THE EMERGING MANDATE OF EU LAW IN HEALTH CARE:

A Legal Analysis of the Influence of Internal Market Implementation on Access to Health Care in Hungary and Slovenia

By

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I hereby declare that this work contains no materials accepted for any other degrees in any other institutions. This thesis contains no materials previously written and/or published by another person, unless otherwise noted.

Abstract

The increasing influence of the European Union has undermined Member States' efforts to keep health care regulation under exclusive national competence. Health care is formally reserved for Member States as a core element of national social policy systems. Nevertheless, litigation based on directly effective EU law provisions has placed access to medical treatment on the European agenda. Cross-border care and patient mobility have become central topics in the discussion about the role of the EU in health care and the future of health systems in Europe.

The dissertation addresses the implications of recent EU law developments concerning access to cross-border care for national health systems with particular focus on two new Member States of Central and Eastern Europe, Hungary and Slovenia. It locates the topic of cross-border health care in the context of theories on European integration and welfare state development. The analysis is centered on the premise of a currently existing competency gap in health care governance that is gradually filled by the EU through the case law of the European Court of Justice and efforts of the European Commission to codify the rulings in a European Directive. Through instruments of legal analysis the dissertation examines how national regulation of access to health care has become affected by legislation promulgated at EU level and litigations based on directly effective provisions of Community law. Towards this end, the European social security co-ordination mechanism and the ECJ case law extending internal market rules over health care are analyzed. Afterwards, the analysis is shifted to the level of countries in order to examine how health care systems of nation states have been affected.

The analysis shows that the central issue in cross-border care is the clash between Member States' efforts to safeguard health care as a national social policy competence unaffected by market integration and efforts of the EU to promote free movement. It argues that cross-border care is an illustrative example for the gradual infiltration of policy fields traditionally reserved for Member States by EU law promoting the internal market. It highlights that the ECJ rulings have initiated the emergence of a transnational aspect of health care policy making, based on a legal background developed through a series of court cases addressing individual situations. In spite of efforts to sustain the territorial focus in health care provision and financing, Member States have to open their social borders in front of individuals and treatment providers from other Member States in order to comply with EU law. This affects new Member States of Central and Eastern Europe differently due to their particular legacies and specific challenges in health care organization that distinguish them from old EU members. Enhancement of cross-border patient mobility is more likely to favor health care providers than patients from the two countries under review. Although cross-border co-operation in health care provision is at a very early stage of development, there are a number of opportunities brought about by the EU that could be used in a way that is beneficial for health care providers, patients and financiers at the same time.

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TABLE OF CONTENT

List of abbreviations and acronyms

ANMC	Alliance Nationale des Mutualités Chrétiennes
CEE	Central and Eastern Europe
DKMT	Duna – Körös – Maros - Tisza Euregio
EC	European Community
ECJ	European Court of Justice
ECR	European Court Reports
EEA	European Economic Area
EHIC	European Health Insurance Card
EU	European Union
GDP	Gross Domestic Product
GP	General Practitioner
HIF	Health Insurance Fund
HIIS	Health Insurance Institute of Slovenia
INAMI/RIZIV	Belgian National Institute for Health and Disability Insurance
NHIF	National Health Insurance Fund
NHS	National Health Service (United Kingdom)
OECD	Organization for Economic Co-operation and Development
OJ	Official Journal of the European Community
SGB V	Fünftes Sozialgesetzbuch (Germany)
TEC	Treaty Establishing the European Community
UK	United Kingdom
WHO	World Health Organization

Introduction

Although the European Union does not have a formal legal competence in the field of health care, European integration has a growing influence on the organization and delivery of health services. Controversial EU law developments related to access to cross-border care illustrate how health care systems of Member States have been affected by the implementation of internal market freedoms. A series of rulings delivered by the European Court of Justice on access to cross-border care illustrate that EU law is an increasingly important factor in health care regulation. Litigation based on directly effective EC Treaty provisions has placed access to medical treatment on the European agenda. The dissertation addresses the consequences of the emerging role of EU law in health care for national health systems with particular focus on new Member States of Central and Eastern Europe. Towards this end, it examines the implications for access to health care in two new members, Hungary and Slovenia.

The Treaty establishing the European Communities stipulates that Member States are fully responsible for the organization and delivery of health services and medical care[1]. EU countries have been safeguarding their authority to establish the rules on access to medical treatment, determine the benefit packages and regulate entitlement to social coverage (whether insurance-based or provided within the framework of a national health service). Health care has traditionally constituted a core component of national social policy systems. Health systems of European countries differ in terms of institutional features and underlying social philosophies, legacies and normative aspirations[2]. There are significant cross-country differences in organization, delivery and funding of medical services. At the same time, most

[1] See Article 152 of the Treaty of Amsterdam.
[2] See also Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4): 645-670, 2002.

health systems are characterized by a strong public role and a high degree of government intervention[3]. It is thus no surprise that health care governance has been traditionally regarded as a national competence. Attempts to harmonize in this field and establish uniform EU rules are likely to encounter strong opposition in Member States.

1. Cross-border care: placing access to health care on the EU agenda

EU Member States have designed their health care systems so as to serve primarily the needs of their own citizens. Health systems were originally conceived as territorially closed systems that guarantee access to medical care as a right restricted to the national territory. Health care coverage has been traditionally limited to services and goods obtained from providers located within the country. This is generally known as the principle of territoriality in health care coverage[4].

Despite the lack of a formal legal competence in health care regulation, EU law has interfered in several ways with this domains reserved for nation states. Interference is an outcome of efforts of the Union to implement the fundamental principle of freedom of movement. The European mechanism for the regulatory co-ordination of Member States' social security systems (shortly, the social security co-ordination mechanism) was created in order to ensure that European citizens can exercise their right to free movement without being constrained by lack of access to quality medical care and/or fears of loosing health care entitlements

[3] High degree of government intervention generally characterizes the health systems in Europe. See also the 2007 report commissioned by the European Parliament: DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007, p. 1. Chapter 4 will discuss the reasons why it is necessary to maintain state authority and regulatory ability in health care.

[4] See, for further details on the territoriality principle in health insurance, Cornelissen, R. 'The Principle of Territoriality and the Community Regulations on Social Security'. *Common Market Law Review* 3, 1996; Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, p. 83; Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven, Instituut Sociaal Recht, 2004-2005.

acquired in the country of insurance. EEC Regulations 1408/71[5] and 574/72[6] were originally designed to cover migrant workers and their dependent family members moving to or residing in another Member State for the purpose of work and employment. The scope of the co-ordination regulations has been subsequently extended to all EU citizens including inactive persons and legally residing third-country nationals who have a situation that is not confined in all respects within a single Member State[7]. The social security co-ordination regulations require EU countries to provide exemptions to the territoriality principle in health care coverage. For example, Member States are required under co-ordination law to cover health care that becomes medically necessary during a temporary visit abroad and planned medical treatment obtained in another EU country on the basis of authorization issued by the competent insurance institute. These constitute typical examples of cross-border health care.

'Cross-border health care' means health care provided in a Member State other than the state where the patient is insured[8]. The term 'cross-border health care' is also used to define situations when medical treatment is provided in a Member State other than that where the provider resides, is registered or established[9]. Cross-border patient mobility is defined as any

[5] Council of the European Communities. Regulation (EEC) Council No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (Consolidated version), *OJ* L 28 of 30 January 1997, pp. 0001-0147. Regulation 1408/71 is amended regularly**.** For the latest text, see the online source of EU legislation: http://eur-lex.europa.eu/en/index.htm (Last accessed on May 26, 2009).

[6] Council of the European Communities. Regulation (EEC) Council No 574/72 of 21 March 1972 laying down the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to their families moving within the Community (Consolidated version), *OJ* L 28 of 30 January 1997, pp. 0001-0235.

[7] Council of the European Union. Council Regulation (EC) 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, *OJ* L 124, 20 May 2003, 0001-0003, Art. 1.

[8] In case of cross-border care the state of treatment does not coincide with the state of insurance.

[9] See the definition provided by the proposed EC Directive on the application of patients' rights in cross-border health care. European Commission. 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 of 2 July 2008. Brussels: Commission of the European Communities. As discussed further in this paper, the state of insurance coincides in some cases with the state of residence, but the two can also differ. Chapter 2 discusses the conditions for access to health care in cases when persons are insured in a Member State and reside habitually in another Member State.

movement of patients from one Member State to another in order to obtain medical treatment[10]. This includes crossing the border to seek health care in the neighboring country and also transnational movement of patients within the European Union, as patients cross sometimes several borders and target remote countries in order to obtain the necessary treatment.

The scope of EU law in this field was meant to be restricted to coordinating the social security systems of Member States through Regulations 1408/71 and 574/72. Originally, EU competence did not include regulation of access to health care within a given country or establishment of rules beyond the co-ordination mechanism. Member States generally took a restrictive approach towards covering the cost of medical services and goods obtained outside of the national territory. This is particularly relevant in case of planned medical treatment where the state of insurance retained considerable discretion in defining the authorization policy[11]. Cost coverage for health care obtained abroad did not constitute a general entitlement but an exception that had to be well justified.

