The social role of healthcare system. A comparative analysis of case-law regarding patients' right to mobility within the European Union

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Abstract: Il ruolo sociale del sistema sanitario. Un'analisi comparativa della giurisprudenza sul diritto alla mobilità nell'Unione europea – The article analyses the implementation of Directive 2011/24/EU in Italy and France through the analysis of national case-law. In particular, it highlights how the margin of maneuver of Member States could distort the objectives of the uniform rule. Indeed, the provision of healthcare services is relevant both to the competence of the Member States, which guarantee their use, and to European law, which ensures their coordination when the service is performed in a state other than that of affiliation. The right to patient mobility to choose cross-border medical treatment is however restricted by the role of national administration.

Keywords: Directive 2011/24/EU; Right to patient mobility; Healthcare system; Cross-border medical treatment; Social health insurance.

1. Introduction

The right to healthcare is characterized by imperfect protection within the European Union (EU) as the latter, lacking exclusive competence in the matter, may only intervene by favoring cooperation between Member States[1]. Though assuming the protection of human health as a fundamental principle[2], the Union's intervention in this area consists of rules for the coordination of national systems, which are "holders of the management of healthcare services, medical assistance and the allocation of the resources assigned to them"[3]. In particular, legislative acts on the subject have concerned worker protection, cross-border access to

[1] See arts 4 and 6 TFEU.

[2] Art. 35 of the Charter of Fundamental Rights of the European Union states that: "Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

[3] See art. 168 TFEU, which includes the guarantee of a "high level of human health protection among the scopes of all EU policies". See also the European Commission's White Paper, *Together for Health: A Strategic Approach for the EU 2008-2013*, COM(2007) 630 final from 23 October 2007.

healthcare services and consumer protection, in a sectorial logic that is very different from the universal approach that generally is a central feature of national constitutions[4]. In fact, in the EU, the receipt of economic freedom forms the basis of the protection of an individual's right to healthcare by the market[5].

Accordingly, in the European juridical area healthcare is protected on a mediated basis, to the extent that it is protected in the 'Member States of affiliation' (as per the definition in article 3(c) of Directive 2011/24/EU)[6]. The provision of care services, which ultimately give effect to the right to health, is relevant both to the competence of the Member States, which guarantee their use, and to EU law, which ensures their coordination, when the service is performed in a Member State other than that of affiliation.

The role of the EU is in fact complementary to national healthcare policies and is expressed in the coordination and completion of the actions of Member States[7], as per article 6 of the Treaty on the Functioning of the European Union (hereinafter TFEU)[8]. This has led to an undoubted lack of homogeneity in the transposition of the Directive, because national governments are reluctant to relinquish the control over the organization of their healthcare systems, invoking the requirements of the public hospital service[9]. In particular, uncontrolled patient mobility runs the risk of undermining national health service planning aimed at guaranteeing quality care without wasting resources.

Copious litigation submitted to the European Court of Justice has led to the intervention of the European legislator with the adoption of Directive 2011/24/EU, which has codified the judicial solutions elaborated in Luxembourg[10]. The Court has attempted to reconcile the principles of free

[4] For the good and interest of the community, health has been gradually targeted on the needs of the individual. For Italy, from the establishment of a national health service, with *legge* n. 833 of 23 December 1978, until its reform with the *Decreto legislativo* n. 502 of 30 December 1992, together with a revision of the *livelli essenziali di assistenza* ("essential level of assistance", hereinafter LEA), recently reformulated by *Decreto del Presidente del Consiglio dei Ministri* (hereinafter DPCM) of 12 January 2017.

[5] See L. Uccello Barretta, *Il diritto alla salute nello spazio europeo: la mobilità sanitaria alla luce della direttiva 2011/24/UE*, in *federalismi.it*, 2014, 1.

[6] 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, in OJ L 88, 4.4.2011, 45. See G. Cohen, *Patients with Passports: Medical Tourism, Law, and Ethics*, Oxford, 2014.

[7] See art. 6 TFEU.

[8] The initial reluctance to develop a common healthcare policy, expressed by the same Maastricht Treaty, underwent a major change with the healthcare crisis of the 1990s and, in particular, what was commonly known as the "mad cow crisis". With the Amsterdam Treaty there has been a strengthening of the social policies of the union, finally sanctioned by the Lisbon Treaty.

[9] E. Pataut, *Territorialité et coordination en droit international privé : L'exemple de la sécurité sociale*, in *Mélanges en l'honneur du Professeur Pierre Mayer*, Paris, 2015, 663.

[10] "Community law does not detract from the powers of the Member States to organise their social security systems and by no means implies that the social security sector constitutes an island beyond the reach of Community law and that, as a consequence, all national rules relating to social security fall outside its scope" Joint opinion of AG Tesauro delivered on 16

movement of persons and services with the competence of the Member States regarding the organization of their healthcare systems, which varies across the EU: some are characterized by a universalistic approach, such as Italy (national health system), sometimes mutualistic (social security healthcare system), such as France, and have differing administrative competences regarding the interaction with private, national or foreign healthcare centers[11].

This contribution aims to analyze the articulation of the right to cross-border healthcare in the EU and the consequent and jurisprudential tension arising from the recognition of "patient mobility"[12] in Italy and France, in the absence of harmonized healthcare.

2. The integration of Directive 2011/24/EU within the regime unified by Regulations (EC) No 883/2004 and (EC) No 987/2009.

The embryo of European citizenship has developed in the womb of a specific economic category, that of the community worker[13], which has polarized a set of transnational rights functional to the development of the market through the rights connected to the principle of free movement[14]. Since 1992[15] the difference between 'economically active' and 'non-active' citizens is eroding, and the prerogatives associated with freedom of movement have been progressively granted even to those who are not economically active[16]. In reality, although there are still some differences between these two categories[17], the uniform

September 1997, in case C-120/95, *Nicolas Decker v Caisse de maladie des employés privés* and case C-158/96, *Raymond Kohll v Union des caisses de maladie*, [1998] ECR I-01834, n. 17.

[11] The insurance reimbursement mechanism allows for supplementary insurance funds to reimburse costs relating to healthcare services provided by public and private healthcare facilities. This mechanism is not so common in systems adopting a universal approach whereby the service is free or provided for by the payment of a prescription charge only.

[12] The expression is used by AG Geelhoed in the conclusions delivered on 15 December 2005 in case C-372/04, *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, [2006] ECR I-4331, n. 1.

