OPINION OF ADVOCATE GENERAL SHARPSTON
delivered on 15 July 2010[1]

1. Judgments of the Court concerning the application of the internal market rules to health care services[2] have been controversial. Often they raise issues of constitutional and substantive importance. They demonstrate the potentially disruptive effects on different national social welfare systems of the decision to bring essential and publicly organised services within the European Union's free movement provisions.[3]

2. The present infringement proceedings are no exception. The Commission's first ground of complaint against France alleges a failure to fulfil obligations under Article 49 EC[4] in as much as reimbursement for medical services provided outside a hospital setting requiring the use of major medical equipment[5] is subject to the grant of prior authorisation. The second ground of complaint alleges that the French authorities have failed to introduce specific legislation granting a patient insured under the French social security system additional reimbursement in the circumstances set out in paragraph 53 of the judgment in *Vanbraekel and Others* ('*Vanbraekel*').[6]

3. *Vanbraekel* concerned the basis for calculating the amount to be reimbursed to a patient insured under the Belgian social security system who had received medical treatment in a hospital in France. The question was whether the patient should be reimbursed by the Belgian insurance fund according to the amount which would have been reimbursed under the French legislation (FRF 38 608,99) or the level of reimbursement under the Belgian legislation (FRF 49 935,44).[7] The Court

1 — Original language: English.

2 — See, for example, Case C-120/95 *Decker* [1998] ECR I-1831 (free movement of medical products) and Case C-158/96 *Kohll* [1998] ECR I-1931 (freedom to provide services).

3 — See V.G. Hatzopoulos, 'Killing National Health and insurance systems but healing patients? The European Market for health care services after the judgments of the ECJ in Vanbraekel and Peerbooms', *Common Market Law Review* 2002, p. 683, and C. Nedwick, 'Citizenship, free movement and health care: cementing individual rights by corroding social solidarity', *Common Market Law Review* 2006, p. 1645.

4 — See now Article 56 TFEU.

5 — The French expression in the declaration sought by the Commission is 'équipements matériels lourds'. I shall use the expression 'major medical equipment' throughout this Opinion to express that concept.

6 — Case C-368/98 [2001] ECR I-5363.

7 — Approximately EUR 6 000 and EUR 7 680 respectively.

held that since Article 22 of Regulation No 1408/71 [8] did not regulate this issue, the matter should be considered under Article 49 EC. [9] The Court considered the fact that national law did not guarantee a right to additional reimbursement to be an unjustified restriction on the freedom to provide services [10] and set out, in paragraph 53 of its judgment, the circumstances in which patients are eligible for such additional reimbursement. [11]

States who are established in a State of the Community other than that of the person for whom the services are intended.'

5. Article 55 EC applies the public health derogation from freedom of establishment contained in Article 46 EC to the provision of services under Article 49 EC.

Community legislation

4. *Article 49 EC*

Regulation No 1408/71

The first paragraph of Article 49 EC provides: '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

6. Regulation No 1408/71 ('the Regulation') is not directly at issue in the present proceedings. However, it is necessary to bear it in mind in order to understand the EU legislative framework. The Regulation aims to ensure that workers moving within the EU continue to receive social and health care benefits (see in particular the fifth and sixth recitals). The Regulation follows the principle that social security remains a domain reserved to Member States' competence. It is therefore not a harmonising measure, but merely seeks to establish a degree of coordination by making provision for fundamentally different systems to work together so as to secure minimal

8 — Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, English special edition: Series I chapter 1971(II), p. 416. The regulation was then amended further. At the material time, the latest changes were those to be found in Regulation (EC) No 629/2006 of the European Parliament and of the Council of 5 April 2006, OJ 2006 L 114, p. 1 (a consolidated version was published in OJ 1997 L 28, p. 1).

9 — At the time of the decision in *Vanbraekel*, the relevant provision was Article 59 of the EC Treaty.

10 — See *Vanbraekel*, cited in footnote 6 above, paragraphs 43 to 52.

11 — See point 43 below.

social and health care benefits.[12] Article 22(1)(c) requires prior authorisation for medical treatment received outside the Member State where the patient is insured (a fact that does not preclude the patient from relying on Article 49 EC).[13] Article 36 sets out the procedure for reimbursement between the institutions of the State where the insured person is affiliated and those of the State where medical services are provided.

The national framework

The Code de la sécurité sociale

7. Decree No 2005-386 of 19 April 2005 introduced Articles R.332-3 and R.332-4 into the Code de la sécurité sociale (the French Social Security Code). Within the section dealing with medical treatment provided outside France, Article R.332-3 states: 'Health insurance funds shall reimburse the cost of treatment given to insured persons and to those entitled under them in a Member State of the European Union or party to the Agreement on the European Economic Area, under the same conditions as if the treatment had been received in France, subject to the proviso that the amount reimbursed may not exceed the total sum paid out by the insured person and subject to the adjustments provided by Articles R.332-4 to R.332-6.'

