JUDGMENT OF THE COURT (Grand Chamber)

5 October 2010 *

In Case C-173/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Administrativen sad Sofia-grad (Bulgaria), made by decision of 28 April 2009, received at the Court on 14 May 2009, in the proceedings

Georgi Ivanov Elchinov

v

Natsionalna zdravnoosiguritelna kasa,

THE COURT (Grand Chamber),

composed of V. Skouris, President, A. Tizzano, J.N. Cunha Rodrigues, K. Lenaerts, J.-C. Bonichot and R. Silva de Lapuerta, Presidents of Chambers, A. Rosas, K. Schiemann, P. Kūris (Rapporteur), J.-J. Kasel, M. Safjan, D. Šváby and M. Berger, Judges,

* Language of the case: Bulgarian.

Advocate General: P. Cruz Villalón,
Registrar: R. Grass,

after considering the observations submitted on behalf of:

— Mr Elchinov, by L. Panayotova, advokat,

— the Bulgarian Government, by T. Ivanov and E. Petranova, acting as Agents,

— the Czech Government, by M. Smolek, acting as Agent,

— the Greek Government, by K. Georgiadis, I. Bakopoulos and S. Vodina, acting as Agents,

— the Spanish Government, by J. M. Rodríguez Cárcamo, acting as Agent,

— the Polish Government, by M. Dowgielewicz, acting as Agent,

— the Finnish Government, by A. Guimaraes-Purokoski, acting as Agent,

— the United Kingdom Government, by S. Ossowski, acting as Agent,

— the Commission of the European Communities, by S. Petrova, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 10 June 2010,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 49 EC and 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996 (OJ 1997 L 28, p. 1), as amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006 (OJ 2006 L 392, p. 1) ('Regulation No 1408/71').

2 The reference has been made in proceedings between Mr Elchinov and the Natsionalna zdravnoosiguritelna kasa (national social security fund; 'NZOK') concerning its refusal to authorise him to receive hospital treatment in Germany.

Legal context

European Union legislation

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

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

…

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

shall be entitled:

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

…

2. …

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

…'

4 Article 36(1) of Regulation No 1408/71 provides:

'Benefits in kind provided in accordance with the provisions of this chapter by the institution of one Member State on behalf of the institution of another Member State shall be fully refunded.'

5 On the basis of Article 2(1) of Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 (OJ, English Special Edition, 1972 (I), p. 159), the Administrative Commission on Social Security for Migrant Workers, set up pursuant to Article 80 of Regulation No 1408/71, adopted a model for the certificate necessary for the application of Article 22(1)(c)(i) of that regulation, that is to say, form 'E 112'.

National legislation

6 Under Article 224 of the Bulgarian Code of Administrative Procedure:

'The directions of the Supreme Administrative Court on the interpretation and the application of the law are mandatory for the subsequent examination of the case.'

7 Under Article 81(1) of the Law on health (DV No 70 of 10 August 2004):

'Every Bulgarian citizen has the right of access to health care on the terms and in accordance with the conditions laid down in the present law and by the Law on sickness insurance.'

8 By virtue of Article 33 of the Law on sickness insurance (DV No 70 of 19 June 1998), all Bulgarian citizens who are not also citizens of another State are compulsorily covered by NZOK.

9 Article 35 of that law provides that insured persons are entitled to obtain the document required for the exercise of their sickness insurance rights in compliance with the rules on the coordination of social security schemes.

10 Article 36(1) of that law provides:

'Persons insured under the compulsory scheme shall be entitled to obtain reimbursement in part or in full of expenses incurred for medical treatment abroad only if they have obtained prior authorisation to that end from NZOK.'

11 The types of healthcare benefits covered by NZOK are listed in Article 45 of the Law on sickness insurance, paragraph 2 of which provides that the basic package of healthcare benefits is to be determined by a decree of the Minister for Health. On that basis,

that Minister adopted Decree No 40 of 24 November 2004 on the determination of the package of basic healthcare benefits guaranteed by the NZOK budget (DV No 88, 2006), the single article of which states that that basic package is to include those benefits the type and range of which are set out in Annexes 1 to 10 to that Decree. Annex 5 thereto, entitled 'List of clinical treatments', refers, under number 136, to 'other operations on the eyeball' and, under number 258, to 'high-technology radiotherapy for oncological and non-oncological conditions'.

The dispute in the main proceedings and the questions referred for a preliminary ruling

12 Mr Elchinov, a Bulgarian citizen covered by NZOK, suffers from a serious illness, on account of which he asked that fund, on 9 March 2007, to issue form E 112 with a view to his undergoing advanced treatment in a specialist clinic in Berlin (Germany), since such treatment was not available in Bulgaria.

