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Effects of Directive 24/2011/EU on the Application of Patients' Rights in Cross-Border Healthcare and Its Implementation in Croatian Law

1. Introduction

Freedom to provide services represents one of the four fundamental freedoms granted by the Treaty on the Functioning of the European Union¹ (hereinafter: TFEU), provisions of secondary legislation, Directive 2006/123/EC of the European Parliament and of the Council on services in the internal market² (hereinafter: the Services Directive) and by the European Court of Justice case law.³

In order to deem a particular situation involving freedom to provide services as a situation comprised by the scope of EU law, the following three criteria shall be met: there must be a service defined by the TFEU, there must be substantial restriction of free movement of services and at least two Member States have to be included in the situation, i.e. there must be

¹ Treaty of Lisbon amending the Treaty on the European Union and the Treaty Establishing the European Community, OJ C 306 of 17 December 2007, for the consolidated version thereof see Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, OJ C 115 of 9 May 2008. Article 56 of the TEU (ex Article 49 of the TFEU) stipulates that freedom to provide services refers to the right of Member State citizens and of legal entities having the seat in a Member State to, within the EU, provide persons from other Member States with services under the same conditions as their fellow citizens do. Article 57 (ex Article 50 of the TFEU) sets out that services shall be considered to be "services" if they are, in the principle, provided for remuneration and if they are not subject to regulations referring to freedom of movement of goods, capital and persons. This particularly relates to activities of an industrial and a commercial character, activities of craftsmen and self-employment.

² Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376/36 of 27 December 2006. Such services are subject to numerous other regulations such as Directive 2005/36/EC of the European Parliament and the Council of 7 September 2005 on the recognition of professional qualifications, OJ L 255/22 of 30 September 2005, and many others.

³ Various judgements of the European Court have included the issue of differentiating between freedom to provide services and other economic freedoms (e.g. judgement in case C-55/94 *Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano* [1995] ECR I-4165 regards company establishment, judgement in case C-155/73 *Giuseppe Sacchi* [1974] ECR 409 regards free movement of goods etc.) and the issue of the economic character of a service.

'cross-borderness'.⁴ Also, the respective service must be chargeable and it has to be provided occasionally and on a temporary basis.

Freedom to provide medical services is an integral part of freedom to provide services granted by Article 56 and 57 of the TFEU, which has been acknowledged in a number of judgments of the European Court of Justice.⁵ Due to their special status and character, healthcare services differ from other services, particularly with regard to the significance of healthcare within national policies of Member States and to competences of Member States in the field of their regulation.

This paper offers analysis of freedom to provide healthcare services granted by the TFEU, new Directive 2011/24/EU on the application of patients' rights in cross-border healthcare⁶ (hereinafter: The Patients' Rights Directive) and the practice of the European Court of Justice⁷ which serves as a basis for the Patients' Rights Directive. Freedom to provide services in the field of healthcare has effect on other freedoms as well and on some special areas such as freedom of movement for workers and members of their families. Moreover, this freedom has a direct influence on social rights considering the importance of the patients' rights to be provided with healthcare services in another Member State under the same conditions as in their own state and of the right to be refunded treatment costs by the national health insurance system. The key issue with respect to freedom to provide healthcare services refers to the transparency of procedures for getting authorization for medical treatment in another Member State as a prerequisite for reimbursement for treatment-related costs and to harmonization of administrative procedures concerning the accession of the Republic of Croatia to the European Union in 2013.

2. Freedom to Provide Healthcare Services within EU Law

Member States are liable for setting out their healthcare policies and for organization and providing health services and medical care.⁸ Healthcare is extremely important and has effect on all citizens either directly in the form of medical treatment or indirectly through taxation and cost reimbursement.⁹ The principle of the individual possibility of cross-border choice, which is based on fundamental economic freedoms, is actually in contradiction with the principle of solidarity defining national healthcare systems in the European Union. Based on its numerous judgements, the European Court has developed a concept of freedom to provide healthcare services. This concept has been shaped pursuant to interpretation and application of Regulation 1408/71 on the application of social security schemes to employed persons and

⁴ Čapeta, T., Rodin, S.: *Osnove prava Europske unije (Basics of EU Law)*, 2nd edition, Narodne novine (Official Gazette), Zagreb, 2011, page 70.

⁵ Judgement in case C-158/96 Kohll [1998] ECR I-1931; C-70/95 Sodemare [1997] ECR I-3395 and others.

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, OJ L88/45 of 4 April 2011.

⁷ Judgments in cases C-120/95 Nicolas Decker v Caisse de maladie des employés privés (Decker) [1998]; case C-158/96 Raymond Kohll v Union des caisses de maladie ECR I-1931; case C-368/98 Abdon Vanbraekel et al. v Alliance nationale des mutualités chrétiennes (Vanbraekel) [2001] ECR I-5363; case C-157/99 B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen (Smits and Peerbooms) [2001] ECR I-5473; case C-372/04 The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health [2006] ECR I-4325; case C-286/06 Commission v Spain [2008] ECR I-8025; case C-173/09 Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa of 5 October 2010, ECR I-0000, OJ C 328 of 4 December 2011.

⁸ Provisions of Article 168 paragraph 7 of the TFEU.

⁹ Sokol, T.: *Rindal and Elchinov: A(n) (impending) revolution in EU Law on patient mobility?*, CYELP 6, 2010, page 167.

members of their families¹⁰ (hereinafter: Regulation 1408/71) amended by Regulation 883/2004¹¹ and Regulation 987/2009¹². The latter lays down the procedures for implementation of Regulation 883/2004. These Regulations are aimed at coordination of social security systems pursuant to conflict-of-laws rules. Since in practice, the EU principle catering for individual choice of cross-border healthcare basically opposes the principle of solidarity being a prerequisite for establishment of Member State healthcare systems, one needs a regulation to resolve this conflict. This task is performed by Regulation 1408/71 and Regulation 883/2004, interpretation of which leads to numerous conflicts between the European Court practice broadening cross-border rights and the rights of Member States to protect national competences in the area of social security.¹³ This is the reason why the rules regulating the right to compensation for the costs of cross-border medical treatment have emerged pursuant to the European Court practice.

