Case C-489/23

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

1 August 2023

Referring court:

Înalta Curte de Casație și Justiție (Romania)

Date of the decision to refer:

27 March 2023

Applicant and appellant in the appeal on a point of law:

AF

Defendants and respondents in the appeal on a point of law:

Guvernul României

Ministerul Sănătății

Casa Județeană de Asigurări de Sănătate Mureș

Subject matter of the main proceedings

Action brought by the applicant AF against Guvernul României (Romanian Government), Ministerul Sănătății (Ministry of Health, Romania) and the Casa Județeană de Asigurări de Sănătate Mureș (District Health Insurance Fund, Mureș, Romania) ('the CJAS'), against the judgment in civil matters of 30 December 2019 by which the Curtea de Apel Târgu Mureș (Court of Appeal, Târgu Mureș, Romania) dismissed his action for the annulment of certain provisions of Hotărârea Guvernului nr. 304/2014 (Government Decision No 304/2014), the annulment of the decisions refusing reimbursement and the reimbursement of the amount of EUR 13 069, which constitutes the consideration, paid by AF, for the health services which he received at a clinic in Germany.

Subject matter and legal basis of the request

On the basis of Article 267 TFEU, the interpretation of Articles 49 and 56 TFEU, Article 7(7) of Directive 2011/24/EU, Article 22(1)(c) of Regulation (EEC) No 1408/71, and the principle of free movement of patients and services, the principle of efficiency and the principle of proportionality is sought.

Questions referred for a preliminary ruling

1. Must Article 49 and Article 56 TFEU and Article 7(7) of Directive 2011/24/EU be interpreted as precluding legislation which automatically makes reimbursement of the costs incurred by a compulsorily insured person in the Member State of residence subject to a medical assessment carried out by a health professional providing health services under the health insurance system of that State and the subsequent issuing of a request for hospitalisation by that professional, without it being permissible to present equivalent medical documents issued by private medical establishments, even in a situation where the hospitalisation has taken place and the health service has been provided in a Member State other than that in which the insured person resides?

2. Must Article 49 and Article 56 TFEU, Article 22(1)(c) of Regulation No 1408/71, the principles of free movement of patients and services, as well as the principle of efficiency and the principle of proportionality, be interpreted as precluding national legislation which, where prior authorisation is not obtained, sets the amount of the recoverable services at the level of the costs which would have been borne by the Member State of residence, had the medical care been provided in its territory, using a calculation formula which limits the amount of that reimbursement significantly as compared with the costs actually incurred by the insured person in the Member State which provided the health services at issue?

Provisions of European Union law and case-law relied on

Articles 49 and 56 TFEU.

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare; Article 7.

Council Regulation (EC) 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; Article 22.

Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems; Articles 1 and 2.

Judgment of 9 October 2014, *Petru* (C-268/13); order of 11 July 2013, *Luca* (C-430/12); judgment of 12 July 2001, *Vanbraekel and others* (C-368/98); judgment of 5 October 2010, *Elchinov* (C-173/09); judgment of 16 May 2006, *Watts* (C-372/04); judgment of 25 February 2003, *IKA* (C-326/00); judgment of 12 April 2005, *Keller* (C-145/03); judgment of 15 June 2010, *Commission* v *Spain* (C-211/08); judgment of 12 July 2001, *Smits and Peerbooms* (C-157/99); judgment of 13 May 2003, *Müller-Fauré and van Riet* (C-385/99); judgment of 19 April 2007, *Stamatelaki* (C-444/05); judgment of 6 October 2021, *Casa Națională de Asigurări de Sănătate and Casa de Asigurări de Sănătate Constanța* (C-538/19); and judgment of 29 October 2020, *Veselības ministrija* (C-243/19).

