

Jurisprudential Analysis on the Implementation of and Compliance with European Safety Standards on Patient Mobility in the Romanian Health System

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Abstract

Since the Directive on cross-border healthcare regulates the provision of pan-European medical services, but without taking into account of the organization, provision and financing of such services, this article examines the need to reform national legislation in order to eliminate any restrictions to the fundamental freedoms of European citizens. This article aims to analyse, by presenting the jurisprudence of the Court of Justice of the European Union, the degree of harmonization of national policies in view of reforming the Romanian health system, in order to create a modern health system. In order for a modern health system to be created, it needs to be centred on patient needs, to have dynamic and integrated structures, adaptable to the various and changing healthcare needs of society in general and of individuals in particular and which, not least, must recognize the active role of the patient as partner in healthcare policies.

Keywords: patient's rights, European law, the Court of Justice of the European Union, the reformation of national legislation, health system, healthcare policies

1. Introduction

The Court of Justice of the European Union has paved the way for the implementation of the right recognized at Article 35 of the Charter of Fundamental Rights of the European Union [1] for every person to have access to preventive healthcare and to benefit from medical treatment.

As stated in the Council Conclusions on Common values and principles in European Union Health Systems, "*health is a value in itself*" [2], also being a prerequisite for the economic prosperity of the Union, because people's health influences the economic results in terms of productivity, manpower, human capital and public expenditure.

To achieve the strategic objectives of the Union (ensuring access to high quality healthcare and the more efficient use of public resources), the Report of the European Commission for 2013 on economic growth and cohesion [3] recommends reforming health systems to ensure their profitability and sustainability and performance evaluation.

In order to remove the restrictions on the fundamental freedoms of European citizens, the Directive on cross-border healthcare [4] creates a standard of protection at EU level, by harmonizing national policies in the field, thus ensuring patient mobility and the freedom of healthcare benefits and regulates the provision of pan-European medical services, but without taking into account of the organization, provision and financing of such services.

2. Theory

In the field of the provision of cross-border healthcare services a certain overlap of EU law with national law is reached, so that in many cases European law is essentially limited to indicating a compulsory aim, namely achieving the free movement of citizens patients and their equal treatment, irrespective of nationality, in relation to national authorities, while maintaining the powers of Member States.

On the background of this overlap, Member States are obliged to comply with the legal framework imposed by primary law and secondary legislation, to the extent that they are not allowed to violate European Union law when exercising their powers [5].

In the absence of the legal force of a European regulation, the free movement of patients would have created a competition between the health systems of Member States to attract more patients, thus raising the likelihood that, by the free access to cross-border services, a drop in the price of medical services throughout the European Union take place, to the detriment of the quality of healthcare services; such a law could have adverse effects on short and medium term, on the sensitive economics in the European health sector [6].

As part of the wider framework of services of general interest to the Union, health systems are a central component of social protection, and contribute both to social cohesion and social justice and to the sustainable development of the European Union.

The Strategy for Sustainable Development [7] of the European Union cannot be achieved without investment in health, ensuring in this way, a smart, sustainable and inclusive growth of national health systems.

Investing in health helps the Union to overcome the challenges identified in the EU Health Strategy [8], which were worsened by the economic crisis: an aging population, increasing chronic disease, a greater demand for health and the high cost of technological progress.

3. Results and Discussions

Important institution of the European Union, the Court of Justice is the one that assesses the scope of the EU legal framework established by Article 49 EC for the exercise of the competences of the Member States. It is also incumbent on the Court, assigned by the founding treaties, that by the interpretation given to a provision of European law, to clarify and specify its meaning and scope, such as to be understood and applied from the time of its entry into force.

In addition, the Court case law expressly emphasized that the mandatory adaptations of national social security systems aiming to achieve the fundamental freedoms guaranteed by the Treaty should not be considered by Member States as interference in their sovereign competence in the field of public health [9].

To examine what degree of harmonization of national policies in view of reforming the Romanian health system, in order to create a modern health system, we will refer to Petru case who was a first in the case law of the Court.

Mrs Elena Petru was suffering from severe vascular disorders, which resulted in a surgical procedure in 2007. As her condition worsened, in 2009 Mrs Petru addressed the Institute of Cardiovascular Diseases in Timisoara where, following the medical report, it was established that she required urgent surgery.

Given the seriousness of the necessary surgery, as well as poor material conditions provided at the Institute of Cardiovascular Diseases, Mrs. Petru requested from the County Health Insurance House (CJAS) Sibiu an authorization to perform the surgery in Germany and not in the said hospital in her State of residence.

By the issued decision, CJAS rejected the Mrs Petru's request, based on the health condition of the insured person, the evolution of the disease in time and the time required until surgery, as well as on the invoked reason (the poor material conditions).

Following the rejection of her application, Mrs Petru addressed a clinic in Germany, where the surgery was performed, with the total cost, including postoperative hospitalization of 17,714.70 euro.

Immediately after the treatment carried out in another Member State, Mrs Petru filed a civil suit at the Sibiu Court, through which she requested CJAS, under Article 22, paragraph (1), letter (c) and Article 22, paragraph (2), second subparagraph of Regulation no. 1408/71 [10] the reimbursement of the expenses incurred in Germany.

