OPINION OF ADVOCATE GENERAL TRSTENJAK delivered on 14 April 2011 [1]

Table of contents

I — Introduction ..... I - 10553

II — Legislative context ..... I - 10555

A — European Union law ..... I - 10555

B — National law ..... I - 10556

III — Pre-litigation procedure ..... I - 10557

IV — Procedure before the Court of Justice and forms of order sought ..... I - 10559

V — Main arguments of the parties ..... I - 10560

A — Provisions of Portuguese law ..... I - 10560

B — European Union law ..... I - 10562

VI — Legal assessment ..... I - 10565

A — Applicability of Article 49 EC ..... I - 10565

1. Law applicable ratione temporis ..... I - 10566

2. Scope ratione materiae ..... I - 10567

a) Competences of the European Union and its Member States in the field of health policy ..... I - 10567

b) Coverage of the national rules at issue ..... I - 10569

B — Restriction of the freedom to provide services ..... I - 10571

1. Possibility of reimbursing non-hospital medical expenses incurred in another Member State ..... I - 10572

1 — Original language of the Opinion: German. Language of the case: Portuguese.

2. Requirement of prior authorisation for 'highly specialised' medical treatment . . . . . I - 10574

3. Ineligibility for reimbursement in the case of 'other' medical treatments . . I - 10576

C — Justification of the restriction . . . . . I - 10578

1. Justification in the case of 'highly specialised' medical treatments . . . . . I - 10578

a) Maintaining the financial balance of the social security system . . . . . I - 10580

i) Legitimate justification . . . . . I - 10580

ii) Requirements for an authorisation procedure consistent with European Union law . . . . . I - 10584

— General . . . . . I - 10584

— Specific requirements of case-law . . . . . I - 10584

— Proportionality . . . . . I - 10586

b) Controlling the quality of healthcare services provided abroad . . . . . I - 10588

c) Interim conclusion . . . . . I - 10589

2. Justification in the case of 'other' medical treatments . . . . . I - 10591

a) Maintaining the financial balance of the social security system . . . . . I - 10591

i) Legitimate justification . . . . . I - 10591

ii) Proportionality . . . . . I - 10591

b) Supervising the quality of health services provided abroad . . . . . I - 10593

c) Interim conclusion . . . . . I - 10593

D — Definitive conclusion . . . . . I - 10593

VII — Costs . . . . . I - 10594

VIII — Conclusion . . . . . I - 10594

I — Introduction

1. The present case forms part of a long series of cases in which the Court has set out the limits imposed by European Union law on Member States' restrictions of cross-border receipt of healthcare services in the European internal market. In the exercise of the powers conferred on it to interpret European law (in this case the provisions of primary law on the freedom to provide services), the Court has, over time, developed a comprehensive case-law which has been further refined with each request for a preliminary ruling submitted to it by the courts of the Member States. Not least as a result of the comprehensive case-law in this respect it has been possible to clarify the right of European Union citizens to the most unimpeded possible cross-border receipt of healthcare services, which is generally known by the term 'patient mobility'.[2] To date the Court has in certain respects played a leading role in enforcing every person's right to access preventive health care and the right to benefit from medical treatment now conferred by Article 35 of the Charter of Fundamental Rights of the European Union.[3] The case-law has had the effect of making it possible to reduce restrictions in the form of national provisions impeding the establishment of an internal market for healthcare services in spite of a failure to act on the part of the Union legislature. This has given rise to certain important principles governing the conditions on which patients may, under the provisions on the freedom to provide services, receive medical treatment in another Member State and be reimbursed for the costs incurred for that treatment by the national sickness insurance funds to which they are affiliated.

2. The principles developed in this case-law can now be regarded as part of the European Union *acquis* which the Union legislature will have to take into account when drawing up a future 'Directive concerning the application

2 — See Opinion of Advocate General Geelhoed in Case C-372/04 *Watts* [2006] ECR I-4325, point 1.

3 — Article 35 of the Charter of Fundamental Rights of the European Union provides: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'

of patients' rights in cross-border healthcare'.[4] The actions for failure to fulfil obligations which the Commission has brought against a number of Member States, and which have thus far led to the judgments of 15 June 2010 (Case C-211/08 *Commission* v *Spain* [2010] ECR I-5267), 5 October 2010 (Case C-512/08 *Commission* v *France* [2010] ECR I-8833) and 27 January 2011 (Case C-490/09 *Commission* v *Luxembourg* [2011] ECR I-247), are evidence of the Union's efforts to enforce this right consistently in the interest of Union citizens.

3. In the present case the European Commission is bringing, pursuant to Article 226 EC,[5] an action for a declaration that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC, by not providing in national law for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation (EEC) No 1408/71,[6] and by making the reimbursement of non-hospital medical expenses subject to prior authorisation.

4. The present case revolves around the question whether the rules contained in Decree-Law No 177/92 objected to by the Commission, whose content must be examined in detail, can be classified in law as a restriction on the freedom to provide services within the meaning of Article 49 EC in so far as they lay down the requirement of prior authorisation by the competent authority to receive medical services abroad. If that question is answered in the affirmative in the light of the Court's case-law, the further question arises as to whether this restriction could be justified by

4 — This would appear to be the case thus far. In its Proposal of 2 July 2008 for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, COM(2008) 414 final., the Commission expresses its intention for the new directive to put in place a mechanism 'based on the principles of free movement and building on the principles underlying decisions of the Court of Justice'. A corresponding reference to the Court's case-law is to be found in recital 6 in the preamble to this proposal for a directive. It states that some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. As healthcare was excluded from the scope of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ 2006 L 376, p. 36) it is important 'to address these issues in a specific Community legal instrument in order to achieve a more general and effective application of principles developed by the Court of Justice on a case by case basis'. Position No 14/2010 of the Council with a view to the adoption of a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare adopted at first reading on 13 September 2010 (2010/C 275 E/01) (OJ 2010 C 275 E, p. 1) contains a large number of references to the Court's case-law. According to recital 8 in the preamble thereto, this directive aims inter alia 'to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States'.

5 — Since the Commission brought its action on the basis of Article 226 EC and claims that the Portuguese Republic is in breach of the EC Treaty, the legislative context for the purposes of this Opinion, in terms of European Union law, is that preceding the entry into force of the Treaty of Lisbon.

6 — 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 (OJ, *English Special Edition, Series I, Chapter 1971(II), p. 41*).

overriding reasons in the public interest, in which case the fact that the main proceedings relate solely to non-hospital treatment is relevant to the assessment.

II — Legislative context

A — *European Union law*[7]

5. Article 49(1) 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 States who are established in a State of the Community other than that of the person for whom the services are intended.’

6. The first sentence of Article 152(5) EC provides as follows:

‘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.’

7. Under 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, taking account where appropriate of the provisions of Article 18, and:

…

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

shall be entitled:

(i) to benefits in kind provided on behalf of the competent institution by the

7 — In accordance with the terms used in the EU Treaty and in the FEU Treaty, the expression ‘European Union law’ will be used as an umbrella expression for Community law and European Union law. Where individual provisions of primary law are relevant hereinafter, the rules which are applicable *ratione temporis* will be cited.

institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State;

2. … The authorisation required under paragraph 1(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned 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 the disease.'

B — *National law*

8. Decree-Law No 177/92 of 13 August 1992 governs individual aspects relating to healthcare abroad for persons insured under Portugal's national health system (SNS). Under the Decree-Law, it is for the Directorate-General responsible for hospitals to coordinate any referral for medical treatment abroad.

9. Article 1 defines the scope of the Decree-Law by providing as follows:

'(1) This Decree-Law shall govern highly specialised medical care abroad which cannot be provided in Portugal on account of a lack of technical resources or personnel.

(2) Persons insured under the national health system shall be beneficiaries of this care.

(3) Requests for referrals abroad made by private establishments shall not fall within the scope of this Decree-Law.'

10. Article 2 of the Decree-Law lays down the conditions for full reimbursement of medical costs (set out in Article 6):

'The following conditions must be satisfied before the benefits provided for in Article 6 can be granted:

(a) a comprehensive, favourable medical report, to be drawn up by the doctor treating the person concerned and approved by the competent service manager, must be submitted;

(b) that report must be approved by the medical director of the hospital in which the patient was treated;

(c) the Director-General for Hospitals must grant consent on the basis of an opinion of the technical service.'

11. Article 4 provides as follows with regard to the power of the Director-General for Hospitals to take decisions:

'It shall be for the Director-General for Hospitals to rule on the medical care abroad requested by the party concerned in accordance with the conditions laid down in Article 2.'

III — Pre-litigation procedure

12. On 12 July 2002 the Commission Directorate-General for the Internal Market sent the Member States a questionnaire on the compatibility of national law and practice with the Court's case-law on the applicability of rules of the internal market on healthcare services. The Portuguese authorities replied to the Commission's request for information on Portuguese legislation by letter of 17 January 2003.

13. On 28 July 2003 the Commission published a 'Report on the application of internal market rules to health services. Implementation by the Member States of the Court's jurisprudence'. [8]

8 — SEC(2003) 900.

14. On the basis of the information available to it the Commission sent a letter of formal notice to the Portuguese Republic on 18 October 2006 in which it expressed the view that the Portuguese Republic had failed to fulfil its obligations under Article 49 EC, as interpreted by the case-law of the Court, by making, in the relevant provisions of Decree-Law No 177/92 of 13 August 1992, the reimbursement of non-hospital medical expenses incurred in another Member State subject to prior authorisation, which is granted only on very restrictive conditions. The Commission also invited the Portuguese authorities to submit any observations they might have in that regard within two months, pursuant to Article 226 EC.

15. In their reply of 12 January 2007 the Portuguese authorities stated that it was 'difficult to imagine that healthcare services could be subject to the rules of the internal market' and that a Member State was authorised to enact legislation making reimbursement of non-hospital medical expenses subject to prior authorisation.

16. On 29 June 2007 the Commission sent the Portuguese authorities a reasoned opinion in which it informed them that the reply of 12 January 2007 contained no new aspects capable of generally calling into question the settled case-law of the Court. The Commission again took the view that the Portuguese Republic had failed to fulfil its obligations under Article 49 EC, as interpreted by the case-law of the Court, by maintaining in force those provisions of Decree-Law No 177/92 of 13 August 1992 which made reimbursement

of non-hospital medical expenses incurred in another Member State subject to prior authorisation. The Commission requested the Portuguese authorities to take the necessary measures to comply with the opinion within two months.

17. By letter of 4 September 2007 the Portuguese authorities replied that Decree-Law No 177/92 did not preclude the application of European Union legislation concerning Portuguese citizens' access to healthcare services within the European Union or even the fundamental freedoms of Union citizens, as enshrined in the Treaty establishing the European Union.