Nevertheless, efforts of the European Union to implement the fundamental principle of free movement have strongly challenged Member States' reluctance to give up the territorial focus in health care provision and coverage. The case law of the European Court of Justice has been instrumental in this process. A series of cases addressed by the Court[12] involved patients

[10] Glinos, I. A. and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union.* Brussels: Observatoire Social Européen, 2006, p. 18.
[11] See the discussion on Member States' prior authorization policies in Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, p. 84-85.
[12] The most relevant ECJ decisions are: Case C-120/95 *Decker* [1998] ECR I-1831; Case C-158/96 *Kohll* [1998] ECR I-1931; Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473; Case C-326/00 *Ioannidis* [2003] ECR I-1703; Case C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-4409; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-145/03 *Keller* [2005] ECR I-2529; Case C-372/04 *Watts [*2006] ECR I-4325; Case C-466/04 *Herrera* [2006] ECR I-5341; Case C-444/05 *Stamatelakis* [2007] ECR I-3185.

who challenged the national-level impediments to accessing cross-border care within the EU. These rulings have confronted Member States with the fact that they cannot shield their health systems from the effects of market integration. The ECJ judgments established the application of the EC Treaty provisions stipulating the freedom to provide services and free movement of goods to health care. In spite of Member States' opposition, the Court held and confirmed in the series of judgments that Regulation 1408/71 did not constitute an exclusive framework for access to health care in another Member State. As a result of the ECJ case law, insured persons have now a choice to rely on the directly effective primary law provisions of the EC Treaty stipulating the freedom to provide services and seek medical treatment in other EU countries outside of the co-ordination mechanism. By holding that health services are economic services within the meaning of the EC Treaty, the ECJ judgments extended the internal market rules to health care organization and delivery and turned access to health care into an EU law issue. Cross-border care has become a central topic in the discussion about the role of the EU in health care and the future of health systems in Europe[13].

Despite the limited number of patients crossing the border for health care and the (so far) marginal financial implications for social security systems[14], the ECJ decisions have raised a

[13] See also Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007.

[14] Studies have estimated the total spending on cross-border treatments at 0.1-0.2% of the total public spending on health care in the European Union. Busse, R. 'Border-Crossing Patients in the EU'. *Eurohealth* 8(4):19-21, 2002; Busse, R., Drews, M. and M. Wismar. 'Consumer Choice of Healthcare Services across Borders', in R. Brusse, M. Wismar and P.C. Berman (eds.) *The European Union and Health Services: The Impact of the Single European Market on Member States*. Biomedical and Health Research. Amsterdam: IOS Press, 2002. A 2001 German study revealed that the cost of cross-border outpatient services obtained by patients insured at a German sickness fund represented less than 0.5% of the fund's total expenses, although the sickness fund members travelled a lot to other countries. Techniker Krankenkasse. 'Medizinische Leistungen im Ausland. Erfahrungen und Erwartungen der TK Mitglieder', 2001, cited by Rosenmöller, M., McKee, M., Baeten, R. and I. A. Glinos. 'Patient Mobility: the Context and Issues', in Rosenmöller, M., McKee, M., and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization, 2006, p. 2. It should be noted that official statistics do not reflect the number of patients seeking cross-border care outside of any pre-arranged context. Since such patients often target non-contracted health care providers and cover the costs out-of-pocket, the magnitude of this type of patient mobility is still unexplored. See, for examples from Southern Europe, Albreht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria

lot of political turmoil within Europe. The rulings have been predicted to turn health care into a 'first Europe-wide testing-ground' in the competence-struggle between Member States and the EU[15]. Starting with the landmark *Kohll*[16] and *Decker*[17] cases, national governments have tried to stop the gradual extension of internal market rules to health care and keep this field within the power-safeguarding boundaries of exclusive national competence. Particularly, they have tried to limit the regulation of access to cross-border care to the framework established by the social security co-ordination mechanism (Regulations 1408/71 and 574/72)[18].

Extension of internal market rules to medical care has been continuing since *Kohll* and *Decker* despite the attempts of national governments to stop it. The influence of EU rules on health care regulation has increased on a case-by-case basis through ECJ judgments addressing individual and often atypical situations. The judgments have been preliminary rulings on specific questions referred to the ECJ by national courts requesting a binding interpretation of relevant EU law. As such, they presented a higher degree of abstractness and resulted in a number of open questions and uncertainties related to their application[19]. Since Member States cannot veto ECJ decisions like they can veto direct legislative action by the EU in social policy fields, they have not managed to stop the infiltration of health care

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and Italy'. In: *Patient Mobility in the European Union: Learning from Experience*. Copenhagen: World Health Organization, 2006, pp. 9-21.

[15] Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition. Oxford: Oxford University Press, 2000, pp. 267-292, on p. 283.

[16] C-158/96 *Kohll* [1998] ECR I-1931.

[17] C-120/95 *Decker* [1998] ECR I-1831.

[18] See, for example, the observations submitted by Member States in *Kohll, Decker* and *Geraets-Smits/Peerboms* cases.

[19] As discussed further in this paper, preliminary rulings pronounce the interpretation of EU law provisions whenever a doubt arises related to the compatibility of a national rule with EU law. The Court can only give a preliminary ruling if the question referred to it is related to the actual facts of the case, and it cannot rule on hypothetical issues. Nevertheless, the ECJ interpretations retain a certain degree of abstractness that can lead to uncertainties in further application of the rules established. See also Hatzopoulos, V. G. 'Do the Rules on Internal Market Affect National Health Care Systems?', in M. McKee, E. Mossialos and R. Baeten (eds.) *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E.-Peter Lang, 2002, pp. 123-160, on p. 156.

governance by internal market rules. Thus, the development of EU rules concerning access to medical treatment has not been constrained by the limited legal basis of Union action in this field. As a result, Member States have raised the issue of necessity and appropriateness of a legislative response at EU level in order to prevent that further case law extends internal market rules in health care at the detriment of nation states' regulatory authority[20].

Further to Member States' reluctance to implement the rulings and their repeated complaints about persisting legal uncertainties, the European Commission decided to codify the elements of relevant ECJ case law. Adopted by the Commission in July 2008, the proposed EC Directive on the application of patients' rights in cross-border care constitutes at present one of the most controversial health-related developments in Europe[21]. As declared by the European Commission, the goal of the proposed Directive is to establish a clear regulatory framework for safe, high quality and efficient cross-border care and to ensure the freedom to provide and receive health services and a high level of health protection in the EU. The Commission proposes to achieve this goal by shifting several competences pertaining to health care organization to the EU. As discussed further in the dissertation, a number of elements included in the proposed Directive represent a step towards positive integration (harmonization) in health care[22].

The ECJ case law illustrates how individual litigants, national courts referring questions for a preliminary ruling and the Court itself have become crucial actors in putting access to health care on the European agenda. As a consequence of a steady stream of court cases, health

[20] See the synopsis of the German EU Presidency preparatory meeting held in Bonn on November 23-24, 1998: Gobrecht, J. 'National Reactions to Kohll and Decker'. *Eurohealth* 5(1):16-17, 1999.
[21] European Commission. 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, Brussels, July 2, 2008.
[22] See Chapter 2 for an analysis of the proposed Directive. See also the analysis of Sauter, W. 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU.' Tilburg Law and Economics Center (TILEC): Discussion Paper No. 2008-034, 2008.

policy makers are at present confronted with controversial developments leading to an emerging scope of EU law in access to medical treatment.

2. Existing research on health care and the European Union

Available literature on health care and the EU can be grouped broadly into three categories. The first category includes studies that trace the developments in EU law that are relevant to access to health care. Some studies analyze the EU rules concerning cross-border care and propose to identify the implications for national health systems, individuals, health care providers and insurers[23]. Others focus on aspects such as consequences of harmonization of patients' rights[24] or assuring the quality and safety of medical services in the context of cross-border mobility of patients[25]. Commentators have voiced diverse opinions concerning the implications of the ECJ judgments for national health systems. For example, Kavanos regards the ECJ rulings as the possible beginning of a process that could ultimately lead to the creation of a European health policy[26]. Sieveking considers that the judgments represent the

[23] The ECJ rulings attracted a lot of attention and responses on behalf of academics and other commentators. Below is a selected list of studies: Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002; McKee, M., Mossialos, E. and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E. - Peter Lang, 2002; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004; Rich, R. R. and K. R. Merrick. 'Cross Border Health Care in the European Union: Challenges and Opportunities'. *The Journal of Contemporary Health Law and Policy* 23(1): 64-105, 2006; Lenaerts, K. and T. Hermans. 'Contours of a European Social Union in the Case Law of the European Court of Justice'. *European Constitutional Law Review* 2: 101-115, 2006; Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007; Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008. Further studies will be cited throughout the dissertation.

[24] Nys, H. 'Comparative Health Law and the Harmonization of Patients' Rights in Europe'. *European Journal of Health Law* 8, 2001; Nys, H. 'The Harmonization of Patient Rights in Europe and Its Consequences for the Accession Countries', in Den Exter, A. P. (ed.) *EU Accession and Its Consequences for Candidate Countries' Health Care Systems*. Rotterdam: Erasmus University Press, 2004, pp. 37-47.

[25] See, for research on the quality of care from the patient's perspective and from a functional perspective, Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008.

[26] Kavanos, P. 'Health as a Tradable Service: A Prospective View of the European Union'. *EuroHealth* 5(1):18-20, 1999.

breaking point for the nationally focused principle of territoriality in health care[27]. Koivusalo emphasizes the conflict between commercialization of medical services and equity in access to health care[28]. Hervey and McHale predict that the overall impact of the ECJ rulings on Member States' competence to organize their health systems will be limited[29].

The second category includes research zooming into specific country situations through case studies examining the contemporary developments in patient mobility across national borders. Such case studies propose to explore the extent of patient mobility between a number of countries under review, the pull and push factors of mobility, as well as potential implications for the Member States concerned. Research along this line looks in-depth at current situations and contemporary developments on the ground. The aim is to explore existing opportunities to benefit from the enhancement of patient mobility within the EU.