Provisions of national law relied on

Hotărârea Guvernului nr. 304/2014 pentru aprobarea Normelor metodologice privind asistența medicală transfrontalieră (Government Decision No 304/2014 approving detailed rules on cross-border healthcare):

- Article 3(1)(b)(i) of the detailed rules set out in the Annex to the Government Decision, according to which, at the written request of the insured person, accompanied by supporting documents, the health insurance fund shall reimburse the consideration for cross-border healthcare provided in the territory of a Member State of the European Union and paid for by the insured person, provided that, inter alia, that healthcare was provided following a medical assessment carried out by a health professional providing health services in the Romanian health insurance system, concluded by issuing a request for hospitalisation;

- Article 3(2) of the detailed rules, which provides, in essence, that the supporting documents referred to in paragraph (1) mean any medical document, including the request for hospitalisation, showing that the insured person has received health services, [and the document must be] dated and signed by the health professional who issued it, as well as the documents relating to payment showing that the health services have been paid for in full by the insured person;

- Article 3(4) of the detailed rules, according to which, if the provisions of paragraph (3) are complied with, the health insurance fund shall draw up the calculation note relating to the reimbursement of the consideration for the cross-border healthcare using the model calculation note set out in Annex No 3;

- Article 4 of the detailed rules, according to which, in essence, reimbursement of the consideration for cross-border healthcare provided for in Article 3(1) shall be made at the level of the costs paid for the health services provided on Romanian territory.

Ordinul Ministerului Sănătății și al Casei Naționale de Asigurări de Sănătate nr. 397/836/2018 privind aprobarea Normelor metodologice de aplicare în anul 2018 a Hotărârii Guvernului nr. 140/2018 pentru aprobarea pachetelor de servicii și a

Contractului-cadru care reglementează condițiile acordării asistenței medicale, a medicamentelor și a dispozitivelor medicale în cadrul sistemului de asigurări sociale de sănătate pentru anii 2018-2019 (Decree No 397/836/2018 of the Ministerul Sănătății (Ministry of Health, Romania) and the Casa Națională de Asigurări de Sănătate (National Health Insurance Fund, Romania) on the approval of detailed rules of application in 2018 for Government Decision No 140/2018 for the approval of the basket of services and the framework contract governing the conditions for the provision of healthcare, medicines and medical devices within the health insurance system for the years 2018-2019)

Succinct presentation of the facts and procedure in the main proceedings

1 On 8 March 2018, AF was diagnosed with an adenocarcinoma of the prostate, as is apparent from the medical letter issued by the Clinica de Urologie și Andrologie Endoplus (Endoplus Clinic of Urology and Andrology) in Cluj-Napoca (Romania), according to which a radical prostatectomy to be carried out by traditional laparoscopy or robotic surgery was recommended.

2 AF was informed that it was possible to carry out surgery with the DaVinci robot (Robot-assisted radical prostatectomy), surgery which has benefits for the health and subsequent recovery of the patient compared to traditional radical prostatectomy surgery, and the doctor's recommendation was made to that effect. In addition, AF was informed that a DaVinci robot was located in the public hospital in Cluj-Napoca (Romania), which was not, however, operational because, at that time, the consumables needed for its operation had not been purchased, so, for that reason, AF was told that it was possible to carry out the surgery at issue under the private health scheme, at a clinic in Brașov (Romania), at an approximate cost of EUR 13 000.

3 As it had already been about 4 months since the diagnosis was established, AF decided to undergo treatment at the same costs in a centre with extensive experience, devoted exclusively to the pathology at issue, in a hospital in Germany.

4 With a view to carrying out the treatment abroad, AF addressed to the CJAS an application to issue the E 112 form, under Regulation No 1408/71, but his application was not accepted.

5 In parallel with that procedure, following correspondence with the clinic in Germany, AF was offered the opportunity to have the surgery at issue on 9 May 2018, since another patient had cancelled his booking for that date. Otherwise, AF would have had to wait approximately a further 8 weeks after receiving the approval of the CJAS in order to organise a new surgery schedule.