13 Given his state of health, however, Mr Elchinov was admitted to hospital in Germany on 15 March 2007 and was treated there before receiving NZOK's answer.

14 By decision of 18 April 2007, taken after the opinion of the Minister of Health had been obtained, the director of NZOK refused to give Mr Elchinov the authorisation sought, on the ground, inter alia, that the conditions for grant of such authorisation laid down in the Article 22 of Regulation No 1408/71 were not met, since that treatment, in the director's view, was not one of the benefits provided for by the Bulgarian legislation and reimbursed by NZOK.

15 Mr Elchinov appealed against that decision to the Administrativen sad Sofia-grad (Administrative Court of Sofia). An expert medical opinion obtained during the proceedings confirmed that the treatment in question was an advanced therapy which was not yet available in Bulgaria.

16 By judgment of 13 August 2007, the Administrativen sad Sofia-grad annulled that decision, taking the view that the conditions for grant of authorisation laid down by Article 22(2) of Regulation No 1408/71 were met in the present case. That court found, inter alia, that the treatment in question did not exist in Bulgaria, but corresponded to the services numbered 136 and 258 in the list of clinical treatments.

17 NZOK appealed against that judgment before the Varchoven administrativen Sad (Supreme Administrative Court), which, by judgment of 4 April 2008, set aside the judgment and referred the case back to a different chamber of the lower court. The Varchoven administrativen Sad held that the finding of the court at first instance that the treatment received by Mr Elchinov fell within the services numbered 136 and 258 in the list of clinical treatments was incorrect. In addition it pointed out that if the specific treatment for which the issue of form E 112 had been applied for was reimbursable by NZOK, it had to be presumed that such treatment could be given in a Bulgarian healthcare institution, so that the lower court should have ruled on whether such treatment could be given in such an institution within a period which would not endanger the state of health of the person concerned.

18 In the course of re-examination of the case by the Administrativen sad Sofia-grad, a fresh medical report confirmed that treatment such as that given to Mr Elchinov in Germany was not available in Bulgaria.

19 In those circumstances, the Administrativen sad Sofia-grad decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Is the second subparagraph of Article 22(2) of … Regulation … No 1408/71 … to be interpreted as meaning that, where it is impossible to give in a Bulgarian healthcare institution the specific treatment that has been the subject of an application for the issue of form E 112, it is to be assumed that this treatment is not financed from the budget of [NZOK] or the Ministry of Health or, conversely, where such treatment is financed from the budget of NZOK or the Ministry of Health it is to be assumed that it can be given in a Bulgarian healthcare institution?

2. Is the phrase "the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides" in the second paragraph of Article 22(2) of Regulation … No 1408/71 to be interpreted as encompassing cases in which the treatment that is given in the territory of the Member State in which the insured person resides is much less effective and more radical than the treatment that is given in another Member State, or does it encompass only those cases in which the person concerned cannot be treated without undue delay?

3. Having regard to the principle of procedural autonomy: is the national court obliged to take account of binding directions given to it by a higher court when its decision is set aside and the case referred back for reconsideration if there is reason to assume that such directions are inconsistent with Community law?

4. If the particular treatment concerned cannot be given on the territory of the Member State in which the person with medical insurance resides is it then sufficient, in order for that Member State to be obliged to issue authorisation for treatment in another Member State under Article 22(1)(c) of Regulation … No 1408/71, for the type of treatment concerned to be included within the benefits provided for under the legislation of the first mentioned Member State even if that legislation does not expressly stipulate the specific method of treatment?

5. Are Article 49 EC and Article 22 of Regulation … No 1408/71 inconsistent with a national provision such as Article 36(1) of the Law on health insurance, according to which persons insured under the compulsory scheme have the right to receive in part or in full [reimbursement of] the value of the expenses for medical care abroad only if they have received a preliminary permit?

6. Must the national court oblige the competent institution of the State in which the patient has medical insurance to issue the document for treatment abroad (form E 112) if it considers the refusal to issue such a document to be unlawful, where the application for the issue of the document has been lodged before the treatment was carried out abroad and the treatment has been completed by the date on which the court decision is pronounced?

7. If the aforementioned question should be answered in the affirmative and the court should consider the refusal of authorisation for treatment abroad to be unlawful how is the person with medical insurance to be reimbursed the costs of his treatment:

   (a) directly by the State in which he is insured or by the State in which the treatment has been given, following submission of authorisation for treatment abroad?

(b) to what extent, if the range of benefits that are provided for under the legislation of the Member State where he resides should differ from the range of benefits provided for under the legislation of the Member State in which the treatment is given, in the light of Article 49 EC, which prohibits restrictions on freedom to provide services?'