[13] As is known, in order to ensure effective free movement of workers, the EU legislator established a mechanism in 1958 to provide social security coverage for migrant workers by ensuring, under certain conditions, access to healthcare in another Member State, to be paid by the healthcare system of their home Member State. See V.H. Compte, N. Levrat (Eds), *Aux coutures de l'Europe. Défis et enjeux juridiques de la coopération transfrontalière*, Paris, 2006.

[14] See S. Van Raepenbusch, *La securité sociale des travailleurs européens*, Brussels, 2001; M. Morsa, *Sécurité sociale, libre circulation et citoyenneté européennes*, Limal, 2012. The notion of worker and that of consumer are the basis of the construction of the internal market and are those on which the right to European healthcare has been built. See A. Papa, *La tutela multilivello del diritto alla salute nello spazio europeo: opportunità o illusione?*, in *federalismi.it*, 2018, 80.

[15] Treaty on European Union (TEU), as signed in Maastricht on 7 February 1992.

[16] See art. 8 TEU; see also E. Ferrari, *L'uguale libertà del cittadino europeo: linee di frattura della corrispondente concezione nazionale di uguale libertà*, in *Riv. Trim. dir. Pubb.*, 2007, 931.

[17] See art. 7(1)(b) Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States in OJ L 158, 30.4.2004, 77.

interpretation by the Court of Justice has affected national disciplines, giving precedence to belonging to community citizenship over foreign citizenship[18] and has expanded the concept of worker, extending the right of free movement also to those no longer active or not yet employed, thus configuring "an individual right whose enjoyment is direct and generalized, even in a supranational order"[19].

Directive 2011/24/EU, concerning cross-border healthcare, adopts article 114 TFEU as the appropriate legal basis as most of the provisions contained in the Directive are intended to improve the functioning of the internal market and the free movement of goods, persons, services and capital, while the protection of healthcare is cited in a generic way[20], though permeating the substantive law of the Directive itself[21].

There are several reasons as to why the development of a common and harmonized healthcare policy is particularly difficult, the main reason being due to the various structures of the healthcare systems in the Member States. While all European models share the same values—and are based on the principles of solidarity, fairness and universality—the management and provision of healthcare services has been implemented through different models. Most Member States have adopted the Bismarckian model, mutualistic or insurance-based, (this is the case of Belgium, France, Germany, Luxembourg, and the Netherlands) and the Beveridgean model, which supports the national health system or universal tax system (adopted in Denmark, Greece, Italy, Norway, Portugal, Spain, Sweden, and the United Kingdom), and some operate through mixed models[22].

The significant differences in these models make harmonious coexistence somewhat difficult. The Bismarckian model, both in terms of financing and the right to access, uses an insurance system and is usually financed jointly by employers and employees. This means that only working citizens who contribute to social security may benefit from healthcare insurance.

On the contrary, the Beveridgean model provides healthcare for all citizens,

[18] See CJEC, 7 July 1992, case C-369/90, *Mario Vicente Micheletti and others v Delegación del Gobierno en Cantabriail*, [1992] ECR I-04239, 15, in which the European Court of Justice resolved the request for a preliminary ruling proposed by a Spanish court in the sense that "the provisions of Community law on freedom of establishment preclude a Member State from denying a national of another Member State who possesses at the same time the nationality of a non-member country entitlement to that freedom on the ground that the law of the host State deems him to be a national of the non-member country".

[19] M. Cartabia, *Principi inviolabili e integrazione europea*, Milan, 1995; B. Gagliardi, *La libera circolazione dei cittadini europei e il pubblico concorso*, Naples, 2012.

[20] See art. 114(3) TFEU, stating that the protection of health is a common goal: "The Commission, in its proposals envisaged in [art. 114(1)] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective".

[21] See art. 168(1) TFEU, expressly referred to in the first recital of Directive 2011/24/EU.

[22] In 1942 the English economist William Beveridge proposed a plan for a free national health service and a pension system: it is the first step of a wide system of protection that will have to accompany citizens "from the cradle to the grave".

whether employed or not, and is financed by the government through general taxation[23].

The role of the private healthcare sector is also different in these two healthcare models. While in some Member States such as Italy, healthcare is provided by the public system, there are others in which there is a significant participation of private healthcare insurance through private supplementary and almost compulsory insurance policies, as in France.

These models obviously have their strengths and weaknesses. In theory, tax-based health systems find it easier to control spending (as it is inherently budgetary), but pressure from demand may result in longer waiting lists, revealing the inadequacy of services. In insurance-based systems, which in many cases separate healthcare providers from the financial provider, an increase in demand or costs translates into increased expenses. This increase can be unsustainable for public finances, which, while trying to contain costs, often face the opposition of the interested parties, especially given the difficulty of choosing the priorities to be met.

This difference in national models has a substantial impact on the cross-border movement of citizens, as neither the right of access to the system nor the form of access and benefits management are the same in all Member States[24].

Generally, healthcare is requested and provided in the place closest to where the patient has established the center of his interests. However, reasons of work, tourism, study or even due to an explicit choice to seek treatment abroad may give rise to the need to obtain healthcare services in a European country other than that of residence[25]. Within the broader notion of freedom of movement of persons and provision of services[26], the EU guarantees the patient's right to access healthcare services in a country other than that of residence or affiliation, and for this purpose has issued Directive 2011/24/EU, which recognizes the freedom of movement of patients and the consequent right to access cross-border healthcare services.

The possibility of being able to opt for healthcare in a Member State other than the country of affiliation has been accused of posing a threat to the territorial and solidarity base of the public hospital service: it would seem to legitimize the egoistic search for the most efficient service, allowing the interests of individual patients to prevail over those of the collective, thus obliging public healthcare

[23] For a recent analysis of the factors that contribute to distinctions between the models of health systems, see G. Lopez-Casasnovas, L. Maynou, M. Saez, *Another Look at the Comparisons of the Health Systems Expenditure Indicators*, in 121 *Social Indicators Research* 149 (2015).

[24] See F. De Montalvo, *A European Common Framework for Health: A Real Possibility or an Improbable Myth? Lessons for the Future Healthcare System in the United States*, 14 *DePaul J. Healthcare L.* 189 (2012).

[25] European Commission, *Evaluative study on the cross-border healthcare Directive (2011/24/EU) Final report*, 21 March 2015; R. Baeten, *Cross-border patient mobility in the European Union: in search of benefits from the new legal framework*, in *Journal of Health Services Research & Policy*, 2014, 19.

[26] F. Costamagna, *I servizi socio-sanitari nel mercato interno europeo*, Naples, 2011, 135.

services to satisfy increasing needs with finite financial, technical and human resources. In fact, the costs of reimbursement of care provided abroad represent a loss of investments in medical infrastructures within national territories, which would otherwise benefit the citizens residing in a given territory[27].

