to remove healthcare services from the scope of the directive, thereby incorporating amendments proposed by the European Parliament.
2. Notes that the Commission has stated that it will develop a Community framework for safe, high-quality and efficient services, by reinforcing co-

²⁸ Case C-372/04

²⁹ <http://www.consilium.europa.eu/Newsroom>

operation between Member States and providing clarity and certainty over the application of Community law to health services and healthcare.

3. Recognises that recent judgments in the European Court of Justice have highlighted the need to clarify the interaction between the EC Treaty provisions, particularly on the free movement of services and the health services provided by national health systems.
4. Considers that health systems are a central part of Europe's high levels of social protection and make a major contribution to social cohesion and social justice.
5. Recalls the overarching values of universality, access to good quality care, equity and solidarity.
6. Endorses the attached Statement on common values and principles that underpin the health systems in the Member States of the European Union (Annex).
7. Invites the Commission to ensure that common values and principles contained in the statement are respected when drafting specific proposals concerning health services.
8. Invites the institutions of the European Union to ensure that common values and principles contained in the Statement are respected in their work.

Statement on Common values and Principles that underpin Europe's health systems (by 25 Member States).

We strongly believe that developments in this area should result from political consensus, and not solely from case law.

Different Member States have different approaches to making a practical reality of these values; they have, for example, different approaches to questions such as whether individuals should pay a personal contribution towards the cost of elements of their healthcare, or whether there is a general contribution, and whether this is paid from supplementary insurance. Member States have implemented different provisions to ensure equity; some have chosen to express it in terms of the rights of patients; others in terms of the obligations of healthcare providers. Enforcement is also carried out differently – in some member states it is through the courts, in others through boards, ombudsmen etc.

It is an essential feature of all our systems that we aim to make them financially sustainable in a way which safeguards these values into the future.

Beneath these overarching values, there is also a set of operating principles that are shared across the European Union, in the sense that all EU citizens would expect to find them, and structures to support them in a health system anywhere in the EU. These include:

Quality:

All EU health systems strive to provide good quality care.

Safety:

Care that is based on evidence and ethics:

All systems have to deal with the challenge of prioritizing health care in a way that balances the needs of individual patients with the financial resources available to treat the whole population.

Patient Involvement:

All EU systems aim to be transparent with patients and to offer them choices where this is possible eg a choice between different health care service providers.

All systems should also be publicly accountable and ensure good governance and transparency.

Redress:

Patients should have a right to redress if things go wrong. This includes having a transparent and fair complaints procedure, and clear information about liabilities and specific forms of redress determined by the health system in question (eg compensation)

Privacy and confidentiality

Whilst it is not appropriate to try to standardise health systems at an EU level, there is immense value in work at a European level on health care. Member States are committed to working together to share experiences and information about approaches and good practice, for example through the Commission's High Level Group on Health Services and medical care, or through the ongoing Open method of Co-ordination on healthcare and long-term care, in order to achieve the shared goal of promoting more efficient and accessible high-quality healthcare in Europe.

We believe there is particular value in any appropriate initiative on health services ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and in enshrining these values and principles in a legal framework in order to ensure legal certainty.

In conclusion, our health systems are a fundamental part of Europe's social infrastructure. We do not under-estimate the challenges that lie ahead in reconciling individual needs with the available finances, as the population of Europe ages, as expectations rise, and as medicines advance. In discussing future strategies, our shared concern should be to protect the values and principles that underpin the health systems of the EU. As Health Ministers in the 25 Member States of the European Union, we invite the European institutions to ensure that their work will protect these values as work develops to explore the implications of the European Union on health systems

UK Consultation Response to Commission Communication on Health Services³⁰

1. This response takes account of the views of UK stakeholders that contributed to a consultation in the UK, and views expressed in the UK Parliament, following appearances by the Right Honourable Rosie Winterton MP, the Minister of State for Health Services, before both a House of Commons Standing Committee,³¹ and Sub-Committee G of the House of Lords European Union Select Committee.³²
2. This is an important piece of work. Member States face an increasing challenge in providing sustainable health services in the face of demographic ageing and

³⁰

³¹ Minutes of the Commons appearance are available at:

<http://www.publications.parliament.uk/pa/cm200607/cmgeneral/euro/070116/70116s01.htm>