18. On 12 February 2008 the Portuguese authorities informed the Commission of their intention to examine the financial impact on the health system, which would take at least one month, particularly since the composition of the government had changed.

19. On 18 June 2008 the Commission invited the Portuguese authorities to provide it with information on the planned amendments to Decree-Law No 177/92 with a view to putting a swift end to the infringement of European Union law.

20. By letter of 24 July 2008 the Portuguese authorities reaffirmed the view which they had set out in their reply of 4 September 2007 that Decree-Law No 177/92 was not contrary to European Union law.

21. On 15 April 2009, the Commission sent the Portuguese authorities an additional reasoned opinion in order to set out in greater detail, in the interests of transparency and legal certainty, the scope of the infringement of European Union law to which it objected. In that opinion the Commission pointed out that, in its view, the Portuguese Republic had failed to fulfil its obligations under Article 49 EC, as interpreted by the case-law of the Court, by not allowing, either in Decree-Law No 177/92 or in any other provision of national law, for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation No 1408/71.

22. By letter of 15 May 2009 the Portuguese authorities replied to the additional reasoned opinion by stating that provision was made in Decree-Law No 177/92 for the reimbursement of non-hospital medical expenses incurred in another Member State. They further stated that the provisions of Portuguese law did not preclude reimbursement of medical expenses even where they related to specialist treatment, provided that the procedure

for prior certification of the medical need for treatment abroad was complied with.

24. In the defence, lodged on 2 October 2009, the Portuguese Government claims that the action should be dismissed as unfounded and that the Commission should be ordered to pay the costs.

IV — Procedure before the Court of Justice and forms of order sought

25. The written phase of the proceedings concluded following submission of the reply on 16 November 2009 and the rejoinder on 4 February 2010.

23. By application lodged with the Registry of the Court on 9 July 2009, the Commission brought the action that is the subject of the present proceedings, in which it claims that the Court should:

26. By order of the President of the Court of 17 November 2009, the Kingdom of Spain was granted leave to intervene in support of the form of order sought by the Portuguese Republic.

— declare that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC, by not providing for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation (EEC) No 1408/71, either in Decree-Law No 177/92 of 13 August, which lays down the conditions for reimbursement of medical expenses incurred abroad, or in any other provision of national law; or to the extent that that Decree-Law allows for the reimbursement of non-hospital medical expenses incurred in another Member State, by making such reimbursement subject to prior authorisation;

— order the Portuguese Republic to pay the costs.

27. The representatives of the parties and the Government of the Kingdom of Spain presented oral argument at the sitting on 9 February 2011.

28. By document of 24 March 2011, the Commission withdrew its action in part and reformulated the order sought. It now claims that the Court should:

— declare that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC in so far as it makes no provision in Decree-Law No 177/92 of 13 August 1992 laying down the conditions for reimbursement of medical expenses incurred abroad, or in any other measure of national law, for the reimbursement of non-hospital medical expenses incurred in another Member State, other

than in the circumstances specified in Regulation (EEC) No 1408/71 or, to the extent that Decree-Law No 177/92 allows such reimbursement, it makes such reimbursement subject to prior authorisation (with the exception of the reimbursement of expenses for some medical services which, although provided in a consulting room, require the use of major and costly equipment set up and subsidised by the Member State of insurance and which are exhaustively listed in the national legislation, such as a scintillation camera, with or without a positron emission coincidence detector; emission tomography; a positron camera; nuclear magnetic resonance imaging or spectrometry apparatus for clinical use; a medical scanner; a hyperbaric chamber or a cyclotron for medical use);

— order the Portuguese Republic to pay the costs.

29. By document of 6 April 2011 the Portuguese Republic reformulated the order which it sought. It now contends that the Court should:

— dismiss the action as unfounded;

— in so far as it considers the action to be well founded, in any event declare that the Commission has withdrawn its action in part;

— order the Commission to pay the costs.

V — Main arguments of the parties

A — *Provisions of Portuguese law*

30. The *Commission* expresses certain difficulty understanding the Portuguese Government's point of view, particularly since the information on the reimbursement of non-hospital medical expenses has been ambiguous or even contradictory.

31. The Commission concluded from the Portuguese Government's reply to the Directorate-General for the Internal Market's questionnaire on the compatibility of national law with the case-law of the Court that Decree-Law No 177/92 was the national legislative act which contained the applicable provisions on the reimbursement of non-hospital medical expenses incurred abroad.

32. However, the Commission points out that in their reply to the reasoned opinion the Portuguese authorities had stated that the objectives of Decree-Law No 177/92 did not include, for example, making the reimbursement of non-hospital medical expenses incurred abroad subject to prior authorisation and there was no other provision in Portuguese law which makes provision for this. The Commission stated that it had therefore concluded that Portuguese law did not allow for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation No 1408/71.

33. The Commission notes that in their reply to the additional reasoned opinion the Portuguese authorities stated, however, that access to healthcare services in another Member State is subject to a procedure in which clinical need must be certified, which indicates that in Portugal there is a system of prior authorisation for the reimbursement of non-hospital medical expenses incurred in another Member State.

34. Finally, the Commission states that in their defence the Portuguese authorities expressly acknowledged that reimbursement of non-hospital medical costs incurred in another Member State was not allowed other than in the circumstances laid down in Regulation No 1408/71.

35. The *Portuguese Government* disputes the purported ambiguities and contradictions in the explanation of the rules in force in Portugal.

36. The Portuguese Government states that there are two possibilities for accessing healthcare services abroad in Portuguese law, which are laid down, on the one hand, by Regulation No 1408/71, in particular Article 22 thereof, and, on the other, by Decree-Law No 177/92, which provides for 'highly specialised medical care abroad which cannot be provided in Portugal'.

37. The Portuguese Government states that Decree-Law No 177/92 is intended to be an instrument for hospital care. Under that law, medical treatment abroad is possible where the Portuguese health system does not have the necessary means to treat those affiliated to it. This solution is intended to provide patients with the healthcare they need with a guarantee of quality and medical effectiveness.

38. Treatment abroad is subject to certain conditions, which are laid down in Decree-Law No 177/92. Under that law, requests for highly specialised medical care must be submitted by hospitals belonging to the national health system and a comprehensive medical report, to be approved by the relevant service manager and medical director (Article 2(1) and (2)), must be attached to them. The final decision lies with the health director.

The medical report must also provide a number of details about the patient's state of health and the treatment and the places abroad where the patient is to be operated on or treated. Where the statutory requirements are satisfied, the patient has a right to full reimbursement of the costs, including the outward travel and accommodation costs of the patient and a companion. Payment is made by the clinical unit which is responsible for the prior certification procedure (Article 6).

39. The Portuguese Government considers that no distinction should be made between the costs of hospital and non-hospital treatment. Highly specialised medical care abroad in the form of institutional cooperation can encompass both kinds of treatment. Moreover, the Portuguese Government draws a parallel between the procedure for prior certification of the clinical need for treatment abroad and the procedure for referral to a specialist.

40. It further notes that the medical cooperation provided for in Decree-Law No 177/92 satisfies the requirements of the national health system which, in accordance with the constitution, is distinguished by its universal, general and self-sufficient nature and, in addition, is funded by the State.

B — *European Union law*

41. The *Commission* considers that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC, as interpreted by the case-law of the Court. The effect of that case-law is that Article 49 EC applies to the situation of a patient who receives, in a Member State other than his Member State of residence, medical services which are provided for consideration. In Portugal, Decree-Law No 177/92, which lays down the conditions for reimbursement of medical expenses incurred abroad, does not specifically provide for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation No 1408/71, or, in accordance with the interpretation put forward by the Portuguese authorities, makes the reimbursement of those non-hospital medical expenses subject to prior authorisation, on restrictive conditions.

42. The Commission considers that even if it is accepted that a system which makes the reimbursement of medical expenses subject to prior authorisation can be justified in spite of the case-law of the Court of Justice, the conditions for the grant of such authorisation are restrictive and consequently contrary to European Union law.

43. As regards the arguments put forward by the Portuguese Government in favour of justification by overriding reasons in the public interest, that is to say the ability to fund the national health system and ensuring access

to general healthcare, the Commission argues that the requirement of prior authorisation cannot be justified by grounds of public health or a risk of seriously undermining the financial balance of the social security systems. In addition, the Commission claims that the Portuguese authorities provided no evidence or proof of a genuine risk of disrupting the financial balance of the Portuguese health system posed by the reimbursement of non-hospital medical expenses incurred abroad.

44. The *Portuguese Government* argues that there is no provision in the Treaty which confers on Union citizens the right to claim reimbursement of medical expenses incurred abroad or permits them to exercise such right unreservedly, without it being governed by a mechanism of prior authorisation.

45. The Portuguese Government regards the present action for failure to fulfil Treaty obligations as an attempt by the Commission to force through in law a solution which is not only devoid of any legal basis but has also been rejected by the Member States, which have competence for shaping the social security and health systems. It expresses its surprise at the Commission's actions since a legislative process is presently under way to lay down the Member States' rights and obligations in this regard. It is clear from recital 23 of the preamble to Directive 2006/123 that only a legislative solution that contains sufficiently clear requirements can justify a judicial ruling. In the belief that a judgment by the Court would result in an unwanted overlapping of judicial and policy decision-making processes, it claims that the Court should stay proceedings pursuant to Article 82a(1)(a) of the Rules of Procedure.

46. In the view of the Portuguese Government, the Court's case-law on the applicability of Article 49 EC to cross-border healthcare services is characterised by two factors, namely the specific procedural framework and its lack of legal certainty and clarity. All the Court's judgments have been given in proceedings for a preliminary ruling pursuant to Article 234 EC, which prevents the solutions found in those cases from being applied to the main proceedings.

47. Even if prior authorisation could perhaps constitute a restriction of the freedom to provide services, according to the Court's case-law Article 49 EC does not preclude such authorisation, provided that it is subject to objective criteria which must also be satisfied as requirements for the reimbursement of medical expenses for treatments carried out in the national territory.

48. Furthermore, Article 22 of Regulation No 1408/71 also makes the provision of cross-border healthcare services subject to prior

authorisation. In addition, Article 49 EC must be brought into line with the other provisions of the Treaty. In this respect the Portuguese Government refers to Article 152(5) EC, which reserves competence to the Member States, and the effective application thereof precludes any application of other provisions of the Treaty which undermine the powers of the national decision makers in relation to the organisation, funding and design of the model for the national health system.

49. The Portuguese Government does not propose any change to the case-law, but rather calls on the Court to establish a proper balance between Article 49 EC and Article 152(5) EC in such a way that Article 49 EC must be subordinate on overriding reasons in the public interest. It invokes several grounds which have been regarded as legitimate in the Court's case-law, including the need to maintain the financial balance of the social security and healthcare systems.