In this context, the references suggest that the European Court interpretation of the rules for protection of the fundamental freedoms granted by the TFEU is contrary to the efforts of Member States to organize their healthcare systems in compliance with their national policies.¹⁴

These are the most current issues in this field, resolution of which is expected within the framework of application of the provisions on freedom to provide medical services.¹⁵ In accordance with the aforementioned lines, one can ascertain that the rules defining freedom to provide and use medical services and regulating reimbursement for the costs of such are still blur. In the light thereof, the European Court has in every case assumed a posture concerning the relation between various healthcare systems and fundamental economic freedoms, particularly with respect to the rules regulating prior authorization for cross-border medical treatment.¹⁶ Many Member States have though criticized such an attitude of the European Court for unjustified "europeization" of healthcare systems. This actually means that the possibility of healthcare choice is governed in Europe by economic and not social goals despite the fact that healthcare and social security systems are guided by social goals.¹⁷ Perhaps that is why some authors¹⁸ share the opinion that in this area, the European Court practice has most probably contributed to legal insecurity and the principle of solidarity and financial sustainability of national healthcare systems and that it is the practice of the European Court that sets the boundaries of the internal market, i.e. how far this court can go

¹⁰ Regulation (EEC) No. 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L149/2

¹¹ Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L 166/1.

¹² 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 (Text with relevance for the EEA and for Switzerland) OJ L 284, 30.10.2009, p. 1–42.

¹³ For more details see Lhernould, J-P: New rules on conflicts: Regulations 883/2004 and 987/2009, ERA forum (2011) 12, 25-38, 4 February 2011.

¹⁴ Sokol, T.: *Rindal and Elchinov...*, op.cit. page 168; Morton, A.: A Single European Market in Healthcare: The impact of European Union policy on national healthcare provision, European Public Service Briefings 3, March 2011, available at www.european-services-strategy.org.uk on 23 November 2011, Hatzopoulos, V.: *Killing national health and insurance systems but healing patients? The European Market for Health Care Services after the Judgements of the ECJ in Vanbraekel and Peerbooms*; CMLRev 39; 2002, page 684, Goldner Lang, I.: *Patient Mobility in the European Union*, Medicine and Law. 28 (2009), 4; 661-672, page 5.

¹⁵ <http://www.imtj.com/news/?EntryId82=270809>

¹⁶ Morton, A.: *A Single European Market ...*, op.cit., page 7.

¹⁷ Ibidem.

¹⁸ Goldner Lang, I.: *Patient Mobility ...*, op.cit., page 5.

in terms of interpretation of the rules for regulating the internal market, particularly regarding areas not covered by any law and beyond EU competences.¹⁹

After the judgment in the case of *Kohll*²⁰, the European Court practice expanded the scope of the fundamental right to freely provide and receive services in the up-to-then traditional area of healthcare, precisely in situations when people cross borders for getting healthcare services or medical treatment.²¹ In authors' words²², the judgement generated concern for social and health insurance funds since the European Court broadened, accepting the opinion of advocate general Tesouro, application of Article 49 of the TEU (now Article 56 of the TFEU) to healthcare services even if they are provided within the scope of social security. That way, the judgement has indirectly "weakened" the right of Member States to independently organize their healthcare systems and allowed the rules for free movement²³ to use 'the back door' to enter the field of healthcare as specified in the judgement in the case of *Decker*²⁴, which was delivered on the same day.

In this area, the European Court practice frequently overlaps with the right of Member States to independently organize their social security systems on one side and with the right to freely provide services as a fundamental economic freedom granted by Article 56 of the TFEU on the other side, taking account of the fact that social systems of Member States are organized in different ways.²⁵ Nevertheless, being based on Article 56 of the TFEU, this kind of approach, which is characterized by non-harmonized restrictions of free movement between Member States, might bring to restrictions for both service providers and service users and to double restrictions which are contrary to freedom to provide services. The Patients' Right Directive was adopted as a solution for this problem and it partially regulates possible action in this sphere and gives space to various ways of its implementation into national legislation²⁶. It also singles out numerous procedural issues appearing when respective rules are applied and coordinated by administrative bodies and stresses the need for transparency and a precise definition of the rules for reimbursement for medical treatment costs, i.e. authorization procedures for medical treatment in another Member State.

In terms of freedom to provide healthcare services, the emphasis is here put on studying patients' social rights at a national level. This reflects in the right of patients to be provided with a medical service abroad under the same conditions as in their own state. The

¹⁹ Hatzopoulos, V.: *Killing national health and insurance systems ...*, op.cit., page 684

²⁰ Case C-158/96 *Raymond Kohll v Union des caisses de maladie* [1998] ECR I-1931.

²¹ Sokol, T.: *Rindal and Elchinov...*, op.cit. page 168

²² Hatzopoulos, V.: *Killing national health and insurance systems ...*, op.cit., page 688

²³ Goldner Lang, I.: *Patient Mobility in the European Union...*, op.cit., page 5.

²⁴ Judgement in case C-120/95 *Decker* [1998] ECR I-1831.

²⁵ The references differentiate between two basic types into which public healthcare systems can be classified. These are national health services and social insurance systems. National health services are funded by public taxation and based on privileges (Such systems exist in the UK, Ireland, Portugal, Spain, Italy, Denmark, Sweden and Finland). National health service systems are also called Beveridge systems. Social insurance systems lean on mandatory insurance of various categories of insured persons and comprise the entire population. Contributions in these systems are in most cases related to salaries (Such systems characterize Belgium, Luxembourg, the Netherlands, Germany, France and central and eastern European countries. Social insurance systems are also called Bismarck systems. See in Morton, A.: *A Single European Market in Healthcare: The impact of European Union policy on national healthcare provision*, European Public Service Briefings 3, March 2011, available at www.european-services-strategy.org.uk on 23 December 2011; Hervey, T. K., McHale, Jean, V.: *Health Law and the European Union*, Cambridge University Press, 2004, page 21.; Meyer, H.J.: *Current legislation on cross-border healthcare in the European Union*, presentation at a conference entitled 'The globalization of health care: legal and ethical challenges', 21 May 2011, Harvard Law school, page 2.