8. Article R.332-4 provides:

'Except in the case of unexpected treatment, health insurance funds may not, without prior authorisation, reimburse the cost of hospital treatment or treatment requiring the use of [major medical equipment] referred to at section II of Article R.712-2 of the public health code that is provided to insured persons and to those entitled under such funds in another Member State of the European Union or party to the Agreement on the European Economic Area …'

9. The prior authorisation referred to in Article R.332-4 may be refused where either of the following conditions applies: the proposed treatment is not one that is reimbursed under the regulations applicable in France; or treatment that is identical or equally effective can be obtained without undue delay in France, taking into account the patient's condition and the likely development of his illness. Article R.332-4 also sets out the process by which a request for prior authorisation may be made. Essentially, patients are required to apply to the health insurance fund to which

12 — See Case 100/78 *Rossi* [1979] ECR 831, paragraph 13.

13 — See Case C-372/04 *Watts* [2006] ECR I-4325, paragraphs 46 to 48.

they are affiliated; and any decision refusing prior authorisation must be reasoned and is subject to appeal.

The Code de la santé publique

10. Article L.6121-1 of the Code de la santé publique (the French Public Health Code), in the version applicable at the relevant time, sets out the objectives regarding public health care, which include taking account of the need to plan for the allocation of resources to ensure public access to health services. Article L.6122-1 states: 'Projects relating to the creation of any healthcare establishment, the creation, conversion and merging of healthcare services, including alternatives to hospitalisation, and the installation of [major medical equipment] shall require prior authorisation by the regional hospital authority. The list of healthcare services and [major medical equipment] subject to authorisation shall be laid down by decree of the Council of State.'

11. Article L.6122-14 defines equipment that falls within the scope of the list as: '… movable equipment intended either for diagnosis, treatment or functional rehabilitation in the event of injury, illness or pregnancy, or for data processing, the use of which imposes particular constraints in terms of installation and operation, or is likely to give rise to an excessive number of medical procedures.'

12. The list of such equipment is set out in Article R.6122-26 (corresponding to the former section II of Article R.712-2 of that code), which provides: 'The following [major medical equipment] requires prior authorisation:

1. Scintillation camera with or without positron emission coincidence detector, emission tomography or positron camera ("PET scanner"); [14]

2. Nuclear magnetic resonance imaging or spectrometry apparatus for clinical use; [15]

3. Medical scanner; [16]

14 — A nuclear medical imaging technique which produces a 3D image or picture of functional processes within the body.

15 — The best-known medical application of this apparatus (also known as magnetic resonance imaging apparatus or MRI scanner) is to visualise the detailed internal structure of the body. It is especially useful in neurological, musculoskeletal, cardiovascular and oncological imaging.

16 — An apparatus that uses X-rays to enable the study of anatomical structures.

4. Hyperbaric chamber; [17]

5. Cyclotron for medical use.' [18]

13. The French authorities have issued three circulars to explain the position in national law regarding the reimbursement of the costs of medical treatment for persons insured under the French social security scheme who receive medical care in another Member State or within the European Economic Area ('EEA') and the requirement to obtain prior authorisation for medical treatment received abroad involving the use of major medical equipment. [19]

14. Circular DSS/DACI/2003/286 explains that persons insured under the French social security scheme may request the additional reimbursement set out in *Vanbraekel*.

15. Circular DSS/DACI/2005/235 states: 'Decree No 2005-386 of 19 April 2005 relative to payment for treatment received outside France completes the integration into national law of Community case-law relating to freedom to provide services and the free movement of goods in the area of medical care. …' The circular explains that requests for prior authorisation should not systematically be refused by the competent authorities, but only where the conditions in Article R.332-4 of the social security code apply. [20]

16. Circular DSS/DACI/2008/242 confirms that the additional reimbursement referred to in *Vanbraekel* shall be available to insured persons. It notes that, although insurance providers are to apply the Court's case-law, there are obstacles to calculating the amount of the additional reimbursement (such as the lack of a common frame of reference for comparing the different cost of health care throughout the Member States), but nevertheless encourages the competent authorities to continue to process applications for the additional reimbursement.

17 — An apparatus initially used to treat disorders suffered by divers, such as decompression sickness. The chambers are often used in a hospital setting, but may also be used in a patient's home. They are used in the treatment of various conditions, such as cerebral palsy; and are also recommended by some practitioners for the treatment of tinnitus.

18 — An apparatus used to treat cancer. For example, ion beams from cyclotrons can be used in proton therapy to penetrate the body and kill tumours whilst minimising the damage to surrounding healthy tissue.

19 — Circular DSS/DACI/2003/286 of 16 June 2003, circular DSS/DACI/2005/235 of 19 May 2005 and circular DSS/DACI/2008/242 of 21 July 2008, which modified circular DSS/DACI/2005/235.