50. The *Spanish Government* argues primarily that Article 49 EC does not impose any obligation on the Member States to adopt positive implementation measures, particularly since the directive is the legal instrument expressly provided for in European Union law to create such positive implementation measures in the provisions of national law. It points out that Article 52 EC expressly provides for the directive as a means of liberalising the internal market for services. That is precisely what the Commission is seeking to do with its proposal for a directive.[9] The fact that Portugal did not create a procedure for reimbursing medical expenses in addition to that laid down in Regulation No 1408/71 cannot constitute failure to fulfil obligations under Article 49 EC.

51. Furthermore, the Commission has failed to prove that the Portuguese authorities apply their laws in breach of their obligations under Article 49 EC, for example by systematically refusing the authorisation for treatment abroad provided for in the system.

52. As regards the compatibility of Portuguese law with Article 49 EC, the Spanish Government points out that a system which provides for prior authorisation does not necessarily constitute an unjustified restriction of the freedom to provide services. There are overriding reasons in the public interest which justify such a system, in particular in connection with hospital health services. It is wrong to apply the Court's judgments in *Kohll* and *Müller-Fauré and van Riet* concerning dental services to any non-hospital

9 — Cited in footnote 4.

healthcare service. As a precaution, the Spanish Government recalls that in *Kohll* the Court ruled that 'Article 56 of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of a treatment facility or medical service on national territory is essential for the public health and even the survival of the population'.

53. As for the proportionality of the rules at issue, the Spanish Government points out that it is necessary to consider whether the Portuguese system introduces an administrative authorisation procedure based on objective and non-discriminatory criteria which are known in advance to the person concerned and allow him to determine the limits of the national authorities' discretion.

VI — Legal assessment

A — *Applicability of Article 49 EC*

54. According to settled case-law and under the rules which determine the European Union's procedural law, in proceedings for failure to fulfil obligations it is incumbent upon the Commission to prove the allegation that the obligation has not been fulfilled. It is the Commission which must provide the Court with the evidence necessary for the Court to establish that the obligations have not been fulfilled, and it may not rely on mere presumptions. [10] The burden of proof in the proceedings is reversed only when the Commission has produced sufficient evidence to show the failure to fulfil obligations. In such a case it is for the Member State to put up a substantiated and detailed defence to prove compliance with European Union law on its part. [11]

55. By its action, the Commission complains that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC. The Portuguese Government challenges this complaint, firstly by pointing to the legislative process currently aimed at adopting a directive on the application of patients' rights in cross-border healthcare – in particular the consultation presently under way in Council – and secondly by calling into question

10 — See inter alia Case 96/81 *Commission* v *Netherlands* [1982] ECR 1791, paragraph 6; Case 272/86 *Commission* v *Greece* [1988] ECR 4875, paragraph 17; Case C-404/00 *Commission* v *Spain* [2003] ECR I-6695, paragraph 26; Case C-434/01 *Commission* v *United Kingdom* [2003] ECR I-13239, paragraph 21; Case C-194/01 *Commission* v *Austria* [2004] ECR I-4579, paragraph 34; Case C-507/03 *Commission* v *Ireland* [2007] ECR I-9777, paragraph 33; Case C-438/07 *Commission* v *Sweden* [2009] ECR I-9517, paragraph 49; and Case C-246/08 *Commission* v *Finland* [2009] ECR I-10605, paragraph 52.

11 — See Case C-298/95 *Commission* v *Germany* [1996] ECR I-6747, paragraph 17, and *Commission* v *Greece*, cited above in footnote 10, paragraph 21. To that effect, see Burgi, M., in: *Handbuch des Rechtsschutzes in der Europäischen Union* (published by H.-W. Rengeling/A. Middeke/M. Gellermann), Munich 2003, § 6, paragraph 45, p. 79, and Schwarze, J., *EU-Kommentar* (published by Jürgen Schwarze), 2nd edition., 2009, Art. 226 EGV, paragraph 27, p. 1755.

the applicability to cross-border healthcare services of the provisions of primary law on the freedom to provide services, in particular Article 49 EC. Both arguments concern, legally, both the temporal and material scope of Article 49 EC to the present dispute and I will now examine them.

1. Law applicable *ratione temporis*

56. As regards the Portuguese Government's first-mentioned objection to the present action, it should first be noted that a Member State cannot successfully rely on a legal instrument which is not yet in force and which accordingly produces no legal effects in the European Union legal order. Considered objectively, the expectation that a particular Commission proposal will remain unchanged cannot be regarded as legitimate, particularly since such proposals can be subject to numerous amendments by the Council and Parliament in the course of the legislative procedure. That is also why it has only limited utility as an aid to interpretation.

57. Leaving that aside, it should be borne in mind that the purpose of the procedure under Article 226 EC is to establish infringements of European Union law by Member States which occurred at a particular, relevant time. According to the settled case-law of this Court, the question whether a Member State has failed to fulfil its obligations under the Treaty must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion. This is the sole material time in assessing an infringement of the Treaty. [12] Therefore, later amendments to European Union law, like subsequent regularisations by the Member State concerned, are not taken into account. [13] The real probability that the legislative procedure will be successfully concluded in the foreseeable future and a directive will be adopted that lays down precise rules on the application of patients' rights in cross-border healthcare in no way alters the subject-matter of the action and therefore has no effect at all on the present proceedings for failure to fulfil obligations.

58. Accordingly, the Portuguese Government's objection to the applicability of Article 49 EC must be dismissed for the purposes of examining a possible infringement of European Union law.

12 — See Case C-182/94 *Commission* v *Italy* [1995] ECR I-1465; Case C-61/94 *Commission* v *Germany* [1996] ECR I-3989; Case C-316/96 *Commission* v *Italy* [1997] ECR I-7231, paragraph 14; Joined Cases C-232/95 and C-233/95 *Commission* v *Greece* [1998] ECR I-3343, paragraph 38; Case C-355/98 *Commission* v *Belgium* [2000] ECR I-1221, paragraph 22; Case C-47/01 *Commission* v *Spain* [2002] ECR I-8231, paragraph 15; Case C-519/03 *Commission* v *Luxembourg* [2005] ECR I-3067, paragraph 18.

13 — See also Burgi, M., cited above in footnote 11, paragraph 38, p. 75; Cremer, W., *EUV/EGV- Kommentar* (published by Christian Calliess/Matthias Ruffert), 3rd edition., Munich 2007, Art. 226 EGV, paragraph 33, p. 1991.

2. Scope *ratione materiae*

59. The second objection of the Portuguese Government must be understood as essentially calling into question the applicability *ratione materiae* of the provisions of primary law on the freedom to provide services. In support of its view it refers to Article 152(5) EC, a provision which confers on the Member States responsibility for the organisation and delivery of health services and medical care. The Portuguese Government also highlights the need for provisions of secondary law in this field.

(a) Competences of the European Union and its Member States in the field of health policy

60. I agree with the statements made by the Portuguese Government in so far as they relate to the competence, in principle, of the Member States in the field of healthcare. Put simply, the Member States do in fact remain in principle 'the masters of health policy',[14] which means that the European Union cannot go against their policy. In the field of activity outlined by Article 152 EC the competences of the European Union are less distinct than in other fields. They are limited, in substantive terms, to 'complementing' national policies under subparagraphs 2 and 3 of paragraph 1, and, in organisational terms, to 'encouraging' cooperation between the Member States under the first subparagraph of paragraph 2. This subordination in principle of European Union activity in the field of health protection to national policies must be regarded as a manifestation of the principle of subsidiarity enshrined in Article 5 EC. However, this does not affect the European Union's power to create European-Union-wide standards of protection when harmonising health policies on the basis of Article 95 EC in order to remove restrictions on fundamental freedoms. The Commission's proposal for a directive which, according to recital 8 of the preamble thereto, aims to ensure patients' mobility and

14 — Recital 8 in the preamble to the Commission proposal for a 'Directive on the application of patients' rights in cross-border healthcare', cited above in footnote 4, reads: 'This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.'

freedom to provide healthcare, is based on precisely this enabling provision.

61. The Court is aware of the complex division of competences between the European Union and its Member States. As it has consistently stated, European Union law does not detract from the powers of the Member States to organise their social security systems. [15] This in turn means that in the absence of harmonisation at European Union level it is thus for the legislation of each Member State to determine the conditions for granting social security benefits. [16] In this connection reference should be made to *Watts* [17] in which the Court pointed out very clearly that European Union action is to respect fully the responsibilities of the Member States for the organisation and delivery of health services and medical care.

62. However, as the Court stated in the same judgment, this provision in turn does not exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or European Union measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their healthcare and social security systems. [18] In previous judgments the Court had stressed that when exercising the power conferred on them under Article 152(5) EC Member States must comply with European Union law and, in particular, with the provisions on the freedom to provide services. [19] Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of this freedom of movement in the healthcare sector. [20] It should further be noted that the Court has expressly recalled that the Member States should not regard the unavoidable adjustments to their systems of social security, which they must make to the achieve the fundamental

15 — See Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16; Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 27; Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 17; Case C-8/02 *Leichtle* [2004] ECR I-2641, paragraph 29; Case C-372/04 *Watts* [2006] ECR I-4325, paragraph 92; and Case C-211/08 *Commission* v *Spain* [2010] ECR I-5267, paragraph 53.

16 — Case 110/79 *Coonan* [1980] ECR 1445, paragraph 12; Case C-349/87 *Paraschi* [1991] ECR I-4501, paragraph 15; Joined Cases C-4/95 and C-5/95 *Stöber and Piosa Pereira* [1997] ECR I-511, paragraph 36; *Watts*, cited above in footnote 15, paragraph 92; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, cited above in point 52, paragraph 100; *Commission* v *Spain*, cited above in footnote 15, paragraph 53; and Case C-490/09 *Commission* v *Luxembourg* [2011] ECR I-247, paragraph 32.

17 — *Watts*, cited above in footnote 15, paragraph 146. See also *Commission* v *Spain*, cited above in footnote 15, paragraph 75.

18 — *Watts*, cited above in footnote 15, paragraph 147.

19 — Case C-120/95 *Decker* [1998] ECR I-1831, paragraph 19; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraphs 44 to 46; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 100; Case C-56/01 *Inizan* [2003] ECR I-12403, paragraph 17; *Watts*, cited above in footnote 15, paragraph 92; and *Commission* v *Spain*, cited above in footnote 15, paragraph 53.