³² Minutes of the House of Lords appearance are published at:

<http://www.publications.parliament.uk/pa/ld/ldeucom.htm#evid> House of Lords European Union Committee 8th Report of Session 2006-07, HL Paper 48, Cross Border Health Services in the European Union. This Report makes available the oral evidence provided by the Rt. Hon. Rosie Winterton MP, Minister of State for Health Services to EU Sub-Committee G on 25 January relating to cross border health services in the European Union. The meeting with the Minister helped to improve the Sub-Committee's understanding of the significant and sensitive issues, of both a legal and political nature, that need to be resolved in order to find an acceptable way forward in this case. In particular, Sub-Committee G recognized the point the Minister made that there was a need to get the framework for European Health Services right so that it can provide a fair and transparent system for people seeking health care and, at the same time, ensure that it does not undermine the UK health service. (Point 5 of the Report). Sub-Committee G will look further at these issues when the Commission publish firm proposals. (Point 6).

globalisation. Cross-border healthcare, and non-regulatory co-operation, can add value to Member State's efforts in this field, provided that the fundamental rights of Member States for the organisation and management of their health care systems are respected.

3. Recent developments in the case law of the European court of Justice, have raised other, fundamental issues.

- The first is the underlying question of the wider impact of the Treaty on health systems. Here, we think that it is important to continue the discussion that was started in the High Level Reflection process, and which was reflected in the Statement on Values and Common Principles that the EU Health Ministers agreed at the Health Council in June 2006. Further work is needed on how the impact of the Treaty might be managed to ensure that Member States continue to be able to discharge their responsibilities for the management and operation of the health systems of the European Union;
- The second is the growing need to address the tensions that are arising between the principles that underpin the long-standing EU Regulations in this area (Regulation 1408/71, as recently amended) and the case law of the European court of Justice. Although relatively few people are currently interested in going abroad from the UK in order to access treatment, there is considerable use made of other rules which allow access to treatment while people are abroad. More work is needed, including at the Ministerial level, to ensure that this key practical benefit of EU membership is managed in a way that is financially sustainable for the longer term.

What is the current extent of cross-border healthcare?

7. Whilst significant use is made in many Member States of the provisions under Regulation (EC) No. 1408/71 that allow EU citizens who are retired, working or traveling in other Member States to access healthcare in other Member States, the number of patients interested in going abroad specifically for treatment is relatively low in many Member States: in the UK, around 280 people went abroad for such treatment in 2005-2006.

What legal certainty is needed in this area?

8. The UK thinks that there are certain fundamental underlying principles that need to underpin, and be reflected in, any proposals in order to ensure a system of patient mobility that is manageable and sustainable in the long-term, and also that respects the rights and responsibilities of Member States to organize and manage their health care systems: (MS orientated)

- The home health system in the individual Member State needs to be able to determine what health care services are offered to individual patients, and to manage the clinical decision (substantively, but EU procedures (ECJ reviewable) and mechanisms will be better for patient in a framework) about whether, given the individual circumstances of the patient, ‘undue delay’ applies. In the UK this is done through referral processes as an integral part of the process of determining what health services will be offered to the patient. Such processes must be respected in any legislative proposals.
- Patient mobility needs to be ‘cost-neutral to the home health system: where patients choose to go abroad this shouldn’t cost their home health system more than it would have done to treat them at home. Where the cost of treatment abroad is lower than at home, the home health system should only be required to pay for the actual cost of treatment.
- Clarification that, when patients request to go abroad in order to be treated, it is the standards of care, governance, and redress arrangements of the Member State of treatment that apply: health systems can’t take responsibility for the actions of providers they don’t regulate or assess.
- A principle of transparency could be established making it clear what information should be made available to patients by providers before they travel abroad for treatment. This information should include: the nature of the service being offered; full costs; what is covered by consent; full details of what is included in the package; which systems of redress, care and governance will apply. What this means in practice may well differ substantially between Member States.
- That there is no ‘requirement to treat’ on Member States receiving patients travelling abroad for elective treatment (in other words, that Member

States can prioritise their own residents above patients travelling to them specifically for treatment).

- The principles of equity and solidarity³³ need to be respected with regard to patient mobility, thereby avoiding the risk of creating a system whereby those EU citizens who can afford to pay for services up front can access health care services faster than those with greater needs.