20 — See point 9 above.

Background and pre-litigation procedure

17. On 18 October 2006 the Commission issued a letter of formal notice raising three grounds of complaint. In the light of the French authorities' reply on 1 March 2007 the Commission was satisfied that French legislation did require the administration to issue a formal acknowledgement of receipt of a request from the hospital authorities of another Member State confirming that prior authorisation for care had been granted, and therefore dropped that ground of complaint.

18. The French Government did not contest the Commission's other two grounds of complaint. Indeed, the French authorities indicated that they intended to amend the Social Security Code so as to address the complaints concerning the prior authorisation requirement for treatment involving major medical equipment and the lack of specific legislation to implement the *Vanbraekel* ruling.

19. On 23 October 2007, the Commission issued a reasoned opinion in respect of those two remaining grounds of complaint. In their reply of 13 December 2007, the French authorities again indicated that they intended to amend their legislation in order to comply with the Commission's reasoned opinion. In a further letter of 28 July 2008, the French authorities reiterated their intention of removing the requirement to obtain prior authorisation and informed the Commission of the text of circular DSS/DACI/2008/242 clarifying payment of the additional reimbursement.

20. Meanwhile, however, on 2 July 2008 the Commission had adopted a proposal for a directive on the application of patients' rights in cross-border health care ('the Commission's proposal'). [21]

21. The French authorities reviewed their position in the light of that proposal and decided to contest the infringement proceedings.

22. The Commission therefore introduced the present action on 25 November 2008, asking the Court to declare that:

— by making, pursuant to Article R.332-4 of the Social Security Code, reimbursement for medical services received in another Member State that are provided in a non-hospital setting and that require the use of

21 — The Council agreed on the draft directive concerning patients' rights in cross-border health care on 8 June 2010.

major medical equipment listed in part II of Article R.6122-26 of the Public Health Code subject to the grant of prior authorisation; and

— by failing to provide, in Article R.332-4, or in any other provision of French law, for the possibility of granting a patient – insured under the French social security system – additional reimbursement in the circumstances set out in paragraph 53 of the judgment of 12 July 2001 in Case C-368/98 *Vanbraekel*,

the French Republic has failed to fulfil its obligations under Article 49 EC; and

— order the French Republic to pay the costs.

23. The Commission, France, the Spanish and the United Kingdom Governments made oral submissions at the hearing on 2 March 2010. The Finnish Government made written observations, but did not present oral argument to the Court.

Assessment

Preliminary remarks

24. I shall begin by considering the French authorities' submission that their change of approach does not have procedural implications for the action before the Court. I shall also examine briefly the Court's case-law on the burden of proof in infringement proceedings.

25. According to the Court's settled case-law, the proper conduct of the pre-litigation procedure is an essential guarantee required by the Treaty in order to protect the rights of the Member State concerned and to ensure that any contentious procedure will have a clearly defined dispute as its subject-matter. [22] Once the subject-matter is defined, the Member State has the right to raise all of the pleas available to it in order to defend itself. Moreover, there is no rule of procedure which requires a Member State to put forward during the pre-litigation phase of an infringement procedure all of the arguments in its defence.

22 — See Case C-414/97 *Commission* v *Spain* [1999] ECR I-5585, paragraph 19; Case C-34/04 *Commission* v *Netherlands* [2007] ECR I-1387, paragraph 49; and, more recently, Case C-274/07 *Commission* v *Lithuania* [2008] ECR I-7117, paragraph 21.

26. The Commission's complaints are clearly set out in the pre-litigation procedure. There has never been any ambiguity or uncertainty in the Commission's position. Accordingly, no prejudice to France arises as a result of the way in which events have evolved. By the same token, since those rules exist to protect the defendant Member State (not the Commission), there is nothing to prevent France from changing its position.

27. Thus, the position of the Commission and the defendant Member State in infringement proceedings is not the same. In particular, the rule that the Commission cannot introduce new grounds of complaint at the contentious stage does not apply *mutatis mutandis* to the Member State in relation to its defence. [23]

28. I therefore agree with the French authorities that they are not prevented by any rule of procedure from defending the action and contesting both grounds of the Commission's complaint.

23 — See *Commission* v *Spain*, cited in footnote 22 above, paragraphs 18 and 19.

29. Regarding the burden of proof, it is clear from the Court's case-law that the Commission must prove the allegation that the obligation at issue has not been fulfilled and place before the Court the information necessary to enable it to determine that question. [24]

30. Accordingly the onus of proof is, in the present case, upon the Commission to prove that a particular national measure (as regards the first ground of complaint), or the lack of a particular national measure (as regards the second ground of complaint) constitutes an obstacle to the freedom to provide services within the meaning of Article 49 EC. [25]

The substance of the action

31. I shall deal first with the Commission's second ground of complaint (implementation of the ruling in *Vanbraekel*), before turning to consider the requirement for prior authorisation for non-hospital medical services dispensed in another Member State requiring the use of major medical equipment.