20 — Case C-173/09 *Elchinov* [2010] ECR I-8889, paragraph 40; *Commission* v *Spain*, cited above in footnote 15, paragraph 23; Case C-444/05 *Stamatelaki* [2007] ECR I-3185, paragraph 23; and *Watts*, cited above in footnote 15, paragraph 92.

freedoms guaranteed by the EC Treaty, as undermining their sovereign powers in this field. [21] Finally, mention should be made of the fact that the European Union can have considerable influence over the Member States' health systems, for example by measures to implement fundamental freedoms. [22]

63. In the field of cross-border healthcare services there is, so to speak, a crossover between European Union and national law and in such a way that European Union law in essence merely imposes, as is so often the case, a binding objective, namely to achieve freedom of movement for patients and the equal treatment thereof by the national authorities regardless of their nationality, whilst the competences of the Member States continue to exist but have to comply with the normative framework laid down by primary and secondary law in so far as the Member States may not infringe European Union law in exercising their competences. [23] How far the framework in European law which Article 49 EC imposes on the exercise of the Member States' competences extends is determined by the Court. It has the task assigned to it in the founding Treaties to illuminate and explain the significance and the scope of a rule of European Union law, such as it must be applied from the moment of its entry into force. [24]

64. Consequently, the Portuguese Republic likewise cannot successfully rely on its inherent responsibility for the organisation and delivery of health services and medical care within its national territory in order to escape from the obligations imposed on it by other primary European Union law, in particular the provisions on the fundamental freedoms.

(b) Coverage of the national rules at issue

65. As regards the other question whether the national rules at issue fall within the scope *ratione materiae* of Article 49 EC, it should

21 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 45; *Watts*, cited above in footnote 15, paragraph 147; and *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 102.

22 — See, for example, Case C-322/01 *DocMorris* [2003] ECR I-14887 – national prohibition on the sale of medicinal products by mail order; Case C-151/02 *Jaeger* [2003] ECR I-8389 – on-call service provided by doctors in hospitals in connection with the protection of the safety and health of workers; *Leichtle*, cited above in footnote 15, paragraph 51 – conditions for reimbursement of expenses incurred in connection with a health cure taken in another Member State; and Case C-411/98 *Ferlini* [2000] ECR I-8081, paragraph 47 et seq.

23 — See to this effect Van Raepenbusch, S., 'Dossier: l'Europe de la santé – L'état de la jurisprudence de la CJCE relative au libre accès aux soins de santé à l'intérieur de l'Union européenne après l'arrêt du 16 mai 2006, Watts, C-372/04', *Gazette du Palais*, December 2006, p. 8.

24 — See Case C-540/07 *Commission* v *Italy* [2009] ECR I-10983, paragraph 63.

be recalled that according to settled case-law, medical services supplied for consideration fall within the scope of the provisions on the freedom to provide services, [25] there being no need to distinguish between care provided in a hospital environment and care provided outside such an environment. [26] 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 without restrictions. [27] It has further been held that a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks the reimbursement of that treatment from a national health service. [28]

66. National provisions, such as those contained in Decree-Law No 177/92, which lay down the conditions for both the receipt of cross-border healthcare services by a patient and the reimbursement of medical expenses by the authorities of a national healthcare system, therefore fall within the scope *ratione materiae* of Article 49 EC. [29]

67. Furthermore – and contrary to the view taken by the Portuguese Government which in this respect has repeatedly put forward this argument against the applicability to the present case of the principles developed by the Court – the fact that Portugal's national health system, unlike the health systems of several other Member States, is not funded by insurance contributions but solely by taxes and other State budget funds in no way precludes an examination of the compatibility of the provisions of Decree-Law No 177/92 with Article 49 EC, as interpreted by the case-law

25 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 34; *Commission* v *Spain*, cited above in footnote 15, paragraph 47; *Stamatelaki*, cited above in footnote 20, paragraph 19; *Watts*, cited above in footnote 15, paragraph 86; Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685, paragraph 18; and *Kohll*, cited above in footnote 15, paragraph 29.

26 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 34; Case C-512/08 *Commission* v *France* [2010] ECR I-8833, paragraph 30; *Leichtle*, cited above in footnote 15, paragraph 28; *Stamatelaki*, cited above in footnote 20, paragraph 19; *Watts*, cited above in footnote 15, paragraph 86; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 103; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraph 41; and *Smits and Peerbooms*, cited above in footnote 19, paragraph 53.

27 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 35; *Commission* v *France*, cited above in footnote 26, paragraph 31; *Elchinov*, cited above in footnote 20, paragraph 37; *Commission* v *Spain*, cited above in footnote 15, paragraph 49; *Stamatelaki*, cited above in footnote 20, paragraph 20; and *Watts*, cited above in footnote 15, paragraph 87.

28 — *Commission* v *Spain*, cited above in footnote 15, paragraph 47; *Stamatelaki*, cited above in footnote 20, paragraph 21; and *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 103.

29 — See *Smits and Peerbooms*, cited above in footnote 19, paragraphs 60 to 69, and judgment of the EFTA Court in Joined Cases E-11/07 and C-1/08 Rindal and Slinning, paragraph 44, which found not only that the provisions of primarily law on the freedom to provide services in the EC Treaty and EEA Agreement are applicable *ratione materiae*, but also the relevant national provisions are restrictive in nature. The first paragraph of Article 49 EC is substantively identical to Article 36(1) of the EEA Agreement, for the interpretation of which the EFTA Court has jurisdiction (in relation to the EFTA/EEA States). In accordance with the requirement of uniform case-law within the European Economic Area, the EFTA Court has applied the abovementioned case-law of the Court of Justice to that provision of the agreement.

of the Court, because, as the Court stated unequivocally in *Watts* [30] specifically in relation to a tax-funded national health system such as the United Kingdom's National Health Service (NHS), the provisions of primary law on the freedom to provide services are applicable 'regardless of the way in which the [relevant] national system … operates'. I would like to point out that the innovation introduced by *Watts* consisted not least in the application of previous case-law on the freedom of movement in connection with primarily-contribution-funded statutory sickness insurance to tax-funded national health systems. [31] In this context reference should also be made to *Müller-Fauré and van Riet* [32] in which the Court expressly stated that there is no need, from the perspective of freedom to provide services, to draw a distinction 'by reference to whether the sickness fund or the national budget pays the provider directly'. Accordingly, the argument put forward by the Portuguese Government to the contrary must be rejected.

68. Consequently, Article 49 EC is applicable.

B — *Restriction of the freedom to provide services*

69. It must also be examined whether the rules contained in Decree-Law No 177/92 constitute a restriction of the freedom to provide services within the meaning of Article 49 EC, as the Commission complains. According to settled case-law, Article 49 EC precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within a Member State. [33]

70. However, a finding that there has been an unjustified restriction of the freedom to provide services, and thus an infringement of European Union law, is made only when the subject-matter of the dispute has been clarified sufficiently. To this end, it is necessary to consider at what the Commission's claims setting out the subject-matter of the dispute are in fact directed.

71. On that point, it must be stated that the Commission bases its action on two alternative infringements. In its application the Commission complains in particular that the Portuguese Republic does not allow in its national law for the reimbursement of

30 — Cited above in footnote 15, paragraph 90.

31 — To this effect, see Schneider, U., 'Patientenmobilität und Wartelistenmedizin in der EG', *European Law Reporter*, 9/2006, p. 348; Schiano, R., 'Arrêt, Yvonne Watts', *Revue du Droit de l'Union Européenne*, 2/2006, p. 461.

32 — Cited above in footnote 16, paragraph 103.

33 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 33; *Commission* v *Spain*, cited above in footnote 15, paragraph 55; *Stamatelaki*, cited above in footnote 20, paragraph 25; *Watts*, cited above in footnote 15, paragraph 94; *Smits and Peerbooms*, cited above in footnote 19, paragraph 61; *Kohll*, cited above in footnote 15, paragraph 33; and Case C-381/93 *Commission* v *France* [1994] ECR I-5145, paragraph 17.

non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation No 1408/71. In the alternative, it complains that the Portuguese Republic has introduced a system which makes the reimbursement of non-hospital medical expenses incurred in another Member State subject to prior authorisation.

1. Possibility of reimbursing non-hospital medical expenses incurred in another Member State

72. It is clear from the first head of claim that the second limb thereof ('or to the extent that that Decree-Law allows for the reimbursement of non-hospital medical expenses incurred in another Member State') must be regarded as a claim in the alternative by the Commission in the event that the Court should rule that the relevant provisions of Portuguese law – contrary to the Commission's suspicions – do indeed provide for reimbursement of medical expenses for non-hospital treatment incurred in another Member State, that is to say also in circumstances not laid down in Regulation No 1408/71.

73. It is therefore first necessary to examine, on the basis of the information which the parties have made available to the Court, whether the national rules at issue provide at all for the reimbursement of non-hospital medical expenses incurred in another Member State.

74. In its application [34] the Commission points out that it assumed from the information which the Portuguese Government communicated to it during the pre-litigation procedure that the provisions of Portuguese law did not allow for the reimbursement of non-hospital medical expenses incurred in another Member State, other than in the circumstances laid down in Regulation No 1408/71. In this respect the Commission refers to the Portuguese authorities' reply of 4 September 2007 to the reasoned opinion, [35] in which they stated that there was no provision in Portuguese law that lay down the right to reimbursement of non-hospital medical expenses incurred in another Member State. Furthermore, the Portuguese authorities acknowledged that in such a case medical expenses are not reimbursed.

75. In its application [36] the Commission also objects to the imprecise information provided by the Portuguese authorities on the regulatory purpose of Decree-Law No 177/92 and the applicability of this law to non-hospital

34 — See paragraphs 32 and 33 of the application.

35 — See p. 15 of the Portuguese authorities' reply of 4 September 2007 to the reasoned opinion.

36 — See paragraph 38 of the application.

treatment provided in another Member State. In this connection, the Portuguese authorities had stated in their reply of 15 May 2009 to the additional reasoned opinion that in Decree-Law No 177/92 reimbursement of medical expenses for treatment in another Member State was subject to prior authorisation. The Commission therefore concludes that Decree-Law No 177/92 must in any event also apply to non-hospital treatment.

76. The present proceedings for failure to fulfil obligations reveal some uncertainty on the part of the Commission in reproducing in great detail the normative content of the rules at issue and the factors capable of justifying a restriction of the freedom to provide services. This is surprising given that the pre-litigation procedure began in 2006 and the correspondence between it and the Portuguese authorities, in which the compatibility of the Portuguese legislation with the case-law of the Court was discussed, dates back as far as 2003. The misunderstandings and contradictory information revealed on reading these letters could have been avoided if the certain relevant aspects, for example concerning the applicability of the provisions of Decree-Law No 177/92 to non-hospital treatment, had been discussed extensively in the pre-litigation procedure. In this context, I wish to note that the Member States are required, under Article 10 EC, to facilitate the achievement of the Commission's tasks, which consist in particular, pursuant to Article 211 EC, in ensuring that the provisions of the Treaty and the measures taken by the institutions pursuant thereto are applied. [37] As the Court has already ruled, this includes a requirement to cooperate in good faith with any inquiry undertaken by the Commission pursuant to Article 226 EC, and to provide the Commission with all the information requested for that purpose. [38]

77. It is clear from Decree-Law No 177/92 that this law at least lays down the conditions for reimbursement of medical expenses incurred abroad, there being nothing in it to indicate that it draws any distinction between non-hospital and hospital treatment. The Portuguese Government clearly seems also to proceed from this understanding because in its defence it, one, questions the sense of this distinction in principle between types of treatment and, two, states unequivocally that the provisions of Portuguese law – by which Decree-Law No 177/92 is meant specifically – allow for the full reimbursement of hospital and non-hospital medical expenses

37 — See inter alia Case C-33/90 *Commission* v *Italy* [1991] ECR I-5987, paragraph 18, and Case C-494/01 *Commission* v *Ireland* [2005] ECR I-3331, paragraph 197.