Criticism of the Directive is not really a novelty as two EU Regulations already provided for the possibility of benefiting from healthcare services in a Member State other than that of residence: the social security Regulations (EC) No 883/2004[28] and 987/2009[29], which introduced the European Health Insurance Card (TEAM), in force since 1 May 2010. However, these two Regulations only guarantee healthcare services in public facilities, or in facilities affiliated to the statutory healthcare system, to certain categories of people (tourists, students, workers, pensioners, family members of resident workers) and for specific situations (temporary stay or residence abroad for work reasons, transfer abroad for treatment), with the exception of the transfer for highly specialized care, which are subject to specific procedures.

Article 20 of Regulation (EC) No 883/2004 subjects the possibility of receiving scheduled treatment in another EU Member State to prior authorization. This authorization is granted by the healthcare authority (in Italy by the local healthcare authority of residence, in France by the competent office of the *Casse nationale de l'assurance maladie*)[30] on condition that the treatment is among the healthcare services provided for by the legislation of one's own State but that cannot be practiced in the country of residence within a time frame considered congruous by medical science. The coordination mechanism established by Regulation No. 883/2004 aims at ensuring that only one Member State is designated as the ultimate competent authority for the claims of the insured persons. This law is configured as a "denationalized" rule: it is in fact a national law but takes into consideration not only the facts that occurred on its own territory but also those that took place in the territory of another Member State. Once the Member State responsible for healthcare services has been designated by the Regulation, the latter distinguishes between entitlement to benefits in the event of residence or in the case of temporary residence outside the Member State of affiliation. In the latter case, the procedure under EU law differs

[27] C. Newdick, *Citizenship, free movement and healthcare: Cementing individual rights by corroding social solidarity*, in *Common Market Law Review*, 2006, 1645.

[28] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ L 166, 30.4.2004, 1.

[29] Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems, OJ L 284, 30.10.2009, 1.

[30] *Agenzia sanitaria locale* ("local healthcare agencies", hereinafter referred to as ASL) constitute the territorial articulation of the national health service, have public legal personality and entrepreneurial autonomy. The *Caisse nationale assurance maladie* (hereinafter CNAM) is the main health insurer in France, covering 93% of the population (wage workers, self-employed workers and students), through 102 local health insurance departments, *Caisse primaire assurance maladie* (hereinafter CPAM). It is under the control of the Ministry of Social Security and the Ministry of Finance and the Economy.

in the case of necessary care or planned treatment[31].

Directive 2011/24/EU integrates the two Regulations, without questioning the principle of equality between resident and non-resident patients of a Member State nor that of the European insurance card and codifies the main principles of the case law established by the European Court of Justice related to cross-border healthcare. It especially codifies the judgments *Decker* and *Kohll*[32], ruling that no prior authorization was required for scheduled outpatient care in another Member State[33], at a later time the traceability of healthcare services in the scope of application of articles 56 and 57 TFEU regardless of whether or not they are provided in a hospital setting and paid directly by the recipient[34].

For reasons of legal certainty, the Directive codifies the Court's jurisprudence with its main purpose being to protect the rights of European citizens when accessing cross-border healthcare and the related reimbursement, quality and safety of healthcare services provided in another Member State and the promotion of cooperation on healthcare

The case-law of the European Court of Justice had identified two important objectives suitable for constituting exceptions to the principle of free movement. In particular, the *Decker* and *Kohll* cases develop around the axes of healthcare planning protection, of patients' rights, of the free movement of the patient-citizen[35] and of the appropriateness of the available treatments[36]. In subsequent rulings, in fact, the Court clarified what is meant by "hospital and non-hospital

[31] See P. Mavridis, *Libre circulation des patients : la protection des personnes et des systèmes de sécurité sociale*, in *Revue de droit du travail*, 2015, 377.

[32] See CJEC, 28 April 1998, case C-120/95, *Nicolas Decker v Caisse de maladie des employés privés*, [1998] ECR I-01831and case C-158/96, *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-01931.

[33] Cases *Decker* and *Kohll* have sanctioned the entry of patients seeking treatment into the category of persons, goods and services entitled to circulate freely in the EU. In the present case, two Luxembourg nationals asked the Court to rule on the question whether the prior authorization required for repayment is such as to constitute an obstacle to the free movement of goods or the freedom to provide services. The Court responded affirmatively and opened a second way for patients to obtain reimbursement directly through their affiliate program for medical expenses incurred in another Member State, within the limit of the cost that would have been incurred by them if the treatment had been received in the Member State of affiliation.

[34] See CJEC, 12 July 2001, case C-157/99, *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen*, [2001] ECR I-05473.

[35] P. Mavridis, *Libre circulation des patients : la protection des personnes et des systèmes de sécurité sociale*, in *Revue de droit du travail*, cit.

[36] See CJEU, 9 October 2014, case C-268/13, *Elena Petru v Casa Judeţeană de Asigurări de Sănătate Sibiu and Casa Naţională de Asigurări de Sănătatele*, ECLI:EU:C:2014:2271. See also L. Busatta, *Carenze sanitarie e mobilità transfrontaliera: si allarga il diritto "europeo" alla salute. Nota alla sentenza C-268/13, Petru, Corte di Giustizia dell'Unione Europea*, in *DPCE Online* from 13 February 2017. According to this ruling, among the circumstances that must be taken into consideration by the authorities to determine the legitimacy of a medical treatment paid abroad and reimbursed by the state of affiliation are also the lack of medicines and medical supplies. This lack must be appreciated at the level of all hospitals in the state of residence. For now, this is the only case in which the need to benefit from the public hospital service in another Member State is based on the lack of medical facilities in the State of residence.

services"[37], "by prior authorization", however subject to jurisdictional control[38], the outlines of the "notion of acceptability of the waiting list"[39] and the criterion of "professional reintegration"[40], in the light of the principle of equal treatment pursuant to article 18 TFEU[41].

The main differences between the Directive and the Regulations relate to the authorization procedure, the reimbursement system and the facilities to which patients can turn. As for the authorization procedure, except in cases of unplanned urgent care, prior authorization by the healthcare authority of the country of residence is the norm in the Regulations and becomes the exception in the Directive, even if it has been noted that the implementation of Community requirements in individual legal systems has weakened the effects of the reform and moved towards the concrete effects of the Regulations under examination.