24 — See Case C-159/94 *Commission* v *France* [1997] ECR I-5815, paragraph 102; Case C-55/99 *Commission* v *France* [2000] ECR I-11499, paragraph 30; and Case C-434/01 *Commission* v *United Kingdom* [2003] ECR I-13239, paragraph 21. See, more recently, Case C-532/03 *Commission* v *Ireland* [2007] ECR I-11353, paragraph 29.

25 — See Case C-507/03 *Commission* v *Ireland* [2007] ECR I-9777, paragraphs 33 to 35.

The second ground of complaint — implementation of the ruling in Vanbraekel

32. Within the Commission's second ground of complaint two separate issues fall to be assessed. First, has the Commission discharged the burden of proof incumbent upon it in infringement proceedings and demonstrated that the lack of a particular national measure constitutes an obstacle to the freedom to provide services guaranteed by Article 49 EC? Second, even if there is no actual evidence of such an obstacle, is a Member State nevertheless required to take the positive step of introducing specific legislation to comply with a judgment of the Court that involves the interpretation of a directly effective Treaty article?

33. The starting point for considering both issues may be described relatively simply. The Commission acknowledges that there is no difference of opinion between itself and France regarding the interpretation of the *Vanbraekel* case-law and the payment of the additional reimbursement. The Commission accepts that circular DSS/DACI/2008/242 correctly reflects that interpretation. There is, moreover, no legislative provision in France which prevents the payment of the additional reimbursement.

34. For their part, the French authorities openly admit that they have not introduced legislation to apply the Court's judgment in *Vanbraekel*. They rely on the administrative circulars DSS/DACI/2005/235 and DSS/DACI/2008/242, taken in conjunction with the fact that individuals are able to rely on their directly effective rights under Article 49 EC.

35. The Commission has not suggested that a persistent administrative practice exists whereby payment of the additional reimbursement is not applied by the French authorities. Nor has the Commission adduced evidence of specific cases where payment of the additional reimbursement has been refused by the French authorities and thus *Vanbraekel* has not, in practice, been applied. There is no material before the Court indicating that patients insured under the French system are dissuaded from seeking medical treatment in other Member States or the EEA, because they might not receive the additional reimbursement if they come within the circumstances outlined in *Vanbraekel*.

36. It seems to me that the Commission has thus failed to demonstrate that the lack of specific legislation amounts to a restriction on the freedom to provide services within Article 49 EC. If the only issue were whether the Commission had discharged the burden of proof in infringement proceedings, I would therefore conclude that the Commission's

second ground of complaint should be dismissed.

37. However, the Commission's second ground of complaint also raises the novel question of principle as to whether a Member State can comply with a preliminary ruling of the Court concerning the interpretation of the EC Treaty only by introducing specific legislation to give effect to that judgment.

38. France contends that Article 49 EC is directly effective and therefore does not require specific transposition into domestic law. It follows that the Court's ruling in *Vanbraekel*, which involved the interpretation of Article 49 EC, has the same legal effect as an EU regulation within the legal systems of the Member States. France submits that Article R.332-3 of the Social Security Code can be interpreted to cover payment of the additional reimbursement as envisaged in *Vanbraekel*. The only action required was therefore the adoption of appropriate administrative circulars to clarify the position at national level. [26] France refers to three actual cases where the additional reimbursement has been, or is in the process of being, paid; and stresses that the French courts have followed *Vanbraekel* by ruling that the additional reimbursement must be paid. [27]

39. The Commission contends that Member States cannot invoke direct effect where national measures are incompatible with Article 49 EC. The circulars adopted by France create a situation of ambiguity and legal uncertainty. The Commission concludes that France is under a positive duty to adopt specific legislation to implement *Vanbraekel* in national law.

40. The Spanish Government supports France. It contends that a ruling of the Court is not analogous to a directive; and that a Member State can give effect to a judgment of the Court by means other than enacting specific legislation.

41. I disagree with the Commission's conclusion.

42. It is well established in the Court's case-law that certain Treaty articles are clear, precise and sufficiently unconditional to be invoked before national courts by a natural or legal person without the need for further

26 — The French authorities refer to the circulars mentioned in points 14 to 16 above.

27 — See the judgment of the Court of Cassation (France) (Social Chamber) of 28 March 2002 in *Magnan* v *CPAM des Hauts de Seine*.

implementing provisions – they are directly effective. [28] A directly effective Treaty provision has such effect between individuals and the State.

43. In *Vanbraekel* the Court interpreted Article 49 EC as meaning that '…, if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the legislation in force in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution.' [29]

44. In my view there is no doubt that Article 49 EC, as interpreted by the Court in *Vanbraekel*, confers directly effective rights on individuals, entitling them to an additional reimbursement of the costs of health care.