12 Patient mobility where patients choose to go abroad specifically to receive treatment poses a big challenge. Although the current level of this sort of mobility is very low in the UK, this may not be the case in all EU Member States. It may also be that this kind of mobility increases across Europe in the future. Any system that is put in place to facilitate patient mobility therefore needs to be both sustainable and flexible enough to take account of long-term developments.

14 The Court has stated that prior authorisation systems were justified for ‘hospital’ services as they sought to ensure ‘sufficient and permanent accessibility to a balanced range of high-quality treatment in the State concerned’; that they assisted in controlling costs; and that they assisted in preventing ‘any wastage of financial, technical, and human resources’. We think that this justification applies equally to some services that are delivered in a non-hospital setting, as they require no less planning, funding, or careful management than ‘hospital’ services. Consideration should be given to the drive in many Member States, including the UK, to move more services from being delivered in hospital to being delivered in a primary care setting.

15. European Court of Justice case law has stated that the decision as to whether a patient faces ‘undue delay’ in accessing services should be based on ‘an objective medical assessment of the patient’s medical condition, the history and probable cause 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’ (*Watts*, para. 119). The UK government is firmly of the view that this is a sufficient definition of the factors that need to be taken into account when assessing ‘undue delay’. Any attempts to define the concept of ‘undue delay’ further will contradict the logic of the ECJ case law, which is that it should always be clinically assessed

³³ The fact or quality, on the part of communities, etc., of being perfectly united or at one in some respect, esp. in interests, sympathies, or aspirations. (Oxford English Dictionary)

against the need and circumstances of the individual. (mechanisms for review/appeal, procedures – EU framework)

16. Any proposals on patient mobility should develop the existing case law on this point. In line with the key principles put forward in paragraph 8 of this response, the most effective way to do this would be to state the principle that prior authorisation systems are justified for treatments that are assessed on referral in the home Member State.

17. The basic principles of the system by which patients can access medical treatment in another Member State by way of entitlements under Article 49 of the Treaty differ from the principles of the system of referrals under Regulation 1408/71 (E112 referrals). This has the potential to cause confusion, particularly to patients (eg the reimbursement principles for the two systems are entirely different). One simple way of addressing this confusion for the circumstances where patients ask to go abroad would be to make the use of the E112 referral system optional for Member States. In the long term, the principles developed in the Court's case law (eg that reimbursable costs for mobile patients are restricted to the level that the treatment would have cost in the home Member State) seems a more sensible and sustainable basis to handle requests to go abroad for treatment.

What work can usefully be done through non-regulatory co-operation?

19 The UK believes that it would be appropriate to consider developing further the work of groups such as the Commission's High Level Group on Health Services and Medical Care, so that there will be a standing mechanism of Member State experts who can advise the EU institutions on the implications of EU activity and proposed legislation for the health systems of the EU.

20. The UK believes that there is much benefit to be gained from EU-level networking of clinical and health management professionals and from facilitating the exchange of good clinical practice.

21 Cross-border commissioning of services may be a fruitful area for developing information sharing systems, in order to promote intergovernmental co-operation.

This kind of information sharing will also help to promote continuity of care in patient mobility, which is a key concern.

What sort of legal instrument would be appropriate?

26 It is important that any proposed solution is proportionate to the demand from patients, which may grow. Any system that is put in place to facilitate patient mobility needs to be both sustainable and flexible enough to take account of long-term developments.

27. In the context of 27 different health systems, and in accordance with the statement of Values and Common Principles that EU Health Ministers endorsed in June 2006, the detailed implementation of any systematic approach to patient mobility will differ. The key aim for any EU-level proposal should be to ensure that such implementation does in fact happen, in accordance with the key principles listed in paragraph 8. Any proposals should be based on these high-level principles, and should not attempt to construct an overly-detailed system that would prove unwieldy or unworkable.

28. There would be very limited value in a proposal that simply transposes ECJ case law into legislation. There are real uncertainties that arise from the existing case law that need to be addressed, for example, the question of ‘hospital’ and ‘non-hospital’ care. Clarifying these uncertainties is in the interests of both citizens and those planning and managing services. (doesn’t give very much to citizens/patients – very self centred)

House of Commons Session 2006-07 European Standing Committee EC Action on Health Services Tuesday 16 January 2007. Published on the Internet.