The Regulations stipulate that the reimbursement of expenses related to previously authorized (or urgent and unscheduled) services must take place directly without the patient having to anticipate payment[42]. The cost of healthcare services performed under the Directive must instead be anticipated by the patient who will be able to obtain reimbursement from the competent healthcare authority

[37] See CJEU, 5 October 2010, case C-512/2008, *Commission v France*, [2010] ECR I-08833 according to this ruling, the use of specialized medical equipment (such as an MRI) requires prior authorization. The Court ruled in favour of France, believing that such assistance could actually be subject to prior authorization. The Court rejects a formal approach in favour of a functional approach linked to the high cost of treatment and the need to plan medical equipment expenses. See CJEU, 27 October 2011, case C-255/09, *Commission v. Portugal*, in *Rev. EU*, 2013, 45.

[38] See CJEC, 23 October 2003, case C-56/01, *Inzian v CPAM des Hauts-de-Seine*, [2003] ECR I-12403, in which the refusal of the French *Caisse* to grant a preliminary authorization to its insured to follow a treatment for pain in a German hospital, judged necessary and authentic because of the absence of a corresponding structure in France has been disputed. See CJEC, 12 July 2001, *Smits v Stichting Ziekenfonds VGZ* e *H.T.M.* and case C-157/99, *Peerbooms v Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-05473. In *Smits*, the Court clarified that in order for a system of prior administrative authorization to be justified, it must in any case be based on objective, non-discriminatory and known in advance criteria, in order to regulate the exercise of the discretionary power of the national authorities in a manner that it is not exercised arbitrarily; the condition of the usual nature of hospital treatment under national legislation refers to what is sufficiently tested and validated by international medical science.

[39] See CJEC, 16 May 2006, case C-372/04 *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, [2006] ECR I-12403. The Court essentially affirms that the obligation to take on hospital care provided in another Member State also applies to a national health service which offers the same services for free. In order to deny a patient permission to seek treatment abroad that has been requested due to the existence of a waiting period for hospital treatment in the state of residence, the NHS (National Health Service of the United Kingdom) must establish that this period does not exceed the acceptable time from the medical point of view in consideration of the state of health and the clinical needs of the person concerned.

[40] See CJEC, 13 May 2003, case C-385/99, *Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA*, [2003] ECR I-4509.

[41] See CJEC, 3 October 2000, case C-411/98, *Ferlini v Centre hospitalier de Luxembourg*, [2000] ECR I-8081.

[42] See arts 19 and 20 of Regulation (CE) No 883/2004.

within the limits of the health insurance of their country of residence[43].

As for the type of healthcare facilities, the Regulations limit the application to public or facilities affiliated to the statutory healthcare system only, while the Directive extends coverage to private structures.

The Directive has substantially innovated legislation in sanctioning, based on judgments made by the European Court of Justice, the principle of freedom of choice of the place in which EU citizens may obtain healthcare services, although tempered by a limit in the reimbursement of medical expenses[44].

The results of regulatory innovation have however been limited by the prudence of several Member States[45]—including Italy—which have implemented the Directive in a restrictive way, by the economic crisis, which has also constricted public spending in the healthcare sector[46] and by language barriers[47].

[43] See arts 8 and 9 of Directive 2011/24/EU.

[44]See CJEU, 11 July 2013, case C-430/12, *Luca v Casa de Asigurări de Sănătate Bacău*, ECLI:EU:C:2013:467. The case involved a Romanian citizen who underwent several stages of treatment in an Austrian clinic between 2008 and 2009. Having only subsequently informed his social security organization of the care received, without any request for prior authorization to receive assistance abroad, he received a partial reimbursement from the competent Romanian body of the expenses incurred. The applicant contested this situation and the Court of Appeal referred to the question therefore asked the competent Romanian body the question of the compatibility of the Romanian legislation allowing this partial repayment with Article 22 of Regulation (EEC) No. 1408/71. The European Court of Justice has clarified that Member States must agree to reimburse medical care without prior authorization in some cases, such as in urgent cases, or to freely use medical services as they belong to the taxonomy of free movement of services. In the first case, Article 22 of Regulation (EEC) No. 1408/71, which provides that, for insured persons authorized to undergo treatment in another State, such benefits in kind are to be paid by the competent institution up to the amount established by the social legislation of the Member State in which the assistance is received, as if the patient were insured. In the second case, if the patient has simply intended to exploit the freedom of movement and the freedom to provide medical services pursuant to Article 49 of the Treaty, without a prior authorization request if this procedure is justified, he can only request coverage for his care within the limits of the provisions of his insurance status. This solution has the double merit of guaranteeing both a repayment, even partial, of the care received abroad and being neutral to the finances of the health insurance plan to which the patient is affiliated. See L. Driguez, *Prestations de soins transfrontalières*, commentaire 402, in *Europe* n. 10, October 2013.

[45] A. Den Exter, A. Santuari, T. Sokol, *One Year After the EU Patient Mobility Directive: A Three-Country Analysis*, in *European Law Review*, 2015, 281.

[46] See M. Karanikolos et al., *Financial Crisis, austerity and health in Europe*, in 381 *The Lancet* 1323 (2013) and A. Maresso et al. (Eds), *Economic Crisis, Health Systems and Health in Europe: Country Experiences*, Copenhagen, 2015.

[47] Speaking different languages obstructs the serene performance of the doctor-patient relationship, also in relation to the acquisition of information in general and in informed consent. For example, these barriers are not present in the United States. See F. De Montalvo, *A European Common Framework for Health: A Real Possibility or an Improbable Myth? Lessons for the Future Healthcare System in the United States*, cit.

3. The resistance of the Member States to the transposition of the Directive: the Europe of rights and that of auditors

The prudence of Member States in transposing the Directive and the limits imposed with regard to reimbursement benefits connected to the prior authorization regime have slowed down the spread of healthcare mobility. In France, meticulous administrative regulations have highlighted considerable disputes rooted in specifically-created committees, such as the *Commissions de recours amiable* within the French National Healthcare Administration, *Caisse Primaire Assurance Maladie*, while in Italy access methods differ from region to region[48].

Though it has been said that the rigidity of the internal transposing regulations is largely linked to the economic crisis of the last decade and to the need to contain public spending, in particular healthcare spending, not all countries have reacted in the same way[49]. Of the 28 EU Member States and the 4 EFTA Member States that committed themselves to implementing the Directive, only six (the Czech Republic, Estonia, Finland, Lithuania, the Netherlands, Norway, and Sweden) have chosen not to introduce any prior authorization system[50].