38 — See inter alia Case 192/84 *Commission* v *Greece* [1985] ECR 3967, paragraph 19; Case C-478/01 *Commission* v *Luxembourg* [2003] ECR I-2351, paragraph 24; Case C-82/03 *Commission* v *Italy* [2004] ECR I-6635, paragraph 15; and *Commission* v *Ireland*, cited in footnote 37 above, paragraph 198. To that effect, see also Lenaerts, K./Arts, D./Maselis, I., *Procedural Law of the European Union*, 2nd edition., London 2006, paragraph 5-057, p. 163.

incurred abroad, provided that they are justified from a medical point of view. [39]

78. Accordingly, it must be found that, contrary to the Commission's conclusion, Decree-Law No 177/92, as the relevant national law, does indeed allow in principle for the reimbursement of non-hospital medical expenses incurred in another Member State.

2. Requirement of prior authorisation for 'highly specialised' medical treatment

79. In the alternative, the Commission complains that the Portuguese Republic has introduced a system which makes reimbursement of non-hospital medical expenses incurred in another Member State subject to prior authorisation. In this respect it should be noted that the Court has already held that the mere requirement of prior authorisation for reimbursement of costs constitutes, both for patients and service providers, an obstacle to the freedom to provide services, [40] where it is apparent that such a system deters, or prevents, patients from approaching providers of medical services established in a Member State to obtain the treatment in question. [41]

80. More particularly, the Commission complains about the maintenance in Portuguese law of a provision which is contrary to European Union law. Contrary to the view taken by the Portuguese and Spanish Governments, [42] for the purpose of assessing the restrictive effect of national rules it is by no means absolutely necessary to establish the existence of a specific administrative practice contrary to European Union law, that is to say in the present case a possible restrictive practice of the Portuguese authorities when issuing authorisations. As can be inferred from the Court's case-law on Article 49 EC, the scope of the freedom to provide services is interpreted so broadly that for a finding that national rules have a restrictive effect it is sufficient for them to be liable to prohibit, impede or render less advantageous use by the recipient of a service offered in another Member State. [43] Accordingly, it is sufficient for the purposes of the present proceedings merely to consider whether the national rules at issue could have a deterrent affect on potential recipients of the service.

39 — See paragraphs 16, 24 and 58 of the defence.

40 — Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377, paragraph 16; Case C-204/90 *Bachmann* [1992] ECR I-249, paragraph 31; and *Kohll*, cited above in footnote 15, paragraph 35. See judgment of the EFTA Court in Rindal and Slinning, cited above in footnote 29, paragraphs 44 and 45.

41 — *Commission* v *France*, cited above in footnote 26, paragraph 32; *Watts*, cited above in footnote 15, paragraph 98; *Leichtle*, cited above in footnote 15, paragraph 30; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 41 and 44; and *Smits and Peerbooms*, cited above in footnote 19, paragraph 69.

42 — See paragraph 21 of the Spanish Government's observations.

43 — See Case C-42/07 *Liga Portuguesa de Futebol Profissional and Bwin International* [2009] ECR I-7633, paragraph 51.

81. Whether or not the rules contained in Decree-Law No 177/92 have such a deterrent effect on potential patients as to comply with the definition of restriction, can be determined only by examining the relevant national provisions.

82. As stated above, Decree-Law No 177/92 lays down the conditions for reimbursement of medical expenses incurred abroad. It subjects reimbursement of medical expenses incurred abroad to authorisation and to this end creates a special administrative procedure which provides for cooperation on the part of various hospital authorities. Under that law, a patient who requires highly specialised treatment abroad must, before he is treated abroad, obtain authorisation from three hospital authorities pursuant to Article 2. It is clear from both the recital to the Decree-Law and Articles 1(1) and 3(1)(a) thereof that the authorisation essentially certifies that the necessary treatment must be provided abroad as part of medical cooperation because it cannot be provided in Portugal on account of a lack of technical resources or personnel. Requests for highly specialised medical care must be submitted by hospitals of the national health system and there must be attached thereto a comprehensive doctor's report which must be approved by both the relevant service manager and the medical director.

83. Thus, Decree-Law No 177/92 makes the reimbursement of medical expenses incurred abroad subject to prior authorisation which, if it is not obtained, means that the patient alone must ultimately bear his medical expenses himself. Although the rules at issue do not prevent patients from approaching providers of services in another Member State, the prospect of a potential loss in the event of failure by the national health system to meet the medical costs as a result of an unfavourable administrative decision is per se objectively liable to deter potential patients who wish to receive medical treatment abroad. This view is confirmed in *Kohll*, *Smits and Peerbooms* and *Müller-Fauré and van Riet,* [44] in which the Court confirmed inter alia the deterrent affect of such requirements to obtain authorisation which seek to certify the medical need for treatment abroad. The complexity of this authorisation procedure, which is manifested in particular in its three-stage arrangement, can also be cited as a further deterrent factor to receiving cross-border healthcare services. The possibility of the individual authorities taking a different view as to the medical need for treatment abroad cannot be ruled out.

84. It is true that during the written procedure the Portuguese Government argued that the procedure contained in Decree-Law No 177/92 for 'prior certification of the clinical necessity' ('referenciação prévia da

44 — See *Kohll*, cited above in footnote 15, paragraphs 33 to 36; *Smits and Peerbooms*, cited above in footnote 19, paragraphs 62 and 64; and *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 41 and 42.

necessidade clínica') of treatment abroad was comparable with a referral to a specialist in Portugal. [45] This argument obviously seeks to undermine the idea that the rules at issue might make it more difficult to provide services between the Portuguese Republic and other Member States of the Union than to provide services within a Member State. I doubt that this argument is well founded, particularly since the Portuguese Government has made no submission capable of supporting this contention. For example, there is no proof that referral to a specialist in Portugal requires authorisation from three different authorities. It must therefore be concluded that a referral to a specialist in Portugal involves far less administration than a referral abroad in the authorisation procedure at issue. Despite these considerations, it should be noted that these rules specifically cover cross-border situations and clearly seek to make it difficult for citizens living in Portugal to receive healthcare services abroad.

85. Consequently, it must be found that the system of prior authorisation at issue is liable to deter potential patients and thus also to prevent them from approaching providers of healthcare services in another Member State. The national rules at issue thus ultimately make it more difficult to provide services between the Member States than to provide services within a Member State. Therefore, they constitute both for patients and service providers an obstacle to the freedom to provide services.

3. Ineligibility for reimbursement in the case of 'other' medical treatments

86. The Commission's suspicion, mentioned above, concerning the possible ineligibility for reimbursement of medical costs [46] under Portuguese law also appears to be justified in another context. As established above in describing this law, Decree-Law No 177/92 does not encompass all types of medical treatment. Instead, it merely applies to so-called 'highly specialist' medical treatment abroad. Consequently, reimbursement of expenses is possible – subject to the relevant authorisation being granted – only in respect of this type of treatment. In the light of the fact that, in the absence of information to the contrary provided by the Portuguese Government, there is no provision in the law of the Portuguese Republic which expressly confers a right to reimbursement of medical expenses incurred abroad in connection with 'other' non-hospital treatment, it must be concluded that such reimbursement is not allowed for in Portuguese law.

45 — See paragraphs 22 and 23 of the defence.

46 — See point 74 of this Opinion.

87. Support for this conclusion is to be found not only in the regulatory purpose, scheme and wording of Decree-Law No 177/92 but also in the Portuguese Government's submissions on the principal features of the Portuguese healthcare system, which is characterised essentially by its autonomy and for that reason clearly does not regard medical treatment abroad as equally worthy of promotion as equivalent medical treatment at home. The Portuguese Government's statement that the Portuguese Republic is unable to ensure the reimbursement of expenses for treatment abroad of any kind can be cited as further evidence. [47] The fact that the Portuguese Government contests the Commission's contention that there is no provision in Portuguese law which provides for the relevant reimbursement of medical costs with reference to Decree-Law No 177/92 likewise cannot be cited as an argument against the understanding of the national legal framework set out in this Opinion, since, as I said above, Decree-Law No 177/92 precisely does not provide for the reimbursement of medical expenses incurred in connection with 'other' non-hospital treatments.

88. Given their nature as healthcare services, 'other' non-hospital treatments abroad are also protected by the freedom to provide services. The categorical refusal to grant a right to reimbursement of medical expenses incurred in connection with such treatments abroad clearly constitutes a restriction of the freedom to provide services within the meaning of the abovementioned definition, [48] since it makes it more difficult for patients established in Portugal to receive healthcare services in other Member State than if they received the same healthcare services in Portugal. Only if they are treated in Portugal do they also have a right to a reimbursement of costs by the national health service. As I have already stated in connection with the requirement of authorisation under the Decree-Law, [49] although the failure to meet the medical expenses does not directly prevent patients from approaching service providers in another Member State, the prospect of a potential loss is per se objectively liable to deter potential patients who wish to receive medical treatment abroad. [50] The restrictive nature of these rules is ultimately expressed in their effect.

89. Accordingly, the ineligibility for reimbursement of medical expenses in the case of 'other' medical treatment must also be regarded as a restriction of the freedom to provide services.

47 — See paragraph 54 of the defence.

48 — See point 69 of this Opinion.

49 — See point 83 of this Opinion.

50 — See *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 41.

C — *Justification of the restriction*

90. Having established a restriction of the freedom to provide services in respect of 'highly specialised' and 'other' medical treatments respectively, it is now necessary to determine whether either restriction can be objectively justified.

91. To this end, the two situations must be strictly separated. In the case of 'highly specialised' treatments the question arises as to the justification of the restriction resulting from the requirement of authorisation. [51] In the case of the 'other' medical treatments it is the justification of the restriction arising from the ineligibility for reimbursement of medical expenses [52] that is under examination. Firstly, the different intensity with which the national rules at issue restrict the freedom to provide services and, secondly, the fact that legal requirements on justification under European Union law are partially different, militate in favour of a separate examination.

