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CASEBOOK

JUDICIAL PROTECTION OF HEALTH AS A FUNDAMENTAL RIGHT

UNIVERSITY OF TRENTO

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1 Cross-Border Healthcare

1.1 Cross-Border Healthcare: Its Definition and Importance in EU Health Law

The phenomenon of cross-border healthcare involves patients who travel from their home State to another country to receive medical treatment. Reasons that force patients to move for healthcare might be very different in nature, which has quite a significant impact on the variability of the phenomenon. Depending on the kind of healthcare required and on state legal frameworks, the rules under which patients can access treatments abroad and the possibility of obtaining a reimbursement of medical expenses can considerably differ from case to case. Therefore, a brief definition of the main legal concepts that are relevant in this matter might help to better draw the boundaries of the issue and to highlight the most salient legal points regarding the effectiveness of EU intervention in the field of health and its impact on national healthcare services and individual rights.

First of all, it is worth underlining that cross-border healthcare is a portion of a wider phenomenon known as "patient mobility" or "medical tourism." This latter expression has a wider meaning, and it is actually used to describe the phenomenon of patient worldwide mobility, but is not appropriate to describe the phenomenon of cross-border healthcare which is far more specific. In fact, by medical tourism, we usually refer to the possibility of traveling abroad to obtain medical services, but it frequently happens that the related expenses are directly paid by the patient. In other words, the person exercises his/her freedom of circulation, obtains healthcare by private providers, and pays for the services received. There is no link with either the hosting or the home healthcare institution. This can be possible both within the EU territory or in third countries.

On a different note, cross-border healthcare is a purely EU phenomenon, with its own regulation: a patient obtains medical treatment in another member State, following the rules provided by EU legislation. Therefore, individual mobility is limited to the EU territory, which means that medical care can be obtained only in another Member State. Moreover, treatments that could be covered are only those that are already included in the list of treatments available within the home healthcare institution. Thus, to obtain reimbursement of medical expenses, a patient cannot get a treatment that is not already provided by her healthcare service of affiliation. This is due to the fact that the travelling patient relies on the healthcare institutions of both the affiliation state (which economically fund the treatments) and of the hosting state (which provides the medical care needed).

In this respect, we should also note that, depending on the legal scheme applicable, the treatment concerned could be paid by the healthcare institution of affiliation (i.e. from the State where the individual patient is a resident or registered), either directly[70] or by reimbursement of medical expenses to the patient.[71] In order to fulfil the requirements that permit the home health institution to assume medical expenses incurred abroad, the individual patient must meet some features provided for by EU law.

The EU legal framework applicable is based upon the principles of the free movement of persons and services and does not concern the freedom of establishment (with the exception of healthcare professionals) or residence permits. In this respect, a further distinction is necessary: cross-border

[70] As provided for by the Regulation on social security systems (Reg. 883/2004).
[71] As it is currently provided by the Directive on patients' rights in cross border healthcare.

healthcare includes only those treatments available and permitted both in the affiliation healthcare system and in the hosting institution. In this case, the Regulation or the Directive provisions (especially those on prior authorisation and on reimbursement eligibility of medical expenses) are applicable[72].

In cases where a patient travels to another Member State to obtain medical treatment that is strictly limited or prohibited by the home healthcare institution (for example, for ethical or moral reasons, i.e. assisted suicide or abortion), only freedom of movement applies. This means that Member States cannot prevent their citizens or residents from travelling to another country for treatment banned within the territory of the State, but that patients can not claim reimbursement for medical expenses incurred abroad, as the treatment sought is not included within the list of benefits that the home healthcare institution grants to its patients.[73]

This brief explanation is useful to show how, under EU law, the same phenomenon could assume different facets and can intersect with different EU competences. Moreover, when dealing with EU health law, this description shows that under the same phenomenon, different dimensions of the right could take precedence and influence the legal discipline, the interpretation of the relevant legal positions and, finally, the effectiveness of the right. In fact, it is relevant to bear in mind that the EU discipline on cross-border healthcare borrows a strong commitment from the case-law of the CJEU.

Relevant CJEU cases

- C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171
- C-120/95 Decker [1998] ECR I-01831. ECLI:EU:C:1998:167
- C-368/98 Vanbraekel [2001] ECR I-05363. ECLI:EU:C:2001:400
- C-157/99 Smits e Peerbooms [2001] ECR I-05473. ECLI:EU:C:2001:404
- C-385/99 Müller-Fauré e van Riet [2003] ECR I-04509. ECLI:EU:C:2003:270
- C-56/01 Inizan [2003] ECR I-12403. ECLI:EU:C:2003:578
- C-145/03 Keller [2005] ECR I-02529. ECLI:EU:C:2005:211
- C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325
- C-444/05, Stamatelaki [2007] ECR I-03185. ECLI:EU:C:2007:231
- C-466/04 Herrera [2006] ECR I-05341. EU:C:2006:405
- C-211/08 Commission v Spain (Major Medical Equipment) [2010] ECR I-05267. ECLI:EU:C:2010:340
- C-173/09 E. [2010] ECR I-08889. ECLI:EU:C:2010:581
- C-268/13 Petru [2014] ECLI:EU:C:2014:2271

[72] Council Regulation (EEC) 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L 149/2. The 1971 Regulation has now been replaced by the European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems [2004] OJ L 166/1. 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, OJ L 88, 4.4.2011.

[73] On this matter see, for example the so-called abortion information case: C-159/90, Grogan, 4 October 1991, ECLI:EU:C:1991:378.

- C-777/18, Vas Megyei Kormányhivatal (cross-border healthcare), 23 September 2020, ECLI:EU:C:2020:745
- C-243/19, Veselības ministrija, 29 October 2020, ECLI:EU:C:2020:872
- C-538/19, Casa Naţională de Asigurări de Sănătate e Casa de Asigurări de Sănătate Constanţa, 6 October 2021, ECLI:EU:C:2021:809

Main questions addressed

Question 1 How should a judge assess the reciprocity of national provisions on medical services, in light of the Regulation and Directive provision and in light of the fundamental freedoms of the Treaty? Is Art. 35 CFREU somehow relevant? Is there any remedy for the patient in case a state institution does not consider the treatment within the list of treatments provided by the health institution?