The other countries have all based recourse to prior authorization as per the derogation in article 8(2)(a) of the Directive, relating to healthcare subject to planning requirements should hospitalization for at least one night or the use of highly specialized medical infrastructure or medical equipment is required.

In the Report to the European Parliament and the Council on the

[48] See the Italian reform of Title V of Constitution envisaged by the cost law n. 3/2001, which extended the competences of the regions, they are holders of an autonomy that often generates asymmetric procedures.

[49] See N. Ferreira, D. Kostakopolou (Eds), *The Human Face of the European Union. Are EU Law and Policy Humane Enough?*, Cambridge, 2016; L. Dubouis, *La directive 2011/24 relative à l'application des droits des patients en matière de soins transfrontaliers*, in *RDSS*, 2011, 1059; M. Blanquet, *Les soins transfrontaliers en Europe : de la difficulté de codifier une jurisprudence libérale*, in M. Blanquet, N. de Grove-Valdeyron (Eds), *Études de droit communautaire de la santé et du médicament*, Toulouse, 2009, 230. See also doctrine cited by L. Uccello Barretta, L. Prudil, *Implementation of the Directive 2011/24/EU in the Czech Republic*, in *European Journal of Health Law*, 2014, 15; M. Kattelus, *Implementation of the Directive on the Application on Patient's Rights in Cross-border Healthcare (2011/24/EU) in Finland*, in *European Journal of Health Law*, 2014, 23; M.A. Requejo, *Cross-border Healthcare in Spain and the Implementation of the Directive 2011/24/EU on the Application of Patient's Rights in Cross-border Healthcare*, in *European Journal of Health Law*, 2014, 79; L.M.H. Bongers, D.M.R. Townend, *The Implementation of the Directive on the Application of Patients' Rights in Cross-border Healthcare in the Netherlands*, *in European Journal of Health Law*, 2014, 65; M. Schwebag, *Implementation of the Cross-border Care Directive in EU Member States: Luxembourg*, in *European Journal of Health Law*, 2014, 56; S. Olsena, *Implementation of the Patients' Rights in Cross-border Healthcare Directive in Latvia*, in *European Journal of Health Law*, 2014, 46; T. Vidalis, I. Kyriakaki, *Cross-border Healthcare: Directive 2011/24 and the Greek Law*, in *European Journal of Health Law*, 2014, 33; L. Driguez, V. Michel, *La directive 2011/24/UE relative à l'application des droits des patients en matière de soins de santé transfrontaliers : progrès pour la santé ou pour le marché?*, in *Europe*, 2011, étude 9, 4.

[50] See Report on the implementation of the Cross-Border Healthcare Directive, available at www.europarl.europa.eu/doceo/document/A-8-2019-0046_EN.html.

functioning of the Directive, the European Commission has recently reiterated, recalling a judgment of the European Court of Justice[51], stating that Member States can subordinate the reimbursement of cross-border healthcare costs to prior authorization if this is necessary and reasonable, and in any case basing the issuing of authorization on objective criteria, without the necessary prior request becoming a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients.

The Commission has also scrutinized the vague wording of the national legislator or generic references, such as the use of highly-specialized medical devices, which do not guarantee transparency and legal certainty regarding the treatments that are subject to prior authorization and satisfy the related requirements.

Furthermore, the Commission has ruled that over-extensive lists of healthcare services subject to prior authorization are not compliant with the spirit of the Directive, and have indeed urged the countries that adopt a prior authorization system of cross-border healthcare services to slim down and make publicly available a detailed and sufficiently defined list of the healthcare services subject to prior authorization.

To solve the problems of complying with EU legislation, the Commission has initiated numerous structured dialogues with Member States, in particular regarding the lists of treatments subject to prior authorization.

The results of these dialogues are not yet known, but the Commission acknowledges that they have "provided a valid proactive mechanism to stimulate positive effects for patients"[52].

In the five years since the Directive has been in force, it is however possible to evaluate the effects of regulatory innovation by processing the data regarding patient mobility which has been transmitted to the European Commission by the Member States[53].

Although vitiated by some cases of non-transmission, or by the risk of confusion for some countries of healthcare mobility pursuant to the Directive with that pursuant to Regulation (EC) No 987/2009, the picture that emerges is however characterized by a limited number of cross-border healthcare services.

In 2015, 180,704 services not subject to prior authorization were reimbursed, compared to 234,184 requests. In 2016, reimbursements rose to 209,568 out of 239,880 requests. In 2017, the trend reversed and reimbursements

[51] See CJEC, 20 February 2001, case C-205/99, *Analir and others v Administración General del Estado*, [2001] ECR I-1271, n. 35-38, and CJEC 12 july 2011, C-157/99, *Smits and Peerbooms*, n. 80-90.

[52] See COM(2018) 651 final, Report of the Commission to the European Parliament and the Council on the functioning of Directive 2011/24/EU concerning the application of patients' rights relating to cross-border healthcare, of 21 September 2018 available www.eur-lex.europa.eu/legal-content/EN/TXT/?qid=1537521773305&uri=COM%3A2018%3A651%3AFIN.

[53] Art. 20 of Directive 2011/24/EU states that Member States draw up an annual report on patient mobility pursuant to the Directive.

fell to 194,292 out of 234,929 requests.

The number of services subject to prior authorization is almost irrelevant in terms of total mobility: in 2015, 799 healthcare services were previously authorized out of 1,280 requests. In 2016, 3,644 services were previously authorized out of 5,162 requests and in 2017, 1,850 services were previously authorized out of 2,657 requests.

One third of these numbers are French patients requesting healthcare mainly in Belgium, the Czech Republic, Germany, Luxembourg, and Spain. A significant number also comes from Ireland with patients requesting treatment in Great Britain and vice versa. Before the implementation of the Directive, healthcare services between Ireland and Great Britain were regulated by bilateral agreements[54].

In financial terms, EU countries spent approximately 65 million euro on cross-border healthcare services in 2016. Considering that the OECD estimates that in EU countries the average expenditure on healthcare amounts to 10% of GDP[55], and that, according to Eurostat, the EU GDP in 2017 was 15,300 billion euro, spending on cross-border healthcare in the EU under the Directive can be estimated at 0.004% of the annual healthcare budget at Union level.

Finally, if we consider that in 2015 cross-border healthcare pursuant to Regulation (EC) No 987/2009 accounted for more than 2 million cases against 180,000 cases under the Directive, it is clear how the opportunities offered by the European healthcare card introduced by the Regulation is taken advantage of by European patients with a frequency that is fully disproportionate to the services regulated by the Directive.