The Minister of State, Department of Health, Ms Rosie Winterton:

Recent European Court judgments have created some legal uncertainty in health matters, which is unhelpful to Member States. (negative) The communication looks broadly at areas where non-regulatory co-operation – for example in the sharing of best practice between doctors in different EU countries – can be of value to Member State Governments’ work. Last year, the ECJ delivered its verdict in the case of Mrs Watts, who had gone to France to have a hip replacement rather than wait to have it done on the NHS. She is now claiming the cost of the operation from the NHs. Without deciding whether she is entitled to have her costs refunded – the ECJ judgment confirmed that the legal principles of patient mobility developed in previous cases before the ECJ apply to the NHS as well as to health care systems based on a system of social insurance.

Those principles give NHS patients the right in certain limited circumstances to go abroad specifically to seek medical treatment at the expense of the NHS.

That should obviously be distinguished from the arrangements that have existed for many years whereby UK citizens can receive medical treatment that becomes necessary while traveling in the EU for work or on holiday, or while living in another EU Member State. During the past year, the services Directive passed through the Council and the European Parliament. In the course of discussion, health care was excluded from the scope of the Directive. That was a key negotiating point because we thought that it was inappropriate to treat health care in the same way as any other service industry. We and Member States throughout the EU, and the European Parliament felt that it should be considered as a sector with its own specific features and importance.

However, the exclusion of health care from the scope of the Services Directive does not exclude it from the application of the provisions of the European Treaty and the law derived from it. The current legal situation, as defined by ECJ case law, is unhelpful and contains many areas of ambiguity. For example, it is not clear whether Member States can require a patient seeking non-hospital treatment in another Member State to seek authorisation from their local health care fund – in the UK, that would be the local primary care trust – before going for treatment. There is also a lack of clarity about who should take overall responsibility for the well-being of a patient who goes abroad to seek treatment of their own accord, but who suffers medical complications from clinical negligence?

The main driver of the law so far has been the cases in the European Court of Justice. We feel that it is inappropriate for the law to develop without appropriate political input, and that is a view shared by other Member States. Should Member States and the EU institutions fail to take action in that area, the law will continue to develop through individual cases that are brought before the European Court of Justice, rather than through due political process.

As a result, last year the European Council of Health Ministers issued a statement of values and common principles. That was an important stake in the ground for the Member States, and has helped to set the tone for the discussion that has followed. Briefly, the statement emphasized that Member States have the responsibility for managing their own health systems, in the manner of their choosing, and that any proposals at EU level must respect that fundamental point.

The Commission's communication is a logical development from the events noted above. It sets out the areas for discussion and debate among the Member States and with wider groups, such as the health professions, the European Parliament and patient groups. The Commission will publish a formal response on the consultation, probably within two or three months. We expect legislative proposals to follow some time in 2007. Any proposal will follow the co-decision procedure, which means that it will have to pass through and be agreed by both the Council of Ministers and the European Parliament. Any proposal will also be debated initially in the Council by Health Ministers.

In the consultation and the discussions that will follow, we shall work to protect the UK's interests. We shall argue that the following principles be reflected in any proposals. Any legislative proposal must be proportionate, and must not go beyond what is needed to resolve the specific problems that we face. Any proposal must also provide for a sustainable way of managing patient mobility. Member State referral processes must be respected; so, where a referral from a GP is needed to access a

service in the UK, patients should need a similar referral, from a British GP, to access that service in another EU Member State.

Determining what treatment is offered to patients is a matter for Member States to decide. Member States must be able to restrict the level of payment for treatment abroad to the cost of that treatment, if it was delivered in the UK. It must be the standards, governance and system of redress of the Member State where the treatment is carried out that apply. Member States can prioritise treating their own citizens above citizens of other Member States who travel to them specifically to receive medical treatment. That would permit Member States to manage patient mobility in a sensible and sustainable manner.

Robert Schutze, *Cooperative Federalism Constitutionalised: The Emergence of Complementary Competences in the EC Legal Order*, (2006) 31(2) *European Law Review*, 167

p. 179. The Maastricht Treaty granted a competence for health to the Community.