²⁶ On the modes of implementation of the Services Directive see in Horak, H., Dumančić, K.: *Problemi implementacije Direktive o uslugama u pravo RH – odustajanje od socijalnog modela na nacionalnom nivou (Issues of Implementation of the Directive on Services into Croatian Law – giving up on the social model at the national level)?*, Digest of the Faculty of Law of Rijeka, vol. 32, no.2, 2011.

consequences of freedom to provide services in the field of healthcare interfere with other specific areas such as freedom of movement for workers and members of their families.²⁷ Accordingly, it comes to the issue of social rights with respect to workers' needs for healthcare in another Member State.

Internationalization and globalization, and free movement of workers, capital, services and goods lead to new controversies in the field of freedom to provide medical services, e.g. the issue of upper limits of reimbursement for the costs of cross-border medical treatment by national healthcare systems and the issue of free market competition regards foreign service providers.

The European Court has already dealt with cases referring to the patients' needs for using healthcare services abroad, thereby facilitating cross-border patient mobility. The issue of cost refund within social and health insurance systems of Member States has not been part of the decision-making process and neither has been the right of patients to be medically treated abroad. Appertaining payments have also been excluded from the judgements. What has been included in the court decisions is freedom to provide services stipulated by Article 56 of the TFEU and the terms and conditions of Regulation 1408/71 prescribing the conditions for refund of costs of healthcare services abroad if patients are obliged to use respective medical services in their own country.²⁸ The refund may refer either to the cost of a particular medical service in the patient's Member State of affiliation²⁹ (if Article 56 of the TFEU is applied) or to the cost of the same healthcare service in the member state of treatment³⁰ (if refund is based on Regulation 1408/71). If reimbursement settled pursuant to Regulation 1408/71 is lower than that specified in accordance with Article 56 of the TFEU, one is allowed to request compensation for the difference in compliance with the same Article.³¹

As far as the refund settlement period is concerned, the refund is, in the principle, received after the right to use a healthcare service abroad has been confirmed in the patients' Member State of affiliation since Regulation 1408/71 prescribes mandatory issue of prior authorization regardless if it comes to inpatient or outpatient care.

One can draw a conclusion that the European Court practice in the sector of healthcare is connected with existence of the right to reimbursement for the costs of provided healthcare services in a Member State other than the patient's member state of affiliation. Urged by public interest-related reasons, the Court has sustained restrictions³² of settlement of reimbursement for the costs of provided healthcare treatment abroad under the condition that these reasons have been objective and proportional with the rules for award of prior authorization, particularly taking account of the duration of a time period necessary for prior authorization with respect to the condition of every single patient.³³

²⁷ Regarding possible solutions, one needs to consider the importance of the system of harmonization of laws through various procedures such as the procedure for utilization of open coordination methods. More about open methods of coordination see in Bodiřoga-Vukobrat, N., Sander, G.G., Barić, S.(ur.): Open method of coordination in the European Union, Verlag Dr.Kovač, Schriften zum Sozial-, Umwelt- und Gesundheits recht, Band 1.

²⁸ Hancher, Leigh; Sauter, Wolf: *One foot in the grave or one step beyond? From Sodemare to DocMorris: the EU's freedom of establishment case law concerning healthcare*, TILEC Discussion Paper, DP 2009-028, 2009, page 16.

²⁹ Paragraph 8, 33 and 34 of the Patients' Rights Directive Preamble. For definition of the member state of affiliation see Article 3(c) of the Patients' Rights Directive.

³⁰ Paragraph 19, 20 and 23 of the Patients' Rights Directive Preamble. For definition of the member state of treatment see Article 3(d) of the Patients' Rights Directive.

³¹ Hancher, Leigh; Sauter, Wolf: *One foot in the grave or one step beyond*, page 16.

³² Member States can justify the restrictions by setting forth important public interest-related reasons such as maintaining the financial balance of their social security systems and planning of hospital affairs.

³³ Hancher, Leigh; Sauter, Wolf: *One foot in the grave ...*, op.cit., page 16.

3. Specificities of Freedom to Provide Healthcare Services

Freedom to provide healthcare services involves the patients' right to use healthcare services in another Member State. This right also encompasses restrictions which may be imposed by a Member State in case of cross-border healthcare services and financial compensation for such services. The grounds for the compensation refer to the right of patients to be refunded costs which would have been covered if the service had been provided in the patients' member state of affiliation. This principle favours the internal market.

In its practice, the European Court has recognized the right of Member States to determine the scope and justification of social security rights at a national level. The right to compensation for medical treatment costs incurred in a Member State other than the insured person's country by the social security system of the latter has been acknowledged in a number of judgements of the European Court.³⁴ These judgements encouraged the Court to develop a concept of freedom to provide healthcare services by applying the parallel regime of freedom to provide healthcare services granted by the provisions of the TFEU and by Regulations 1408/71 and 883/2004. In most cases, patients have received sooner and better medical treatment in another Member State, on the occasion of which they requested refund of the treatment costs in accordance with the regulations governing social security systems in the patients' member state of affiliation.³⁵