The questions referred

20 It is appropriate to answer the third question first, before examining the other six questions, which relate to the interpretation of Articles 49 EC and 22 of Regulation No 1408/71.

The third question

21 It is apparent from the order for reference that the Administrativen sad Sofia-grad has doubts as to the interpretation of Articles 49 EC and 22 of Regulation No 1408/71 and, in particular, with regard to the interpretation of Article 22 adopted by the Varchoven administrativen sad in its judgement of 4 April 2008. While making a reference to the Court for a preliminary ruling on the interpretation of the abovementioned provisions, the national court questions whether the court dealing with the substance of the case is bound by the legal rulings of a higher court, if there is reason to assume that such rulings are inconsistent with European Union law.

22 The national court states that, pursuant to Article 224 of the Bulgarian Code of administrative procedure, directions given by the Varchoven administrativen sad on the interpretation and application of the law are binding on the Administrativen sad Sofia-grad on re-examination of the case by that court. It also notes that European Union law observes the principle of the procedural autonomy of the Member States.

23 Although the question which it refers to the Court does not appear to exclude the possibility that a national court might consider adjudicating without making a preliminary reference, departing from legal rulings given in the same case by the higher national court, which it regards as inconsistent with European Union law, it must be noted that that is not the situation in the present case, since the national court has made a reference for a preliminary ruling to the Court seeking clarification of the doubts which it has as to the correct interpretation of European Union law.

24 Accordingly, by its third question, the national court asks whether European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.

25 In that regard, it must be borne in mind, firstly, that the existence of a rule of national procedure such as that applicable in the case in the main proceedings cannot call into question the discretion of national courts not ruling at final instance to make a reference to the Court for a preliminary ruling where they have doubts, as in the present case, as to the interpretation of European Union law.

26 It is settled case-law that Article 267 TFEU gives national courts the widest discretion in referring matters to the Court if they consider that a case pending before them raises questions involving interpretation of provisions of European Union law, or consideration of their validity, which are necessary for the resolution of the case (see, to that effect, Case 166/73 *Rheinmühlen-Düsseldorf* [1974] ECR 33, paragraph 3; Case C-348/89 *Mecanarte* [1991] ECR I-3277, paragraph 44; Case C-261/95 *Palmisani* [1997] ECR I-4025, paragraph 20; Case C-210/06 *Cartesio* [2008] ECR I-9641, paragraph 88; and Joined Cases C-188/10 *Melki and Abdeli* [2010] ECR I-5667, paragraph 41). National courts are, moreover, free to exercise that discretion at whatever stage of the proceedings they consider appropriate (see, to that effect, *Melki and Abdeli*, paragraphs 52 and 57).

27 The Court has thus concluded that a rule of national law, pursuant to which courts that are not adjudicating at final instance are bound by legal rulings of a higher court, cannot take away from those courts the discretion to refer to the Court questions of interpretation of the point of European Union law concerned by such legal rulings. The Court has held that a court which is not ruling at final instance must be free, if it considers that a higher court's legal ruling could lead it to give a judgment contrary to European Union law, to refer to the Court questions which concern it (see, to that effect, *Rheinmühlen-Düsseldorf*, paragraphs 4 and 5; *Cartesio*, paragraph 94; Case C-378/08 *ERG and Others* [2010] ECR I-1919, paragraph 32; and *Melki and Abdeli*, paragraph 42).

28 However, it must be pointed out that the possibility thus given to the national court by the second paragraph of Article 267 TFEU of asking the Court for a preliminary ruling before, if necessary, disapplying directions from a higher court which prove to be contrary to European Union law cannot be transformed into an obligation (see, to that effect, Case C-555/07 *Kücükdeveci* [2010] ECR I-365, paragraphs 54 and 55).

29 Secondly, it must be borne in mind that it is settled case-law that a judgment in which the Court gives a preliminary ruling is binding on the national court, as regards the interpretation or the validity of the acts of the European Union institutions in question, for the purposes of the decision to be given in the main proceedings (see, inter alia, Case 29/68 *Milch-, Fett- und Eierkontor* [1969] ECR 165, paragraph 3; Case 52/76 *Benedetti* v *Munari* [1977] ECR 163, paragraph 26; order in Case 69/85 *Wünsche Handelsgesellschaft* [1986] ECR 947, paragraph 13; and Case C-446/98 *Fazenda Pública* [2000] ECR I-11435, paragraph 49).

30 It follows from those considerations that the national court, having exercised the discretion conferred on it by the second paragraph of Article 267 TFEU, is bound, for the purposes of the decision to be given in the main proceedings, by the interpretation of the provisions at issue given by the Court and must, if necessary, disregard the rulings of the higher court if it considers, having regard to that interpretation, that they are not consistent with European Union law.