6 In order to book the date of 9 May 2018 for the surgery, AF paid for it on 24 April 2018. The surgery took place on the scheduled date, in Germany, and hospitalisation was set for the period from 9 May 2018 to 14 May 2018.

7 Subsequent to the above payment, and in view of the CJAS's refusal to accept his application, AF decided to send in advance the application to the CJAS using the postal service, by registered letter with acknowledgement of receipt, and on 17 May 2018, he was informed that his application was not drafted in the standard form and that it did not contain all the necessary documents.

8 On his return to Romania, AF requested from the CJAS payment of the amount paid in Germany, relying on Regulation No 1408/71 and the *Elchinov* judgment.

9 In addition to rejecting the request for payment, the CJAS stated that the issuance of the E 112 form takes place before the departure of the beneficiary and that, for the purposes of reimbursement of the amount, the procedure provided for in Government Decision No 304/2014 should be followed.

10 AF maintains that he followed that procedure, however without success. Therefore, on 5 September 2018, AF asked the CJAS to reimburse the amount of EUR 13 069, which constitutes the consideration for the health services paid to the clinic in Germany, and at the same time submitted all the necessary documents, with the exception of the request for hospitalisation issued by a health professional providing health services in the Romanian health insurance system.

11 On 1 October 2018, that application was rejected on the ground that he had not provided evidence of a medical assessment carried out in Romania, which concluded with a request for hospitalisation.

12 In that context, AF brought an action before the Curtea de Apel Târgu Mureș (Court of Appeal, Târgu Mureș, Romania) in which he sought the annulment of the provisions relating to the conditions for reimbursement of the consideration for health services and those concerning the method of calculation as regards the reimbursement of the healthcare consideration provided for by the detailed rules, and also the annulment of the refusal decisions, resulting in the reimbursement of the amount of EUR 13 069, which constitutes the consideration for the health services paid in Germany.

13 In the grounds of his action, AF claimed that the contested provisions constitute an incorrect transposition of Directive 2011/24, since they infringe the principle of the primacy of EU law, more specifically Article 56 TFEU and Regulation 1408/71, as interpreted by the Court in the *Elchinov* judgment, as well as Regulation No 883/2004, in so far as they exclude, in any event, reimbursement of costs incurred in relation to hospital treatment provided without prior authorisation in another Member State.

14 AF argued that his application for reimbursement had been unlawfully rejected, that it fulfilled the conditions for granting the E 112 form and that the fact that the treatment and payment for the services had been carried out before the defendant examined his application for granting the form could not have the effect of nullifying his personal right.

15 Following the dismissal of that action, AF brought an action before the referring court, the Înalta Curte de Casație și Justiție (High Court of Cassation and Justice, Romania), which decided to request a preliminary ruling from the Court of Justice.

The essential arguments of the parties in the main proceedings

16 AF seeks the preliminary reference to the Court of Justice because, in his view, the national legislation imposes conditions which are not provided for in the text of the Directive and which it is impossible to fulfil in practice. Furthermore, even if, for the purposes of the payment of a health service granted on Romanian territory, it is necessary to provide evidence of a request for hospitalisation, such a condition is incompatible with the right recognised by the Directive, because, where the treatment is carried out in another Member State, the issue of a request for hospitalisation no longer arises, since only a medical assessment carried out by a specialist doctor is necessary. In addition, although EU law recognises the possibility for the Member State to limit the amount paid, the way in which the national legislation does so infringes the principle of proportionality, and thereby undermines the essence of the patient's right.

17 The CJAS is opposed to the preliminary reference to the Court, because it considers that the interpretation sought by AF does not contain a new element. It refers in that regard to the judgment in *Petru* and the order in *Luca*.