Question 2 What is the meaning of undue delay in access to medical treatments? Are waiting lists a possible cause of undue delay? In light of the principle of non-discrimination in access to medical treatments, could the provision of waiting lists be a possible cause of inequality in access to medical treatments? Can an individual obtain a medical treatment abroad, paid for by the home healthcare institution, if undue delay is caused by waiting lists? Which remedies are available for the individual in case the waiting list is irrational? Are they effective?

Question 3 Could a structural lack of medication and basic medical supplies be claimed as "undue delay"?

Question 4 Shall an authorisation to get medical treatment in another Member State be granted, when a treatment is available in the State of residence, but the method of treatment used is contrary to that person's religious beliefs?

Question 1 – List of Reimbursable Medical Treatments

How should a judge assess the reciprocity of national provisions on medical services, in light of the Regulation and Directive provision and in light of the fundamental freedoms of the Treaty?

Is Art. 35 CFREU somehow relevant?

Is there any remedy for the patient in case a state institution does not consider the treatment within the list of treatments provided by the health institution?

The analysis is based on the *E.* case (C-173/2009)

The case

Mr. E. was a Bulgarian citizen, affiliated with Bulgarian health insurance (NZOK), and suffered from a serious illness. In 2007 he asked NZOK to cover the expenses for an advanced treatment in a specialist clinic in Berlin (Germany), since such treatment was not available in Bulgaria. He was admitted to hospital in Germany and treated before receiving a reply from NZOK, due to the state of his health.

ZNOK refused to give Mr. E. the authorisation requested, because the requirements for granting such authorisation, as laid down in Art. 22 of Regulation No 1408/71, were not met: the treatment required was not included in the list of treatments reimbursed by NZOK.

E. challenged this refusal. The administrative tribunal in Sofia (Bulgaria) annulled the decision, stating that the conditions for granting authorisation laid down by Article 22(2) of Regulation No 1408/71 were met. In fact, the treatment in question did not exist in Bulgaria, but corresponded to the services enumerated in the list of clinical treatments.

NZOK appealed the judgment before the Supreme Administrative Court, which referred the case back to a different chamber of the lower Court. This Court found that the treatments received by Mr. E. were not included in the list of Bulgarian clinical treatments. Moreover, if those treatments were reimbursable, they would have been available in a Bulgarian healthcare institution. Therefore, it decided 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. As the treatment was not available in Bulgaria, the administrative judge referred the question for a preliminary ruling to the Court of Justice.

Preliminary questions referred to the Court

After asking whether the lower Court was bound to the higher Court's decision, even if there was reason to assume that these directions were inconsistent with EU law, the main preliminary question concerned the interpretation of the concept of a reimbursable list of treatments.

For prior authorisation disciplined by Art. 22(1)c of regulation 1408/71, if the treatment cannot be given in the territory of the Member State of affiliation, is it sufficient that the treatment is 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?

Are the provisions of the regulation (Art. 49 and 22) in conflict with a national provision that provides that an insured person has the right to receive, in part or in full, reimbursement for the value of medical expenses abroad only if that person has received prior authorisation?

Reasoning of the Court

The Court observed that, in principle, it is not incompatible with EU law for a Member State to draw up limited lists of reimbursable medical services for its social security system. It is solely up to the national bodies to determine whether such treatments fall within the provisions of the list of benefits. In this case, the national Court had to decide whether the treatment received by Mr. E. in Germany fell under clinical care protocols (par. 61).

If the list of medical treatments available at a national level did not expressly specify the method applied in the concrete case, but only defined types of treatments, it was for the competent home institution to assess by applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria and taking into consideration all the relevant medical factors and available scientific data, whether that treatment method corresponded to benefits provided for by the legislation of that Member State. If such was the case, prior authorisation cannot be refused.

In order to assess whether a treatment with the same degree of effectiveness for the patient can be obtained in good time within the Member State of residence, the competent institution is required to take into consideration all the circumstances which characterize each specific case, taking into account not only the clinical picture of the patient when authorization is requested but, if necessary, the degree of pain or the nature of the infirmity of the latter, which could, for example, make it impossible or excessively difficult to exercise a professional activity, but also its antecedents (par. 63).

Conclusion of the Court

With regard to medical treatment which cannot be given in the Member State in whose territory the insured person resides, prior authorisation required under the Regulation on coordination of social security systems cannot be refused if the following conditions are met.

Where the **list of treatments** provided at the national level does not expressly and precisely specify the treatment method applied but defines **types of treatment** reimbursed by the competent institution, then the treatment can be reimbursed if it satisfies the following requirements. Firstly, the treatment method in question corresponds to types of treatment included in that list, 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. Moreover, the treatment may be reimbursed 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

Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i) of Regulation No 1408/71, and following amendments, 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.

Elements of judicial dialogue

The reason to focus so deeply on cross-border healthcare in a casebook which deals with the effective protection of the right to healthcare in the European Union rests on the importance that the case-law of the CJEU had on the development of this area of law and, furthermore, on the indirect influence that this new discipline had on national systems and on the effective guarantee of the right to healthcare within state healthcare services.

The starting point for any consideration of the CJEU's case law on healthcare rights is the 1984 Luisi and Carbone decision.[74] It actually paved the way for all subsequent case law of the CJEU in the field of healthcare (not only for those decisions related to patients' mobility). On that occasion, the Court stated that not only providers of services, but also recipients of those services are included within the scope of the protection of the freedom of movement. This means that the freedom to provide services, as depicted in the Treaties, includes a freedom, for those who want to use these services, to go to another Member State in order to receive a service there, without undue restrictions. The innovative content of the decision is that healthcare shall be considered as a service under the provisions of the Treaties.[75] This statement opened the box for the subsequent interpretation of the CJEU on freedom to provide services in healthcare matters.[76]

The decision in E. represents a further consequence of the cross-border healthcare saga, whose leading case is represented by the 2006 Watts decision (see *infra*). As we will see in the following paragraphs, after Luisi and Carbone, the Court of Justice was required to intervene on issues concerning cross-border healthcare on several occasions. Since the 1998 Kohll decision, interpretation of the Regulation on the coordination of social security systems was oriented towards promoting free movement of EU patients to receive healthcare abroad.[77]

E. added that, even if treatment is not expressly included in the list of treatments reimbursable, it is enough that it is of the same type of treatments provided. This decision adds a new element because it was therefore possible to obtain a treatment abroad which is more advanced than those available in the home health system. This is possible only if the list of treatments available in the state of residence comprehends the typology of treatments and if within those typologies more advanced treatments are included, even if they are not expressly specified.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Spain

Judgement of the Superior Court, Cantabria, Social jurisdiction, 5 October 2006: an insured person, authorized by the Spanish competent institution to go to France to receive treatment appropriate to his condition, is not entitled to a reimbursement of travel, accommodation, and subsistence costs related to that medical treatment, because the insured person would not be entitled to the reimbursement of those costs where the treatment would have been provided in a hospital covered by the Spanish national system. Note that the case was decided five years before the E. case and the Directive's approval.