31 In addition, it is appropriate to point out that, in accordance with settled case-law, a national court which is called upon, within the exercise of its jurisdiction, to apply provisions of European Union law is under a duty to give full effect to those provisions, if necessary refusing of its own motion to apply any conflicting provision of national legislation, that is to say, in the present case, the national procedural rule set out in paragraph 24 of this judgment, and it is not necessary for the court to request or await the prior setting aside of that national provision by legislative or other constitutional means (see, to that effect, Case 106/77 *Simmenthal* [1978] ECR 629, paragraph 24, and Case C-314/08 *Filipiak* [2009] ECR I-11049, paragraph 81).

32 In the light of the foregoing, the answer to the third question is that European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.

The questions regarding the interpretation of Articles 49 EC and 22 of Regulation No 1408/71

33 It is appropriate to examine first the fifth question, concerning the extent of the power of Member States to make reimbursement in respect of hospital treatment given in another Member State subject to prior authorisation, next, the first, second and fourth questions, concerning the conditions set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 and, finally, together, the sixth and seventh questions, concerning the means of reimbursement in respect of that treatment to the person insured.

The fifth question, concerning the extent of the power of Member States to make reimbursement in respect of hospital treatment given in another Member State subject to prior authorisation

34 By its fifth question, the national court asks, in essence, whether Articles 49 EC and 22 of Regulation No 1408/71 preclude legislation of a Member State which excludes, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

35 The national court, recalling that Mr Elchinov had treatment in Germany before he had received NZOK's response to his request for authorisation, asks whether an insured person can seek reimbursement in respect of hospital treatment given in a Member State other than that in which he resides without having first obtained authorisation from the competent institution, where his state of health so required, or whether obtaining the treatment without such prior authorisation entails the insured person losing his right to seek reimbursement of its cost. Pointing out that Article 36

of the Law on sickness insurance permits reimbursement for treatment given in another Member State only if the insured person has obtained prior authorisation for that treatment, it asks whether that provision is consistent with Articles 49 EC and 22 of Regulation No 1408/71.

36 In that regard, firstly, it should be noted that, according to settled case-law, medical services provided for consideration fall within the scope of the provisions on the freedom to provide services, including situations where care is provided in a hospital environment (see, to that effect, Case C-372/04 *Watts* [2006] ECR I-4325, paragraph 86 and the case-law cited, and Case C-211/08 *Commission* v *Spain* [2010] ECR I-5267, paragraph 47 and the case-law cited).

37 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 (*Watts*, paragraph 87 and the case-law cited, and *Commission* v *Spain*, paragraphs 48 to 50 and the case-law cited).

38 The applicability of Article 22 of Regulation No 1408/71 to the situation in this case does not mean that provisions on the freedom to provide services and, in the circumstances, Article 49 EC, cannot apply at the same time. On the one hand, the fact that national legislation may possibly be in conformity with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that legislation from the scope of the provisions of the EC Treaty (see, to that effect, *Watts*, paragraphs 46 and 47, and *Commission* v *Spain*, paragraph 45).

39 On the other hand, the purpose of Article 22(1)(c)(i) of Regulation No 1408/71 is to confer a right to the benefits in kind provided, on behalf of the competent institution, by the institution of the place where the insured person is staying, in accordance

with the provisions of the legislation of the Member State in which the benefits are provided as if the person concerned were registered with that institution (see, to that effect, Case C-120/95 *Decker* [1998] ECR I-1831, paragraphs 28 and 29; Case C-158/96 *Kohll* [1998] ECR I-1931, paragraphs 26 and 27; Case C-368/98 *Vanbraekel and Others* [2001] ECR I-5363, paragraphs 32 and 36; Case C-56/01 *Inizan* [2003] ECR I-12403, paragraphs 19 and 20; and *Watts*, paragraph 48). The sole purpose of the second subparagraph of Article 22(2) of Regulation No 1408/71 is to identify the circumstances in which the competent national institution is precluded from refusing authorisation sought on the basis of Article 22(1)(c) (see, to that effect, *Vanbraekel and Others*, paragraph 31).

40 Secondly, it must also be borne in mind that, as submitted by the Governments which have submitted observations in the present case, it is established that European Union law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits. The fact nevertheless remains that, when exercising that power, Member States must comply with European Union law and, in particular, with the provisions on the freedom to provide services which prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector (see in particular, to that effect, *Watts*, paragraph 92 and the case-law cited; Case C-444/05 *Stamatelaki* [2007] ECR I-3185, paragraph 23; and *Commission* v *Spain*, paragraph 53).