As stated in the above lines, the European Court practice has confirmed that healthcare services are covered by the scope of Article 56 of the TFEU and that the right to provide cross-border services encompasses the patients' right to go to a foreign country to get the needed service³⁶ and the right to provide services abroad. For instance, the judgement in the case of *Kohll* included the free movement rules (this basically refers to freedom to provide and receive medical services) and their application irrespective of harmonization of national measures with the European legislation, precisely with Article 22 of Regulation 1408/71, since these provisions are aimed at enabling insured persons to use, following a given authorization, a healthcare service in another Member State, accompanied with the right to claim reimbursement for the costs of received healthcare service in the amount corresponding to the service cost in the country where the service was provided. It is forbidden to restrain freedom to provide medical services among Member States since it can make a healthcare service harder to get than within the healthcare system of a Member State. The thesis that freedom to provide healthcare services belongs to the scope of Article 56 of the TFEU has been acknowledged in a number of judgements of the European Court (*Decker, Vanbraekel, Geraets-Smits and Peerbooms* and others). In terms of differentiating between hospital and non-hospital care in the case of *Vanbraekel*, it was established that freedom to provide medical services refers to both hospital and non-hospital treatment.³⁷

³⁴ Judgements in case C-120/95 Nicolas Decker v Caisse de maladie desemployés privés (*Decker*) [1998]; case C-158/96 Raymond Kohll v Union des caisses de maladie ECR I-1931; case C-368/98 Abdon Vanbraekel et al. v Alliance nationale des mutualités chrétiennes (*Vanbraekel*) [2001] ECR I-5363; case C-157/99 B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen (*Smits and Peerbooms*) [2001] ECR I-5473; case C-372/04 *The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325; case C-286/06 *Commission v Spain* [2008] ECR I-8025; case C-173/09 *Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa* of 5 October 2010, ECR I-0000, OJ C 328 of 4 December 2010.

³⁵ Notably, judgements in the cases of *Kohll, Vanbraekel, Geraets-Smits and Peerbooms*, judgement in case C-145/03 *Keller* [2005] ECR I-2529; *Watts; Elchinov et al.*

³⁶ See paragraph 20 of the judgment in the case of *Kohll* stating that "the specific nature of particular services does not make them immune to the fundamental principle of free movement."

³⁷ See paragraph 41 of the judgment in the case of *Vanbraekel*

The particular issue of coverage of the difference in costs of a healthcare service between the country where the patient is insured and the country where the healthcare service was provided, which is to be faced when specifying the amount of reimbursement for medical treatment costs, also appeared in the case of *Vanbraekel*. If the price of a healthcare service in the patient's Member State is lower than in the Member State where the treatment was provided, then one needs to ensure additional compensation to cover the difference in the price. In the case of *Vanbraekel*, the European Court asserted that Article 22 of Regulation 1408/71 is founded on the principle that the costs of medical treatment born by the patient shall be refunded in compliance with the rates applicable in the country where the treatment was performed. The reimbursement in the case of *Vanbraekel*, which was prescribed by the French legislation, was lower than that foreseen by Belgian law, i.e. the country where the service was provided. The Court laid down that the intention of Article 22 of Regulation 1408/71 is not specification of the reimbursement amount and does not prevent compensation for costs by the patients' member state of affiliation. However, if patients are not compensated for the incurred costs of medical treatment to the same extent as they would be compensated if the same treatment had taken place in the country where they are insured, then such a situation shall be considered as restriction of freedom to provide services stipulated by Article 56 of the TFEU.³⁸ If the amount of reimbursement calculated according to the respective rules of the country where the treatment was conducted is higher than the amount of reimbursement calculated pursuant to the respective rules of the country where the patient is insured, the health insurance fund is obliged to cover the difference in the reimbursement.³⁹ The judgement of the European Court in the aggregated cases of *Geraets-Smits* and *Peerbooms* was derived from the decision on the patient's right to reimbursement for the costs of healthcare treatment which was provided outside the Netherlands. In both cases, the national court refused to give consent for hospital care abroad, referring to the fact that the care was neither common nor necessary. The prerequisite for prior authorization for the care was to deem it in both cases common and necessary by competent national doctors, i.e. that it can be provided within the national healthcare system within a reasonable period of time.⁴⁰ In the Netherlands, foreign healthcare is part of the insurance system, pursuant to which insured persons are obliged to make nominal payments to providers of public services (funded by contributions of workers and state funds) as to be provided with free healthcare by contractors of these providers (the contractors are exclusively situated in the Netherlands). The authorization system for medical treatment abroad foresaw meeting two requirements. The first one was to consider treatment as "common (ordinary)" by Dutch professional circles

³⁸ Paragraph 45 of the judgement in the case of *Vanbraekel*

³⁹ Paragraph 67 of the judgement in the case of *Vanbraekel*

⁴⁰ In the case of *Geraets Smits* and *Peerbooms*, the European Court was to make a decision on patients who were Dutch citizens and claimed reimbursement for the expenses of medical treatment provided in Germany and Austria from the Dutch health insurance fund. Mrs Geraets Smits was administered a multidisciplinary therapy for Parkinson's disease in a German hospital. Regulations of the Dutch health insurance fund would have approved of reimbursement for the costs only if the treatment had been completed in compliance with "the common procedure for medical treatment", which actually entailed mandatory treatment in the Netherlands. The therapy applied to Mrs Geraets Smits was not deemed as "common" and thus the request was rejected. The decline of the request also resulted from the fact that an appropriate therapy for Parkinson's disease was available in Holland as well and that there was no "medical necessity" for treatment in Germany. Mr Peerbooms, aged 35 at that time, fell into a coma after a car accident and was transferred from a Dutch hospital where he was initially treated to a clinic in Austria. In the latter centre, he was administered a special intensive therapy based on neurostimulation. This kind of therapy was used only on an experimental basis and was not available to patients over 25 years of age. Mr Peerbooms went for expense refund but the claim was declined due to the fact that he could have been provided with adequate medical treatment by a Dutch provider appointed by the Dutch health insurance fund based on an agreement. Moreover, the medical treatment provided in Austria was not considered "common" by Dutch medical circles.

and as necessary in the sense that appropriate treatment could not be realized in the Netherlands without a major delay. The judgement confirmed the earlier viewpoints of the Court that freedom to provide services should be applied in case of inpatient (hospital) care too.