4. The reaction of the courts in Italy and France

Directive 2011/24/EU was incorporated into Italian law with *Decreto legislativo* 4 March 2014, n. 38[56] and regulates indirect assistance, i.e. the procedures for reimbursement to patients of the expenses fully paid by the same to the healthcare facilities or to medical professionals, whether public or private and affiliated to the public healthcare system in the country of treatment[57].

[54] See the report of the Member State data Commission on cross-border patient healthcare following Directive 2011/24/EU accessible at http//ec.europa.eu/health/sites/health/files/cross_border_care/docs/2017_msdata_en.pdf.

[55] See OECD, *Health at a Glance*, Paris, 2017, accessible at www.oecd.org/health/health-at-a-glance-europe-23056088.htm

[56] D.Lgs of 4 March 2014, n. 38, implementation of Directive 2011/24/EU, concerning the application of patient's rights relative to cross-border healthcare and of Directive 2012/52/EU, involving measures designed to facilitate the recognition of medical prescriptions issued in another Member State, in GU Serie Generale 21 March 2014, n. 67.

[57] The regulations govern direct assistance, however, characterized by the direct payment of the healthcare service belonging to that of the country of treatment. In the case of scheduled treatment, that is, for the healthcare defined in the context of a precise therapy, and therefore prescribed in advance, it is necessary to request a prior authorization form S2 from the patient's competent institution.

In this case, the patient anticipates the costs of healthcare, authorized in the foreseen cases, and subsequently requests reimbursement from the healthcare service in their country of residence[58].

The implementing legislative decree provides for the reimbursement of cross-border healthcare services if they correspond to benefits included in essential level of assistance, (hereinafter referred to as LEA accordingly to Italian acronym of *livelli essenziali di assistenza*)[59], the direct payment of cross-border healthcare provision to the Member State where treatment is provided, and the obligation to request prior authorization in three cases: i) for services subject to planning requirements, which involve the patient's hospitalization for at least one night or the use of a highly-specialized healthcare facility or medical equipment, including those used for instrumental diagnostics; ii) for treatments considered to be of high risk to the patient or the population at large; iii) for services provided by a structure that raises doubts about the quality and safety of care available.

If the hypotheses referred to in i) are of an objective nature such as to allow the timely identification of the services to be subjected to prior authorization, on the contrary it does not appear possible to identify *a priori* the services referred to in ii) and iii) which require specific assessments in relation to specific cases.

Italy, like most other Member States, has opted for the request for prior authorization for a wide range of hypotheses. A specific ministerial decree precisely identifies the services for which the patient's right to seek healthcare within the EU is subject to the authorization of the Italian healthcare authority.

Pending the adoption of the decree, prior authorization is stipulated for the services that involve the patient's hospitalization for at least one night and those that require the use of highly specialized and expensive medical infrastructure or medical equipment, including those used in instrumental diagnostics, with particular reference to the services provided indirectly and to the additional healthcare services referred to in articles 3 and 5 of law 595/1985, and to the subsequent implementing ministerial decrees implementing, without prejudice to the possibility, for the regions, to also request prior authorization for additional services.

The Ministry of Health has fulfilled the aforementioned regulatory obligation with Ministerial Decree n. 50 of 12 April 2018[60], which further extended the need to resort to prior authorization not only for services that require the use of diagnostic equipment such as computerized axial tomography and magnetic resonance, but also for outpatient surgery operations considered routine, such as for example the removal of cataracts, tonsillectomy, circumcision,

[58] In case of indirect admission to highly specialized structures abroad, the patient has the right to request an advance of the estimated costs corresponding to 70% of 80% refundable pursuant to D.M. 3.11.89 - Art. 6-comma 13.

[59] The essential levels of assistance indicate, in Italy, the set of all the services, services and activities that citizens have the right to obtain from the national health service, in order to guarantee uniformity to all and throughout the national territory

[60] D.M. 12 April 2018, n. 50 in GU Serie Generale 22.5.2018, n. 117.

abortion, carpal tunnel release etc.

Furthermore, pursuant to article 8(6) of the Directive, the D.Lgs 38/2014 states that the healthcare authority of the country of affiliation may refuse authorization in the following cases: i) in case of risk for patient safety based on clinical evaluation; ii) in the event of a risk to public health due to cross-border assistance; iii) if the cross-border healthcare service provider raises serious and specific concerns regarding compliance with the quality standards of assistance; iv) in the event that medical assistance can be provided in the patient's country of residence within a justifiable period of time from a medical point of view[61].

The formulation of the hypothesis referred to in iv) is mirrored in the provision of article 9, comma 5 of D.Lgs 38/2014 which states that the authorization cannot be refused when assistance cannot be provided within the national territory within a justifiable period of time based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorization was made or renewed[62].

The concept of "justifiable period of time from a medical point of view" appears central to the evaluation by the Italian healthcare authority, whose subjectivity and discretion risks becoming a tool to limit the flow of patients, aimed at containing costs and avoiding interference with healthcare planning. In this sense, the scope of the Directive is greatly reduced in terms of national application, leaving Italian regions ample discretion in interpreting concepts such as the "acceptability of waiting lists" [63].

On this point, reference needs to be made to the jurisprudence of the European Court of Justice which, in referring to the interpretation of Art. 22(2) of Regulations (EC) No 1408/1971 has specified that healthcare authorities should not refer exclusively to the existence of a long waiting list when determining whether or not to accept a request for prior authorization but must instead also take into consideration the circumstances that characterize the medical situation of the patient. In other words, the patient's complete medical situation must be contemplated when authorization is required in addition to any environmental conditions, such as a lack of medication and medical materials or the lack of specific equipment or specialized skills[64].

The provision of concession or refusal of prior authorization must be communicated to the applicant within thirty days of receipt of the request, a term that is reduced by half in the case of proven particular urgency[65].

[61] See art. 9 comma 6 of D. Lgs. n. 38/2014.

[62] See art. 9 comma 5 of D. Lgs. n. 38/2014.

[63] See G. Boggero, *Gli ostacoli alla mobilità sanitaria transfrontaliera in Italia*, in *Corti supreme e salute*, 2018, 384. The paper by the author is particularly interesting because it takes into account both European and extra European contexts.

[64] See CJEU, 9 October 2014, case C-268/13, *Petru*, cit.

[65] See art. 10 comma 7 of D. Lgs. 38/2014.

The authorization provision must contain an indication of how much of the cost of medical treatment may be reimbursed, as per the principle of reimbursement within the limits of the costs that the service would have incurred had the treatment been performed in the patient's country of residence, where applicable[66].