41 Although prior authorisation, such as that required by Article 36 of the Law on sickness insurance, constitutes, for both patients and service providers, an obstacle to the freedom to provide services (see, to that effect, *Kohll*, paragraph 35; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473, paragraph 69; Case C-385/99 *Müller-Fauré and van Riet* [2003] ECR I-4509, paragraph 44; and *Watts*, paragraph 98), the Court has nevertheless held that Article 49 EC does not in principle preclude the right of a patient to receive hospital treatment in another Member State at the expense of the

system with which he is registered from being subject to prior authorisation (*Smits and Peerbooms*, paragraph 82, and *Watts*, paragraph 113).

42 The Court has held that it cannot be excluded that the possible risk of seriously undermining the financial balance of a social security system may constitute an overriding reason in the public interest capable of justifying an obstacle to the freedom to provide services. The Court has likewise acknowledged that the objective of maintaining a balanced medical and hospital service open to all may also fall within the derogations on grounds of public health under Article 46 EC in so far as it contributes to the attainment of a high level of health protection. It has also held that Article 46 EC permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health, and even the survival of the population (see, to that effect, *Kohll*, paragraphs 41, 50 and 51; *Smits and Peerbooms*, paragraphs 72 to 74; *Müller-Fauré and van Riet*, paragraphs 67 and 73; and *Watts*, paragraphs 103 to 105).

43 The Court has also pointed out that the number of hospitals, their geographical distribution, the mode of their organisation and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For another thing, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited,

whatever the mode of funding applied (*Smits and Peerbooms*, paragraphs 76 to 79, and *Watts*, paragraphs 108 and 109).

44 Thirdly, it must also be borne in mind that, 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 must be justified in the light of the imperatives mentioned above, that they do not exceed what is objectively necessary for that purpose and that the same result cannot be achieved by less restrictive rules. 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 (see, to that effect, *Smits and Peerbooms*, paragraphs 82 and 90; *Müller-Fauré and van Riet*, paragraphs 83 to 85; and *Watts*, paragraphs 114 to 116).

45 In the present case, it is clear that a national rule excluding, in all cases, payment for hospital treatment given in another Member State without prior authorisation deprives the insured person who, for reasons relating to his state of health or to the need to receive urgent treatment in a hospital, was prevented from applying for such authorisation or was not able, like Mr Elchinov, to wait for the answer of the competent institution, of reimbursement from that institution in respect of such treatment, even though all other conditions for such reimbursement to be made are met.

46 Reimbursement in respect of such treatment, in the particular situations described in the preceding paragraph, is not likely to compromise achievement of the objectives of hospital planning referred to in paragraph 43 above, nor seriously to undermine the financial balance of the social security system. It does not affect the maintenance of a balanced hospital service accessible to all, or that of treatment capacity and medical competence on national territory.

47 Consequently, such legislation is not justified by such imperatives and, in any event, does not satisfy the requirement of proportionality referred to in paragraph 44 of this judgment. Thus, it constitutes an unjustified restriction on the freedom to provide services.

48 In addition, with regard to the application of Article 22(1)(c) of Regulation No 1408/71, the Court held, in paragraph 34 of *Vanbraekel and Others*, that, where the request of an insured person for authorisation on the basis of that provision has been refused by the competent institution and it is subsequently established, either by the competent institution itself or by a court decision, that that refusal was unjustified, that person is entitled to be reimbursed directly by the competent institution in an amount equivalent to that which it would ordinarily have borne if authorisation had been properly granted at the outset.

49 It follows that the legislation of a Member State cannot exclude, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

50 With regard to the legislation at issue in the case in the main proceedings, as the Advocate General observed, in essence, in points 49 and 50 of his Opinion, Article 36 of the Law on sickness insurance is ambiguous. In any event, it is for the national court to assess, in the light of the guidance given in the present judgment, whether that article is consistent with Articles 49 EC and 22 of Regulation No 1408/71 as interpreted by the Court and, in so far as the said Article 36 may be subject to a number of interpretations, to interpret it in a way which accords with European Union law (see, to that effect, *Melki and Abdeli*, paragraph 50 and the case-law cited).

51 In the light of all the foregoing, the answer to the fifth question is that Articles 49 EC and 22 of Regulation No 1408/71 preclude legislation of a Member State which is interpreted as excluding, in all cases, reimbursement in respect of hospital treatment given in another Member State without prior authorisation.