45. It is clear that there are circumstances in which, following a ruling of the Court, Member States must act to amend or repeal existing national measures that are incompatible with EU law in order to comply with their obligations under the Treaties. Three specific examples come to mind.

46. First, a Member State may originally have misunderstood the extent of its obligations under a directive and may, in consequence, have implemented that directive incorrectly. Following a ruling of the Court (whether in a direct action or a reference for a preliminary ruling), the Member State concerned may have to legislate to rectify the position. [30]

47. Second, the national legislation at issue may have a positive element that contradicts a directly effective Treaty article. In such circumstances, the Member State will have to legislate to remove the contradiction and give effect to the Court's ruling. [31]

28 — See, for example, Case 13/68 *Salgoil* [1968] ECR 453 (Article 28 EC, free movement of goods); Case 41/74 *Van Duyn* [1974] ECR 1337 (Article 39 EC, free movement of workers); Case 2/74 *Reyners* [1974] ECR 631 (Article 43 EC, freedom of establishment); Case 33/74 *van Binsbergen* [1974] ECR 1299 (Article 49 EC, freedom to provide services).

29 — See *Vanbraekel*, cited in footnote 6 above, paragraph 53.

30 — See, for example, Case C-58/89 *Commission* v *Germany* [1991] ECR I-4983, paragraphs 13 to 16, and Case C-60/01 *Commission* v *France* [2002] ECR I-5679, paragraphs 25 to 28.

31 — See, for example, Case C-358/98 *Commission* v *Italy* [2000] ECR I-1255, paragraph 17.

48. Third, the national legislation at issue may be ambiguous or unclear and there may be evidence to demonstrate that that has created (or risks creating) a situation of legal uncertainty. In such circumstances, the legal position will again require clarification through legislation. [32]

49. The position in the present case does not correspond to any of the three situations outlined above. The Court has given a ruling in *Vanbraekel* interpreting a directly effective Treaty provision. There is no contradictory national legislation. The competent national authorities have been notified of the circumstances in which the additional reimbursement should be made. Such evidence as has been placed before the Court suggests that: (a) individuals in France are aware of their right to claim the additional reimbursement; (b) such claims have indeed been submitted to the competent authorities; and (c), where disallowed by the competent authorities, it is possible to pursue a claim in this regard successfully before the French courts. [33]

50. It is true that the Court has consistently held that the right of individuals to rely on directly effective provisions of the Treaty before tional courts is only a minimum guarantee and is not sufficient in itself to ensure the full and complete implementation of the Treaty. [34] It is likewise established that, in order to guarantee legal certainty, Member States must create a legal situation that is sufficiently precise, clear and foreseeable to enable individuals to ascertain their rights and obligations. [35]

51. I accept that enacting specific legislation is one way to ensure that EU obligations are given effect at national level. Such an approach may also facilitate the Commission's task of monitoring Member States' compliance with EU law (although the mere fact that legislation exists does not always necessarily guarantee that an EU right has been implemented fully and effectively). However, I do not take the view that such obligations can be given proper effect *only* through legislation, in circumstances in which the EU obligation in question flows from a directly effective Treaty provision as interpreted by a ruling of the Court and there is no conflicting

32 — See, for example, Case C-129/00 *Commission* v *Italy* [2003] ECR I-14637, paragraph 33.

33 — See *Magnan,* cited in footnote 27 above.

34 — See Case 168/85 *Commission* v *Italy* [1986] ECR 2945, paragraphs 9 to 11; Case C-120/88 *Commission* v *Italy* [1991] ECR I-621, paragraph 10; and Case C-119/89 *Commission* v *Spain* [1991] ECR I-641, paragraph 9. See also Joined Cases C-46/93 and C-48/93 *Brasserie du Pêcheur and Factortame* [1996] ECR I-1029, paragraph 20.

35 — See Case C-456/08 *Commission* v *Ireland* [2010] ECR I-859, paragraph 61 and the case-law cited there.

national legal provision and no evidence that a situation of legal uncertainty pertains that requires to be remedied.

52. I therefore conclude that the French authorities are not obliged to introduce into national law a specific provision requiring that a patient insured under the French social security system be granted additional reimbursement in the circumstances set out in paragraph 53 of *Vanbraekel*. The Commission's second ground of complaint should accordingly be dismissed.

The first ground of complaint

Is the requirement for prior authorisation a restriction under Article 49 EC?

53. The Commission contends that the requirement in French law to be granted prior authorisation in order to obtain reimbursement for non-hospital medical services involving the use of major medical equipment received in another Member State is a restriction under Article 49 EC.