1. Justification in the case of 'highly specialised' medical treatments

92. As the Court has stated on many occasions, although European Union law does not preclude, in principle, a system of prior authorisation, it is nevertheless necessary that the conditions attached to the grant of such authorisation be justified and satisfy the requirement of proportionality. [53] In this respect, it is necessary, in accordance with settled case-law, that the restriction does not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules. [54] Such a system must, in addition, 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. [55]

93. From the point of view of legal method, the level of justification is the point in the examination at which the 'proper balance', called for by the Portuguese Republic, between the Member States' organisational and regulatory sovereignty in the field of healthcare, on the one hand, and the rules of the internal market, on the other, is established. [56] In this respect, it is for the Court to reconcile as far as possible the interest of the person insured under the national health service in enjoying the benefits of the internal market in terms of the free trade in healthcare services and

51 — See point 85 of this Opinion.

52 — See point 89 of this Opinion.

53 — See *Elchinov*, cited above in footnote 20, paragraph 44, and *Smits and Peerbooms*, cited above in footnote 19, paragraph 82.

54 — *Watts*, cited above in footnote 15, paragraph 106.

55 — *Elchinov*, cited above in footnote 20, paragraph 44: *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 83 to 85; and *Smits and Peerbooms*, cited above in footnote 19, paragraphs 82 and 90.

56 — See Cousins, M., 'Patient Mobility and National Health Systems', *Kluwer Law International*, 2007, p. 190.

the desire of the Member States to maintain the financial stability of their health services in order to be able to continue to provide the insured person with high-quality healthcare services. [57]

94. However, a restriction of fundamental freedoms can be justified only where there is a legitimate justification therefor. In its case-law on cross-border healthcare services the Court recognises a number of justifications which are laid down in writing or have been developed by the courts. However, until now the Court has not expressed its opinion on whether in a case such as the present, in which the restriction of the freedom to provide services results from the application of discriminatory national rules – in so far as it lays down a requirement of authorisation solely in respect of medical treatment abroad – can be justified at all. In this connection it should be recalled that according to traditional case-law overriding reasons in the public interest cannot be invoked to justify restrictions of fundamental freedoms which are applied in a discriminatory manner. [58] It is therefore questionable whether the Court may consider at all the justifications on which the Portuguese Government relies to restrict the freedom to provide services. On the other hand, there are clear indications in the Court's more recent case-law that overriding reasons in the public interest can be invoked in certain areas also to justify discriminatory restrictions of fundamental freedoms, in which case it is naturally necessary always to observe the principle of proportionality. [59] However, in my view there is no need in the present case to answer definitively the question whether the discriminatory restriction of the freedom to provide services at issue here can in principle be justified by overriding reasons in the public interest, particularly since such justification always requires that the

57 — See Schiano, R., cited above in footnote 31, who considers that in every case the Court is required to strike an appropriate balance between the two conflicting interests. See also Van Raepenbusch, S., cited above in footnote 23, p. 8, according to whom the Court has the difficult task of reconciling, on the one hand, the requirements of the freedom of movement of people and, on the other, the need to maintain the financial balance of national health systems in the interests of general healthcare.

58 — Case C-55/94 *Gebhard* [1995] ECR I-4165, paragraph 37, a fundamental decision. Regarding discriminatory restrictions of the freedom to provide services, see Case C-153/08 *Commission* v *Spain* [2009] ECR I-9735, paragraph 36; Case C-451/03 *Servizi Ausiliari Dottori Commercialisti* [2006] ECR I-2941, paragraph 36 et seq.; and Case C-388/01 *Commission* v *Italy* [2003] ECR I-721, paragraph 19. Regarding the principle that no justification by overriding reasons in the public interest applies to restrictions of the freedom of establishment based on nationality, see Case C-89/09 *Commission* v *France* [2010] ECR I-12941, paragraph 50 et seq.; Joined Cases C-570/07 and C-571/07 *Blanco Pérez and Chao Gómez* [2010] ECR I-4629, paragraph 61 et seq.; Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 25 et seq.; and Case C-169/07 *Hartlauer* [2009] ECR I-1721, paragraph 44 et seq.

59 — This is the case, for example, in relation to environmental measures of a discriminatory nature. To that effect, see my Opinion of 16 December 2010 in pending Case C-28/09 *Commission* v *Austria*, point 82 et seq.

principle of proportionality be observed. As I have shown in my analysis, this requirement is not satisfied here.

this system is characterised by its autonomous nature and its universal cover. The structure of this system prescribed in Portuguese constitutional law of necessity limits patients' access to medical care abroad and reimbursement of medical expenses.

(a) Maintaining the financial balance of the social security system

(i) Legitimate justification

95. As justification for a restriction of this fundamental freedom the Portuguese Government primarily cites the need to maintain the financial balance of the national social security system. It argues that Article 64(2)(c) of the Portuguese Constitution requires the State to set up a national healthcare system which provides the public with largely free services. The free nature of the system means that it must be funded from tax revenue and the State budget. Funding the national healthcare system is the most important, and at the same time most costly, duty of the State. In the view of the Portuguese Government, [60] the fact that the national healthcare system is funded from public resources prohibits it from meeting medical expenses which arise as a result of treatment abroad. Furthermore,

96. In reply to the Portuguese Government's argument, it should be stated that according to the Court's case-law aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services. On the other hand, this argument cannot be automatically dismissed on that ground, particularly since the Court has not excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason of public interest capable of justifying a barrier of that kind. [61] For example, in its judgment of 5 October 2010 in *Commission* v *France* the Court recently recalled its previous case-law, according to which planning requirements may justify the requirement of prior authorisation for the assumption of costs on the part of the competent institution for treatment proposed in another Member State. [62]

60 — See paragraph 20 of the defence.

61 — See *Kohll*, cited above in footnote 15, paragraph 41; *Smits and Peerbooms*, cited above in footnote 19, paragraph 72; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 73; and *Stamatelaki*, cited above in footnote 20, paragraph 30.

62 — *Commission* v *France*, cited above in footnote 26, paragraph 33, with reference to *Smits and Peerbooms*, cited above in footnote 19, paragraphs 76 to 81, *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 76 to 81, and *Watts*, cited above in footnote 15, paragraphs 108 to 110.

97. However, these considerations, which relate to medical services provided in hospital, cannot be applied to the situation at the heart of the present dispute. An analysis of the case-law reveals that the Court has allowed this ground to be invoked only in cases concerning health services in the hospital and not in the non-hospital sector. [63] I will explain this aspect in greater detail below.

98. In examining this justification the Court draws a distinction between hospital and non-hospital medical services and recognises a need for planning by the Member States only in respect of the former. In the view of the Court, this planning is generally designed to satisfy various needs. 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. [64] This planning by the Member States relates to different aspects, such as the number of hospitals, their geographical distribution, the mode of their organisation and the equipment with which they are provided, and even the nature of the medical services which they are able to offer. The Court takes the view that, from both those perspectives, a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in another Member State must be subject to prior authorisation appears to be a measure which is both necessary and reasonable. [65]

99. However, it is clear that these considerations cannot be applied to non-hospital treatments, particularly since this type of

63 — See *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 72 to 92, in which the Court carries out a different examination of hospital and non-hospital services. See *Commission* v *France*, cited above in footnote 26, paragraph 34, in which the Court made it clear that planning requirements to avoid any waste of financial, technical and human resources could constitute justifications, in so far as medical services provided in hospital are concerned. See point 94 of the Opinion of Advocate General Mengozzi in *Commission* v *Spain* (judgment cited above in footnote 15).

64 — *Elchinov*, cited above in footnote 20, paragraph 43, and *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 80. Becker, U./Walser, C., 'Stationäre und ambulante Krankenhausleistungen im grenzüberschreitenden Dienstleistungsverkehr – von Entgrenzungen und neuen Grenzen in der EU', *Neue Zeitschrift für Sozialrecht*, 2005, p. 450, therefore conclude that receipt of non-hospital services may no longer be made subject to prior authorisation. Bieback, K.-J., 'Neue Rechtsprechung des EuGH zur grenzüberschreitenden Beanspruchung von Gesundheitsleistungen – zugleich eine Anmerkung zum Urteil des EuGH in der Rs. C-372/04', *Zeitschrift für europäisches Sozial- und Arbeitsrecht*, 7/2006, p. 242, understands the Court's case-law as meaning that prior authorisation for use of cross-border services constitutes an impairment of the freedom to provide services under Article 49 EC which is not permitted when non-hospital services are received, but is where hospital treatment is received since service planning and service reliability must be protected in the case of hospital services.

65 — See *Smits and Peerbooms*, cited above in footnote 19, paragraphs 62 and 64.

healthcare service is provided by a practitioner himself in his surgery and therefore the question of State planning does not normally arise.

100. The Portuguese Government's concerns about the difficulty of drawing a clear distinction between hospital and non-hospital services must in principle be accepted, [66] the Court having itself highlighted this difficulty in its case-law. [67] In actual fact it cannot be ruled out that 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 with the result that drawing a distinction may prove difficult in an individual case. [68] However, for the purposes of the present proceedings for failure to fulfil obligations the distinction is entirely irrelevant since firstly – unlike in other cases resolved by the Court – the distinction in the main proceedings is immaterial and, secondly, according to the information provided by the Portuguese Government the provisions of Decree-Law No 177/92 apply to both types of treatment without distinction.

101. Accordingly, unlike in *Commission* v *France* which concerned planning requirements resulting from the use of major medical equipment, [69] the Court does not have to examine whether certain non-hospital treatment could possibly be placed on the same footing as medical services provided in hospitals on account of their cost. For the purposes of the present case it is sufficient to recall that in that judgment the Court ultimately opted not to draw a distinction between the two kinds of medical treatment on account of the particular circumstances involved in the use of major medical equipment. In this respect, the Court concurred with the view of the French Government which had referred to the onerous costs of this equipment and thus to planning requirements. As the Court has rightly acknowledged, the use of exhaustively listed major medical equipment can – regardless of the setting, hospital or otherwise, in which it is intended to be installed and used – be the subject of planning policy. In this respect, the Court took the view that this planning policy concerned the quantity and geographical distribution of such equipment and was necessary both in order to help ensure throughout national territory a supply of up-to-date treatment, and also to avoid, so far as possible, any waste of resources. As correct as these considerations may have been in the abovementioned case, there is no evidence to show that a comparable situation exists in the present case. Although this does not mean that some of the non-hospital treatments covered by the scope of the Decree-Law could satisfy the requirements to be put on an equal footing in the above sense, the

66 — See paragraph 34 of the defence.

67 — See *Müller-Fauré and van Riet*, cited above in footnote 16, paragraphs 76 to 80.

68 — See *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 75, and point 67 of the Opinion of Advocate General Sharpston in *Commission* v *France* (judgment cited above in footnote 26).

69 — See *Commission* v *France*, cited above in footnote 26, paragraphs 34 to 37.

facts as presented to the Court do not permit such a conclusion to be drawn.