[74] Joined cases 286/82 and 26/83, Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro, 31 January 1984, ECLI: ECLI:EU:C:1984:35.
[75] Luisi and Carbone, para 16: "It follows that the freedom to provide services includes the freedom, for the recipients of services, to go to another member state in order to receive a service there, without being obstructed by restrictions, even in relation to payments and that tourists, persons receiving medical treatment, and persons travelling for the purpose of education or business are to be regarded as recipients of services."
[76] See Case 131/85, Gül, 1986 ECR 1573; Grogan (the so-called abortion information case).
[77] Council Regulation (EEC) 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, now replaced by the European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems.

In the proceedings, the Spanish Court referred a **preliminary ruling** to the ECJ on the interpretation of Article 22, section 1, letter c) and Article 22, section 2 of the Council Regulation (ECC) No 1408/71. The ECJ Decision was June 15, 2006, Manuel Acereda c. Servicio Cántabro de Salud, C-466/04.

Judgement of the Superior Court, Galicia, Social Jurisdiction, 29 May 2014:

The Spanish Court decided that an insured person, authorized by the Spanish competent institution to go to France to receive treatment appropriate to his condition, was entitled to the reimbursement of travel and medical costs related to that medical treatment, because, according to the Spanish rules applicable at the time of the events, the insured person would be entitled to the reimbursement of those costs where the treatment would have been provided in a hospital covered by the Spanish national system. The Spanish Court based its decision on the interpretation of Article 49 EC established in the ECJ case C-372/04 Watts [2006].

1.2 Procedural Requirements

In the landmark *Watts* case in 2006,[78] the CJEU went further in specifying its previous case-law, to the point that it stated that the refusal of prior authorisation cannot be justified on the mere existence of waiting lists in the health service of affiliation.

The case concerned an English woman that went to France for a hip replacement without prior authorisation of the competent English health institution. The woman's position was that the English NHS could not grant her the medical intervention within a time limit that was compatible with her clinical condition, whereas the NHS argued that the system of waiting lists is built in a non-discriminatory way based on evaluation of the clinical needs of patients.

To solve the case, the Court of Justice analysed the organisation of the English health service in depth, which is completely publicly funded and universal in nature (i.e. individuals affiliated with the service are all equal with regard to point of access to healthcare treatments and clinical priorities are dealt with through waiting lists). As a result, EU judges provided a strong contribution to the definition of undue delay in access to medical treatment, as a reason for cross-border healthcare, by stating that it must be considered with reference to an individual patient's clinical needs.

As an aftermath of the decision, the EU legislature began working on a Directive to harmonise national rules and to give legislative shape to the principles progressively established by the Court of Justice. At the same time, the decision raised harsh criticism because it was considered to be unbalanced towards a mere consumeristic approach to healthcare services.[79] For example, it was argued that "EU institutions have misconceived the relationship between the economics of free market individualism and the politics of social welfare in the EU."[80] More precisely, the peak of criticism towards CJEU activism dealt with

[78] C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325

[79] Dougan M, Stalford H. The Impact of Migration on Healthcare in the European Union. *Maastricht Journal of European and Comparative Law*. 2007;14(3):209-212.

[80] Newdick, C. (2011) *Disrupting the community: saving public health ethics from the EU internal market.* In: van de Gronden, J., Szyszczak , E., Neergaard , U. and Krajewski, M. (eds.) Health Care and EU Law. Legal Issues of Services of General Interest. Asser Press, The Hague, pp. 211-239, 211.

the individualistic and libertarian approach to healthcare, without due consideration to the difficult needs of balancing national healthcare services.

From this viewpoint, CJEU case-law was summarised in these terms: "firstly, patients have cross-border rights to hospital care which cannot be modified solely by reference to economic constraints, secondly, the right may become enforceable once the patient has a health need generally recognised by international medical science which cannot be treated at home without undue delay. If these conditions are satisfied, then the patient may obtain treatment in a "host" state and return to present the bill to his "home" health authority. Clearly, this promotes an individualistic approach to healthcare resource allocation."[81]

Question 2 – Undue Delay

What is the meaning of undue delay in access to medical treatments? Are waiting lists a possible cause of undue delay?

In light of the principle of non-discrimination in access to medical treatments, could the provision of waiting lists be a possible cause of inequality in access to medical treatments?

Can an individual obtain medical treatment abroad, paid for by the home healthcare institution, if undue delay is caused by waiting lists?

Which remedies are available for the individual in case the waiting list is irrational? Are they effective?

The analysis is based on the *W.* case (C-372/04)

The case

Ms. W. suffered from hip arthritis and had inquired at her referral healthcare facility in England about the possibility of having surgery abroad using an E 112 form (within the framework of Regulation 1408/1971 and following amendments, which have now been replaced by Regulation 883/2004).

The local health authority classified her clinical case as "habitual," a category to which a waiting time of about one year is attributed. In the meantime, the health administration refused her authorization for surgery abroad, without taking the second requirement provided for by Art. 22 of Reg. 1408 (the health service could be obtained "without undue delay") into account. After filing an appeal against this denial, Ms. W.'s clinical condition was re-examined and her case was reconsidered with a four-month waiting period, but the prior authorisation to obtain the medical treatment abroad was refused again.

Faced with a new refusal of authorization, the woman still underwent surgery in France and continued the judicial procedure in order to obtain reimbursement for the medical expenses incurred. The Court of Appeal (England & Wales), Civil Division, invested with the appeal, decided to suspend the proceedings and to submit a request for a preliminary ruling before the Court of Justice of the EU.

Preliminary questions referred to the Court

The national judge elaborated several questions for the Court of Justice, ranging from the features of a universal healthcare service vis-à-vis EU law, to the legitimacy of the provision of waiting lists. These questions were raised in light of the freedom of circulation of EU citizens, restrictions that could

[81] Newdick, C. (2011) *Disrupting the community: saving public health ethics from the EU internal market*, cit., 219.

eventually be provided at a national level and freedom to provide (and receive) services in the territory of the EU.