54. It is by now well established in the Court's case-law that medical services fall within the scope of Article 49 EC. [36] As early as *Luisi and Carbone* [37] the Court held that the Treaty provisions cover recipients as well as providers of medical services and that the freedom for the recipient to move was the necessary corollary of the freedom for the service provider. [38] More recently the Court has stated categorically that medical activities fall within the scope of Article 60 EC (now Article 57 TFEU) and that there is no need to distinguish between care provided in a hospital environment and care provided outside such an environment. [39] It is also clear that a system whereby prior authorisation is required in order that a patient obtain reimbursement of the cost of hospital treatment in another Member State from the authorities of his own Member State constitutes, both for the patient concerned and for the service provider, an obstacle to the freedom to provide services. [40]

55. Accordingly, the condition making reimbursement of the cost of medical services for non-hospital treatment involving major medical equipment in another Member State

36 — See *Decker* and *Kohll*, both cited in footnote 2 above.

37 — Joined Cases 286/82 and 26/83 [1984] ECR 377, paragraph 16.

38 — See Case 186/87 *Cowan* v *Trésor Public* [1989] ECR 195, paragraph 17 and *Kohll*, cited in footnote 2 above, paragraph 29.

39 — See Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraph 53, and *Watts*, cited in footnote 13 above, paragraphs 86 and 87.

40 — See *Watts*, cited in footnote 13 above, paragraph 98.

or EEA State subject to prior authorisation by the French authorities constitutes a restriction on the freedom to provide services. [41]

Justification

56. The Court has already considered whether a requirement of prior authorisation for the provision of medical services delivered within the infrastructure of a hospital ('hospital medical services') can be justified. [42]

57. The Court examined three factors in its assessment of that question: first whether the overriding considerations in the general interest established in the Court's case-law apply and are capable of justifying obstacles to the freedom to provide such services; second, whether such a restriction falls within the derogations on grounds of public health under Articles 46 and 55 EC; and third, whether the requirement of prior authorisation is discriminatory.

58. The Court has held that the need to guard against the risk of seriously undermining the financial balance of the social security system is an overriding consideration in the general interest capable of justifying a restriction requiring prior authorisation. [43]

59. The Court has acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within the public health derogations in Articles 46 EC and 55 EC in so far as it contributes to the attainment of a high level of health protection. [44] Furthermore, the Court has acknowledged 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 a national territory is essential for public health and even the survival of the population. [45]

60. The Court has made it clear that in order to be justified, a system of prior authorisation must 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, to ensure that it is not used arbitrarily. [46] In this context, I take the Court's reference to 'non-discriminatory criteria' to mean criteria that do not discriminate unlawfully between comparable

41 — See *Kohll*, cited in footnote 2 above, paragraph 35.

42 — See *Watts*, cited in footnote 13 above, paragraphs 103 to 110 and the case-law cited there.

43 — See *Watts*, cited in footnote 13 above, paragraph 103 and the case-law cited there.

44 — See *Watts*, cited in footnote 13 above, paragraph 104 and the case-law cited there.

45 — See *Watts*, cited in footnote 13 above, paragraph 105 and the case-law cited there.

46 — See *Watts*, cited in footnote 13 above, paragraph 116.

cases in which prior authorisation is requested for treatment in another Member State. Thus, the actual requirement to obtain prior authorisation in order to receive treatment in another Member State involving major medical equipment is a restriction (which may not apply, in precisely the same way, to receipt of such treatment in France). In order for the requirement to be justified, the system surrounding its application must satisfy the test set out above (and, *at that stage*, any criteria applied must be applied in an objective and non-discriminatory way).

61. However, the Court has not yet considered the equivalent issues in relation to medical services provided outside a hospital setting ('non-hospital medical services').

62. The Commission submits as a matter of principle that the justification for a requirement of prior authorisation in order to obtain reimbursement for hospital medical services is intrinsically linked to the nature of such services. It argues that it follows from the costly nature of hospital medical services that there is a need to plan for their delivery. However, non-hospital medical services do not share the same characteristics as hospital medical services; therefore, a requirement of prior authorisation for non-hospital medical services cannot be justified. The Commission's proposal states that a requirement for prior authorisation should be limited to cases where there is evidence that patient migration (for example, to avoid waiting lists) is likely to undermine healthcare. [47]

63. The Commission has not challenged the content of the list of equipment in Article R.6122-26 and has not made any submissions addressing the question of whether the items listed should be considered to be major medical equipment.

64. France, supported by the Finnish and United Kingdom Governments, contends that the principles established in the Court's case-law in respect of prior authorisation for hospital treatment are transposable to non-hospital medical services involving major medical equipment. The acquisition and use of such equipment requires planning in order to ensure permanent and sufficient access to a balanced range of health care, irrespective of whether the equipment in question is located in a hospital or a clinic or indeed a general practitioner's surgery. The significant costs involved mean that the considerations at issue

47 — See COM(2008) 414 final, mentioned in point 20 above, point 7.3 of the explanatory memorandum, and recital 31 to the Commission's original proposal.

are analogous to those applied to the planning of hospital care and that it is essential to avoid wasting resources. France refers in particular to PET scanners which, in that Member State, may be installed inside or outside a hospital. [48] The French authorities also emphasise that Article R.6122-26 of the Public Health Code contains a limited list of equipment which is subject to prior authorisation. Finally, France relies on the fact that the Commission's proposal [49] provides (in Article 8) that healthcare which requires the use of 'highly specialised and cost-intensive medical infrastructure or medical equipment' falls within the definition of 'hospital care'.