Furthermore, the ASL is obliged to justify the refusal to authorize by explicitly referring to one or more of the four hypotheses regulated by article 9 comma 6 of the law, and indicating the healthcare facility capable of providing the service requested in the event that the refusal is based on that condition. Should refusal be received, patients may submit an appeal against the refusal to the director of the ASL concerned within 15 days of receipt of the same.

The director of the ASL is required to reply to the appeal within 15 days of receipt. Naturally, this does not preclude recourse to judicial authorities. Though there is not much Italian jurisprudence on this point, it is clear that exclusive jurisdiction is given to judicial authorities when disputes regarding refusal to provide prior authorization and/or reimbursement for healthcare arise following "a request by a private individual for prior authorization/reimbursement of medical treatment through a healthcare authority and/or the negative outcome of an appeal by the same"[67].

This is due to the principle affirmed by the United Sections of the *Corte di cassazione* in 2010, for which the administrative judge has exclusive jurisdiction over disputes "also in the matter of fundamental rights protected by the Constitution, such as the right to healthcare (Art. 32 of the Italian Constitution) when damages are awarded as a result of an authority carrying forward an act by the public administration whose illegality is reported"[68].

The recent ruling by the *Consiglio di Stato* n. 5861/2018, regarding a refusal of prior authorization to reimburse a medically-assisted procreation treatment to be carried out abroad[69], is also of particular interest. The Italian *Consiglio di Stato*, confirming the ruling of the TAR Lazio, annulled the refusal of prior authorization due to lack of motivation for not having indicated the reasonable term within which the healthcare in question could have been provided on the national territory.

In the case in question, the competent ASL had denied prior authorization indicating three Italian healthcare facilities capable of providing the service, without however specifying whether such treatment could be provided within a justifiable period from a clinical point of view.

In particular, the Italian *Consiglio di Stato* ruled that the exceptional nature and derogation from EU rules by the institution of prior authorization imposes an

[66] See art. 10 comma 8 of D. Lgs. 38/2014.
[67] See *Consiglio di Stato*, sez. III, 11 October 2018, n. 5861.
[68] See *Cass., Sez. Un.*, 5 March 2010, n. 5290.
[69] See *Consiglio di Stato*, sez. III, 11 October 2018, n. 5861

additional motivational obligation should a request be refused[70].

As for the necessary content of the motivation, the administrative judge referred to the Guidelines provided by article 19, comma 3 of D.Lgs 38/2014, adopted in an agreement between the Ministry of Health and the Conferenza Stato Regioni on 21 December 2017, which state that in case of refusal "the ASL must provide the applicant concerned with indications of a healthcare provider that can provide the service [within the national territory] and the number of days within which the service can be provided by such provider"[71].

It follows that in the absence of the precise time limit within which the patient can obtain the required healthcare service in Italy, the denial can be annulled and the expense for the care provided abroad reimbursable by the competent ASL.

In France, Directive 2011/24/EU was implemented with the *Loi* n. 2014-201 of 24 February 2014, *portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la santé*[72], and, to the extent and purpose of this comparative case-law analysis, by the *décret* n. 2015-1865 of 30 December 2015-article 2[73] and n. 2018-929 of 29 October 2018-article 11[74]. In general, the rules for coverage of care are set forth by articles R 160-1 et seq of the French *Code de la sécurité sociale*.

In France, there is a single system of prior authorization under the Directive and the Regulations for certain planned treatments (treatments that require at least one night of hospitalization or the use of specialized equipment). Routine outpatient care (excluding complete hospitalization) is not subject to prior authorization. Care is reimbursed only on the basis of French social security rates, within the limits of the costs incurred.

Article R. 160-1 concerns unplanned or urgent treatment ("medically

[70] See whereas recital 38, Directive 2011/24/EU: "in the light of the case-law of the Court of Justice, making the assumption by the statutory social security system or national health system of the cost of healthcare provided in another Member State subject to prior authorisation is a restriction to the free movement of services. Therefore, as a general rule, the Member State of affiliation should not make the assumption of the cost of healthcare provided in another Member State subject to prior authorisation, where the costs of that care, if it had been provided in its territory, would have been borne by its statutory social security system or national health system".

[71] See paragraph 5.4 of Guidelines adopted with Intesa, article 19 of Legislative Decree n. 38, 4 March 2014, n. 38, between the Italian government, the Regions and the Autonomous Provinces of Trento and Bolzano on the proposal by the Ministry of Health concerning cross-border healthcare guidelines.

[72] In JORF, 25 February 2014. The provisions of the Directive concerning the recognition of prescriptions established in another EU Member State are implemented by décret n. 2013-1216 of 23 December 2013 (medicinal product) and n. 2014-1525 of 17 December 2014 (medical devices).

[73] *Décret* n. 2015-1865 of 30 December 2015 relatif aux bénéficiaires et aux prestations de la protection universelle maladie et à la cotisation forfaitaire prévue à l'article L. 381-8 du code de la sécurité sociale, in JORF n. 0303 of 31 December 2015, 25321.

[74] *Rapport* relatif au *décret* n. 2018-929 of 29 October 2018 *portant virement de crédits* in JORF n. 0251 of 30 October 2018.

necessary during a temporary stay") in another Member State, a State of the European Economic Area (Iceland, Liechtenstein and Norway) or in Switzerland, and are covered by the *européeene assurance maladie* card (CEAM) or the provisional replacement certificate. The CEAM can attest the rights to health insurance and allow the use of healthcare services in the country of residence at the same conditions as the citizens of that country.

Article R. 160-2 concerns the so-called "programmed" assistance when the journey to another European State, a State of the European Economic Area or to Switzerland is due precisely to a medical treatment, which in this case requires prior authorization to be paid by the *casse maladie* of the Member State of affiliation. Article R. 160-2 as amended by the 2015-1865 decree limits prior authorization to scheduled assistance that involves at least one hospitalization and medical services that require the use of specialized equipment (including ultrasound and MRI). The list of treatments and specialized treatments subject to prior authorization for assistance is set forth by the *arrêté* of 27 May 2014[75].

The *décret* n. 2015-223 of 26 February 2015 on the organization and adaptation of the tasks of the *Centre des liaisons européennes et internationales de sécurité sociale* (CLEISS) designates the latter as a contact point pursuant to Directive 2011/24/EU[76].