A noteworthy example is a collection of nine case studies on cross-border patient mobility that was put together within the framework of the 'Europe for Patients' project[30]. One of the outcomes of the case studies is a typology of patients crossing borders for health services. Glinos and Baeten[31] and Legido-Quigley et al. identified two main groups of 'mobile' patients[32]. The first group includes patients who are abroad when in need of health care. This

[27] Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007, p. 32.
[28] Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004; Baeten R. 'The Proposal for a Directive on Services in the Internal Market Applied to Healthcare Services'. Paper presented for the public hearing in the European Parliament. Brussels, November 11, 2004.
[29] Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 140.
[30] Launched in February 2004, the 'Europe for Patients' project brought together a multidisciplinary and international team of researchers in order to study the advantages and challenges of the enhancement of patient mobility in Europe. See, for the case studies, Rosenmöller, M., McKee, M. and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization, 2006.
[31] Glinos, I. A. and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union.* Brussels: Observatoire Social Européen, 2006, pp. 18-21.
[32] Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008, pp. 43-44.

includes people on a temporary stay abroad who need urgent care and people residing on longer term in Member States other than that of insurance (for work, professional development or retirement). The second category includes patients who travel abroad with the purpose of obtaining health care. This includes three sub-categories: people who obtain treatment abroad through the prior authorization mechanism (i.e., in a pre-authorized context), people seeking treatment abroad on their own initiative (outside of any pre-authorized context) and people living in the frontier regions who cross the border for health care. The types identified are not exhaustive or exclusive because several and interacting incentives can play a role in determining a patient to obtain health services in another Member State. However, the typology mentioned above is helpful for understanding the different needs, characteristics and expectations of patients obtaining health care outside of the country of insurance. It also helps in analyzing and comparing the different pull and push factors of cross-border patient mobility.

In a review and synthesis of existing research exploring the characteristics of cross-border patient mobility in the European Union, Glinos and Baeten identified a number of push factors that motivate patients to seek health care outside of the country of insurance[33]. The authors listed the following factors existing in the state of insurance: unavailability of the necessary treatment or long waiting time, high co-payments, perceived low quality of health services, legislation forbidding certain medical interventions (such as abortion or specific fertilization techniques) or the restriction of specific treatments to certain age groups[34]. The authors have also identified a number of pull factors attracting patients to a given country. These include geographic, linguistic and cultural proximity characterizing especially the border areas, as well as better quality of medical services, faster access and more favorable

[33] Glinos, I. A. and R. Baeten, 2006, note 31.
[34] See for example, the *Peerbooms* case involving special neuro-stimulation therapy restricted for persons younger than twenty five in the Netherlands. C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473.

price. A specific combination of these pull and push factors can be detected in each case study analyzed by the authors of the literature review.

The third research category includes studies that shift the focus to the European (supranational) level and examine the developments in health competence allocation between the EU and Member States. Towards this end, studies appeal to concepts and premises of theories of European integration and welfare state development. Concepts of intergovernmentalism have been applied to explain why health policy has not been initially transferred to the EU and remained within the competence of Member States.[35] Neo-functionalist concepts have been applied to explain how the EU has gained competence over health care-related policy aspects traditionally reserved for the authority of Member States[36]. Some studies link concepts of intergovernmentalism and neo-functionalism in order to address the topic of health care and the EU. For example, Weiler[37] contrasts European law as supranational due to the doctrines of direct effect, supremacy and state liability[38] and European policy making as predominantly intergovernmental and remaining within the competence of states. Within this framework, health care is located somewhere in between: while health care regulation is formally within the competence of Member States, supranational law has a considerable influence on it (even if the influence is often indirect). Some authors regard European integration as an exogenous source of pressures on national welfare states that together with endogenous pressures, weakens the monopolistic control of

[35] See, for the relevance of intergovernmentalism for analyzing competence allocation between the EU and Member States in health policy, Mossialos, E., M. McKee, W. Palm, B. Karl and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union, Brussels, 2001, pp. 20-22.
[36] Kostera, T. 'Europeanizing HealthCare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008; Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002.
[37] Weiler, J. A. 'Quiet Revolution: The European Court of Justice and Its Interlocutors'. *Comparative Political Studies* 26, 1994, pp. 51-534.
[38] See Chapter 2 for further discussion on the doctrines of direct effect, supremacy and state liability.

EU countries over their social boundaries. This has resulted in the loss of Member States' competence in social policy fields including health care and the emergence of a competence gap, because no corresponding authorities have been developed yet at EU level[39].

3. Relevance of EU law developments for CEE Member States

The literature on health care and the EU has so far rarely focused on new Member States of Central and Eastern Europe that joined the Union in 2004 and 2007. Available research on the consequences of EU law for nation states' health systems deals mostly with 'old' Member States[40]. (See, for example, Den Exter's analysis on the consequences of the ECJ rulings for the Dutch social health insurance system[41], Kostera's research on the implications of cross-border patient mobility for the German and Danish health care systems[42] and Sieveking's legal analysis on the implementation of the ECJ rulings in Germany[43]). A number of studies focusing mainly on old members included also a couple of new CEE members. For example, a 2007 research commissioned by the European Parliament explored the impact of the ECJ judgments on seven national systems for cross-border health care provision including also Poland and the Czech Republic[44]. The Czech Republic and Poland were also included in a

[39] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003; Ferrera, M. *The Boundaries of Welfare: European Integration and the New Spatial Politics of Social Protection*. Oxford: Oxford University Press, 2005.

[40] For the purposes of this paper, the term 'old Member States' refers to the fifteen countries that formed the EU before the 2004 enlargement. The term 'new Member States' refers to the countries that joined the EU in 2004 and 2007.

[41] Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008.

[42] Kostera, T., 'Europeanizing Healthcare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Healthcare Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008.

[43] Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007.

[44] The five old Member States included in the study were France, Germany, the United Kingdom, Spain and Sweden. European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.

2009 study estimating the volume and characteristics of cross-border care and patient mobility in eight European countries[45].

Besides the Czech Republic and Poland, a case study on Estonia[46] and one on Slovenia[47] proposed to explore the existing trends in patient mobility to and from these countries. These case studies did not focus on the regulatory framework. They involved field research exploring the current extent of patient mobility, its underlying pull and push factors and Estonian/Slovenian treatment providers' incentives to seek foreign patients. The studies concluded that EU accession was likely to increase the number of patients crossing the border for health care as it created a more favorable setting for cross-border co-operation. Especially in case of Slovenia an increasing potential for mobility has been detected due to a number of incentives that might be attractive for patients from Western Europe. Examples include lower prices for certain hospital interventions, existence of small, flexible private practices offering good quality, cheaper and faster services, as well as medical treatment and rehabilitation in spas. These pull factors, combined with push factors existing in the neighboring EU countries (notably, increasing co-payments in Austria and Italy) were expected to increase the movement of foreign patients towards Slovenia. Spa tourism has also been detected in case of Estonia as a pull factor. The Estonian case study found that 70 percent of spa patients were coming to the country from aborad, mainly from Sweden, Finland, Germany and Russia. Foreign patients also come to Estonia for dental care and aesthetic surgery.

[45] The six old Member States included in the research were Belgium, France, Ireland, the Netherlands, Spain and the United Kingdom. Vallejo, P., Sunol, R., Van Beek, B., Lombarts, M.J.M.H., Nruneau, C. and F. Vlcek. 'Volume and Diagnosis: An Approach to Cross-Border Care in Eight European Countries'. *Qual Saf Health Care* 2009, 18(Suppl l):i8-i14.

[46] Jesse, M. and R. Kruuda. 'Cross-border Care in the North: Estonia, Finland and Latvia', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006, pp. 23-37.

[47] Albreht, T., Pribakovic Brinovec, R., and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006, pp. 9-21.

There is very little research focusing specifically on questions pertaining to health care and enlargement. One notable study was carried out by Österle on access to health care in the neighboring regions of Austria, the Czech Republic, Slovakia, Hungary and Slovenia. The study discusses perspectives for cross-border health care activities in the region following the 2004 enlargement. It highlights the new opportunities brought about by EU accession for accessing health care across these borders. The research concludes that treatment across CEE borders not planned before travelling, as well as planned treatment outside of pre-authorized contexts is growing. However, the extent of pre-authorized and pre-arranged cross-border care remains limited.

The few available studies suggest that specific opportunities and challenges brought about by EU enlargement for the health systems of new CEE members are increasingly recognized but largely unexplored[48]. Health care systems in CEE countries have generally gone through a development process that is different from the path followed by old members. New CEE members inherited a centralized health system from the state socialist years, and have been struggling since with challenges in moving towards a more decentralized and cost-efficient system. These countries have gone through major economic and social transformations such as the transition from state socialist to market economy and then the transformation from EU membership candidate status to EU membership. Throughout this process, CEE health systems have been struggling with the legacies of the state socialist years such as outdated management systems, persistent informal payments[49] and inefficient management of

[48] See the discussions on the implications of Eastern enlargement for new members' health care systems, included in McKee, M., MacLehose, L. and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004.

[49] As discussed further in Chapter 4, informal payments are unofficial out-of-pocket payments for health services and goods that should be provided free of charge at the point of delivery. Informal charges are sometimes called 'gratitude payments' (*parasolventia*), although the meaning of the term is broader because it encompasses the idea of unofficial fees paid by patients to secure better and faster treatment.

resources available for health care[50]. Although resource allocation in health care is a sensitive issue in most EU countries, this challenge has become even more severe in case of new CEE members in the context of limited resources and decreasing expenditures[51].

Thus, the double burden faced at present by all Member States, i.e., catching up with EU requirements that are themselves evolving and safeguarding at the same time social solidarity in health care, becomes particularly challenging for new members of CEE. Following accession, new members have been confronted with the fact that health care organization and financing is no longer a matter reserved exclusively for national competence. Upon accession, EU law – including the ECJ case law on cross-border care and the EC social security co-ordination mechanism – became applicable. Consequently, new members are required to ensure the legal and practical conditions for access to cross-border care. It is thus important to explore how the enhancement of cross-border care in the EU affects the new CEE members, given their different background, legacies and complex challenges.