18 As regards the interpretation of Article 7(2) of Directive 2011/24, in relation to the possibility for the patient's State of origin to make the subsequent reimbursement of the consideration for the cross-border health service subject to a medical assessment which results in a request for hospitalisation, to the exclusion of any other type of medical document demonstrating the assessment, the CJAS submits that, in interpreting Regulation No 1408/71, the Court has delivered numerous decisions in which it draws a distinction between scheduled hospital treatment (judgments in *Vanbraekel and Others*, *Petru*, *Elchinov* and *Watts*) and non-scheduled hospital treatment (judgments in *IKA*, *Keller* and *Commission v Spain*). As regards the prior authorisation requirement – in so far as it is justified by the need to ensure sufficient and continuous access to a balanced series of high-quality medical treatment in the State in question, ensure the control of costs and avoid waste of financial, technical and human resources – the Court has ruled in the judgments in *Smits and Peerbooms*, *Müller Fauré and van Riet*, *Stamatelaki* and *Vanbraekel and others*.

Succinct presentation of the reasoning in the request for a preliminary ruling

19 The referring court states that, in order to rule on the action pending before it brought by AF, it will have to give a final judgment, which, under national law, is no longer open to appeal, within the meaning of Article 267 TFEU.

20 That court maintains, first, that, although AF's attempt at the beginning of April to submit an application to obtain the E 112 form is a proven fact, the refusal to register that application is irrelevant, since, in the present case, the legality of administrative measures issued after the date on which the cross-border healthcare intervention took place and the related costs were paid is at issue.

21 As regards the plea concerning the inclusion of the medical treatment to which AF was subject in the basket of basic services paid by the Fondul național unic de asigurări sociale de sănătate (Joint National Health Insurance Fund, Romania; 'the National Fund') provided for by Decree No 397/836/2018, the referring court states that, without being able to rule with certainty on that aspect of legality at this stage of the proceedings, it is apparent from its research that there is evidence which appears to contradict the position of the CJAS, accepted by the Curtea de Apel (Court of Appeal, Romania), that the medical intervention to which AF was subject would not be included in the basket of basic services paid by that fund. That finding by the referring court is based, inter alia, on the fact that the list contained in the abovementioned decree constitutes, in accordance with the submissions of the defendants and respondents in the appeal on a point of law ('the defendants'), a list of diagnostic groups and that *the medical method or technique of treatment is not mentioned as such in the national legislation* governing the grant of healthcare under the Romanian health insurance system.

22 According to the referring court, it is also necessary to take into consideration, in order to rule on that aspect, point 3 of the operative part of the judgment in *Elchinov* and recital 34 of Directive 2011/24.

23 In the event that, following the decision on that plea, the medical treatment to which AF was subject should be regarded as included in the basket of basic services paid by the Romanian State's national fund, then the questions [referred for a preliminary ruling] have a connection with the outcome of the case.

24 **The first question** presented concerns (i) the condition that an assessment has been carried out exclusively by a doctor from the health system of the State (and not by the private health service of the State concerned) and (ii) the formal condition that a request for hospitalisation has been issued by the State from which the patient comes, even if the service is provided in another Member State.

25 In its analysis of the first question, which the defendants have argued is permitted by Article 7(7) of Directive 2011/24, the referring court recalls, first of all, the Court's findings in paragraphs 23, 30 and 34 to 37 of the judgment in *Stamatelaki* and maintains that the imposition of such a formal condition, in any event, without objective justification or relating to a certain type of critical assessment of the quality of the medical document appears disproportionate in the light of the objective of ensuring a financial balance of the social security system.

26 The Court's findings in paragraphs 40, 44, 45, 47, 51 to 53 and 55 of the judgment in *Casa Națională de Asigurări de Sănătate e Casa de Asigurări de Sănătate*

Constanța also lead to that conclusion, since the abovementioned condition appears to go beyond the requirements of Article 20 of Regulation No 883/2004.

27 As regards the second condition, in respect of which the CJAS states that it is permitted by Article 7(7) of Directive 2011/24, while AF states that it is not provided for by the directive and that it is impossible to fulfil in practice, the referring court submits that serious difficulties arise in justifying the relevance of maintaining that condition for the grant of prior authorisation (grant of a request for hospitalisation under the terms of national law), where, clearly, the hospitalisation does not take place in a hospital of the Member State and the request for hospitalisation as such is not needed for the purpose of hospitalisation even in the Member State of destination.