The recent practice of the European Court concerning the conditions for granting the right to reimbursement for the costs of foreign healthcare services makes a distinction between hospital and non-hospital care.⁴¹ This distinction commenced with the judgement in the case of *Geraets-Smits and Peerbooms*.⁴² The European Court practice has ascertained that the requirements for prior authorization for reimbursement for non-hospital care costs by the social security scheme of the patient's member state of affiliation is not justified. Unlike in terms of non-hospital care, the European Court does not exclude the possibility of prior authorization for reimbursement for the costs of foreign non-hospital care. In fact, when it comes to hospital care, just reasons for restriction of freedom to provide services may refer to the inability of prevention of the possible risk of serious disturbance of social security systems or to the inability to maintain balanced medical and hospital care available to all citizens, which can be seen as a public interest⁴³, and to the procedure of prior authorization for reimbursement for the costs of healthcare services provided abroad, which is not incompatible *per se* with freedom to provide healthcare services. Still, these conditions need to be justified and to correspond to what is objectively necessary for that purpose, suggesting that the same goal cannot be accomplished by less repressive measures (the principle of proportionality).⁴⁴

Justifications for restriction of freedom to provide healthcare services have been differently accepted in different periods by national legislation. In the beginning, there was a "conservative" perception of freedom to provide healthcare services which allowed restriction of free movement aimed at using foreign healthcare services. The restriction was interpreted as a denial of the rights of entrepreneurs to use public funds from social security systems of Member States other than their own. By the time, this approach has been amended and now existence of measures intended for prevention of the fundamental freedoms granted by the Treaty or making their exercise less attractive is considered such a restriction. The grounds of the Court for the decision-making process in this context span the relation between the claims and rights of individual patients to use a service on one side and public claims and interests focused on financially sustainable healthcare on the other side.⁴⁵

This and other sectors are more and more characterized by an economic approach⁴⁶, preventing Member States from restriction of freedom to provide services by broad interpretation of the Treaty. Member States are supposed to enact their laws and resolutions in accordance with reasonable economic claims in the field of healthcare too. If the goal of creation of an internal market is to be achieved by shaping economic freedoms, then Member States shall meet economic criteria in the sphere of free movement.

⁴¹ See in Goldner Lang, I., Vukorepa, I.: *Izješće o hrvatskom zakonodavstvu koje uređuje radno pravni status radnika migranata (iz Eu i trećih država), te pravima koja proizlaze iz njihovog radno pravnog statusa (njihovim socijalnim pravima) u odnosu na pravnu stečevinu EU [Report on the Croatian Legislation Regulating the Legal Status of Migrant Workers (from the EU and Third Countries) and on the Rights Arising from Their Legal Status on the Labour Market (Their Social Rights) with Respect to the *acquis* of the EU]* Council of Europe, Coordination of Social Security Systems and the Reform of the Social Security System, October 2010, page 11.

⁴² Paragraph 79 and 80 of the judgement in the case of *Geraets Smits and Peerbooms*.

⁴³ Patients' Rights Directive makes no distinction between inpatient (hospital) and outpatient care.

⁴⁴ See judgements in the cases of *Smits and Peerbooms*, *Müller Fauré* and *van Riet*, *Commission v. France*, *Elchinov*. For more details see in Goldner Lang, I., Vukorepa, I: *Report...*, page 11.

⁴⁵ *Ibidem*, page 32.

⁴⁶ Bodiroga Vukobrat, N., Horak, H: *Cross border provisions of health services (freedom to provide services or health tourism?)*, presentation at an international conference entitled *Economic integrations, competition and cooperation*, Economic Faculty of the University of Rijeka, Opatija 2009.

Attempts of coordination of Member State healthcare policies encompass the adoption of the Patients' Rights Directive. The Directive has been tailored to cater for a unique and transparent framework for cross-border healthcare.⁴⁷ Considering the fact that the Directive mostly codifies the former judicial practice, it in fact facilitates harmonization of healthcare at the European level. The draft Directive has, in the principle, induced positive comments⁴⁸, although some Member States claimed that it basically legalizes "medical tourism", hence confronting their interests.⁴⁹

4. Directive Patients' Rights Directive

The Charter of Fundamental Rights of the European Union⁵⁰ lays down the following fundamental rights: Everyone has the right of access to preventive health care 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.⁵¹

Pursuant to Article 168 (1) of the TFEU, a high level of protection of human health shall be guaranteed when defining and implementing all the EU policies. The Patients' Rights Directive was adopted in order to improve the functioning of the internal market and the free movement of goods, persons and services. The provisions on free movement make an appropriate legal basis even when it comes to protection of public health as the decisive decision-making factor. Healthcare systems of Member States also constitute a wide framework for services of general interest.⁵²

The area of healthcare services has been exempted from the scope of the Services Directive.⁵³ In accordance with its Article 3, the Services Directive shall not be applied in situations

⁴⁷ Press releases, text available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1080&format=HTML&aged=1&language=EN&guiLanguage=hr>

⁴⁸ See European Federation of Public Services Unions (EPSU), Press Communication-for immediate release, 18. 1.2011., International Medical Travel Journal: News, available at epsu@epsu.org on 1 September 2011. Likewise, in the Republic of Croatia, in the interview published in Slobodna Dalmacija on 5 December 2011, Mirando Mrišić asserted that "the Croatian Institute for Health Insurance rarely gives consent for reimbursement for the costs of medical treatment abroad. The consent is given only in cases when appropriate treatment is not available in Croatia. Croatian citizens who opt for healthcare services abroad due to a higher quality of medical treatment in foreign hospitals or reliance on skills of foreign doctors despite the possibility of undergoing adequate interventions in Croatia have to find the funds for their treatment themselves since the Croatian Institute for Health Insurance is not willing to bear the respective expenses. However, this situation should change in the year 2013 when the EU Directive on Cross-Border Healthcare becomes effective. The Directive prescribes that EU citizens are entitled to, if desired, use healthcare services in other Member States and that national social security systems, even if the treatment could be provided in the patient's country, shall cover the accompanying expenses up to the amount of the inland cost of the appertaining medical intervention. The greatest benefit from "healthcare without borders" will relate to Croatian patients suffering from rare diseases since they will have a chance to be treated in specialized centres throughout Europe. Healthcare without borders is a good idea, but its implementation might face some obstacles because health insurance schemes need to be harmonized as they differentiate between each other, available at, <http://www.suprazdravlje.hr/clanak/616/165/pogodnosti-za-hrvatske-pacijente-nakon-pristupanja-eu> on 24 January 2012.