This competence grant had been a compromise between those Member States that did not wish to endow the federal level with an express mandate and those who wanted to 'centralise' health issues even further.³⁴ The introduction of the new competence was certainly no clear victory for a comprehensive European health policy. On the contrary, the competence was a prime illustration of the inter-governmental corset increasingly placed around Community competences: the sharp textual edges of the new provision constituted a tight constitutional frame designed to contain Community action that might otherwise have been based on Article 95 EC. The Amsterdam Treaty loosened the corset a little – after the BSE and CJD crisis had p. 180 demonstrated the European dimension of certain health threats even to the more skeptical defenders of state responsibility in this field. Today, we find the Community's competence for public health codified in a single Article that by itself forms Title XIII of the Treaty. Article 152 EC is the prototype of the new complementary competences and assembles (almost) all the novel constitutional techniques. It reads:

Public Health – Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight

³⁴ T.K.Hervey and J.V. McHale, *Health Law and the European Union*, Cambridge University Press, 2004, p. 74.

against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.
4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

P. 181. Article 152(4)(c) grants a 'general' public health competence to the Community. However, this competence is limited to the adoption of 'incentive measures' excluding any harmonisation of the laws and regulations of the Member States.

p. 182. It seems that the national 'pre-emption' of Community action will only be lifted, where the diverse national laws create genuine obstacles to intra-Community trade and/or distortions of competition. The Community would then be entitled to have recourse to Article 95 EC.

(Footnote 72) In Case C-376/98, *Federal Republic of Germany v European Parliament and Council of the European Union* (Tobacco Advertising), the Court clarified that Article 95 EC could not be used for a legislative measure the aim of which was the protection of public health. Article 95 EC must not be used to circumvent the express exclusion of harmonisation found in Article 152(4)(c) EC. A

‘health’ measure adopted under Article 95 EC must therefore ‘genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market’. A mere finding of disparities between national rules and of the abstract risk of obstacles to the exercise of fundamental freedoms or of distortions of competition’ would not be sufficient (at paras. 79 and 84)

In Article 152(5) the Treaty constitutionally recognises the ‘responsibility’ of the Member States for the organization and delivery of health services and medical care. This provision will not have any effect beyond the scope of Article 152 EC. Where harmonisation under Article 95 EC ... is necessary, the Community legislator can well enter into this field.

High Level Group on Health Services and Medical Care

The 2003 report of the patient mobility reflection process represented a political milestone by recognizing the potential value of European cooperation in helping Member States to achieve their health objectives. The Commission set out its response to the report of the reflection process in Communication COM (2004)301, 20 April 2004. The primary mechanism for taking forward the work set out in the Communication was to establish a High Level Group on health services and medical care, which Group started work in July 2004. It brings together experts from all the Member States and it works in seven main areas: Cross-border healthcare purchasing and provision; Health professionals; Centres of reference; Health technology assessment; Information and e-health; Health impact assessment and health systems; and Patient safety. The High level Group has also contributed to other work relevant to health services and medical care, including the open method of coordination on health care and long-term care as outlined in Communication COM(2004) 304, 20 April 2004, ‘Modernising social protection for the development of high quality, accessible and sustainable health care and long-term care: support for the national strategies using the open method of coordination’. The High level Group reports annually to the EPSCO Council (Employment, Social Policy, Health and Consumer Affairs).³⁵

³⁵ http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc-en.htm Documents of the High Level Group and its working groups are available on the Internet at http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_documents_en.htm

European Commission Health and Consumer Protection Directorate General,
Brussels, 10 October 2006. HLG/2006/8 FINAL

High Level Group on Health Services and Medical Care

Report on the work of the High Level Group in 2006

This is the third report of the High Level Group on health services and medical care. It summarises the main issues addressed by the High Level group, progress made in 2006 and orientation for future work. The work of the Group has been taken forward through six working groups, reporting regularly to the full High Level Group where all the Member States have been represented.

Cross-border healthcare purchasing and provision (including patient rights):

The work of the Group in 2006 has been focused on three main goals. First, the working group conducted a mapping exercise on information for patients on quality, safety and continuity of care and on patient rights and responsibilities and liability issues related to cross-border care. The results have shown that there is a wide variety in the way Member States provide information about cross-border care and their own systems. Conclusive information on the system for complaints and compensation was not available. The working group also aimed to gather data about trends and impacts of cross-border care. However, there is a serious lack of these data, and the group recommends that consideration be given to how to collect complete and comparable data regarding cross-border healthcare. Third, the working group aimed to provide further analysis of the financial impact of patient mobility. However, this proved impossible given the lack of data.