With regard to "undue delay" and "procedural requirements," the national judge asked:

In determining whether treatment is available "without undue delay" for the purposes of Article 49 EC, to what extent is it necessary or permissible to give regard to waiting times; the clinical priority accorded to the treatment by the relevant NHS body; the management of the provision of hospital care in accordance with priorities aimed at giving best effect to finite resources; the fact that treatment under the NHS is provided free at the point of delivery; finally, the individual medical condition of the patient, and the history and probable course of the disease in respect of which that patient seeks treatment.

Then, the Court of Appeals also asked the CJEU how to correctly interpret the words "within the time normally necessary for obtaining the treatment in question" as provided by Art. 22(1)(c) of Regulation No 1408/71. The Court asked whether this expression made reference to the same criteria applicable in determining the concept of "undue delay" for the purposes of Art. 49 EC.

Other issues raised concerned the amount of reimbursable costs.

Reasoning of the Court

Referring to previous judgments (*Initan, Smits and Peerbooms, Müller Fauré and Van Riet*), the Court stated that, in order to assess whether a treatment presenting the same degree of effectiveness for the patient can be promptly obtained in the Member State of residence, the competent institution is required to take into consideration the set of circumstances that characterize each specific case, taking due account not only of the patient's clinical situation at the time the authorization is requested and, if necessary, the degree of pain or the nature of the illness. This has to be evaluated with reference to his/her professional activity and his/her medical history.

However, "where the demand for hospital treatment is constantly rising, primarily as a consequence of medical progress and increased life expectancy, and the supply is necessarily limited by budgetary constraints, it cannot be denied that the national authorities responsible for managing the supply of such treatment are entitled, if they consider it necessary, to institute a system of waiting lists in order to manage the supply of that treatment and to set priorities on the basis of the available resources and capacities."

Waiting lists, therefore, arise from objectives relating to the planning and management of the supply of hospital care pursued by the national authorities on the basis of generally predetermined clinical priorities. In this context, when the patient cannot receive the treatment in question without undue delay, it means that the waiting time exceeds the period which is acceptable for an objective medical assessment of the clinical needs of the person concerned, in light of their medical condition and the history and probable course of their illness, the degree of pain they are in and/or the nature of their disability at the time when the authorisation is sought (par. 68).

In light of the abovementioned conditions, the CJEU set a system of **procedural requirements** that the scheme of prior authorisation must fulfil in order to be considered objectively justifiable under EU law. This system must be strictly fulfilled because it derogates from a fundamental freedom of the Treaty. Therefore, the system of prior authorisation that the patient must follow to be entitled to obtaining medical treatment (hospital care) abroad at the expense of the home healthcare institution must in any

event 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 (par. 116).

Such a system must furthermore be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings (par. 116).

Conclusion of the Court

Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration. It does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the granting of prior authorisation by the competent institution.

A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists (even if they are based on the need to safeguard the general equilibrium of the healthcare service involved), without carrying out an objective medical assessment of the patient's medical condition. This assessment must involve the history and probable course of their illness, the degree of pain they are in and/or the nature of their disability at the time when the request for authorisation was made or renewed. Where the delay arising from such waiting lists appears to exceed an acceptable time with regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists.

The refusal of prior authorisation must be challengeable in judicial or quasi-judicial proceedings.

Elements of judicial dialogue

As already noted, the discipline progressively drawn by the CJEU is based upon free movement provisions and on the EU Regulation on the coordination of social security systems. Indeed, the Regulation provision on free movement of workers represents the starting point that gave origin to the Court of Justice's saga on cross-border healthcare.

The 1998 Kohll decision originated from a question surrounding a preliminary ruling raised by the Luxembourg Cour de Cassation. The CJEU was required to verify whether the Treaty Articles on free movement of services (now Arts. 52 and 62 TFEU) precluded reimbursement of the costs of benefits obtained in another Member State subject to prior authorisation of the home healthcare institution and if the compatibility of the authorisation regime somehow changed if the reason for such a rule was to maintain a balanced medical and hospital service.[82]

To summarize: is the system of prior authorisation a restriction on the freedom to provide (and receive) services in the territory of the EU? If this is the case, could this restriction be justifiable under the Treaty provision? If yes, could the need to maintain a balanced medical service be regarded as a valid justification?

The CJEU held that the provision of **prior authorisation** established by the national healthcare institution for the reimbursement of costs for medical care incurred abroad does not preclude EU citizens from travelling to another Member State to obtain medical service, but nevertheless represents a

[82] C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171.

restriction on the freedom to provide services. In fact, a similar authorisation is not required for costs incurred within the State of affiliation. This principle was confirmed in Watts.

The CJEU examined whether this barrier on the freedom to provide services (to obtain services) was **objectively justified** (Kohll, para 35). In the words of the Court: "aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services," but "it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind" (Kohll, para 41).

Treatment in the concrete case was quite limited (dentist care for the daughter of the appellant). Thus, the Court found that the need to safeguard the internal financial balance of the healthcare service was not relevant to the case. It also examined whether there were any justifications on grounds of public health that could make the restriction legitimate, but found that the protection of the quality of medical services provided in the Member State and the objective of maintaining the general balance of the medical service could abstractly fall within the general justification of the grounds of public health, but they were not met in the concrete case.

This decision generated opposite reactions: on the one hand, it was read as the starting point for the new EU freedom of medical services and was intended as the launch of a consumer oriented health Union. On the other hand, Member States, under the fear of being forced to pay for medical treatment received abroad by their patients, started to limit the impact of the decision. For example, some States argued that "hospital services did not constitute an economic activity within the meaning of Article 57 of the TFEU, particularly when they are provided in-kind and free of charge under the relevant sickness insurance scheme."[83]

Inevitably, the tension between EU institutions' willingness to open healthcare services to mobility and intra-European exchange and a not-irrelevant trend towards a consumer-oriented approach to healthcare treatments, on the one hand, and the strong reaction of Member States seriously concerned about the maintenance of the internal balance of healthcare services, on the other, soon brought intense litigation before the CJEU.

To summarize, the CJEU progressively specified whether **national restrictions** on the freedom to travel for medical services (such as a regime of prior authorisation or the exclusion of some treatments) could be **objectively justifiable** under the Treaty, by verifying whether the risk of distortion of economic equilibrium of the national healthcare system was real, with respect to the specific medical treatment sought by the patient.