28 In order to establish whether the refusal to grant a necessary authorisation under Article 22 of Regulation No 1408/71 is well founded, a factor which must be assessed by the referring court is the requirement imposed by the national legislation of the existence of the request for hospital treatment granted as such to AF. According to the referring court, the imposition of such a strictly formal condition, in the circumstances of the present case, in which the conformity of the national rule that precludes the drawing up of a medical assessment report by a doctor who does not belong to the national health insurance system is also at issue, appears to impose a condition that goes beyond what is laid down in Article 20 of Regulation No 883/2004.

29 That court considers, referring, first, to recitals 8 and 43 and Articles 7(1) and (4) and 8(1) of Directive 2011/24, and, secondly, to paragraphs 72 to 77 of the judgment in *Veselības ministrija*, that there are doubts as to a reasonable justification for the second condition at issue.

30 As regards the **second question [referred for a preliminary ruling]**, the connection between that question and the outcome of the case arises if the referring court were able, following the assessment of the arguments in the case, to find, first, that the refusal to grant prior authorisation was justified and legitimate and, secondly, that the medical treatment to which AF was subject was included in the basket of basic services paid by the national fund.

31 According to the defendants, the provisions of Article 4 of the detailed rules, which set the ceiling for the amount reimbursed, do not constitute additional conditions which lead to the denial or alteration of the substance of the right to reimbursement, as AF asserts, even if that ceiling entails a reduction in the amount to be reimbursed. Those provisions constitute the transposition of Article 7(4) of Directive 2011/24, since it is normal for there to be a calculation algorithm. Thus, according to standard practice, for a patient who is a member of the Romanian health insurance system, reimbursement of the costs of the healthcare received by that patient in the territory of another Member State must be made at the level of the costs paid for the health services provided in the territory of Romania. That

limitation, although drastic, is permitted by EU law and is reasonable, since it is justified on *grounds of general interest relating to public health*.

32 AF submits that, if the right of the Member State to limit the amount of the amount paid is recognised, that right cannot have the effect of rendering the patient's right devoid of substance.

33 Although the defendants stated that the medical treatment to which AF was subject is not subject to payment in the national system and they avoided carrying out a specific calculation of the costs of that treatment, several documents from the defendants and in the file mentioned, for the year 2018, amounts of between 1 367 Romanian lei (RON) and RON 4 618. According to the evidence in the file, AF incurred a cost of EUR 13 069 (approximately RON 60 000 according to the exchange rate of the Banca Națională a României (National Bank of Romania) of May 2018).

34 The referring court states that, if it considers, following the assessment of the evidence, national law and the principles of EU law, that AF should have and could have obtained, within a reasonable period and without endangering his life or recovery under similar conditions, the prior authorisation required by Article 8 of Directive 2011/24, it will have to examine the compatibility of the national provision laying down a calculation formula, which limits the amount of that compensation significantly in relation to the costs actually incurred by the insured person.

35 Recalling the findings of the Court in paragraph 29 of the order in *Luca* and in paragraph 80 of the judgment in *Elchinov*, as well as recitals 5, 7, 21 and 22, and Articles 5(b) and 7(3) of Directive 2011/24, the referring court states that, by its second question referred for a preliminary ruling, it seeks to ascertain whether the method of calculating the payment in the health sector governed by the national legislation complies with the obligation imposed by Article 5(b) of the Directive and, by implication, in the event of failure to comply with the conditions for the grant of prior authorisation, whether the refusal to reimburse or reimbursement in a derisory proportion in relation to the amount actually paid by the insured person complies with the principle of proportionality, starting from the premiss of the insured person's lack of actual information as regards the prospect of the amount which could have been reimbursed.