The first, second and fourth questions, concerning the conditions set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

52 By its first, second and fourth questions, the national court asks, in essence, whether, with regard to medical treatment which cannot be given in the Member State in whose territory the insured person resides, the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that the authorisation required under Article 22(1)(c)(i) cannot be refused where, on the one hand, the treatment in question is among the benefits provided for under the legislation of the Member State on whose territory the person concerned resides, but that legislation does not expressly and precisely stipulate the method of treatment applied, and, on the other hand, he cannot be given alternative treatment offering the same level of effectiveness without undue delay. In addition, it wishes to know whether that article is to be interpreted as precluding the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in that Member State is not included in the benefits for which reimbursement is provided for by the legislation of that State or, conversely, that the hospital treatment included in those benefits can be given in that Member State.

53 The second subparagraph of Article 22(2) of Regulation No 1408/71 lays down two conditions which, if both are satisfied, render mandatory the grant by the competent institution of the prior authorisation applied for on the basis of Article 22(1)(c)(i) (see, to that effect, *Inizan*, paragraph 41, and *Watts*, paragraph 55).

54 The first condition requires the treatment in question to be among the benefits provided for by the legislation of the Member State on whose territory the insured person resides, whereas the second condition requires that the treatment which the latter plans to undergo in a Member State other than that on the territory of which he resides cannot be given within the time normally necessary for obtaining the treatment in question in the Member State of residence, taking account of his current state of health and the probable course of his disease (*Inizan*, paragraphs 42 and 44, and *Watts*, paragraphs 56 and 57).

55 Since the fourth question referred to the Court concerns the first of those conditions, it is appropriate to consider it first. Next, the second question, which concerns the second of those conditions, will be analysed and, finally, the first question, which concerns the presumption referred to in the order for reference, will be examined, since the answer to that question follows from those given to the other two questions.

– The fourth question, concerning the first condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

56 In order to establish whether the first condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, it is necessary to ascertain whether the 'the treatment in question', namely as appears from the documents presented to the Court, the treatment for the eye prescribed by medical prescription and consisting of the attachment of radioactive applicators ?or proton therapy, is among the 'benefits provided for by the legislation of the Member State on whose territory the person concerned resides', that is to say among the benefits for which the Bulgarian social security scheme provides for reimbursement.

57 In that regard, it must be pointed out that, as recalled in paragraph 40 of the present judgment, European Union law does not detract from the power of the Member States to organise their social security systems and that, in the absence of harmonisation at European Union level, it is for the legislation of each Member State to determine the conditions for the grant of social security benefits.

58 Thus, it has already been held that it is not, in principle, incompatible with European Union law for a Member State to establish exhaustive lists of the medical benefits reimbursed under its social security scheme and that that right cannot, in principle, have the effect of requiring a Member State to extend such lists of medical benefits (see, to that effect, *Smits and Peerbooms*, paragraph 87).

59 It follows that, as submitted by the Governments which have made observations in the present case, it is for each Member State to decide which medical benefits are reimbursed by its own social security system. To that end, the Member State concerned is entitled to list precisely treatments or treatment methods or to state more generally the categories or types of treatments or treatment methods.

60 In that context, it is only those national bodies called upon to rule on an application for authorisation to receive treatment in a Member State other than that on the territory of which the insured person resides which can determine whether that treatment is included on such a list. In the present case, it is for the national court to decide whether the treatment received by Mr Elchinov in Germany is included in the clinical treatments listed in Annex 5 to Decree No 40.

61 Nevertheless, the fact remains that, since the Member States are required not to disregard European Union law in the exercise of their powers, it must be ensured that the second subparagraph of Article 22(2) of Regulation No 1408/71 is applied in a way which accords with that law, in compliance with the requirements set out in paragraph 44 of the present judgment.

62 It follows from the above, where the list of medical benefits reimbursed does not expressly and precisely specify the treatment method applied but defines types of treatment, on the one hand, that it is for the competent institution of the Member State of residence of the insured person to assess, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, whether that treatment method corresponds to benefits provided for by the legislation of that Member State. It also follows, on the other hand, that, if such is the case, an application for prior authorisation cannot be refused on the ground that such a treatment method is not available in the Member State of residence of the insured person, since such a ground, if it were accepted, would imply a restriction on the scope of the second subparagraph of Article 22(2) of Regulation No 1408/71.

– The second question, concerning the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71

63 In order to establish whether the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, it is necessary to ascertain whether the treatment in question can be given to the insured person within the time normally necessary for obtaining that treatment in the Member State of residence, taking account of his current state of health and the course of the disease.

64 In the present case, the national court states that the treatment in question cannot be given in the Member State of residence of the person concerned, where he would have undergone surgery which, in its opinion, cannot be considered an identical treatment or one having the same degree of effectiveness. Although the fact that the treatment proposed in another Member State is not carried out in the Member State of residence of the insured person does not imply, per se, that the second condition set out in the second subparagraph of Article 22(2) of Regulation No 1408/71 is met, clearly and conversely, that it must be the case where no treatment having the same degree of effectiveness can be given without undue delay.