In this respect, the CJEU confirmed that **hospital care** also fell under the meaning of services and, therefore, Articles 56 e 57 TFEU should apply. For the purposes of the right to reimbursement of medical expenses incurred abroad, in other words, there was no need to distinguish between hospital and non-hospital care.[84]

In any case, considering the need to safeguard the internal balance of healthcare services both as a financial necessity of Member States and as a way to ensure healthcare service open to all that contributes

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[83] H.J. Meyer, Current legislation on cross-border health care in the European Union, in I.G. Cohen, The Globalization of Health Care: Legal and Ethical Issues, Oxford 2013, 91.

[84] C-157/99 Smits e Peerbooms [2001] ECR I-05473. ECLI:EU:C:2001:404.

to attaining a high level of health protection, the CJEU stated that, in general terms, prior authorisation for hospital care abroad could be acceptable under EU law, only if some conditions were met. In particular, the treatment required must be included in the list of benefits of the healthcare system of affiliation and must be considered "normal in the professional circles concerned"[85] and that the individual patients' medical situation must require that treatment.[86]

Subsequent decisions went on to further specify these assumptions. For example, in Vanbraekel the reimbursable amount was clarified, considering the different nature of national healthcare systems, whereas Herrera excluded the reimbursement of complementary expenses, in addition to the cost of the treatment obtained, such as travel, accommodation, and subsistence costs that the patient or any person accompanying her incurred.[87]

Interestingly enough, the CJEU gradually developed some **procedural requirements** that must be followed by State authorities during the evaluation of patient authorisation. The conditions for granting authorisation must be justified under imperative criteria – which were set out since Smits and Peerbooms and later specified further – and must not exceed what is objectively necessary and proportionate. The issue of authorisation must be funded on objective and non-discriminatory parameters known in advance, so that the exercise of discretionary power by State authorities is limited.[88] Furthermore, refusals to grant authorisation shall be challengeable in judicial or quasi-judicial proceedings.[89]

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Spain

Tribunal Superior de Justicia, Madrid, Resolucion 405/2018, of 12/06/2018: a woman was refused reimbursement for medical expenses incurred during a staying abroad in the context of the Erasmus programme. The Court stated that the health authority should have informed her that she could have had access to the reimbursement procedure provided by the cross-border healthcare framework, instead of opposing a mere refusal based on the fact that the woman did not satisfy the requirements for reimbursement she had applied for.

Judgment of the Superior Court, Islas Canarias, Social Jurisdiction, 22 October 2008:

The Court decided that a person insured in Spain was entitled to the reimbursement of costs (35.000 euros) related to medical treatment provided in an emergency in a hospital covered by the German national system. Moreover, the medical assessment of the emergency didn't have to be approved by the Spanish competent institution (Article 22.1.a), i) Council Regulation (ECC) No 1408/71). The decision referred to ECJ case C-120/95 Decker [1998].

Judgments of the Superior Courts, Extremadura, Social Jurisdiction, 15 February 2018; Castilla y León, 31 October 2016. The issue here was whether a person insured in Spain was entitled to the reimbursement of medical costs when the service was provided by a private Spanish hospital. The Court interpreted the national law according to ECJ case C-385/99 Müller-Fauré e van Riet [2003] and Article 22.2 of the

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[85] C-157/99 Smits e Peerbooms, para 43

[86] It is worth pointing out that a further distinction between hospital and non-hospital care was later introduced by the Müller-Fauré decision in 2003. See C-385/99 Müller-Fauré e van Riet [2003] ECR I-04509. ECLI:EU:C:2003:270.

[87] Case C-466/04 *Acereda Herrera* ECLI:EU:C:2006:405, para. 39.

[88] *Smits e Peerbooms*, para. 90; *Müller-Fauré e van Riet*, para. 85; *Watts*, para. 116; *E.*, para 44.

[89] *Watts*, para. 116.

Council Regulation (ECC) No 1408/71: "authorisation may be refused (…) only if treatment which is the same or equally effective for the patient can be obtained without undue delay in an establishment which has concluded an agreement with the fund."

1.3 The Impact of CJEU Caselaw on the Directive on Patient's Rights in Cross-Border Healthcare

After such intense litigation, a clarification of the principles progressively affirmed by the CJEU was felt to be necessary both by EU institutions and Member States.

Moreover, the need for a Directive on patient mobility also arose during the legislative process that led to the Services Directive 2006/123/EC, from which healthcare, because of its particular nature, was finally excluded.[90] The patients' Rights Directive was finally approved in 2011, after a very long drafting process which attests to how many issues were at stake.[91] It has three fundamental objectives, which are: the setting of **rules on procedures** and **reimbursement of costs** for cross-border healthcare; the definition of Member States' responsibilities in cross-border healthcare and correlatively the establishment of measures to ensure patients' safety and, finally, the setting of a broad framework of cooperation for Member States in the field of healthcare, from reference networks for highly specialised care and rare diseases, to the exchange of good practices. A central part of the act concerns the **procedures for cross-border healthcare** and reimbursement of costs, which is also related to the problem of **effective protection** of fundamental rights.

First of all, the Directive clarifies that access to medical care in a Member State other than that of affiliation runs on two parallel tracks under EU law. In fact, the Regulation on the coordination of social security systems shall be the main framework for regulating access to healthcare abroad. The Directive provisions are basically residual: "Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met." (recital 31). The application of the Directive is therefore limited to those cases that do not fall under the Regulation provisions.

The Directive outlines the limited circumstances in which Member States may lawfully restrict freedom of movement for medical treatment. The Directive provides for a detailed procedural framework that today regulates cross-border healthcare provisions across the entire EU territory.[92] These rules have been defined first by case law.

Briefly, patients can obtain medical treatments in another MS and be reimbursed mainly freely afterwards, unless they need **highly specialised or hospital care**. In this case, they need to obtain **prior authorisation** from the healthcare institution of affiliation. More specifically, the Member State of affiliation shall reimburse the costs for medical care received in another State, if this treatment is among the benefits to which the insured person is entitled in the Member State of affiliation (Art. 7.1). Member States shall determine the competent institution that must deal with the reimbursement request of the patient and the costs to be reimbursed are up to the level that the affiliation institution would have paid if that treatment had been provided within the territory, without exceeding the actual costs of the

[90] M. Peeters, Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border healthcare, in European Journal of Health Law, 19, 2012, 29-60, 30.
[91] S. De la Rosa, The Directive on Cross-Border Healthcare or the art of Codifying Complex Case Law, in Common Market Law Review, 49, 2012, 15-46, 26
[92] Articles 7, 8, and 9.

treatment received (Art. 7.4). To make these rights effective, Member States shall also define internal procedures for prior authorisation, including the individual right to challenge a refusal within a judicial or quasi-judicial mechanism.