102. In view of the fact that the subject of the action for failure to fulfil obligations is solely non-hospital treatments provided abroad, the Portuguese Republic cannot successfully rely on any planning requirements or risk to the financial balance of the national healthcare system in order to restrict the freedom to provide services by making the reimbursement of medical expenses subject to obtaining prior authorisation.

103. Leaving that aside, the Portuguese Government has, as the Commission rightly complains, [70] thus far failed to prove that such a risk actually exists. As mentioned in my introductory remarks, [71] in the present proceedings for failure to fulfil obligations the duty to adduce evidence and the burden of proof in relation to the existence of a justification lies with it. The Portuguese Government has failed to fulfil this duty. Neither does the number of insured persons stated by it who, in the recent past, received reimbursement of their medical expenses, [72] appear, objectively, to be excessively high, nor does it contend, for example, that the number of insured persons who travelled abroad and requested reimbursement is so considerable that the financial balance of the Portuguese healthcare system could be upset, thereby jeopardising the overall level of public health protection.

104. In my view, in its arguments on the purported risk to the ability to fund its national healthcare system the Portuguese Government also ignores certain factors relating to patient mobility which the Court correctly highlighted in *Müller-Fauré and van Riet* [73] and which must be regarded as significant since they also influence the patient's decision to be treated abroad, irrespective of the eligibility for reimbursement of the medical expenses. They militate against the subliminal concern that patients would primarily receive treatment abroad. Firstly, these factors concern the type of treatment itself. Non-hospital care is generally provided near to the place where the patient resides, in a cultural environment which is familiar to him and which allows him to build up a relationship of trust with the doctor treating him. This necessarily means that, if emergencies are disregarded, the most obvious cases of patients travelling abroad are in border areas or where specific

70 — See paragraph 21 of the reply.

71 — See point 54 of this Opinion.

72 — At paragraph 16 of its reply the Portuguese Government puts the number of insured persons who received medical treatment and reimbursement for medical expenses incurred in other European countries in the years 2006 to 2008 at 1 275, with most of these treatments being carried out in Spain, Germany, France, the United Kingdom and Switzerland.

73 — Cited above in footnote 16, paragraphs 95 and 96.

conditions are to be treated. Secondly, it is not possible to ignore the factors which normally have an obstructive effect on patient mobility, such as, for example, the inevitable linguistic barriers, the geographic distance, the cost of staying abroad and the lack of information about the kind of care provided there. It was incumbent on the Portuguese Government also to take account of these aspects in its risk analysis. Instead, it appears to have proceeded on the basis of assumptions which are not substantiated in detail.

105. For the abovementioned reasons, I consider that the concern voiced by the Portuguese Government as regards maintaining the financial balance of the social security system does not constitute a legitimate justification.

(ii) Requirements for an authorisation procedure consistent with European Union law

— General

106. If, contrary to its previous case-law and in spite of the, in my view, insufficient evidence for the risk to the financial balance of the Portuguese social security system claimed by the Portuguese Government, the Court should conclude that there is a legitimate justification, the national rules at issue must satisfy both the requirements that the Court has placed on an authorisation procedure consistent with European Union law and the requirement of proportionality referred to at point 92 of this Opinion.

107. The Commission doubts that the authorisation procedure provided for in Decree-Law No 177/92 satisfies these requirements. Furthermore, it considers that the conditions which that law attaches to the grant of authorisation are excessively strict and disproportionate to the aim pursued. [74]

— Specific requirements of case-law

108. The Court has developed specific criteria which enable an assessment to be made of whether requirements laid down in national law for the grant of authorisation for treatment abroad, on which the reimbursement of medical expenses ultimately depends, are consistent with European Union law. As regards the examination scheme, the case-law shows that although these requirements for an authorisation procedure consistent with European Union law are closely connected with the examination of a national measure's

74 — See paragraph 13 of the reply.

proportionality, they constitute a separate element in assessing the justification for a restriction of a fundamental freedom. [75] Consequently, the examination of whether these requirements have been fulfilled does not replace but rather supplements the proportionality test. For that reason I will consider both elements separately below.

109. According to settled case-law, a prior authorisation scheme is justified even though it derogates from the freedom to provide services, if it is 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. [76]

110. Decree-Law No 177/92 confers on the competent authorities the power to decide on the 'clinical need' for medical care abroad. The law seeks to ensure that the competent authorities take a swift decision, as can be seen from the fact that Article 4(3) provides that the interested parties must be notified of the decision and the measures ordered without delay. Under normal circumstances the notification period is to be 15 days, under Article 4(4), which is to be reduced to five days in cases of urgency, under Article 5(1). Consequently, there are no concerns as to the reasonableness of the prescribed periods for processing a request for a referral abroad. The possibility of the Portuguese Minister for Health reviewing the administrative decision is provided for in Article 4(5), but this gives no cause for concern in principle, provided that the person making the request retains the possibility of challenging that decision in the courts.

111. However, there are doubts as to the compatibility of the provisions of Decree-Law No 177/92 since the criteria on which the competent authorities may base their decision on a patient's request to be referred abroad are not clear from the provisions of this law. Criteria for granting or refusing authorisation clearly do not exist. Therefore, there are no objective criteria which could circumscribe the exercise of the national authorities' discretion and ensure that this decision-making power is not used arbitrarily. As there are no clear criteria, it would appear impossible for a patient to foresee the decision taken by the national authorities empowered to take it. The lack of a legal framework in

75 — See *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 85; *Watts*, cited above in footnote 15, paragraph 116; *Commission* v *Spain*, cited above in footnote 15, paragraph 43; and *Elchinov*, cited above in footnote 20, paragraph 44.

76 — Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 38; *Smits and Peerbooms*, cited above in footnote 19, paragraph 90; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 85; *Watts*, cited above in footnote 15, paragraph 116; and *Commission* v *France*, cited above in footnote 26, paragraph 43. See judgment of the EFTA Court in Rindal and Slinning, cited above in footnote 29, paragraph 48.

that regard also probably makes it difficult to exercise judicial review of decisions refusing to grant authorisation. [77]

112. For example, it is questionable whether the impossibility of providing highly specialist medical care in Portugal on account of a lack of technical resources or personnel can be regarded as a legal requirement for referral abroad, particularly since, as I have already stated, it is this characteristic that makes the law applicable in regulatory terms in the first place. If it is in fact a condition, the question remains open as to what discretion the relevant authority has available to it and whether it is bound by certain requirements (for example, value for money, quality of treatment, etc.). The law contains no information in this regard.

113. Furthermore, the Portuguese Government has made no submissions which could dispel the doubts expressed here as to the transparency of the decision-making process provided for in Decree-Law No 177/92 and of the amenability to judicial review of the resultant opinions. In its observations, the Portuguese Government merely reproduces the relevant provisions of the law, without explaining in detail the process by which those decisions come about.

114. In my view, the provisions at issue of Decree-Law No 177/92 do not satisfy the abovementioned requirements which the Court has placed in its case-law on an authorisation procedure consistent with European Union law.

— Proportionality

115. Assuming that such a justification is legitimate, it must further be examined whether the requirement of prior authorisation for a referral abroad for medical treatment is *appropriate* and *necessary* to maintain the financial balance of the Portuguese healthcare system. According to the Court's case-law, a measure is appropriate to ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a consistent and systematic manner. [78] A measure is also necessary if, from among several measures which are appropriate for meeting

77 — See the parallels with *Watts*, cited above in footnote 15, paragraph 118, in which the Court complained that the regulations at issue did 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.

78 — See Case C-384/08 *Attanasio Group* [2010] ECR I-2055, paragraph 51, and Case C-169/08 *Presidente del Consiglio dei Ministri* [2009] ECR I-10821, paragraph 42.

the objective pursued, it is the least onerous for the interest or legal right in question. [79] Finally, such a measure must be *reasonable*, that it is to say it must not be disproportionate to the objective pursued. Consequently, there is an unreasonable restriction of the freedom to provide services where the national measure concerned, despite helping attain an objective in the public interest, results in an excessive derogation from the freedom to provide services.

116. Contrary to the view of the Spanish Government, [80] it is not for the Commission, but rather for the defendant Member State to provide evidence and proof that the measure objected to is consistent with the principle of proportionality. [81]

117. On that point, it must be stated that the Portuguese Government has failed to set out grounds for the extent to which examination by the State of individual requests to establish whether the requested highly specialist medical treatment can also be carried out in Portugal is appropriate to maintaining the financial balance of the Portuguese healthcare system. In particular, it is unclear as to where such a risk to this system could come from. The Portuguese Government has not explained whether this risk lies in higher treatment costs or possible misuse by unrecognised treatment centres. *A fortiori*, the Portuguese Government has not expressed its view on alternative measures to avert such risks.

118. However, even if the requirement of prior authorisation were appropriate and necessary to maintain the financial balance of the Portuguese healthcare system, it would be doubtful whether it could be regarded as reasonable in its specific legal form, particularly since the administrative procedure provided for in Decree-Law No 177/92 requires that the authorisation be obtained from three different authorities. This increases the uncertainty on the part of the person making the request as to the outcome of the procedure which already stems from the fact that Decree-Law No 177/92 does not lay down the criteria for deciding to grant or refuse individual authorisations. In particular, it is unclear as to what extent the authorities involved are bound by a favourable opinion of the doctor treating the person concerned and the conditions under which it is possible to derogate from it. In my view, the authorisation procedure therefore goes farther than is necessary to achieve the aim sought.

119. Consequently, the rules at issue are not consistent with the principle of proportionality.

79 — Case 265/87 *Schräder* [1989] ECR 2237, paragraph 21.

80 — See paragraph 34 of the Spanish Government's observations.

81 — See *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 44.

(b) Controlling the quality of healthcare services provided abroad

120. The Portuguese Government further argues that the requirement of prior authorisation is necessary to ensure the quality of the services provided by the national healthcare service or on its behalf. In legal terms, this argument must be construed as the Portuguese Government thereby relying on protection of public health under Article 55 EC, in conjunction with Article 46(1) thereof.

121. The Commission considers that the refusal to reimburse medical expenses on the ground that the healthcare services provided in another Member State were not of the same quality as those provided in Portugal would be based on a subjective, manifestly unreasonable and discriminatory criterion.