65 The Court has already held that the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that the authorisation to which that provision refers cannot be refused when it appears that the first condition set out therein is met and that the same or equally effective treatment cannot be given without undue delay in the Member State of residence of the insured person (see, to that effect, *Inizan*, paragraphs 45, 59 and 60, and *Watts*, paragraphs 59 to 61).

66 The Court has pointed out in that regard that, in order to determine whether treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is required to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history (*Inizan*, paragraph 46, and *Watts*, paragraph 62).

67 Thus, in a situation where the treatment in question cannot be given in the Member State on whose territory the insured person resides and the benefits provided for by the legislation of that Member State are not given as an exact list of treatments or

treatment methods but as a more general definition of categories or types of treatment or treatment methods, the second subparagraph of Article 22(2) of Regulation No 1408/71 implies that, if it is established that the treatment proposed in another Member State falls within one of those categories or corresponds to one of those types, the competent institution is required to give the insured person the authorisation necessary for the reimbursement of the cost of that treatment, when the alternative treatment which can be given without undue delay in the Member State of his residence is not, as in the situation described by the national court, equally effective.

– The first question, concerning the presumption referred to in the order for reference

68 As background to that question, the national court states that, according to the indications given in the case in the main proceedings by the Varchoven administrativen sad, if the hospital treatment under consideration cannot be given in Bulgaria, it is appropriate to presume that that treatment is not included in the medical treatment reimbursed by NZOK and, conversely, if such treatment is reimbursed by NZOK, it may be presumed that it can be given in Bulgaria. That court is doubtful where such a presumption is consistent with Article 22 of Regulation No 1408/71, since in its view it means that the two conditions set out in the second subparagraph of Article 22(2) can be met only if treatment that is equally effective is available in the Member State of residence, but cannot be given without undue delay.

69 In that regard, it must be noted that it follows from the interpretation of the second subparagraph of Article 22(2) of Regulation No 1408/71 given in the context of the examination of the fourth and second questions that a decision on an application for authorisation required under Article 22(1)(c)(i) cannot be based on such a presumption.

70 Firstly, it follows from the findings in paragraph 62 of the present judgment, on the one hand, that in each case an assessment must be made, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, as to whether the treatment method in question corresponds to benefits provided for by national legislation and, on the other, that an application for prior authorisation cannot be refused on the ground that such a treatment method is not available in the Member State of residence of the insured person.

71 Secondly, it follows from what has been stated in paragraphs 64 to 67 of the present judgment that an application for authorisation cannot be refused where the same or equally effective treatment as that proposed cannot be given in the Member State of residence without undue delay, which must also be ascertained in each case.

72 Apart from the fact that use of the presumption referred to in the first question referred by the national court would have the effect of restricting the scope of the second subparagraph of Article 22(2) of Regulation No 1408/71, it would lead to the creation of an obstacle to the freedom to provide services in the health sector which could not be justified by the imperatives referred to in paragraphs 42 and 43 of the present judgment.

73 In the light of those considerations, the answer to the first, second and fourth questions is that, with regard to medical treatment which cannot be given in the Member State on whose territory the insured person resides, the second subparagraph of Article 22(2) of Regulation No 1408/71 must be interpreted as meaning that authorisation required under Article 22(1)(c)(i) cannot be refused:

— if, where the list of benefits for which the national legislation provides does not expressly and precisely specify the treatment method applied but defines types of

treatment reimbursed by the competent institution, it is established, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, that the treatment method in question corresponds to types of treatment included in that list, and

— if no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides.

That article precludes the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in the Member State on whose territory the insured person resides is not included in the benefits for which reimbursement is provided for by the legislation of that State and, conversely, that the hospital treatment included in those benefits can be given in that Member State.

The sixth and seventh questions, concerning the arrangements for reimbursement of the insured person for hospital treatment given in another Member State

74 By its sixth and seventh questions, the referring court asks whether the national court must oblige the competent institution to issue the insured person with form E 112 if it considers, even where the treatment has been completed by the date on which the court decision is pronounced, the refusal to issue such a document to be unlawful. In addition, it asks whether, in that case, the cost of the hospital treatment must be reimbursed to the insured person by the competent institution or by the institution of the

place where the treatment was given and to what extent the reimbursement must be made, where the range of the benefits provided for by the legislation of the Member State of residence of the insured person differs from that of the benefits provided for by the Member State on whose territory the treatment was given.