4. Contribution of the dissertation

The dissertation brings together in the context of EU enlargement the three research focal points mentioned above. First, it locates the topic of cross-border health care in the context of theories on European integration and welfare state development. Further on, it applies instruments of legal analysis in order to examine how Member States' competence to regulate access to health care has become affected through legislation adopted at EU level and litigations based on the directly effective free movement provisions of the EC Treaty. Afterwards, it shifts the analysis from the European level to the level of countries in order to

[50] See Chapter 4 for further discussion.
[51] Chapter 4 will show that new members of CEE spend significantly less on health care as a share of their national GDP than old members, and health care expenditures have decreased in these countries during the nineties. See section 2.1. of Chapter 4 for comparative data.

examine how health care systems of nation states have been affected through these EU law developments. Towards this end, it includes a comparative analysis focusing on two new Member States of Central and Eastern Europe: Hungary and Slovenia. Examples from other, old and new Member States are used for comparison.

Chapter 1 identifies analytical tools provided by theories on European integration and welfare state development that are suitable for anchoring the discussion around the emergence of an EU role in health care. The analysis is centered on the premise of a competency gap in social policy governance. According to this premise, Member States' authority and *de facto* regulatory ability in the field of social policy have been gradually limited through constraints imposed by a series of exogenous and endogenous pressures[52]. As a result, a competency gap has emerged since no adequate regulatory competence has been formalized yet at EU level. The neo-functionalist premise of spill-over is used for analyzing the extension of EU law over health care as a side-effect of internal market creation. The intergovernmentalist premise of prevalence of national self-interest and the theories on welfare state development are applied to explain why health care is safeguarded by Member States as a core competence of national social policy regimes and shielded from the Union. In addition, Chapter 1 relies on Ferrera's theoretical framework linking together exogenous and endogenous pressures on contemporary welfare states in order to explain the competence loss of Member States in health care regulation.

Applying instruments of legal analysis, Chapters 2 and 3 examine access to cross-border care in the light of the European social security co-ordination mechanism and the ECJ case law

[52] See also Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, pp. 267 – 292, 2000; Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003; Ferrera, M. *The Boundaries of Welfare: European Integration and the New Spatial Politics of Social Protection*. Oxford: Oxford University Press, 2005.

extending internal market rules over health care. The legal analysis traces the consequences of the application of the freedom to provide and receive services to health care. It highlights that the ECJ rulings have initiated the emergence of a transnational aspect of health care policy making based on a legal background developed through a series of court cases addressing individual situations. Chapter 3 shows that the ECJ rulings and Member States' subsequent reactions have resulted in the adoption of the proposed European Directive on the application of patients' rights in cross-border care which includes a number of elements that constitute a step towards positive integration (harmonization) in health care.

Chapter 4 provides a comparative analysis of regulation of cross-border care in two CEE countries, Hungary and Slovenia. The two countries have been selected as first-wave new CEE members who had to incorporate European legal standards (including the ECJ case law on cross-border care) that became applicable upon accession. Preconditions for cross-border mobility of patients and establishment of cross-border co-operation initiatives in health care have existed both in Slovenia and in Hungary. Geographic opportunities (including multitude of borders with current EU Member States) have been present for the development of cross-border/transnational co-operation promoting the mobility of persons, services and goods. Both countries have a shared history with several neighboring Member States, to which they have been linked economically and politically at different times. Both have pre-accession experiences with cross-border co-operation in social security and health care provision, gained during the implementation of bilateral agreements concluded with neighboring countries.

Besides the mobility realized within the framework of bilateral social security agreements, individually-driven patient mobility taking place outside of a pre-authorized context existed

across Hungarian and Slovenian borders also before accession. Both the grey literature and official statistics reported cases of foreign patients travelling to these two countries for health services as a result of perceived advantages such as lower price, better quality, or faster access[53]. Although these cases were poorly documented and evidence was largely anecdotal, they suggested that cross-border patient movement for health care was already present upon EU accession, when the conditions for mobility of persons, services and goods got improved. Chapter 4 discusses existing evidence on the mobility of foreign patients to Hungary for dental treatment, gynecology, internal medicine, elective surgeries and rehabilitation in spas. It also discusses studies showing that Slovenia was active in exploring the possibilities to attract patients from the neighboring states already before EU membership[54]. Studies focusing on the years preceding EU accession reported treatment of patients from Italy and Austria in Slovenian health facilities offering spa and rehabilitation services, gynaecology and urology, dentistry, plastic surgery, vascular and orthopaedic surgery. In addition, it was predicted that Slovenian patients would opt in significant numbers for a broader choice of specialist care providers - even if they had to travel abroad for that – if there was more information available and the treatment obtained abroad was reimbursed[55].

Chapter 4 compares the organizational structure and relevant characteristics of the Hungarian and Slovenian health systems, with specific focus on health insurance and social coverage of health care. Afterwards, it addresses the institutional and legal framework for cross-border care. The analysis compares the extent to which relevant EU law has been transposed into

[53] See Section 4.5 of Chapter 4 for a discussion of individually-driven patient mobility across Hungarian and Slovenian borders.
[54] Albreht, T. 'Opportunities and Challenges in the Provision of Cross Border Care. View from Slovenia'. *Eurohealth* 8(4), 2002; Albrecht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. And E. Turk. *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria, 2005, p. 7.
[55] Albreht, T. 'Accession to the EU – Patient Mobility, a Challenge in the Process'. Paper presented at the conference Health Care and Mobility in an Enlarged Europe. Ljubljana, November 7, 2003.

domestic law and pinpoints the differences between the content and scope of European legislation and the rules adopted and implemented at national level. Further on, it looks at current characteristics of patient mobility across the borders of these countries. The analysis focuses on identifying the implications of the extension of internal market rules to health care with particular attention paid to access to treatment. Several possible scenarios will be identified and discussed. The comparative analysis follows the typology of patients obtaining cross-border care, suggested by Glinos and Baeten and Legido-Quigley et al[56]: it distinguishes between patients who are in need of care during a temporary stay in/ visit to another Member State and patients who travel to another EU country with the specific purpose to receive medical treatment.

The dissertation shows that the central issue in cross-border care is the clash between Member States' efforts to safeguard health care as a national social policy competence unaffected by market integration and efforts of the EU to promote free movement and the internal market. The research highlights the gradual infiltration of social policy fields traditionally reserved for Member States by EU law. It argues that recent EU law developments have rendered untenable the view that health care could be kept unaffected by the process of European integration. It points out the competency loss of nation states in health care governance and current efforts of the European Union to fill in the gap by codifying the ECJ decisions into an EC Directive.

The legal developments of the last ten years illustrate that the role of the EU in health care is increasing. This is relevant not so much from the mainstream cases generated by the application of formal rules but rather from the emerging exceptions. EU law and especially

[56] See notes 31 and 32.

the case law of the ECJ have proved to exercise an - often indirect - influence on organization, delivery and financing of health care at national level. The dissertation intends to contribute to the discussion on the consequences of the extension of internal market rules to health care for national health systems. Focusing on new Member States of CEE, the research intends to fill in a gap and inform the debate on patient mobility in an enlarged Europe from the perspective of the new members.

Chapter 1: Health care and the EU: theoretical concepts

The growing influence of EU law in access to health care has become in the last decade a source of controversies. Although organization, delivery and financing of health services have been traditionally regarded as areas left for the responsibility of national governments, European integration has gradually removed this field from exclusive national competence. The views conceptualizing health care as a matter preserved solely for Member States and kept unaffected by the EU have been challenged and rendered untenable[57]. As a result of a systematic pro-market bias and an unsystematic, law and court-driven policy development, access to health care has become an issue on the European agenda[58].

The goal of this chapter is to identify analytical tools that are suitable for examining and explaining whether and how an EU role in health care has been emerging. Towards this end, it makes recourse to theories on European integration and welfare state development in order to indentify relevant concepts that are suitable tools for anchoring and analyzing the actual political and academic debates. The analysis will be centered on the concept of an emerging competency gap in health care regulation in the European Union.

1. An emerging competency gap in health care regulation

Developments in competence allocation between the EU and Member States in the field of health care have been discussed in the context of a contemporary competency gap in social policy regulation. According to this premise, Member States' legal authority and *de facto*

[57] See also Legido-Quigley, H., Glinos, I., Baeten, R. and M. McKee. 'Patient Mobility in the European Union'. *BMJ* 334:188-190, 2007.

[58] Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, pp. 267 – 292. See also Vandenbroucke, F. 'The EU and Social Protection: What Should the European Convention Propose?'. Paper presented at the Max Planck Institute for the Study of Science, Köln, 2002.

regulatory ability in social policy have been increasingly limited as a result of pressures on national welfare states[59]. Following this process, a competency gap has emerged as no adequate regulatory competence has been formalized yet at EU level. This competency gap is particularly relevant to health care regulation which constitutes a core element of national social policy systems of European states.

Discussions around the competency gap in the realm of social policy in general and health care in particular are embedded in the wider debate on the contemporary crisis of European welfare states[60]. This crisis manifests itself in a diminishing legal authority and regulatory ability of nation states and their failure to maintain control over social policy fields. States are increasingly constrained by diverse pressures caused by direct European interference, market dynamics and societal changes such as population aging. Although the discussion generally starts from the commonly agreed premise that a contemporary crisis exists and results in a competency loss of European nation states in the realm of social policy, views divide on the origins and sources of the crisis.