⁴⁹ National Health Service, Ludwig von Von Mises Institute available at http://vonmisesinstitute-europe.org/newsite/index.php?option=com_frontpage&Itemid=1...

⁵⁰ Charter of Fundamental Rights of the European Union (2000/C 364/01), OJ C 364, 18 December 2000, pages 1-22.

⁵¹ Charter of Fundamental Rights of the European Union, Article 35

⁵² Paragraph 2 and 3 of the Patients' Rights Directive Preamble.

⁵³ Article 2 paragraph 2 (f) of the Directive on Services.

regulated by the provisions of Regulation 1408/71⁵⁴, which excludes healthcare services from the scope of the former. The Draft of the Services Directive contained provisions on healthcare service or more precisely their character and modes of their funding and providing. The European Commission proposed the Patients' Rights Directive in 2008.⁵⁵ It happened before the adoption of the Services Directive. The Patients' Rights Directive⁵⁶ was adopted on 9 March 2011, having the implementation deadline of 25 October 2013. It regulates patients' rights in situations in which they have an opportunity to be provided healthcare in a Member State other than the state of their affiliation. Since its adoption, the Patients' Rights Directive has become the most important source of the right to cross-border healthcare for citizens of the European Union.

The legal regime of the Patients' Rights Directive is applied parallel with Regulation 1408/71⁵⁷ and Regulation 883/2004. As far as patients are concerned, these two systems must be coherent, so that patients are subject to either the provisions of the Patients' Rights Directive or the Regulation of the European legislation referring to coordination of social security systems.⁵⁸

Paragraph 28 of the Preamble of the Patients' Rights Directive does not comprise situations protecting the right of insured persons to reimbursement for the costs of healthcare which was medically necessary during the temporary stay in another Member State. Such situations are covered by Regulation 883/2004. Also, the provisions of the Patients' Rights Directive have no effect on the right of insured persons to be awarded authorization for healthcare in another Member State if the requirements foreseen by regulations on coordination of social security systems have been met, particularly Regulation 883/2004 or Regulation 1408/71 being applied based on Regulation 1231/2010 and Regulation 987/2009.

The aim of the Patients' Rights Directive is establishment of rules which should facilitate an access to safe and high quality cross-border healthcare in order to ensure patient mobility based on the principles established by the European Court and to promote cooperation between Member States in providing healthcare while respecting their responsibility for defining social security benefits relating to health and for organization and delivery of medical care and healthcare, and social security benefits, particularly in case of sickness.⁵⁹

The Directive on Patients' Rights should also offer a clear portrait of their right to reimbursement for the expenses of medical care provided in a Member State other than the

⁵⁴ Council Regulation 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, OJ L 149, 5 July 1971, page 2

⁵⁵ Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare COM (2008) 414 final, 2 July 2008; available at http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf

⁵⁶ 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 L88/45 of 4 April 2011.

⁵⁷ For example, in compliance with Regulation 1408/71 and Regulation 883/2004, prior authorization of medical treatment abroad as a prerequisite for reimbursement for the expenses of both inpatient and outpatient care is always required. Pursuant to Article 56 of the TFEU, prior authorization, which in fact represents an obstacle to freedom to provide services, cannot be required in terms of outpatient care but only when it comes to hospital care. This restriction is deemed as valid following the necessity of maintenance of the financial balance of national healthcare systems and planning in the hospital care sector. What is imposing is the conclusion that concerning authorization of medical treatment in a foreign country, Regulation 1408/71 always presupposes prior authorization while Article 56 of the TFEU governs that Member States are allowed, but are not bound to, to prescribe prior authorization for hospital care but never for outpatient care. Hence in Sauter, W.: The proposed patient mobility Directive and the reform of cross-border healthcare in the EU, TILEC discussion paper, 2008, available at <http://ssrn.com/abstract=1277110>, page 29.

⁵⁸ Paragraph 30 of the Patients' Rights Directive Preamble

⁵⁹ Paragraph 10 of the Patients' Rights Directive Preamble

state of their affiliation and ensure necessary conditions for high quality, safe and efficient healthcare founded on common principles of all EU healthcare systems as well as provide for a specific framework for cross-border healthcare and for European cooperation in this field.

The Patients' Rights Directive is applicable to individual patients who receive for healthcare treatment in a Member State other than the state of their affiliation.⁶⁰ The member state of affiliation means, from the perspective of insured persons, the Member State which is in competent to grant a prior authorization for healthcare treatment to be provided outside the state where the patient resides pursuant to Regulation 883/2004 and Regulation 987/2009, i.e. the Member State which is expected to grant prior authorization to patients for healthcare in another Member State according to Regulation 59/2003 or Regulation 1231/2010. If none of the Member States finds itself competent for such a procedure according to these Regulations, the Member State of affiliation shall be the Member State where the patient is insured or has the right to sickness benefits according to the legislation of that member state.⁶¹

In terms of telemedicine⁶² and therewith related medical services in a foreign country, the Member State where a healthcare service is provided shall be the Member State where the provider has its seat.⁶³

The modes of expense refund by a Member State governed by the Patients' Right Directive are founded on the European Court of Justice case law. However, as the European Court has made judgements in individual cases, the Directive intends to establish general principles and their effective application.⁶⁴ The manner of expense reimbursement regarding cross-border healthcare set out by the Patients' Rights Directive is applicable not only in cases when patients are treated in a Member State other than the Member State of their affiliation but also in situations comprising prescriptions, allocation and supply of medical products and devices that are utilized in the context of healthcare services. The definition of cross-border healthcare should refer to situations in which patients purchase medical products and devices in a Member State other than the Member State of their affiliation as well as to situations in which patients purchase medical products and devices in a Member State other than the Member State where the prescription was issued.⁶⁵ Nevertheless, the Directive on Patients' Rights does not concern the rules of Member States for online sale of medical products and devices.⁶⁶

⁶⁰ Paragraph 11 of the Patients' Rights Directive Preamble .