75 In that regard, it is appropriate to note that the issue of prior authorisation such as that given under form E 112 does not appear to serve any purpose where the hospital treatment has already been given to the insured person except, possibly, if the insured person has not yet received the invoice for the treatment or has not paid it. If that is not the case, as has been pointed out in paragraph 48 of the present judgment, the insured person is entitled to be reimbursed directly by the competent institution in an amount equivalent to that which it would ordinarily have reimbursed if authorisation had been properly granted before treatment began.

76 In any event, it is for the national court to oblige the competent institution, in accordance with national procedural rules, to reimburse the amount referred to in the preceding paragraph.

77 That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject (see, to that effect, *Vanbraekel and Others*, paragraph 32).

78 If the amount of the reimbursement of the expenses incurred for hospital treatment provided in a Member State other than that of residence, resulting from the rules in force in that State, is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, pursuant to Article 49 EC, as interpreted by the Court, complementary reimbursement corresponding to the difference between those two amounts

must, in addition, be made by the competent institution (see, to that effect, *Vanbraekel and Others*, paragraphs 38 to 52, and *Commission* v *Spain*, paragraphs 56 and 57).

79 The Court has stated that where, under the legislation of the competent Member State, hospital treatment provided under the national health service is to be free of charge, and where the legislation of the Member State in which a patient registered with that service was or should have been authorised to receive hospital treatment at the expense of that service does not provide for the reimbursement in full of the cost of that treatment, the competent institution must reimburse that patient the difference (if any) between the cost, objectively quantified, of equivalent treatment in a hospital covered by the service in question up to the total amount invoiced for the treatment provided in the host Member State and the amount which the institution of the latter Member State is required to reimburse under Article 22(1)(c)(i) of Regulation No 1408/71 on behalf of the competent institution pursuant to the legislation of that Member State (*Watts*, paragraph 143).

80 It is appropriate to add, as the Advocate General observed in point 85 of his Opinion, that where insured persons receive hospital treatment in a Member State other than that of residence without applying for authorisation under Article 22(1)(c)(i) of Regulation No 1408/71, they can claim reimbursement of the cost of the treatment given to them, on the basis of Article 49 EC, only within the limits of the cover provided by the sickness insurance scheme to which they are affiliated (see, to that effect, *Müller-Fauré and van Riet*, paragraphs 98 and 106). The same applies where a refusal to issue the prior authorisation required under Article 22 is justified.

81 In the light of those considerations, the answer to the sixth and seventh questions is:

— Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i) of Regulation No 1408/71 was unjustified, when the hospital treatment has been completed and the related expenses incurred by the insured person, the national court must oblige the competent institution, in accordance with national procedural rules, to reimburse that insured person in the amount which it would ordinarily have paid if authorisation had been properly granted.

— That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject. If that amount is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, a complementary reimbursement corresponding to the difference between those two amounts must in addition be made by the competent institution.

Costs

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

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

1. **European Union law precludes a national court which is called upon to decide a case referred back to it by a higher court hearing an appeal from being bound, in accordance with national procedural law, by legal rulings of the higher court, if it considers, having regard to the interpretation which it has sought from the Court, that those rulings are inconsistent with European Union law.**

2. **Articles 49 EC and 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, as amended and updated by Council Regulation (EC) No 118/97 of 2 December 1996, as amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006, preclude a rule of a Member State which is interpreted as excluding, in all cases, payment for hospital treatment given in another Member State without prior authorisation.**

3. **With regard to medical treatment which cannot be given in the Member State on whose territory the insured person resides, the second subparagraph of Article 22(2) of Regulation No 1408/71, as amended and updated by Regulation No 118/97, as amended by Regulation No 1992/2006, must be interpreted as meaning that that authorisation required under Article 22(1)(c)(i) cannot be refused:**

   — **if, where the list of benefits for which the national legislation provides does not expressly and precisely specify the treatment method applied**

but defines types of treatment reimbursed by the competent institution, it is established, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data, that the treatment method in question corresponds to types of treatment included in that list, and

— **if no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides.**

That article precludes the national bodies called upon to rule on an application for prior authorisation from presuming, in the application of that provision, that the hospital treatment which cannot be given in the Member State on whose territory the insured person resides is not included in the benefits for which reimbursement is provided for by the legislation of that State or, conversely, that the hospital treatment included in those benefits can be given in that Member State.

4. **Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i) of Regulation No 1408/71, as amended and updated by Regulation No 118/97, as amended by Regulation No 1992/2006, was unjustified, when the hospital treatment has been completed and the related expenses incurred by the insured person, the national court must oblige the competent institution, in accordance with national procedural rules, to reimburse that insured person in the amount which it would ordinarily have paid if authorisation had been properly granted.**

That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject. If that amount is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, complementary reimbursement corresponding to the difference between those two amounts must in addition be made by the competent institution.

[Signatures]