Prior authorisation may be requested only in the circumstances described in Art. 8, which basically involve hospital care and highly specialised care. The reason for this provision must obviously be found in the principles already stated by the CJEU and in the need to maintain a financial balance of national healthcare services. Prior authorisations might also be requested if the care concerned could be risky for the patient. Art. 8 also clarifies that in some given circumstances the home institution may refuse the prior authorisation, namely for safety reasons. Finally, there is also **a clinical condition that may lead to a refusal** of prior authorisation that echoes both the Regulation provisions and the principles set by the CJEU in its case-law, especially in Watts: "this healthcare can be provided on its territory **within a time limit which is medically justifiable**, taking into account the current state of health and the probable course of the illness of each patient concerned" (Art. 8.6.d).

The last provision concerning cross-border healthcare (Art. 9) is dedicated to the procedures that have to be followed by patients in order to obtain reimbursement. These rules have found slightly different national implementation, due to the different schemes of administrative proceedings. Art. 9 provides for a detailed set of procedural rights which contribute to the definition of the substantial right to cross-border healthcare. In this field, characterised by decisions of a highly technical nature, the **proceduralisation of rights** is the only way to ensure their effectiveness.

This was a precise and conscious choice of both the CJEU and of the EU law-maker: developing concrete standards of healthcare access or treatment and the sharing of competences discussed above would not have been possible under EU law. Instead, a detailed "framework of intertwining principles" was developed first by the CJEU to evaluate Member State rules in the area of patient mobility and, then, it was similarly adopted in the Directive to influence the setting of national rules both in this area and indirectly in the field of access to healthcare.[93] In other words, **procedural rights** force individual behaviour but also national choices: for example, as a consequence of the Directive, national healthcare systems should be more careful in the organisation of waiting lists and in the evaluation of the clinical situation of the individual patient included in a waiting list.

As for the other objectives, the Directive also instituted National Contact Points, to provide information on cross-border healthcare which boosts the cooperation among MSs in key areas such as the treatment of rare diseases, telemedicine through European Reference Networks, and encourages the exchange of good practices among Member States. Above all, the main scope of the Directive was to stop litigation before the CJEU and to definitively clarify the rules concerning healthcare abroad.

Question 3 – A Wide Interpretation of Undue Delay

Could a structural lack of medication and basic medical supplies be claimed as "undue delay?"

The analysis is based on *Petru* (C-268/13).

The case

[93] S.L. Greer, T. Sokol, Rules for rights: European Law, Health Care and Social Citizenship, in European Law Journal, 20(1), 2014, 66-87, 79.

Ms. Petru suffered from serious cardiovascular disease and had undergone surgery following a heart attack. Following the worsening of her health condition, during another hospitalization, the medical examinations to which the lady was subjected led to the decision to proceed with an open-heart operation to replace the mitral valve and introduce two stents.

The applicant therefore decided to go to Germany to undergo this surgery, the cost of which amounted to a total of € 17,714.70.

The choice of a German hospital was determined for Ms. Petru by the lack of material conditions in the Institute of Cardiovascular Diseases of Timişoara (Romania). Before the trip, the applicant requested her enrollment in the sickness fund to pay for the costs of the surgery, but her application (based on form E112) was rejected because, according to the health facility, the requested medical service was available within a reasonable amount of time in Romania.

The case before the Court of Justice of the EU concerned the interpretation, under EU law, of the concept of undue delay in access to medical treatment. Ms. Petru claimed that the enduring and structural lack of medication and basic medical commodities should be interpreted as a reason that forbid the patient to obtain the care she needed in due time.

Preliminary questions referred to by the Court

In the second subparagraph of Article 22(2) of Regulation No 1408/71, is the requirement that the person concerned be unable to obtain treatment in the country of residence which is to be construed as categorical or reasonable. In other words: if the required surgery could, in technical terms, be carried out in due time in the country of residence (i.e. specialists are present there and have the same level of specialist skills as those abroad), does a ***lack of medicines and basic medical supplies and infrastructure*** *mean that such a situation can be equated with a situation in which the necessary medical treatment cannot be provided?*

Reasoning of the Court

In assessing the patients' request for prior authorisation to obtain medical treatment abroad, the competent health institution must take **the lack of medication and basic medical supplies and infrastructure** into account as well. The relevant provision of the Regulation on the coordination of social security systems (Art. 22.2) does not distinguish between the different reasons for which a particular treatment cannot be provided in good time. Clearly however, such a lack of medication and of medical supplies and infrastructure can, in the same way as a lack of specific equipment or particular expertise, make it impossible for the same or equally effective treatment to be provided in good time in the Member State of residence (par. 33).

However, to determine whether it is actually impossible to obtain care in due time, it is necessary to take **all the hospital establishments in the Member State of residence** into account. The applicant, in fact, had the right to approach any other medical establishment in Romania. Therefore, it was for the referring Court to determine whether that treatment could have been carried out within three months in another hospital establishment in Romania.

Conclusion of the Court

The relevant provision of the EU Regulation must be interpreted as meaning that the authorisation necessary cannot be refused due to a lack of medication and basic medical supplies and infrastructure

that the hospital treatment concerned cannot be provided in good time in the insured person's Member State of residence. The question whether it is possible or not must be determined with reference to all the hospital establishments in that Member State capable of providing the treatment in question and with reference to the period within which the treatment can be obtained in good time.

Elements of judicial dialogue

In this case, it is very important to underline that the Court linked a lack of medical supplies to the issue of undue delay, as provided by Art. 22.2 of the Regulation. To do so, the Court cited its previous decision in which it dealt with the concept of undue delay in access to medical treatments. See in particular: Inizan, C 56/01, paragraphs 45 and 60; Watts, paragraph 61; E., paragraph 65.

In order to determine whether the treatment can be obtained in due time in the Member State of residence, the competent institution must consider the circumstances of the specific case and the individual situation of the patient. As provided by previous case law, this consideration must include the degree of pain or the nature of the patient's disability (also in relation to their professional activity), and the patient's medical history (Inizan, paragraph 46; Watts, paragraph 62, E., paragraph 66).