⁶¹ Article 3 (c) of the Patients' Rights Directive.

⁶² Ordinance on the Conditions, Organization and Modes of Conducting Telemedicine (Official Gazette no. 138/11) lays down the conditions, organization and modes of conducting telemedicine and the conditions for getting authorization for opening a tele-medical centre. Article 2 of this Ordinance defines telemedicine as providing remote healthcare services by application of information and communication technologies. Telemedicine encompasses medical consulting, preventive medicine and diagnostic and therapeutic procedures based on data provided by an IT and communication system and exchange of information aimed at continuous vocational training of staff.

⁶³ Article 3 (d) of the Patients' Rights Directive.

⁶⁴ Paragraph 8 of the Patients' Rights Directive Preamble.

⁶⁵ Paragraph 16 of the Patients' Rights Directive Preamble.

⁶⁶ Paragraph 17 of the Patients' Rights Directive Preamble. This provision of the Patients' Rights Directive is based on the European Court practice acknowledged in the judgement in case C-108/09 *Ker Optica* of 2 December 2010, *OJ C 30, 29 January 2011- since online sale of such products is subject to the provisions of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*, *OJ L 109/29 of 6 May 2000* (the so-called 'E-commerce Directive'). The case of *Ker Optika* required the European Court to decide on the Hungarian laws allowing sale of contact lenses exclusively in specialized stores and thus prohibiting their online sale. The European Court points out that decisions on online sale of medical products encompass two starting points. The Court explains the scope of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, *OJ L 109/29 of 6 May 2000*. (the so-called 'E-commerce Directive') relating to Hungarian law: the provisions of this Directive does not exclude online sale of

As far as possible restrictions of freedom to provide cross-border healthcare are concerned, the Patients' Rights Directive takes, following the case law of the European Court, relevant public interest-related reasons into consideration in case the provisions of Article 49 and 56 of TFEU are to be applied.⁶⁷

The Patients' Rights Directive is not applicable to services, the purpose of which is long-term care of people which means support people in need of assistance in carrying out routine, everyday tasks, providing them with assistance in satisfying their everyday's needs. This particularly refers to assistance in making those people capable of independent living such as long-lasting assistance in doing housework or helping people situated in nursing homes and similar institutions.⁶⁸ The Directive is not intended for services related to allocation of and access to organs for the purpose of transplantation.⁶⁹ Except when it comes to cooperation between Member States foreseen in its Chapter IV, the Directive shall not apply to public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory on one Member State and which are subject to specific planning and implementation measures.⁷⁰

The provisions of the Directive do not affect laws and other regulations in Member States referring to organization and financing of cross-border healthcare. In particular, Member States are not obliged to refund the expenses of medical treatment provided on their territory if the providers are neither part of their social security systems or public health system of another Member State.⁷¹

The Directive is applied alongside the regime stipulated by Article 56 of the TFEU and in accordance with a number of regulations and directives stated in its Article 2.⁷² These systems

medical products. However, the national regulations governing manners of supplying end users with medical devices (for instance, only after a trial period) are not comprised by the E-commerce Directive, so they are not subject to the rules stipulated thereby. These regulations shall be taken account of within the framework of European law relating to free movement of goods. Considering the fact that online sale of medical products is included in the E-commerce Directive, the European Court judged that such a sale cannot be banned even if appertaining prior authorization given by a qualified expert is required since the test cannot be detached from the future online sale. Hence, the Court has ascertained that sale of medical products and devices is covered by the E-commerce Directive.

⁶⁷ Paragraph 12 of the Directive Preamble lays down that judgements of the European Court have confirmed several times that important public interest-related reasons represent proper justification for restriction of freedom to provide services. These reasons involve planning aimed at achievement of a sufficient and permanent access to a balanced spectre of high quality healthcare in a Member State or the wish to control costs and avoiding, to the greatest possible extent, waste of financial, technical and human resources. Since the European Court mentions the goal of maintaining balanced medical and hospital care available to all people, this can be deemed as an exception to the rule pursuant to public health-related reasons stated in Article 52 of the TFEU as long as this goal contributes to accomplishment of a high level of healthcare.

⁶⁸ Article 1 (3)(a) of Patients' Rights Directive and Article 14 of the Patients' Rights Directive.

⁶⁹ Paragraph 14 of the Patients' Rights Directive Preamble.

⁷⁰ Articles 1(3) (b) and (c) of Patients' Rights Directive.

⁷¹ Article 1 (4) of Patients' Rights Directive.

⁷² Article 2 of Patients' Rights Directive reads as follows: Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40, 11.2.1989, p. 8.; Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17.; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1.; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1. ; Directive 95/46/EC and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector, OJ L 201, 31.7.2002, p. 37.; Directive 96/71/EC of the European Parliament and of the Council of 16 December 1996

need to be coherent, so that patients are subject either to the Patients' Rights Directive or to the regulation relating to coordination of social security systems.⁷³

The greatest value of this Directive refers to its Article 5 governing the responsibility of the Member State of affiliation for reimbursement of costs for cross-border healthcare and to its Article 7 prescribing general principles for reimbursement of costs. In terms of implementation of the rights granted by this Directive, certain relevance carries its Article 6 regulating the liability for establishment of national contact points regarding cross-border healthcare in order to facilitate exchange of information and exercise of patients' rights. Also, Article 8 of the Directive is significant in the sense of specification of medical services which can be comprised by the prior authorization procedure. Once again, these provisions are worth emphasizing since they are supposed to be implemented into national laws and thus expected to entice transparency and preciseness in the determination of medical treatment lists and corresponding pricelists.