As far as the organization of the healthcare system is concerned, with particular reference to litigation, the system of the *Caisse d'assurance maladie* must be highlighted. In general, French citizens or foreigners permanently resident in France have the right to benefit from healthcare assistance, by registering with one of the 102 *Caisse Primaire d'Assurance Maladie* (CPAM) as per the citizen's place of residence. The coverage of medical expenses in France is partly public, guaranteed by *assurance maladie* in general at 70% (or 80% in the case of hospital care), partly private, for which the remaining 30% (or 20%) can be referred to an *assurance maladie complémentaire* (AMC) or *compleméntaire santé*, which as of 2016 is mandatory for workers and strongly recommended in general for all residents. The so-called *mutuelle complementaire* is underwritten privately, in order to guarantee the policyholder the reimbursement of the difference of the expenses already reimbursed by the *assurance maladie*.

In France, therefore, there is system of indirect healthcare, whereby the patient, for the excess part of the costs covered by the public *assurance maladie*, with the relevant *Carte Vitale*, anticipates the cost medical expenses and then requests reimbursement from supplementary insurance.

The reimbursement of medical expenses is requested from the local office of the CPAM, which has a *Commission de recours amiable* and is responsible for the

[75] See *arrêté* of 27 May 2014 établissant la liste des soins hors de France nécessitant le recours à des infrastructures ou équipements médicaux hautement spécialisés et coûteux, in JORF n. 132 of 8 June 2014, 9667.

[76] Décret n. 2015-223 of 26 February 2015 relatif à la gestion des créances et des dettes internationales de sécurité sociale et au Centre des liaisons européennes et internationales de sécurité sociale, in JORF n. 50 of 28 February 2015, 3847.

prior authorization of cure and treatment abroad. The opinion of the *Caisse* must consider the opinion of the *médecin conseil national*. A possible negative decision can be contested initially through the *Commission de recours amiable*, which can then be challenged before the *Tribunal de grand instance*. An appeal to the competent *Cour d'appel* is also possible, should a negative ruling be reached by the *Tribunal*[77].

Costs incurred abroad are covered in accordance with the legislation and tariff of the country of treatment, but only healthcare covered by the provisions of French law[78] and within the limits of the expenses incurred by the insured, having submitted the prior authorization request form (S2), are reimbursable.

Article R *332-3* of the *Code de la sécurité sociale* also specifies that the reimbursement of assistance expenses provided to persons insured in an EU Member State by the CPAM is met on the same conditions as if the care had been received in France, within the limits of the expenses incurred by the insured. Thus, an applicant who was authorized to receive therapeutic cross-border treatment went to Barcelona for *syringomyelia* and *Arnold-Chiari malformation* but received reimbursement for less than the treatment actually cost and only the amount the same treatment would have cost had it been performed in France[79].

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In another case, a French citizen was refused the reimbursement of 10 hyperthermia sessions carried out in Germany on the basis that these treatments, although not falling within the taxonomy of the treatments that required a prior authorization, were not included in the list of healthcare benefits reimbursed by France[80].

In yet another case, recently ruled by the *Cour d'appel de Montpellier*, the circumstances surrounding the urgency of a therapeutic treatment was considered an essential condition for authorizing the reimbursement of a hip operation carried out in Belgium, where no request for prior authorization had been submitted[81].

5. Conclusions

The financial challenge arising from the mobility of patients presently concerns a small number of citizens and does not, for now, undermine national healthcare systems. Though increasing, the impact of this mobility on EU coffers remains marginal: it mainly concern regions bordering on other Member States, yet there are also more culturally informed niches of citizens searching for highly specialized healthcare treatments to treat specific conditions[82].

[77] See art. L142-2; *Cour d'appel* Douai, *Chambre sociale*, 31 March 2015, *Infirmation* n. 80-15, 12/02859; *Cour d'appel* of Rouen, *Chambre sociale*, 3 April 2019 n. 16/04962.

[78] See art. L162-1-7 of Code de la sécurité sociale.

[79] See *arrêt Cour d'appel* of Lyon, 12 February 2019, n. 17/08520, 34/5000, which confirmed the decision of the *Tribunal des Affaires de Sécurité Sociale* de Lyon of 8 November 2017, n. 20141108.

[80] See *Cour d'appel* of Rouen, 3 April 2019, n° 16/04962.

[81] See *Cour d'appel* of Montpellier, *Chambre sociale* 4 B, 16 January 2019 n° 18/01228

[82] See C. Newdick, *Citizenship, free movement and healthcare: Cementing individual rights by corroding social solidarity*, in *Common Market Law Review*, 2006, 1645.

The role played by prior authorization in the implementation of Directive 2011/24/EU limits its scope, as EU legislator intended it to be regarded as the exception rather than the rule when enabling EU citizens to be able to freely choose where to undergo healthcare treatment.

Of particular value in this sense appears the argument used by the *Consiglio di Stato* in the reported decision that appears to be reminding the public administration—and perhaps also the Italian legislator—that the intent of Directive 2011/24/EU was to provide greater clarity on the rules governing the prior authorization of cross-border healthcare and for it to be an exception rather than a subterfuge to slow down patient mobility.

The tension between domestic law and EU law lies in the fundamental misunderstanding that sees the progressive recognition by the European Court of Justice of fundamental and inviolable rights whose cost is borne in a different Member State from that of affiliation[83]. Even in the absence of a common healthcare service, "human beings should be at the heart of European construction"[84]. Patient mobility has offered judges the possibility of recognizing European citizens' fundamental rights. The implementation of which is caught between social protection and market freedom, between the European ideal and the well-being of the national community to which citizens belong, based on the principle of solidarity. Directive 2011/24/EU, by laying the foundations of a coordinated and integrated healthcare system, does however risk being betrayed by the Member States in their implemention of the Directive into national law.

[83] With the words of K. Lenaerts, *Droit communautaire et soins de santé, Les grandes lignes de la jurisprudence de la CJCE, jurisprudence de la Cour de justice des Communautés européennes* available at www.ose.be/workshop/files/LenaertsFR.pdf « le défi auquel est confronté le droit communautaire dans son appréciation des systèmes nationaux de soins de santé et de sécurité sociale est de concilier, d'une part, les règles du traité, notamment celles consacrées au marché intérieur, aux quatre libertés fondamentales - libre circulation des personnes, des marchandises, des services et des capitaux - et au droit de la concurrence, et, d'autre part, la volonté naturelle des États membres de maintenir en faveur de leurs ressortissants des structures sociales financièrement viables, accessibles à tous et organisées rationnellement de telle sorte à pouvoir constamment garantir une offre de soins variés et de qualité ».

[84] See conclusions of AG Cosmas, delivered on 16 March 1999 in case C-378/97, *Wijsenbeek*, [1999] ECR I-6207, n. 83.