Patient Safety: the working group agreed on the utility of a comprehensive European framework for patient safety, bringing together the key elements of patient safety to support Member States in this area. The working group made the following recommendations:

Information to patients:

Member States might consider appointing a clearly defined contact point for patients that seek information about access to health care across borders.

The national or regional contact points could form a network in order to share experiences and information related to cross border care. The contact details of the participants in the network could be made available through the EU health Portal and

the Commission could provide assistance to the network by raising awareness about the EU legislation.

Principles of care:

Further work is needed to identify the existing procedures regarding complaints' processes, arrangements for handling liability issues and ways to get compensation but also on the differences in the provisions ensuring consent.

Data:

A clear and transparent dataset (numbers of patients, amount of money involved, and preferably the treatment received abroad) is essential to get a grasp of the much discussed issue of patient mobility. This collection of data should be done in relation to Regulation 1408/71, block purchasing and individual patient mobility.

Article 49 EC

Within the framework of the provisions set out below, restrictions on freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community other than that of the person for whom the services are intended.

Article 55

The provisions of Articles 45 to 48 shall apply to matters covered by this Chapter.

Article 46 EC

1. The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.
- 2.

Approximation of Laws

Article 95

1. By way of derogation from article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievements of the objectives set out in Article 14.

2. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.
3. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective
8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.
9. The harmonization measures referred to above shall, in appropriate cases, include a safe-guard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

Opinion of Advocate General Geelhoed delivered on 15 December 2005.

65. The Court has held that Article 49 EC precludes national rules which make the provision of services between Member States more difficult than the provision of services purely within one Member State. (*Smits and Peerbooms* para. 61) It has also determined that national rules which deter or even prevent insured persons from applying to providers of medical services established in another Member State constitute both for insured persons and service providers a barrier to the freedom to provide services (*Smits and Peerbooms* para. 69).

66. In the present case the restriction to persons insured under the NHS to receive medical services in a Member State other than the United Kingdom consists not so much in a concrete provision limiting the possibility of obtaining treatment abroad, but in the absence of a clearly defined procedure for considering applications for such treatment. The absence of such a procedure can indeed be explained by the way in which the NHS operates. Patients have no entitlement to receive treatment at any given time or location, but are dependent on clinical assessments made by care providers within the NHS. It is the NHS bodies which decide on the treatment which will be provided and when and where it will be provided. Persons requiring medical

care are diagnosed, then classified according to the seriousness of their complaint and, depending on that classification, are given a place on a waiting list. It would appear that in this respect the NHS bodies enjoy unlimited discretion.

67. Although it may be inherent to such a publicly financed and operated system that all decisions regarding medical treatment to be provided are taken by the system operators, this very fact implies that persons insured under that system are restricted in their possibilities of seeking treatment outside the system, as they have no certainty that the costs of that treatment will either be paid directly to the care provider or be reimbursed to them. To the extent that they wish to obtain medical services in another Member State, this constitutes a restriction of their freedom to receive services in another Member State.

69 Though it has been found above that the manner in which the NHS operates restricts persons insured under this system in their freedom to obtain medical services in other Member States, this does not mean that these persons enjoy an unrestricted right under Article 49 EC to travel to other Member States for this purpose. As the Court has recognized, member States may impose a prior authorisation requirement before assuming the financial burden of hospital treatment provided in other Member States to persons insured under their social security schemes. Such a requirement is considered as being both necessary and reasonable to ensure that there is sufficient and permanent access to a balanced range of high quality hospital treatment in the State concerned, to assist in controlling costs and to prevent wastage of financial, technical and human resources in an area in which financial resources are, by definition, limited. (*Smits and Peerbooms* paras. 78 to 80). The Court has acknowledged that if insured persons were at liberty, regardless of the circumstances, to go outside the system under which they are insured, all the planning within the system which is designed to guarantee a rationalized, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke. (*Smits and Peerbooms* para. 81).