It is relevant to point out that, in accordance with arguments made by the national government, the patient has the right to obtain treatment in any other medical establishment in the Member State of residence. Therefore, evaluation of the availability of medical supplies must be done with reference to the entire home health system, not only in the location in which authorisation is sought. This was an important specification made by the CJEU in the Petru decision.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

Council of State, sez III, decision 05861/2018, concerning refusal of access to an Italian couple seeking assisted reproduction with gamete donation abroad. The Council of State annulled the health authority's denial because it did not indicate in which Italian structures the treatment sought by the applicants was available.

1.4 Effectiveness of Remedies in Recent Times and New Issues

After the Directive was adopted, litigation before the Court of Justice has been substantially reduced, with the only exception being requests for preliminary references based on pre-existing cases (which led for example to the *Petru* decision in 2013) and to secondary issues concerning the mutual acknowledgement of medical prescriptions.

This should be considered proof of success of the Directive. Indeed, its main aim was to provide for a clear and effective procedural set of rules to clarify patients' rights in cross-border healthcare and the circumstances under which a state institution can legitimately refuse to pay for healthcare abroad.

To summarize, the phenomenon of cross-border healthcare and its complex regulation at the EU level serves as a good example of several interactions between State and EU roles and competences in the effective guarantee of fundamental rights.

First, cross-border healthcare demonstrates that, even though the EU does not have direct competence over the organisation of healthcare services, it can significantly influence state provisions on treatments

and services. Second, it touches upon the delicate chords of enduring tensions between EU and state legal discipline on social rights: enforcing EU Treaties and giving shape to its principles requires state action more and more on social rights and, therefore, a strong public economic commitment to the granting of services. Third, it is strictly linked to realizing the principle of solidarity that, in several fields, has been challenged and questioned by states forced to enact policies and regulations to fulfil EU obligations. Finally, the ongoing pandemic emergency that has impacted most European countries has demonstrated to all of us the essential need for a strong and structured cooperation among MSs in the field of healthcare, which is the only concrete solution to prepare for and seriously face global health challenges.

Question 4 - Cross-Border Healthcare and Non-Discrimination

Shall an authorisation for medical treatment in another Member State be granted, when treatment is available in the State of residence, but the method of treatment used is contrary to that person's religious beliefs?

The analysis is based on *Veselības ministrija*, (C-243/19)

The case

The case arose in Latvia. The applicant's son, a minor who suffered from a congenital heart defect, had to have open-heart surgery. The applicant refused to consent to the use of blood transfusion during the operation, on the ground that he was a Jehovah's Witness.

As the operation in question was not available in Latvia without the use of blood transfusion, the applicant requested that the Latvian National Health Service issue authorisation for his son to receive such surgery abroad in Poland. The Latvian health service refused to give prior authorisation. The Ministry of Health upheld the health service's decision, on the grounds that the surgery at issue could be carried out in Latvia and that a person's medical situation and physical limitations alone must be taken into consideration for issuing the form.

The applicant then initiated an action before the administrative Court in order to obtain a favourable measure for his son, recognising the right to receive scheduled healthcare abroad. His action was again dismissed both in the first instance and in appeals. The latter Court found that the medical procedure at issue (blood transfusion) in the main proceedings, treatment which is publicly funded in Latvia, was indeed necessary to avoid the irreversible deterioration of the vital functions or health of the applicant's son during the surgery. However, at the time the request for authorisation was under consideration the hospital confirmed that that procedure could be carried out in Latvia. Furthermore, the Court found that it was not possible to infer from the applicant's refusal of such a transfusion that the hospital was unable to provide the medical procedure in question.

The applicant in the main proceedings brought an appeal on a point of law before the referring Court, arguing, specifically, that he was a victim of discrimination since the vast majority of those affiliated to the health system were able to receive the healthcare at issue without having to give up their religious beliefs. In the meantime, the son had heart surgery in Poland. The referring Court was uncertain whether the Latvian health authorities were entitled to refuse authorisation for treatment solely on the basis of medical criteria or whether they were also required to take the applicant's religious beliefs into account.

Preliminary questions referred to the Court

The preliminary question concerns the interpretation of Art. 20(2) of Regulation No. 883/2004 (which replaced Art. 22.2 of Regulation No. 1408/71), in conjunction with Art. 21.1 of the EU Charter of Fundamental Rights. On these bases, can a Member State refuse to grant authorisation to receive medical care abroad if the treatment required is available in the Member State of residence, but the method used is contrary to the person's religious beliefs?

The same preliminary question also applies to Art. 56 TFEU and Art. 8(5) of Directive 2011/24, read in conjunction with Art. 21.1 of the EU Charter of Fundamental Rights. Under the Directive's provisions, hospital care is subject to prior authorisation; the care required is available in the Member State of residence, but the method of treatment used is contrary to that person's religious beliefs.

Reasoning of the Court

1. In the case, the operation at issue was necessary in order to avoid irreversible deterioration in the vital functions or state of health of the applicant's son, taking the examination of his condition and the foreseeable course of his illness into account. Furthermore, said operation could be carried out in Latvia using blood transfusion and there was no medical justification for employing another method of treatment. The applicant opposed such a transfusion on the sole ground that it conflicted with his religious beliefs and he expressed a wish for the operation to be carried out without a transfusion, which was not possible in Latvia.

In light of Regulation provisions, the assessment consisted exclusively in examining the patient's medical condition and medical history, the probable course of his or her illness, the degree of his or her pain and/or the nature of his or her disability, and **did not involve taking the patient's personal choice into account** with regard to treatment. Thus, the decision by the Latvian authorities to refuse the authorisation cannot be considered incompatible with that provision.

Nevertheless, the applicant invoked a **violation of Art. 21 of the CFREU**, because of **religious discrimination**. Since the issue was within the field of application of EU law and as the principle of non-discrimination is mandatory as a general principle of EU law, the Court stated that it was for the referring Court to ascertain whether the refusal to grant the applicant prior authorisation established a difference in treatment based on religion. If that were the case, the national judge must ascertain whether that difference in treatment was based on an objective and reasonable criterion.

However, in the case in question, it appeared that the national legislation at issue in the main proceedings was formulated in a neutral way and did not give rise to direct discrimination based on religion. It was also important to examine whether such refusal brought about a difference in treatment which was indirectly based on religious beliefs. In the concrete case, there was no medical justification for the applicant's son not to receive treatment in Latvia.