Identifying the sources of the contemporary crisis of European welfare states constitutes a cherished ambition of scholars. Political scientists, lawyers, economists and sociologists have approached the topic from different angles. One can distinguish two basic lines of reasoning. The first approach talks about *exogenous sources of crisis* and examines factors originating in developments that are beyond Member States. European integration constitutes one of the

[59] Ibid. See also Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003.
[60] Hemerijck, A. 'The Self-Transformation of the European Social Model(s)', in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002, pp. 173-213; Esping-Andersen, G. Towards the Good Society, Once Again?, in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002, pp. 1-25, on pages 4-5.

most often cited factors of external origin[61] and globalization is the other one[62]. European integration imposes on Member States the obligation to apply directly the European social security co-ordination rules and adjust their social policy systems to EU law including internal market rules[63]. Also, the EU requires states to meet the requirements for budgetary discipline, bureaucratic rationalization, as well as containment of non-wage labor costs and enhanced competition within the internal market. Although Member States have been trying to keep the realm of social policy unaffected by these requirements, this has become impossible.

European integration theories address the impact of the integration process on the regulatory competences of Member States. For example, the spill-over premise of neo-functionalism talks about a shift of competence to European institutions in regulatory areas traditionally reserved for Member States[64]. Commentators focusing on exogenous sources of crisis emphasize that economic integration has reduced the ability of Member States to influence their own economies and achieve their socio-political goals. As formulated by Scharpf, '*compared to the repertoire of policy choices that was available two-three decades ago, European legal constraints have greatly reduced the capacity of national governments to*

[61] Ibid.
[62] The well-known statement of the globalization scenario says that global developments originating in a rapidly changing world economy decrease the ability of national governments to control their own affairs and undermine national autonomy and regulatory capacity. See for a discussion on the role of globalization in undermining the autonomy of nation states, Habermas, J. 'The Postnational Constellation and the Future of Democracy', in J. Habermas (ed.) *The Postnational Constellation: Political Essays*. Cambridge Mass: Polity Press, 2001, pp. 58-112.
[63] Chapter 3 will discuss the process and implications of extending internal market rules to health care.
[64] The spill-over premise is a basic tenet of the neo-functionalist perspective together with the idea to conceptualize European integration a self-sustaining dynamic. These two premises will be discussed further at Section 2.1. of Chapter 1. See also Haas, E. B. *The Uniting of Europe: Political, Social and Economic Forces 1950-1957*, 2nd edition. Stanford: Stanford University Press, 1958.

influence growth and employment in the economies for whose performance they are politically accountable'[65].

The second approach talks about *endogenous sources of crisis*. This approach examines factors that originate *within* the organization and functioning of national welfare states of Europe. Towards this end, commentators focus on the post-industrial changes occurring within advanced industrial democracies[66]. Recent changes in internal political, economic, demographic and household conditions are in the center of analysis. The main argument is that multiple transitions occurring within the welfare states of affluent democracies constitute the real source of the contemporary crisis. According to this view, the ambitious welfare programs introduced since the mid-twenty century *'golden age'* of social development have reached their own limits due to extensive coverage and generous commitments. This maturation process resulted in heavy budgetary and institutional strains[67]. Studies emphasizing a crisis of endogenous origin claim that the process of integration and the changing context of international political economy are essentially unrelated to the multiple transitions leading to a competency loss in welfare states of affluent democracies[68]. The following part of this chapter will consider each of these two approaches in order to discuss their relevance for examining the premise of a competence loss of national states in health care regulation and the emergence of an EU role in this field.

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[65] Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4):645-670, 2002, on p. 648.
[66] See, for example, Pierson, P. 'Post-industrial Pressures on the Mature Welfare States', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001. See also Flora, P. (ed.) *Growth to Limits. The West European Welfare States since World War II.* Berlin/New York: De Gruyter, 1986.
[67] Ferrera, M., Hemerijck, A. and M. Rhodes. *The Future of Social Europe*. Oeiras: Celta Editora, 2000.
[68] See, for example, Pierson, P. 'Post-industrial Pressures on the Mature Welfare States', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001.

2. Exogenous sources of competence crisis: relevance of European integration theories

European integration is one of the most often mentioned sources of contemporary crisis of European welfare states[69]. As summarized by Leibfried and Pierson, '*the process of European integration has eroded both the sovereignty (i.e., legal authority) and autonomy (i.e., de facto regulatory capacity) of member states in the realm of social policy*'. Leibfried compares this process to the erosion of welfare regimes in the USA with the development of the American interstate commerce[70].

The following section will consider some basic constructs of European integration theories as potential analytical tools for examining the competency loss of Member States in health care regulation and the emerging role of the EU in this field. The analysis will distinguish between two macro theories of European integration based on whether they consider supranational or intergovernmental factors and actors as main determinants of integration.

2.1. Shift of competence to supranational actors: neo-functionalist concepts

A widely used integration theory until the end of the 1970s, neo-functionalism is rooted in the functionalist approach regarding the European Union as a functional organization aiming at most efficient achievement of collective goals[71]. Neo-functionalism regards European integration as a process of shifting political activities to the supranational level. As Ernst B. Haas, the prominent scholar of this theoretical approach formulated it, '*political integration is the process whereby political actors in several distinct national settings are persuaded to shift their loyalties, expectations and political activities to a new centre, whose institutions*

[69] As mentioned before, another commonly mentioned factor of external origin is globalization.

[70] Leibfried, S. 'Towards a European Welfare State? On Integrating Poverty Regimes into the European Community', in Z. Ferge and J. E. Kolberg (eds.) *Social Policy in a Changing Europe.* Frankfurt/Main and Bouldcr, Colo.: Campus and Westview, 1992, p. 251.

[71] See also Eriksen, E. O. 'The Question of Deliberative Supranationalism in the EU'. *ARENA Working Papers* WP 99/4, Oslo: University of Oslo, 1999. Available at www.arena.uio.no/publications/wp99_4.htm#Title%20note%20#2 (Last accessed on April 3, 2009).

possess or demand jurisdictions over pre-existing national states. The end result is a new political community, superimposed over the existing ones'[72]. Neo-functionalism focuses on political processes, actors and their interactions at the supranational (European) level. It regards the EU as a new and distinct political community imposed over Member States. Following a decline started after 1970, a revival of neo-functionalism occurred during the 1990s as a result of growing integration following the Single European Act[73].

A dominant theoretical construct of neo-functionalism is the concept of *spill-over* effect as a leading dynamic in driving the integration process[74]. The spill-over premise conceptualizes the process through which EU authority over one particular policy field emerges and evolves as a result of policy developments and pressures existing in other fields. Neo-functionalist views emphasize that effective conflict management between different interests of economic and political actors leads to spill-over, defined as a constant demand for more integration to satisfy further interests. Integration occurs when supranational institutions efficiently manage the conflicts between economic and political elites[75]. The existence of such supranational activity unleashes a self-reinforcing dynamic that leads to further and deeper integration[76]. Consequently, supranational actors play an important role in moving forward European integration. Satisfaction of political interests in one field necessarily influences the development of policies in other fields and leads to more integration as a self-sustaining

[72] Haas, E. B. *The Uniting of Europe: Political, Social and Economic Forces 1950-1957*, 2nd edition. Stanford: Stanford University Press, 1968, p. 16.
[73] On the contemporary relevance of neo-functionalism for analyzing the emerging role of the EU in health care see also Kostera, T. 'Europeanizing HealthCare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008.
[74] McGowan, Lee. 'Theorizing European Integration: Revisiting Neo-functionalism and Testing Its Suitability for Explaining the Development of EC Competition Policy'. *European Integration online Papers* 11(3), 2007, p. 6.
[75] See also Mossialos, E. and McKee, M. *EU Law and the Social Character of Health Care*. Brussels: P.I.E. – Peter Lang, 2002, pp. 45-47.
[76] McGowan, Lee. 'Theorizing European Integration: Revisiting Neo-functionalism and Testing Its Suitability for Explaining the Development of EC Competition Policy'. *European Integration online Papers* 11(3), 2007, p. 6.

dynamic[77]. The idea of a self-sustaining and expansive integration constitutes one of the most influential theoretical constructs of this approach and a focal point in theoretical debates[78].

Neo-functionalism applies the spill-over premise in order to highlight that certain European institutions have become supranational stakeholders pursuing interests that are sometimes independent of or even contradictory to the interests of national governments. According to this view, certain EU institutions have gradually become actors with new roles on the arena of European integration. At present, they can and *do* influence the integration process on their own accord.

Burley and Mattli[79]'s view on the role of the ECJ in European policy making provides a good example for this approach. The two authors analyze the ECJ jurisprudence in order to illustrate that preferences of European-level actors have an important influence on policy decisions taken by national governments. They center their argument on the procedure of preliminary reference (or preliminary rulings) in EU law.

Established by Article 234 of the EU Treaty, the procedure of preliminary reference entrusts the ECJ with the exclusive competence to pronounce an authoritative interpretation of EU law if a related question is referred to it by parties in a case brought before a national court. National judges may and in some cases, shall refer questions to the ECJ before the final judgment is delivered at national level[80]. Preliminary rulings delivered by the ECJ have

[77] The idea of an expansive integration process is relevant from the work of E. B. Haas. See Haas, E. B. *The Uniting of Europe: Political, Social and Economic Forces 1950-1957*, 2nd edition. Stanford: Stanford University Press, 1968, pp. 283-317.
[78] See, for example, Garrett, G. 'International Cooperation and Institutional Choice: The European Community's Market'. *International Organization* 46(2):533-560, 1992.
[79] Burley, A. M. and W. Mattli. 'Europe before the Court: A Political Theory of Legal Integration'. *International Organization* 47(1): 41-76, 1993.
[80] According to Article 234 of the EC Treaty, domestic courts and tribunals against whose decision there is no judicial remedy and who are confronted with questions related to the interpretation or the validity of EU law

binding effect on the parties at the given case and also on all other courts within the EU confronted with a similar issue[81]. As an outcome, the ECJ is able to promote a uniform interpretation of EU law across national legal systems[82]. Preliminary rulings constitute the largest share of the ECJ's caseload and represent the means by which the ECJ established some basic doctrines in EU law such as direct effect[83]. Chapter 3 will show that the preliminary rulings delivered by the ECJ have produced important systemic results in the field of access to health care through an ongoing legal conversation with national courts[84].