65. As I understand it, prior authorisation is not being used in this instance solely as a tool to regulate patient migration, although that may be part of its function. Rather, its core purpose seems to be one that is fundamental to healthcare strategy. It is to enable the competent authorities to plan how to use their available resources to finance health services at the initial stage where resources, demographics, infrastructure, the deployment of equipment and personnel are assessed. Thus, the prior authorisation procedure enables the French authorities better to address the general question of allocating resources to the health service, as well as to manage a particular aspect of that service (namely, the effects of patient migration on the financial sustainability of the health and social security system).

66. The overriding considerations capable of justifying a restriction like a requirement of prior authorisation are based on the need for national authorities to plan the use of their resources for social security and health care in order to attain a high level of public health protection. [50] It is that that is crucial to the assessment of whether prior authorisation is justified, rather than whether treatment using major medical equipment is provided inside or outside a hospital.

67. The Court has already acknowledged that it is difficult to draw a distinction between hospital and non-hospital medical services. For example, certain services provided in a hospital might be equally capable of being provided in a clinic, a health centre or in a general practitioner's surgery. [51]

48 — The French authorities state that there are about 20 PET scanners in France, which can be installed either in a hospital or outside a hospital setting (for example, in a town clinic), provided that the appropriate facilities exist. The purchase cost of each machine is approximately EUR 2.6 million, the installation costs are approximately EUR 800 000 per machine and the annual operating costs approximately EUR 1.5 million. Each examination, which takes about an hour, costs approximately EUR 1 200.

49 — Referred to in point 20 above.

50 — See *Smits and Peerbooms*, cited in footnote 39 above, paragraph 76.

51 — See Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 75.

68. There may also be differences between Member States regarding the definition of hospital medical services and non-hospital medical services. The material placed before the Court in the present proceedings shows that there are, for example, such differences between France and the United Kingdom with regard to the location of PET scanners. [52] Indeed, the Commission acknowledges in its proposal [53] that there is no consistent definition of what constitutes hospital medical services (there referred to as 'hospital care') throughout the different health systems of the EU. [54]

69. I do not therefore consider that the location where the medical service is received can be determinative of whether a requirement for prior authorisation can be objectively justified.

70. The French and the Finnish Governments further rely on the Court's decision in *Hartlauer*. [55] Both governments contend that the Court's ruling in that case (that planning which requires prior authorisation for the establishment of new providers of outpatient services may be indispensable to ensure medical care adapted to the needs of the population) should be applied in the present proceedings.

71. *Hartlauer* concerned a German company that intended to establish a private dental clinic in Austria. The question before the Court required consideration of whether Articles 43 EC and 48 EC precluded national legislation making the setting-up of a health institution such as an independent outpatient dental clinic subject to the issue of a prior administrative authorisation. The Court acknowledged that establishments providing outpatient care, such as doctors' surgeries and outpatient clinics may, like hospitals, be the subject of planning. The Court stated: 'Planning which requires prior authorisation for setting up new providers of services may prove indispensable for filling in possible gaps

52 — In the United Kingdom there are 20 PET scanners which are used to treat patients and 3 further scanners that are used for research purposes. However, unlike the position in France (see footnote 48 above), all these scanners are located in hospital settings. There are also six mobile scanners which must be installed in a hospital in order to be used.

53 — COM(2008) 414 final, mentioned in point 20 above, point 7.3 of the explanatory memorandum. See also recital 30 and Article 8(2) of the Commission's original proposal.

54 — In its original proposal (point 7.3 in the explanatory memorandum), the Commission stated: 'The closest commonly-used definition of hospital care is that of inpatient care (meaning treatment that requires at least one night of stay in a hospital or clinic). For this reason, Article 8(1) introduces a minimum Community definition of hospital care on that basis. However, it may be appropriate to also consider certain other kinds of treatment as hospital care if that treatment requires use of highly specialised and cost-intensive medical infrastructure or medical equipment or involving treatments presenting a particular risk for the patient or the population. Article 8(1) therefore also stipulates that a regularly updated technical list of such treatments may be specifically defined by the Commission.'

55 — Case C-169/07 [2009] ECR I-1721.

in access to outpatient care and for avoiding the duplication of structures, so as to ensure medical care which is adapted to the needs of the population, covers the entire territory and takes account of geographically isolated or otherwise disadvantaged regions.' [56]

72. The present case differs from *Hartlauer* in as much as it concerns the freedom to receive services rather than freedom of establishment.