122. In response to the Portuguese Government's arguments, it is necessary first to state that it is true that the Member States may limit the freedom to provide services on grounds of public health. However, that does not permit them to exclude the public health sector, as a sector of economic activity and from the point of view of freedom to provide services, from the application of the fundamental principle of freedom of movement. [82]

123. In addition, I would like to point out that this argument was put forward in the *Kohll* case and rightly rejected by the Court with reference to qualification requirements for doctors in other Member States, which, to a certain extent, must be regarded as comparably high on account of the efforts at harmonisation within the European Union. For example, in that case the Luxembourg Government argued that the requirement of prior authorisation for the reimbursement of medical expenses was necessary to guarantee the quality of medical services, which in the case of persons going to another Member State could be ascertained only at the time of the request for authorisation. [83] However, the Court did not accept this argument since, as it stated, the conditions for taking up and pursuing the profession of doctor and dentist had been the subject of several coordinating or harmonising directives, which meant that doctors and dentists established in other Member States had to be afforded all guarantees equivalent to those accorded to doctors and dentists established on national territory, for the purposes of freedom to provide services. The Court consequently ruled that rules such as those in force in Luxembourg, which laid down a requirement of prior authorisation for reimbursement of medical expenses, could not be justified on grounds of

82 — See Case 131/85 *Gül* [1986] ECR 1573, paragraph 17, and *Kohll*, cited above in footnote 15, paragraph 46.

83 — *Kohll*, cited above in footnote 15, paragraph 43.

public health in order to protect the quality of medical services provided in other Member States. [84]

124. The same considerations must apply to the present case. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, [85] which replaced previous Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications, [86] can be cited as the most significant provision of law concerning the mutual recognition of professional qualifications for doctors. According to recital 19 in the preamble to this directive, it seeks to facilitate freedom of movement and the mutual recognition of the evidence of formal qualifications of a number of professional groups (including professional medical groups such as doctors and nurses responsible for general care, dental practitioners, veterinary surgeons, midwives and pharmacists) by introducing a mechanism for automatic recognition of evidence on the basis of coordinated minimum conditions. The concerns which the Portuguese Government expresses as to the possible differences in the quality of medical services in individual Member States must be rejected as unfounded in view of the comparable training conditions for members of professional medical groups.

125. Consequently, the requirement of prior authorisation for the reimbursement of medical expenses cannot be justified on grounds of public health by the need to supervise the quality of healthcare services abroad.

(c) Interim conclusion

126. In the light of the foregoing, I conclude that in the present case there is a restriction of the freedom to provide services in relation to 'highly specialised' treatment which cannot be objectively justified. The Portuguese Government has failed to put forward any legitimate justifications for it or furnish proof that there is a specific risk to the financial balance of its national social security system. Therefore, there is in principle no need to examine the compatibility of the measure at issue with the principle of proportionality. However, even if the Court were to regard it as a legitimate justification, the rules of Decree-Law No 177/92 would not satisfy the requirements that the Court has placed on an authorisation procedure consistent with European Union law.

84 — *Kohll*, cited above in footnote 15, paragraphs 47 to 49.
85 — OJ 2005 L 255, p. 22.
86 — OJ 1993 L 165, p. 1.

127. For the sake of completeness, I would like, in this context, to consider briefly the parallels which the Portuguese Government draws with the provisions of Regulation No 1408/71. In my view, it cannot rely successfully on the fact that the rule contained in Article 22(1)(c) of Regulation No 1408/71 provides for a requirement of authorisation in order to lay down a requirement of authorisation also in respect of healthcare services which fall within the scope of Article 49 EC. As was shown at the hearing, in its considerations it overlooks the fact that Article 22 of Regulation No 1408/71 has a different regulatory purpose. It confers on the insured person 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. [87] In this regard, the rules governing cover that are in force in the Member State are decisive. [88] The possible differences in cost from one Member State to another and the resulting financial consequences for the party responsible for bearing the costs justify in principle the requirement of prior authorisation. However, this precisely does not apply in the case of Article 49 EC since this provision confers a right to reimbursement of expenses only in accordance with the provisions of the law of the Member State in which the patient resides. [89] Therefore, where the insured person has had to bear higher costs in the Member State of the service provider, it can claim reimbursement under this provision only at the rates of the institution responsible for bearing the costs in the State of insurance. [90] Leaving that aside, it should be borne in mind that in *Müller-Fauré and van Riet* [91] and recently in *Commission* v *Luxembourg* [92] the Court ruled that when applying Regulation No 1408/71, those Member States which have established a system providing benefits in kind, or even a national health service, must provide mechanisms for *ex post facto* reimbursement in respect of care provided in a Member State other than the competent State. Consequently, the argument put forward by the Portuguese Government to the contrary must be rejected.

128. To summarise, it must be concluded that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC by making in Decree-Law No 177/92 the reimbursement of medical expenses for so-called 'highly specialised' non-hospital treatments incurred in another Member State subject to prior authorisation.

87 — *Watts*, cited above in footnote 15, paragraph 48, and *Inizan*, cited above in footnote 19, paragraph 19.

88 — *Commission* v *France*, cited above in footnote 26, paragraph 27.

89 — See *Watts*, cited above in footnote 15, paragraph 48. To that effect, see Schneider, U., cited above in footnote 31, p. 349.

90 — To this effect, see Bieback, K.J., cited above in footnote 64, p. 245.

91 — *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 105.

92 — *Commission* v *Luxembourg*, cited above in footnote 16, paragraph 46.

2. Justification in the case of 'other' medical treatments

129. The Portuguese Government does not expressly give its opinion on the restriction which arises from the ineligibility for reimbursement of medical expenses incurred in connection with 'other' medical treatments. Its observations essentially concern the regulatory purpose of Decree-Law No 177/92 and certain essential features of the Portuguese healthcare system. However, it is possible to deduce from the Portuguese Government's statements that the Portuguese Government is not willing generally to pay the costs of treatment abroad. [93] It justifies its stance by the same arguments underlying the rules of Decree-Law No 177/92. It must therefore be concluded that the abovementioned justifications are also put forward in connection with the 'other' treatments.

(a) Maintaining the financial balance of the social security system

(i) Legitimate justification

130. My comments on the question whether the concern about maintaining the financial balance of the social security system in connection with cross-border non-hospital healthcare services can constitute a legitimate justification at all [94] apply here *mutatis mutandis*. Also in relation to 'other' non-hospital treatments there is no discernible need for planning by the Member States to – as the Court puts it in its case-law – 'prevent... any wastage of financial, technical and human resources'. Furthermore, to date the Portuguese Government has furnished no proof that a risk to the financial balance of the social security system actually exists. In this context too, I consider that the concern expressed by the Portuguese Government regarding maintenance of the financial balance of the social security system cannot be regarded as a legitimate justification.

(ii) Proportionality

131. In the alternative, if the Court accepts that there is a legitimate justification, contrary to its previous case-law and the evidence submitted, the categorical ineligibility for reimbursement of medical expenses incurred in connection with 'other' non-hospital treatment would have to be assessed in the light of the principle of proportionality, to the conditions of which I referred at point 115 of this Opinion.

93 — See point 87 of this Opinion.

94 — See points 95 to 105 of this Opinion.

132. The Portuguese Government has made no submissions to support its argument that the ineligibility for reimbursement of the medical costs in question is appropriate to helping maintain the financial balance of the national social security system. Mere references to the autonomy and funding of the system by taxes and the risk of having also to pay costs arising from treatment in private institutions are no substitute for factual arguments on the appropriateness of these rules.

133. However, even if it were to be accepted that refusal of any reimbursement of medical expenses could help save on costs and was therefore appropriate to maintaining the balance of a national social security system, it is doubtful whether such a measure would satisfy the requirements of necessity and appropriateness. 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.' [95] However, as regards medical expenses incurred in connection with 'other' non-hospital treatments there is, unlike in the case of 'highly specialised' treatments, not even the prospect of reimbursement. The Portuguese Government ultimately uses one of the most onerous measures it can which restricts the freedom to provide services even more than the statutory requirement of prior authorisation. This measure negates the effectiveness of the fundamental freedom in so far as persons insured under the Portuguese health system are unlikely to receive healthcare services from another Member State as they will be aware that they will have to bear the entire costs themselves. Depending on the amount of these costs and the financial resources of the insured person it seems rather unlikely that it would be possible to exercise the freedom to obtain services in such circumstances. [96] Since there are less onerous measures which are capable of attaining the objective sought, that is to say of maintaining the financial balance of the national social security system, the categorical refusal to reimburse costs must be regarded as unnecessary. Nor is it reasonable because it completely undermines the freedom to provide services in order to protect the national social security system from a risk which is not substantiated in detail.

134. Consistently, the rules at issue are inconsistent with the principle of proportionality.

95 — See *Smits and Peerbooms*, cited above in footnote 16, paragraph 90; *Müller-Fauré and van Riet*, cited above in footnote 16, paragraph 84; and *Watts*, cited above in footnote 15, paragraph 132.

96 — See *Commission v Luxembourg*, cited above in footnote 16, paragraph 41, in which the Court rightly held that the prospect of not having costs reimbursed deters insured persons from exercising the freedom to obtain services or even prevents them from exercising this fundamental freedom.

(b) Supervising the quality of health services provided abroad

135. As regards the justification concerning the need to ensure the quality of the services provided by the national healthcare service or on its behalf, I refer to the explanations above, [97] which apply *mutatis mutandis* in this regard. In view of the clear case-law of the Court, which in this respect assumes that there are comparable training conditions for members of professional medical groups and thus ultimately comparable quality standards in the treatment of patients, the concern expressed as to the quality of the care for patients resident in Portugal cannot be regarded a legitimate ground which justifies a restriction of the freedom to provide services.

(c) Interim conclusion

136. I therefore conclude also in relation to the 'other' medical treatments, which are not covered by Decree-Law No 177/92, that there is a restriction of the freedom to provide services which cannot be objectively justified. It must therefore be found that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC by not allowing in the provisions of its law for the reimbursement of medical expenses for 'other' non-hospital treatment incurred in another Member State.

D — *Definitive conclusion*

137. In view of the above considerations, I consider that the Commission's application is well founded. The Portuguese Republic has failed to fulfil its obligations under Article 49 EC by making, in the provisions of its national law, the reimbursement of medical expenses for 'highly specialised' non-hospital treatment incurred in another Member State subject to prior authorisation, [98] whilst not even allowing for such reimbursement for 'other' non-hospital treatment incurred in another Member State. [99]

97 — See points 120 to 125 of this Opinion.

98 — See point 128 of this Opinion.

99 — See point 136 of this Opinion.

VII — Costs

138. Under Article 69(2) of the Rules of Procedure, in Treaty infringement proceedings the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs and the Portuguese Republic has been unsuccessful, it must be ordered to pay the costs.

VIII — Conclusion

139. In the light of the foregoing considerations, I propose that the Court should:

(1) Rule that the Portuguese Republic has failed to fulfil its obligations under Article 49 EC by making, in the provisions of its national law, the reimbursement of medical expenses for 'highly specialised' non-hospital treatment incurred in another Member State subject to prior authorisation and not even allowing for such reimbursement for 'other' non-hospital treatment incurred in another Member State;

(2) Order the Portuguese Republic to pay the costs.