Burley and Mattli claim that the procedure of preliminary reference functions as a gate allowing the policy choices of the European Commission and the ECJ to enter domestic legal systems[85]. The relevance of this argument is recognized also by Scharpf[86]. Scharpf notes that, once the policy preferences of European supranational actors get incorporated into national law via the system of preliminary reference, these choices become safeguarded by the relative autonomy of the domestic legal system. Scharpf's analysis demonstrates that the procedure of preliminary rulings has become an important factor enabling the choices and intentions of supranational actors to influence policy outcomes in the European Union[87]. As shown in

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shall ask the ECJ for preliminary ruling. Not respecting this obligation can trigger the infringement procedure established in Article 226 of the EC Treaty.

[81] See also Streho, I. 'Regional Organizations' Judicial Systems Compared: Is the European Model Transposable and Should It Be?'. *Review of Asian and Pacific Studies* 27, 2004.

[82] See also Den Exter, A. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008.

[83] Chapter 2 will discuss further the doctrine of direct effect. See also Streho, I. 'Regional Organizations' Judicial Systems Compared: Is the European Model Transposable and Should It Be?'. *Review of Asian and Pacific Studies* 27, 2004.

[84] See also Weiler, J. H. H. 'Epilogue: The Judicial Aprés Nice', in G. De Burca and J. H. H. Weiler (eds.). *The European Court of Justice*. Oxford: Oxford University Press, 2001, pp. 215-226, on p. 215.

[85] Burley, A. M., and W. Mattli. 'Europe before the Court: A Political Theory of Legal Integration'. *International Organization* 47(1): 41-76, 1993.

[86] Scharpf, F. W. *Governing in Europe: Effective and Democratic*? European University Institute, 1999, pp. 65-66.

[87] However, Scharpf doubts that the *Cassis* case, chosen by Burley and Mattli as the most illustrative example for supporting the supranationalist argument, is indeed the best option for this purpose. His critical notes put forward the idea that the *Cassis* case reveals nothing more than governments' objection to the application of a rule. This single fact does not prove that governments would also object to the rule itself. Scharpf argues instead that the formulation of rules is generally left largely for the competence of national governments, and the

Chapter 3, regulation of access to health care is a field illustrating these views particularly well. The cases on access to health care in cross-border settings, referred to the ECJ via the system of preliminary rulings have established an alternative way of obtaining health services and goods in other Member States. This alternative way, called the *Kohll and Decker procedure* after the two landmark rulings delivered by the ECJ in 2008, is based on the directly effective primary law provisions of the EC Treaty establishing the freedom to provide services. The Kohll and Decker procedure runs parallel to the cross-border care rules established by the social security co-ordination Regulations (1408/71 and 572/72)[88]. Due to the fact that it is based on the primary law provisions of the EC Treaty, the Kohll and Decker procedure represents an alternative that is distinct from the co-ordination framework and is not affected by amendments of Regulations 1408/71 and 574/72. In order to enhance legal certainty and fill in the gaps in the legal framework, the European Commission proposed a Directive codifying the Kohll and Decker procedure, despite Member States efforts to keep the issue of cross-border care within the framework of the co-ordination regulations. The proposed European Directive on the application of patient's rights in cross-border care represents an illustrative example of the spill-over effect[89].

The ECJ rulings extending internal market rules to medical care support the idea that the Court has become in the last two decades an important center of health policy making[90]. As an arbiter over matters pertaining to the internal market, the ECJ was originally concerned with the elimination of national barriers to the free movement of goods and freedom to

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fascinating feature of negative integration lays exactly in the fact that it has been expanded via judicial processes under institutional conditions that were safeguarding national control over the legislative process. Scharpf, F. W, *Governing in Europe: Effective and Democratic*? European University Institute, 1999, p. 65.

[88] Chapters 2 and 3 include a comparative analysis of the *Kohll and Decker procedure* and the currently co-existing framework established by the social security co-ordination mechanism (Regulation 1408/71).

[89] European Commission. 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 of 2 July 2008. Brussels: Commission of the European Communities, 2008. See Chapters 2 and 3 for further discussion.

[90] See also Begg, I. and J. Berghman. 'Introduction: EU Social (Exclusion) Policy Revisited?'. *Journal of European Social Policy* 12(3):179-194, 2002, p. 189.

provide services (negative integration).[91] However, its activity has increasingly involved actions pertaining to positive integration, such as filling in the gaps emerging with respect to the application of the Single European Act. The ECJ rulings linked to social security issues are particularly illustrative. Cases pertaining to the field of social security represent a growing share of the increasing caseload of the Court[92]. The decisions have often had an indirect impact on health care delivery, financing and organization at national level and resulted in changes in domestic regulations. Changes include amendments to national legal norms and also the introduction of new legislation in the absence of previously existing rules. See, for example, the new reimbursement rules introduced for cross-border outpatient care in Sweden, France, Germany, Hungary and the Czech Republic following the ECJ case law[93].

The institutional characteristics of the ECJ are important prerequisites for the emergence of the Court's activism in the field of health care. As demonstrated by Leibfried and Pierson[94], the functioning of the ECJ enjoys more flexibility compared to the Council of Ministers. Increased flexibility is a result of factors like secret ballot and simple majority voting that safeguard the ECJ from the political immobility characterizing the regular EU policy making institutions[95]. As a result, the details of the integration process have been moved from the

[91] I am using here the distinction between negative and positive integration in order to discuss the role of the ECJ in health policy. The original role of the ECJ as a supranational entity was to promote integration by eliminating barriers to free movement within the internal market. However, recent rulings show that the Court has been successful in generating positive integration involving active harmonization of national legislation (a process normally going through the Council of Ministers, at intergovernmental level). See, for the distinction between negative and positive integration, Scharpf, W. F., 'Negative and Positive Integration in the Political Economy of European Welfare States', in Marks, G., Scharpf, F., Schmitter, P. and W. Streek (eds.) *Governance in the European Union*. London: SAGE Publications, 1996.

[92] See on the changing role of the EU in social policy, Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4):645-670, 2002. See also Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, p. 276.

[93] European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.

[94] Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, p. 276.

[95] Ibid.

highly visible political arena (where it is difficult to reach consensus) to the judicial arena where solutions are reached by an impartial body that is less open to public scrutiny[96]. The ECJ-driven legal developments are not constrained by the limited legal basis of EU action in health care. Member States cannot veto ECJ decisions like they can veto direct legislative action by the EU in social policy fields. All these created the conditions that were necessary and sufficient for the ECJ to become an important center of social policy making. The fact that the ECJ plays such a role is particularly visible in the field of health care. Actors like national courts, social security lawyers and individual litigants have recognized the opportunities provided by the advantages of the institutional setting of the Court and brought before the ECJ a series of cases on access to cross-border health care. The rulings resulted in the establishment of a right of patients in the EU to access cross-border health care based on the directly effective EC Treaty provision of Article 49 (freedom to provide services).

Neo-functionalism is a theoretical construct that is suitable for examining the consequences of European integration for health care. The spill-over premise is a useful tool for explaining the emergence of a governance gap in health care regulation as a side-effect of internal market creation. Implementation of internal market rules has also affected health care organization and delivery despite the efforts of Member States to shield these regulatory fields from the Union. The freedom to provide services and free movement of goods has been extended over health care. As a consequence, Member States have to comply with EU law when exercising their regulatory power in this field. Access to health care has become an EU law topic through the phenomenon of cross-border care.

[96] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 43.

The neo-functionalist constructs of self-sustaining integration and spill-over effect have attracted a lot of criticism on behalf of competing integration theories. The following section will address the counter-arguments brought about by intergovernmentalism as a major challenger.

2.2. Persistence of national control: intergovernmentalist concepts

As an opponent of neo-functionalism, intergovernmentalism puts forward the view that integration cannot succeed without the support and consent of Member States. This approach contests the neo-functionalist arguments of general competence-shift to European actors. It claims that Member States retain a considerable degree of autonomy in policy decisions of increased national importance and the political powers of the EU depend on the decisions of Member States. Associated with the work of Stanley Hoffmann[97], intergovernmentalism links the direction and pace of the integration process to decisions and actions taken by national governments and regards Member States as the main actors on the European political arena. Within the intergovernmentalist framework national governments are viewed as the predominant actors in international relations in general and in the process of European integration in particular. The intergovernmentalist approach criticizes the neo-functionalist emphasis on supranational actors who exercise their powers on their own accord. It claims that Member States prevail over EU institutions in the process of integration and focuses on the policy decisions of states[98].

[97] See, for the basic framework of intergovernmentalism, Hoffmann, S. *Obstinate or Obsolete? The Fate of the Nation State and the Case of Western Europe*. Daedalus, 1966.
[98] See also Mossialos, E., M. McKee, W. Palm, B. Karl and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union, Brussels 19 November 2001, p. 21.

Theoretical constructs of intergovernmentalism are worth to be examined as potential tools for analyzing recent developments in competence allocation between Member States and the EU in health care. The premise of prevalence of national interest can be suitable for explaining why social security and health care have not been originally submitted to Community authority.

While not pushing aside completely the neo-functionalist concept of spill-over, the intergovernmentalist approach questions its unavoidable character and self-sustaining dynamic. In this perspective, spill-over is conceptualized as a process that is tolerated by national governments for as long as it suits their purposes. However, states can stop the spill-over process whenever they decide to do so. The intergovernmentalist approach distinguishes between 'high' politics including security, defense and foreign policy, and 'low' politics including economic issues. This dichotomy provides a framework for criticizing the neo-functionalist concept of self-sustaining integration[99]. The basic idea is that intergovernmental co-operation and spill-over are more likely to happen in matters pertaining to 'low' politics. Member States tolerate the spill-over process when they consider that intergovernmental co-operation improves their own position in international competition. Member States are open to admit that matters like internal market development are better regulated on their behalf by the EU. At the same time, national governments oppose any attempts to encourage spill-over in 'high' sectors.[100] Delegating regulatory powers to the Community in areas of 'low' politics does not necessarily result in extension of integration to 'high' sectors.