70. However, the conditions attached to granting prior authorisation must also be justified by overriding considerations of the general interest and must satisfy the requirement of proportionality. ... In order for a prior administrative authorization scheme to be justified even though it derogates from such a fundamental freedom, it

must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily. Such a prior administrative authorisation scheme must likewise be based on a procedural system which is easily accessible and capable of ensuring that a request for authorization will be dealt with objectively and impartially within a reasonable time and refusal to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings. (*Smits and Peerbooms* para. 81).

71 Although the Court thus accepts that the Member States are competent to impose a prior authorization requirement as a precondition to persons insured under a public insurance scheme receiving hospital treatment outside that scheme and to them being reimbursed for the costs of those services, there are also indications in the case law that Member States may be obliged to take measures in order to facilitate the cross-border provision of medical services.

74 ... the more general principle laid down in Article 10 EC according to which the Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of their Treaty obligations and to facilitate the achievement of the Community's tasks. This principle can require a Member State to adopt particular measures aimed at facilitating the free movement of services where abstaining from taking such measures could lead to a situation which would be in contravention of its obligations under, in this case, Article 49EC.

75. More particularly, this obligation requires Member States to take positive action to prevent obstacles to free movement within the Community arising, as opposed to the simple repeal of provisions causing such problems. ... It also includes the obligation to ensure that a prior authorization requirement is based on a procedural system which satisfies the criteria identified by the Court and reproduced in point 70 above.

76. (applied to persons ordinarily resident in a Member State operating a national health service).

84. As regards waiting lists in particular, the Court in *Müller-Fauré I* explicitly rejected the possibility of a Member State relying not on the fear of wastage resulting from hospital overcapacity, but solely on the fact that such lists exist on national

territory without account being taken of the specific circumstances of the patient's medical condition. It observed that it had not been demonstrated that such waiting times are necessary for the purpose of safeguarding the protection of public health (*Müller-Fauré* para. 58). On the contrary, waiting times which are too long or abnormal are more likely to restrict access to balanced, high quality hospital care. Waiting lists, it noted, appear to be based mainly on considerations of a purely economic nature which cannot as such justify a restriction on the fundamental principle of freedom to provide services. *Müller-Fauré* para. 92).

85. As demand [for hospital services] is generally much greater than supply, waiting lists operate as an instrument for allocating resources with a view to making optimal use of hospital capacity. Though this makes perfect sense from the point of view of the rational management of resources, the (opportunity) cost of using waiting lists in this manner is delaying access of patients to hospital care. It is this latter aspect which the Court clearly had in mind in rejecting the mere existence of waiting lists as a ground for justifying a refusal to grant authorization for receiving treatment abroad.

86. There is, therefore, an inherent tension between, on the one hand, the inevitable existence of waiting lists and their role as an instrument for managing and allocating limited resources and, on the other hand, the interests of patients in receiving adequate and timely treatment. These two conflicting interests can only be reconciled in a manner compatible with the Court's case law if a number of conditions are imposed on the way in which waiting lists are managed. More specifically, waiting lists should not be confined to registering that a given patient is eligible for a given type of treatment with a given degree of urgency. They should be managed actively as dynamic and flexible instruments which take into account the needs of patients as their medical condition develops. This implies that a reassessment of the pathological condition should be able to result in treatment being provided more speedily. In addition, it is important that they should provide for a safety valve, for example by setting maximum waiting times which are reasonable in the light of the medical condition of the persons concerned and beyond which extra efforts should be undertaken to guarantee immediate treatment. Moreover, in the interest of transparency, decisions regarding the treatment to be provided and when that is likely

to be should be taken on the basis of clear criteria restricting the discretionary power of the decision-making body.

88. ...Community law requires the Member States to make the necessary adjustments to their social security systems in order to facilitate the achievement of the fundamental freedoms of the EC Treaty. This may be deemed to include sufficient flexibility within the NHS planning system to accommodate applications for treatment abroad in certain circumstances.

90. Compatibility with Community law of a prior authorization requirement depends on whether the criteria applied in this context are themselves justified. As the only criterion which at present applies within the NHS context is whether treatment can be provided within NHS Plan targets, and as these do not take the individual needs of patients sufficiently into account, the authorization procedure in its present form is incompatible with Article 49 EC.

92. ... Where conditions on granting authorization to receive hospital treatment in another Member State are designed to guarantee the financial stability of the national health system, considerations of a purely budgetary or economic character cannot justify a refusal to grant such authorisation.