The national legal framework applicable in the case of Mrs Petru is the Law no. 95 / 2006 [11], Article 208, paragraph (3) and Order no. 592 / 2008 of 26 August 2008 [12], Article 40, paragraph (1), letter b.

By the preliminary address to the Court [13], the Tribunal of Sibiu presented its doubts about the interpretation of Article 22, paragraph (2), the second paragraph of the Regulation No. 1408/71 in a case in which a Romanian citizen, Elena Petru, requests from the authorities of her country of residence the reimbursement of the costs of surgery incurred in Germany.

The question addressed to the Court through the appeal of the Tribunal of Sibiu was if a generalized deficiency of basic sanitary conditions in the country of residence should be considered a situation where it is impossible to provide the treatment in another Member State.

Admitting that a structural deficiency of healthcare conditions may be a circumstance that would allow the issuance of an authorization under Article 22 of Regulation No. 1408/71, interpreted in the light of Article 56 TFEU [14] and of Article 35 of the Charter of Fundamental Rights of the European Union [15], the Commission adopted an intermediate position which requested the addressing court, the Court of Justice of the European Union, an analysis taking into account all circumstances of the actual case file.

In order to rule in the case of Mrs Petru, the Court had to consider on the one hand, if a deficiency or shortcoming of the material conditions within a healthcare institution, in certain circumstances, can amount to a situation where you cannot timely perform a certain medical benefit, which is still included among the benefits covered by the social security system.

Secondly it had to be examined whether the mentioned shortcomings and deficiencies in the hospital facilities in Romania, which correspond to a systemic situation due to different circumstances (natural, technological, economic, political or social) can be the equivalent to a situation where the medical benefit cannot be provided in a timely manner.

Starting from the main applicable legal and legislative aspects in the case of Mrs Petru, the Court has given an interpretation based on the freedom to provide services, but which takes into account the very different and heterogeneous circumstances characterizing the healthcare sector in Europe.

In its judgment of October 9, 2014 [16], the Court stated that in order to assess whether a treatment that presents the same degree of effectiveness can be obtained in a timely manner in the Member State of residence, the competent institution is obliged to consider all circumstances which characterize each specific case. Among the circumstances which the competent institution is required to take into consideration may be included, in a particular case, the lack of medicines and medical supplies of primary necessity because, as in the absence of specific equipment or specialized competences, their absence may, obviously, make it impossible to grant identical treatment or having the same degree of efficacy in a timely manner in the Member State of residence.

Considering the considerations in the Petru case, the Court ruled that the prior authorization necessary for carrying out cross-border healthcare (Form E112) cannot be refused when the hospital treatment in question cannot be provided in due time in the Member State of residence of the socially insured because of the lack of medicines and medical supply essentials.

If the facts invoked by Mrs Petru on the lack of medicines and medical supply essentials at the Institute of Cardiovascular Diseases in Timisoara are proven, the Court held that it is for the referring court to determine whether this intervention could not be achieved in this timeframe in another hospital in Romania. However, the appreciation of impossibility should be made at the level of the all the hospitals in Romania able to provide such treatment and in relation to the timeframe in which the latter can be obtained in a timely manner.

4. Conclusions

The real problem the Court faced in the Petru case was not that at the level of principle, but that expressed in terms that were characterized as "*dimensional*". In a more circumstantial formulation, the real problem arose when the lack of material

conditions required to perform the medical benefit in question went beyond being a punctual, localized, and essentially an accidental situation, being the expression of a situation of structural, generalized, long-term deficiency, which the Court essentially described as a “systemic” deficiency.

From the jurisprudence of the Court of Justice of the European Union unequivocally results that people normally resident in a Member State operating a national health service, are entitled to receiving hospital treatment in another Member State at the expense of the national health service.

Member States may condition this right by the requirement that the person concerned should have obtained prior authorization, only if such authorization is based on objective, non-discriminatory and transparent criteria within a procedure system. The absence of such criteria and the lack of easily accessible and transparent procedures cannot deprive a person of this right. Also, if the conditions for authorization (form E112) are designed to safeguard the financial stability of the national health system, considerations of a purely budgetary or economic nature cannot justify a refusal to grant such authorization.

To determine whether the treatment is available without undue delay might be considered the waiting time and the priority to treatment granted by the national health authority, only on condition that they are based on concrete indications relating to the patient's condition at the time of evaluation, as well as its medical history and the prognosis for the patient seeking treatment.

Regarding the obligation of a Member State to reimburse the cost of hospital treatment provided in another Member State of the European Union, Article 49 EC does not allow to take into account budgetary reasons, unless it is demonstrated that compliance with this obligation on a more general scale would threaten the financial balance of the respective national health system. Moreover, in accordance with Article 22 (2) of Regulation EEC No. 1408/71 [17], budgetary considerations cannot be taken into account in decisions refusing prior authorization for treatment abroad.

The Petru case was a first in the case law of the Court because it was the first time when was addressed a question regarding cross-border healthcare based on the poor medical conditions affecting the State of residence.

In our view, the Petru case is symptomatic and also relevant for the illustration of the realities of the Romanian health system.

5. References

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