5. Concluding considerations

The legal framework of the Republic of Croatia for providing cross-border healthcare has been, to some extent, harmonized with the *acquis* of the European Union. More precisely, the conditions for getting prior authorization for foreign healthcare have been prescribed and defined. They are available to all patients as stipulated by the Regulation on the Rights,

concerning the posting of workers in the framework of the provision of services, OJ L 18, 21.1.1997, p. 1; Directive 2000/31/EC; Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, OJ L 180, 19.7.2000, p. 22.; Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121, 1.5.2001, p. 34.; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.; Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, OJ L 33, 8.2.2003, p. 30.; Regulation (EC) No 859/2003; Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L 102, 7.4.2004, p. 48.; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.; Regulation (EC) No 883/2004; 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, p. 1.; Directive 2005/36/EC; Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006 on a European grouping of territorial cooperation (EGTC), OJ L 210, 31.7.2006, p. 19.; Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work, OJ L 354, 31.12.2008, p. 70.; Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), OJ L 177, 4.7.2008, p. 6.; Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non- contractual obligations (Rome II), OJ L 199, 31.7.2007, p. 40.; Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ L 207, 6.8.2010, p. 14.

⁷³ Article 30 of the Patients' Rights Directive.

Conditions and Manner of Usage of Healthcare Services Abroad.⁷⁴ However, the prior authorization procedure needs to be amended and harmonized with the provisions of the recently adopted Patients' Rights Directive by introducing mechanisms which will provide patients with the right to be informed about their rights and powers in the Member State of their affiliation with respect to cross-border healthcare, particularly regarding the conditions and modes of refund of the costs of healthcare services abroad granted by Article 5 of the Patients' Rights Directive.

The procedure for getting authorization for healthcare services abroad and the appertaining right of appeal are prescribed by the above Regulation. Still, in order to avoid arbitrary decisions on cross-border healthcare treatment, one shall draw up and adopt lists of acceptable healthcare treatments and corresponding pricelists. The authorization system is in fact restriction of freedom to provide healthcare services⁷⁵ and hence it must have objective and non-discriminatory grounds which should be known from the beginning as to prevent discretionary assessments of competent national boards, i.e. arbitrary decisions on sending someone to a foreign country for healthcare treatment.⁷⁶

The need for preparation of a list of acceptable healthcare treatments accompanied with possible pricelists is derived from the existence of numerous differences between Member States, which depend on various factors such as geographic position, language barriers, hospitals in bordering areas (a social scheme is applicable on the entire territory of a Member State), size and density of population or part of the budget referring to healthcare.⁷⁷ Every Member State is expected to define and justify criteria for possible rejection of prior authorization needed in this specific context. Furthermore, all Member State should specify which healthcare services are subject to the prior authorization system since certain therapeutic procedures (diagnostic and therapeutic procedures, surgeries and similar) are highly specialized and can be encompassed by these procedures despite a certain outflow of patients with respect to other procedures. In that sense, Member States may determine different criteria among regions or other ways of administrative action all in order to organize healthcare as long as the system is transparent, easily accessible and the criteria stable and timely published.⁷⁸

The above Regulation offers broad criteria for using cross-border healthcare in its Article 22, without specifying exact and transparent requirements. One can assert that there is a legal framework for using cross-border healthcare, but it is not transparent. The foundations of the Croatian Regulation and the EU Directive on Patients' Rights refer to the right to reimbursement for the costs of provided healthcare abroad. Article 7 of the Patients' Rights Directive sets out the patients' right to reimbursement of the costs incurred when an insured person was provided with a healthcare service abroad if the service is covered by the health insurance scheme of the insured person's Member State of affiliation. This provision and appertaining benefits of the health insurance scheme are comparable with Article 16 of the Croatian Compulsory Health Insurance Act. The expenses of cross-border healthcare shall be compensated for or directly refunded by the Member State of affiliation in the amount of the costs which would have been covered in the Member State of affiliation, not exceeding the actually born costs of the received healthcare service.⁷⁹ For the sake of calculation of these costs, Member States shall develop a transparent mechanism which will enable insured

⁷⁴ Regulation on the Rights, Conditions and Manner of Usage of Healthcare Services Abroad (Official Gazette no. 50/09, 118/09, 4/10, 13/10, 14/10, 1/11, 31/11 and 93/11).

⁷⁵ Article 37 of the Preamble of the Directive on Patients' Rights.

⁷⁶ Goldner Lang, I.page 11.

⁷⁷ Paragraph 44 of the Preamble of the Directive on Patients' Rights

⁷⁸ Paragraph 44 of the Preamble of the Directive on Patients' Rights

⁷⁹ Article 7 (4) of the Directive on Patients' Rights

persons to be reimbursed for the costs of provided cross-border healthcare, which should be based on objective, non-discriminatory and timely published criteria and which should be applicable at a particular administrative (local, regional or national) level.⁸⁰ Member States may prescribe conditions that shall be fulfilled if a patient wants to be medically treated abroad and these conditions can include assessment of medical experts. Still, the conditions will represent restriction of free movement of patients, services and goods if they are not supported by objective reasons such as achievement of a sufficient and permanent access to balanced possibilities of high quality healthcare in Member States or the wish to control costs and prevent waste of financial, technical and human resources.⁸¹ If such reimbursement is to be restrained, the restriction must be necessary and proportional but never discriminatory. Furthermore, this restriction must not disproportionately prevent free movement of goods, persons and services. Member States shall inform the European Commission about all decisions aimed at restriction of the right to costs reimbursement.⁸²

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