[99] See for details, Hoffman, S. *Obstinate or Obsolete? The Fate of the Nation State and the Case of Western Europe*. Daedalus, 1966, pp. 892-908.

[100] Promoted, for example, by Moravcsik. See, for details, Moravcsik, A. 'Liberal Intergovernmentalism and Integration: A Rejoinder'. *Journal of Common Market Studies* 33(4):611-628, 1995; See also Garrett, G. 'International Cooperation and Institutional Choice: The European Community's Internal Market'. *International Organization* 46:533-560, 1992.

According to this view, the main motivation of Member States to delegate certain powers to the Community is a result of a combination of specific external factors (such as pressures resulting from the process of globalization or environmental problems) and internal circumstances. In other words, States are willing to support the extension of the integration process to new fields out of reasons linked to national self-interest and for consolidating their own position. A supporter of the intergovernmentalist approach, Moravcsik[101] conceptualizes national decision making and international co-operation as two interdependent processes. He pushes aside arguments emphasizing the incapacity of national governments to control the development of legal and policy issues in the EU and their inability to prevent undesirable outcomes. In his opinion, it would be much more adequate to talk about the unwillingness of Member States to undertake responsibility for certain unpopular decisions and their tendency to delegate these difficult and controversial issues to the European Commission and the ECJ[102]. These ideas are reflected also in Rosamond and Hay's analysis of the highly strategic appeal to European integration in contemporary political discourse in EU Member States[103]. The two authors show how public policymakers appeal in their rhetoric to supranational processes when trying to legitimize potentially unpopular social and economic reforms. Their analysis distinguishes well-defined factors that predispose domestic political actors to invoke either European integration or globalization as the main justification of unpleasant reforms for which governments do not want to take direct responsibility[104].

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[101] Moravcsik, A. 'Liberal Intergovernmentalism and Integration: A Rejoinder'. *Journal of Common Market Studies* 33(4): 611-628, 1995.

[102] Moravcsik, A. 'Preferences and Power in the European Community: A Liberal Intergovernmentalist Approach'. *Journal of Common Market Studies* 31:473-524, 1993.

[103] Hay, C. and B. Rosamond. 'Globalization, European Integration and the Discoursive Construction of Economic Imperatives'. *Journal of European Public Policy* 9(2):147-167, 2002.

[104] According to this analysis, there are a series of factors that predispose policy makers to appeal to European integration as the goal to be promoted at the price of painful but necessary reforms. Such factors include: (1) existence of a history of European involvement (institutional and cultural) and a well-established pro-European integration agenda that is widely shared at domestic level; (2) possibility for governments to credibly claim to be able to influence the process of European integration (for example, in France or Germany); (3) existence of negative associations and connotations linked to the concept of globalization (like in France); (4) possibility to identify specific outcomes of integration that can be constructed as an issue of national pride (for example, in

It is the intention of this dissertation to demonstrate that the intergovernmentalist views emphasizing the irrelevance of supranational decision-making and prevalence of national control are untenable in the light of recent developments concerning health care and the EU. The analysis of the emerging role of EU institutions (notably, the ECJ and the European Commission) in governing access to health care[105] will serve this end. In addition, application of the *low vs. high politics* dichotomy to entire policy sectors such as health will also be criticized as limiting the analysis. The dissertation intends to show that the *low vs. high politics* dichotomy can be a useful tool for examining the dynamics of integration with regard to *certain elements* of health policymaking, such as regulating the scope and conditions of health care financed through public schemes. However, attempts to include health policy as a whole in a single category[106] imposes limitations on the analysis and highlights the drawbacks of a one-dimensional approach to this field[107].

2.3. Relevance of integration theories

As seen above, theories of European integration divide on whether they consider intergovernmental or supranational factors and actors as the main determinants of integration. However, the question is to which extent they provide a useful framework for research

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Italy, where the accession to the European Monetary Union has been conceptualized as a sign of healthiness and competitiveness of national economy); (5) existence of a political atmosphere where it is difficult to sell unpleasant economic and social reforms unless they are presented as parts of a broader process that brings general benefits. In opposite cases, i.e., in countries where European integration is contested at domestic level, where parties or coalition partners are divided over this issue and globalization has positive associations and connotations, political actors tend to appeal to globalization as the goal that needs to be pursued even at the cost of unpleasant reforms. The authors mention Great Britain and Ireland as good examples for such strategic rhetoric of globalization invoked by politicians as a non-negotiable external constraint, used in order to legitimize unpopular social and economic reforms. Hay, C. and B. Rosamond. 'Globalization, European Integration and the Discoursive Construction of Economic Imperatives'. *Journal of European Public Policy* 9(2):147-167, 2002.

[105] See Chapters 2 and 3 for further discussion.

[106] i.e., conceptualizing health policy as a whole either as a low or a high policy field.

[107] See, for similar views, Mossialos, E., M. McKee, W. Palm, B. Karl and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union, Brussels 19 November 2001.

focusing on a concrete social policy field such as health care. As pointed out by Mossialos et al.[108], neither of these two perspectives has managed so far to come up with testable hypotheses regarding the conditions under which supranational organizations exert an independent causal impact on European governance and integration in concrete fields of regulation. Similar critical arguments are put forward by Schmidt in connection with her research carried out in two public policy areas in the EU (telecommunications and electricity). Schmidt points out that the theories of European integration rarely go beyond unfounded generalizations starting from empirical findings that are very case-specific. In addition, the premises of integration theories are based on isolated case studies of policies and institutions[109]. Although many reasons support the focus on single case studies as the common method in the field of Community studies (such as sector-specificity of European policy making or the uniqueness of high politics decisions), this method raises concerns related to the extent to which empirical findings can be generalized. Schmidt considers too far-reaching generalizations and arbitrariness of the empirical foundation as the main shortcomings of integration theories[110]. She argues that the outcome of these shortcomings is isolated grasping of only some parts of a complex and inter-related process. She also claims that dichotomous theoretical considerations on European integration are often based on the highly controversial method of generalizing evidence obtained from single case studies[111].

In order to avoid to get stuck in a dichotomous theoretical debate based on unsubstantiated generalizations, Schmidt recommends the use of the multilevel governance approach when

[108] Ibid, p. 22.
[109] Schmidt, S. K. 'Sterile Debates and Dubious Generalizations: European Integration Theory Tested by Telecommunications and Electricity'. *Journal of Public Policy* 16: 233-271, 1996.
[110] Ibid., p. 234.
[111] Ibid. Such generalizations are unsubstantiated given the large differences among various policy sectors. On the other hand, the high degree of cross-sector diversity makes it unrealistic to expect a single variable to explain policy success or failure in all these fields. Studies focusing on various policy fields point out the importance of underlying sectoral characteristics. See, for example, Schmidt's analysis on telecommunications and electricity.

analyzing the developments in concrete policy areas as a framework that can successfully tackle the problem of a too narrow empirical base. She describes this approach as focusing on the interaction effects between different levels of negotiations – i.e., supranational, national, regional and local – that are missed by previous macro-theoretical perspectives on integration[112]. No matter how the nature of the multi-level perspective is conceived (i.e., as an alternative to hierarchical government or as governance by policy networks located within formal, hierarchical government institutions[113]), its main merit lays in the recognition of the fact that integration is the result of a system of continuous negotiations among governments at several territorial tiers[114].

Within such a complex pattern of interactions occurring between supranational and national actors, both intergovernmentalism and neo-functionalism will necessarily end up being very selective in addressing decision making processes. To overcome the problem of empirical idiosyncrasies, Mayntz and Scharpf recommends reconstructing policy interactions under particular policy settings (actor-centered institutionalism)[115]. As described by the authors, the particularity of this approach is that it avoids *a-priori* assumptions about the roles that specific classes of actors might play in the policy cycle. This proposed framework takes into account the specific enabling and constraining conditions of different institutional settings and recognizes the fact that both national governments and other corporate actors might have an influence on policy-shaping in Europe.

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[112] Schmidt, S. K., 'Sterile Debates and Dubious Generalizations: European Integration Theory Tested by Telecommunications and Electricity'. *Journal of Public Policy* 16:233-271, 1996, on pp. 264-267.
[113] Hooghe, L. and G. Marks. 'Unraveling the Central State but How? Types of Multi-Level Governance'. *Political Science Series* 87, 2003, pp. 3-5.
[114] Marks, G. 'Structural Policy and Multilevel Governance in the EC', in A. Cafruny and G. Rosenthal (eds.) *The State of the European Community*. Boulder: Lynne Rienner, 1993, pp. 391–411, on p. 392.
[115] Mayntz, R. and F. W. Scharpf. 'Der Ansatz des Akteurzentrierten Institutionalismus', in R. Mayntz and F. W. Scharpf (eds.) *Gesellschaftliche Selbstregelung und Politische Steuerung*. Frankfurt am Main: Campus, 1995, 39-72, cited by Scharpf, F. W. *Governing in Europe: Effective and Democratic?* European University Institute, 1999, p. 66.

The critical arguments summarized above do not mean, however, that the basic integration theories have lost their explanatory value. They provide some useful concepts that are suitable tools for analyzing the recent developments in health care and the EU. Examples are the neo-functionalist tenets of spill-over and self-sustaining integration and the intergovernmentalist premise of prevalence of national self-interest and distinction between high vs. low politics that could be applied to certain elements of health care regulation. The neo-functionalist premise of spill-over effect fits particularly well in the contemporary theoretical debates on the sources of a present-day regulatory crisis faced by national welfare states in Europe. It constitutes an analytical tool that is suitable for examining how the efforts of European Member States to safeguard social policy fields as exclusive national competence have been thwarted by the effects of integration.