73. I readily accept that it would not be appropriate to permit a prior authorisation requirement to be applied to provision or receipt of medical services that required the use of standard, relatively inexpensive, equipment. However, the major medical equipment with which these infringement proceedings are concerned is far removed from (say) an ordinary x-ray machine. Such equipment is generically different from the equipment found in a (well-equipped) general practitioner's surgery. It is very expensive to acquire. It may need to be installed in a specific setting. It may also need to be used and maintained by suitably qualified and trained personnel.

74. It seems to me, on the one hand, that the acquisition, placement and use of such equipment involve planning considerations similar to those that are applied to hospital services. On the other hand, precisely because the expenditure required to finance such equipment is so significant, the issues behind provision of services can here readily be assimilated to those involved in freedom of establishment; and *Hartlauer* may reasonably be applied by analogy. Whichever approach is adopted, the essential justification for the prior authorisation requirement is the same. The ability to assess expenditure costs against finite resources is crucial to the competent authorities' decision as to what will constitute adequate provision of health care, so as to support the financial balance of the social security system and maintain a quality medical service open to all.

75. I therefore accept that the prior authorisation requirement is, in principle, justified.

Proportionality

76. Where the requirement for prior authorisation can be justified according to those overriding considerations it is nevertheless necessary to assess whether such a requirement is proportionate: that is, to check that it

56 — See *Hartlauer*, paragraphs 51 and 52.

does not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules. [57]

77. The French authorities have confined the requirement for prior authorisation to a restricted list of equipment, contained in Article R.6122-26 of the Public Health Code. Article R.332-4 of the Social Security Code further lays down the conditions that must be met if prior authorisation is refused and ensures that such decisions are subject to a right of appeal. In principle, the legislation therefore does not go beyond what is objectively necessary and the same result cannot be achieved by less restrictive rules.

78. It seems to me that the presence of most if not all of the following elements will tend to suggest that a requirement for prior authorisation *is* proportionate in respect of the use of specific items of equipment for the provision of non-hospital medical services.

79. First, the capital cost of the equipment in question is likely to be very considerable, requiring a substantial investment by the competent authorities. Second, the operating costs may be sufficiently significant to require separate provision within the relevant budget. Third, the equipment in question will probably be specialist equipment, in the sense of equipment that is dedicated to a particular (normally, elaborate) medical procedure or type of analysis. Fourth, it is likely to be equipment that is used only after the patient has been through some kind of preliminary screening process, rather than equipment that is used routinely for first stage diagnosis and/or treatment. Fifth, the equipment may well require suitably-trained staff to install, maintain and operate it.

80. Against that background, what of the equipment listed in Article R.6122-26 of the Public Health Code, that forms the subject-matter of the present action?

81. It seems to me that the French authorities have established that PET scanners are major medical equipment. These are expensive items of specialist machinery which need to be used by qualified, trained personnel. Patients require some form of preliminary medical assessment before being subject to a scan. I consider that it is proportionate to make the

57 — See Case C-205/84 *Commission* v *Germany* [1986] ECR 3755, paragraphs 27 and 29; Case C-180/89 *Commission* v *Italy* [1991] ECR I-709, paragraphs 17 and 18; Case C-106/91 *Ramrath* [1992] ECR I-3351, paragraphs 30 and 31; *Smits and Peerbooms*, cited in footnote 39 above, paragraph 75; and *Watts*, cited in footnote 13 above, paragraph 106.

reimbursement of the costs of service provision involving the use of PET scanners subject to the requirement of prior authorisation.

82. The Commission has not alleged in what way the other items listed are not major medical equipment whose inclusion in the list of equipment requiring prior authorisation is proportionate. [58] Therefore, the Court has no information before it on which to base a finding that those items should not be included in the list.

83. Whilst it is for the Member State, where doubts have been raised as to the proportionality of a particular measure, to explain why that measure is indeed proportionate, the burden of so doing passes to the Member State only once such doubts have been expressed. In the present instance, however, France cannot be expected to respond to an argument that has not been put to it. I therefore conclude that, in the present proceedings, there are no grounds for finding that the requirement for prior authorisation in respect of reimbursement for services provided using the remaining items of major medical equipment contained in the list in Article R.6122-26 of the Public Health Code is other than proportionate. [59]

84. It follows that Article R.332-4 of the Social Security Code, which makes reimbursement for non-hospital medical services requiring the use of the major medical equipment listed in Article R.6122-26 of the Public Health Code subject to the grant of prior authorisation, is objectively justified.

85. The Commission's first ground of complaint should therefore also be dismissed.

58 — Imaging apparatus or nuclear magnetic resonance spectrometer for clinical use; medical scanner; hyperbaric chamber and the cyclotron for medical use.

59 — See *Watts*, cited in footnote 13 above, paragraph 106 and the case-law cited there.

Conclusion

86. For the reasons set out above, I consider that the Court should dismiss the application, and (as requested by France and pursuant to Article 69(2) of the Court's Rules of Procedure) order the Commission to pay the costs.