Thus, on the one hand, a difference in treatment was effectively made on the grounds of religion. On the other hand, however, the context was one of public health, which also found protection within the UE Treaty. In these circumstances, the need to maintain a **balanced healthcare service is an objective justification for a refusal of prior authorisation**. In a situation where benefits in kind provided in the Member State of stay give rise to higher costs than those relating to benefits which would have been provided in the insured person's Member State of residence, the obligation to refund in full may give rise to additional costs for the Member State of residence. If the competent institution were obliged to take account of the insured person's religious beliefs, such additional costs could, given their unpredictability

and potential scale, be capable of entailing a risk in relation to the need to protect the financial stability of the health insurance system, which is a legitimate objective recognised by EU law.

2. The second preliminary question concerned the interpretation of the Directive's provisions. In particular, the reimbursement provided for by Article 7 of Directive 2011/24 may, therefore, be subject to a twofold limit. First, it is calculated on the basis of the fees for healthcare in the Member State of affiliation. Second, if the cost of healthcare provided in the host Member State is lower than that of the healthcare provided in the Member State of affiliation, that reimbursement does not exceed the actual costs of the treatment received.

Since reimbursement of healthcare under Directive 2011/24 is subject to that twofold limit, the healthcare system of the Member State of affiliation is not liable to be faced with a risk of additional costs linked to the assumption of cross-border healthcare costs. Accordingly, in the context of Directive 2011/24, and by contrast with situations governed by Regulation No 883/2004, the Member State of affiliation will not, as a rule, be exposed to any additional financial costs with respect to cross-border healthcare (par. 77).

Conclusion of the Court

1. Article 20(2) of Regulation No 883/2004, read in light of Article 21(1) of the Charter, must be interpreted as not precluding the insured person's Member State of residence from refusing the authorisation provided for in Article 20(1) of that regulation, where hospital care, the medical effectiveness of which is not contested, is available in that Member State, although the method of treatment used is contrary to that person's religious beliefs. (par. 55)

2. Article 8(5) and (6)(d) of Directive 2011/24, read in light of Article 21(1) of the Charter, must be interpreted as precluding a patient's Member State of affiliation from refusing to grant that patient the authorisation provided for in Article 8(1) of that directive, where hospital care, the medical effectiveness of which is not contested, is available in that Member State, although the method of treatment used is contrary to that patient's religious beliefs, unless that refusal is objectively justified by a legitimate aim relating to maintaining treatment capacity or medical competence, and is an appropriate and necessary means of achieving that aim, which it is for the referring Court to determine. (par. 85)

Elements of judicial dialogue

This is the first decision of the CJEU where the Directive found application. Nevertheless, the preliminary questions raised before the Court concerned both the Regulation provisions and that Directive. As to the first question, the Court cited previous case law, particularly in order to determine the extent of the reasons for a denial of authorisation.

In previous judgements, the CJEU already held that the authorisation required cannot be refused if the same or equally effective treatment cannot be given in good time in the Member State of residence of the person concerned (see in particular Watts and Petru). To this end, the Court stated that the home health institution was required to take all the circumstances of each specific case into account, not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, the degree of pain or the nature of the patient's disability, but also of his or her medical history (par. 29).

At the same time, though, in the field of public health, the need to maintain financial balance of the healthcare system is considered an objective justification for a restriction on the freedom to provide

services (see Watts). Therefore, in this case, the amount paid by the applicant's son for healthcare abroad could be reimbursed under the Directive's legal framework, up until the amount the Latvian healthcare system would have paid if the healthcare were provided in the Member State of residence. A refusal of prior authorisation, in this case, was justifiable under the objective need to maintain the internal balance of the healthcare system.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Prior to the judgement, there were other cases in which national Courts had to deal with the reimbursement of elective medical treatments.

Spain

Judgement of the Superior Court, Basque Country, Social Jurisdiction, 18 January 2011:

The main issue was whether an insured person, authorized by the Spanish competent institution to travel to Switzerland to receive treatment appropriate to his condition, was entitled to reimbursement of the extraordinary costs based on the patient's election of surgeon. The Court rejected the claim because the insured person would not have been entitled to the reimbursement of such costs were the treatment provided in a hospital covered by the Spanish national system, because such costs were not necessary for the patient to receive adequate medical service

1.5 Guidelines Emerging from the Analysis

The case law of the CJEU is coherent in stating that medical treatments must be considered as services in light of EU law. Therefore, the fundamental freedom to provide services applies and Member States can only impose those restrictions that are objectively justified under the exceptions provided by treaty norms.

In the case in which a person who is ensured in one Member State obtains medical treatment in another, the provisions of Regulation 883/2004 or those of the Directive 2011/24/EU apply. Therefore, the person is entitled either to have the treatment paid for by the healthcare insurance of affiliation, or to have the costs reimbursed. To this end, some requirements must be satisfied. A very controversial point concerns those cases in which prior authorisation is lacking. The CJEU gave some clarification on the cases in which prior authorisation was not necessary or in which the institution of affiliation must reimburse the costs of medical treatment.

In a recent decision (Case C-777/18 WO v Vas Megyei Kormányhivatal, 23 September 2020), the Court stated that a person without prior authorisation is also entitled to reimbursement for a scheduled treatment in an amount equivalent to that which would ordinarily have been reimbursed by the institution if the insured person had been granted such authorisation.

This principle applies in connection with some specific reasons, linked to the interpretation of EU law and namely for reasons relating to his or her state of health or to the need to receive urgent treatment. It is also relevant if the insured person was prevented from applying for such authorisation or was not able to wait for the decision of the home institution in his or her application ('individual circumstances').

Stemming from the need to assess the relationship between the requirement of prior authorisation and legitimate justifications to restrictions on the freedom to provide services, the CJEU progressively refined its interpretation on individual rights in cross-border healthcare. Among those, the Court specified that the list of medical treatments available in one Member States must be updated, otherwise the patient is entitled to the reimbursement of the more technologically advanced treatment even without prior authorisation. Similarly, the structural lack of medical material and medications is also a reason to recognise reimbursement without prior authorisation. The CJEU provided its contribution in interpreting the notion of undue delay as well, as a reason to be entitled to reimbursement.

More generally, it is possible to observe that the Court worked to carefully define a framework for a set of procedural rights that must be respected by national health authorities and by national Courts when evaluating a request for prior authorisation or when judging a refusal or denial of reimbursement. These are inspired by the principle of good administration and of effectiveness of judicial remedies.