3. Endogenous sources of crisis: relevance of theories on welfare state development

Theories emphasizing endogenous sources of the contemporary competence crisis will be examined next as challengers of the theories focusing on the EU as its major source. Pressures of internal origin that EU Member States face as a result of transition to post-industrialism are widely addressed in the literature on welfare states. Several studies point out that theories attributing the causes of contemporary social predicaments to supranational developments such as European integration miss the core issue[116].

[116] See for example, Pierson, P. 'Post-industrial Pressures on the Mature Welfare States', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001. See also Swank, D. 'Political institutions and Welfare State Restructuring: The Impact of Institutions on Social Policy Change in Developed Democracies', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001.

In his well-known work on European welfare states published in mid-1980s, Flora established the syndrome of 'growth-to-limits' as an institutional characteristic of European welfare states[117]. This concept reflects the idea that the ambitious welfare programs introduced during the twentieth century '*golden age*' of social development have reached their own limits by the eighties due to extensive coverage and too generous commitments. This maturation process has resulted in alarming budgetary and institutional strains. Combined with other transformations, it has created a situation characterized by Pierson as a '*permanent austerity*'[118] and defined by Taylor Gooby as the '*silver age*' of social development. In the silver age, the necessity to ensure cost-reduction and cope with budgetary pressures has decreased European states' ability to sustain the previous level of welfare[119].

Among the various approaches dealing with endogenous sources of the competence crisis, economic arguments are particularly strong in highlighting a profound transition that has taken place in advanced industrial democracies. This transition is the shift from manufacturing to service economy that has resulted in considerable economic decline. The cornerstone of these arguments is Iversen and Wren's elegantly formulated '*trilemma of service economy*'[120]. This thesis highlights that the massive shift to service sector employment resulted in productivity stagnation, slow economic growth and lower wages. These problems can be overcome in two possible ways only: either by keeping wages artificially high in public sector employment or by encouraging private sector employment.

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[117] Flora, P. (ed.) *Growth to Limits. The West European Welfare States since World War II.* Berlin/New York: De Gruyter, 1986.
[118] Pierson. P. 'Coping with Permanent Austerity: Welfare State Restructuring in Affluent Democracies', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001, pp. 410-457.
[119] Taylor Gooby, P. 'The Silver Age of the Welfare State: Perspectives on Resilience'. *Journal of European Social Policy* 31(4):597-621, 2002.
[120] Iversen, T. and A. Wren. 'Equality, Employment and Budgetary Restraint: The Trilemma of the Service Economy'. *World Politics* 50(4):507-546, 1998.

In the first case the cost is increased budgetary pressure, while in the second case, growing wage inequality. Governments that try to sustain wage equality and meet the requirements of budgetary discipline at the same time face a decrease in service sector employment and subsequently rising unemployment. In this sense, the era of service economy confronts governments with a *trilemma* where aims of employment growth, wage equality and the necessity to cope with budgetary constraints come into conflict. Efforts to achieve improvement in one of these fields result in performance decrease in at least one other field. (For example, efforts to increase the level of employment will lead to lower performance in terms of budgetary discipline or ensuring wage equality).

This necessary trade-off and subsequent reactions can take different forms across states. Pierson[121] points out that the three typical governmental reactions to this trilemma reflect in fact the three welfare state regimes (Social-democratic or Nordic, Liberal or Anglo-Saxon and Corporatist–conservative or Continental) identified in Esping-Andersen's well-known *Three Worlds of Welfare Capitalism*[122]. The three regimes described by Esping-Andersen have been completed with a fourth cluster presenting particular characteristics: the Latin (South-European) Rim[123].

The cross-regime differences in addressing the trilemma have been widely studied in recent years[124]. In the followings an example will be given to highlight the different characteristics

[121] Pierson, P. 'Three Worlds of Welfare State Research'. *Comparative Political Studies* 33(6/7):791-821, 2000, on pp. 797-798.
[122] Esping-Andersen, G. *The Three Worlds of Welfare Capitalism*. Princeton, NJ: Princeton University Press, 1990. The categorization concerned only the 'old' Member States that formed the EU before the 2004 enlargement.
[123] See Leibfried, S. 'Towards a European Welfare State? On Integrating Poverty Regimes into the European Community', in Z. Ferge and J. E. Kolberg (eds.) *Social Policy in a Changing Europe.* Frankfurt/Main and Bouldcr, Colo.: Campus and Westview, 1992; Ferrera, M. 'The 'Southern Model' of Welfare in Social Europe'. *Journal of European Social Policy* 6(1):17-37, 1996.
[124] Pierson, P. 'Post-industrial Pressures on the Mature Welfare States', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001; Hemerijck, A. 'The Self-Transformation of the

of the four European social policy regimes. Countries belonging to the corporatist-conservative model (such as Germany or Austria) typically put more emphasis on the protection of workers (in terms of ensuring wage equality and security) implemented via relatively rigid labor market regulations. In the conditions of high fixed costs the result is inflexibility and stagnation of private sector employment which combined with limited public service employment, leads to higher unemployment rates. Unemployment hits especially more vulnerable groups such as women, ethnic minorities and older workers. Welfare states belonging to this league decided to adopt a compensatory strategy by substituting the right to work with a right to social security. As shown by Leibfried, these countries can be characterized as 'institutional welfare states' because they undertake the role of a compensator of first resort[125].

The Anglo-Saxon (liberal) world of welfare capitalism choose to foster employment by increasing labor market flexibility, lessening the strength of norms aiming at workers' protection and reducing non-wage labor costs. These countries perform better in avoiding high unemployment rates and pressing budgetary constraints by encouraging the expansion of low-wage private sector employment. The cost of this choice is raising poverty, social inequalities and the emergence of the 'working poor' due to low wages accompanied by low level of de-commodification. (As defined by Esping-Andersen, '*de-commodification occurs when a service is rendered as a matter of right, and when a person can maintain livelihood without reliance on the market*'[126]).

European Social Model(s)', in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002, pp. 173-213. See also Scharpf, F. W. *Governing in Europe: Effective and Democratic*. European University Institute, 1999, pp. 135-142.

[125] See for a good analysis of the four social policy regimes in the European Community, Leibfried, S. 'Towards a European Welfare State? On Integrating Poverty Regimes into the European Community', in Z. Ferge and J. E. Kolberg (eds.) *Social Policy in a Changing Europe.* Frankfurt/Main and Bouldcr, Colo.: Campus and Westview, 1992, pp. 251-254.

[126] Esping-Andersen, G. in *The Three Worlds of Welfare Capitalism*. Princeton, NJ: Princeton University Press, 1990, p. 21.

The Scandinavian countries belonging to the social-democratic cluster opted for the expansion of public sector employment. They decided to stress universal access to decently paid work for citizen and achieved this by subsidizing entry into the labour market. By undertaking the role of employer of first resort, the Nordic countries managed to increase employment and meet the goals of wage equality. The price was increasing budgetary pressures imposed by public sector service employment. As a result, employment in these countries has become even more prone to 'Baumol's disease'[127]. As Pierson formulates it very clearly, Nordic governments "*have to run faster and faster in order to stand still*".

Finally, the Latin Rim countries of Southern Europe seem to be the least successful in solving the trilemma. Including Spain, Portugal, Greece, and, to some extent, Italy, this cluster has been characterized as the most rudimentary and even more residual than the Anglo-Saxon model[128]. The co-existence of older traditions of welfare (connected to the Catholic Church) with modern redistribution programs and the particularities of labour market structures having a strong agricultural bias convey a specific character to this regime. These features are further entrenched by the clientelistic and paternalistic character of welfare institutions[129] that makes it difficult for many welfare program beneficiaries to find their ways within the highly bureaucratic system in order to enforce their rights.

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[127] William Baumol pointed out already in 1967 that service industries are generally unable to achieve the same productivity increase as the one characterizing the manufacturing economy especially if services are particularly labour-intensive, like in health care, education and child care. As shown by Pierson, such 'non-dynamic' sectors of the welfare state where a large part of jobs is currently concentrated will have to cope with deterioration of the quality of services, increases in outlays, or both, especially if governments want to avoid reduction in salaries for public employees. The result is increasing budgetary pressure. See, for details, Baumol, W. J. 'The Macroeconomics of Unbalanced Growth'. *American Economic Review* 57:415-426, 1967. Also in Pierson, P. 'Post-industrial Pressures on the Mature Welfare States', in P. Pierson (ed.) *The New Politics of the Welfare State*. Oxford: Oxford University Press, 2001, p. 87.

[128] Leibfried, S. 'Towards a European Welfare State? On Integrating Poverty Regimes into the European Community', in Z. Ferge and J. E. Kolberg (eds.) *Social Policy in a Changing Europe.* Frankfurt/Main and Bouldcr, Colo.: Campus and Westview, 1992, p. 253.

[129] Ferrera, M. 'The 'Southern Model' of Welfare in Social Europe'. *Journal of European Social Policy* 6(1):17-37, 1996.

It seems that none of the four welfare models has managed so far to exit the trap of Iversen and Wren's trilemma. Theories talk about a maladjustment spiral involving, as elements of a vicious circle, growing inactivity and unemployment, increasing social spending, taxes and social charges entailing a growth in non wage labor costs, which all result in further decrease of employment[130]. These pressures are combined with other endogenous factors, such as reconfiguration of household structures, changes in the relationship between household and work and population ageing. Dismantling of the male-breadwinner families and the changing gender roles in labour markets and households impose extra financial demands on states that have to undertake new roles in order to fulfill the ones previously accomplished by families. In addition, indicators illustrating the alarming extent of population ageing in European countries predict severe additional fiscal burdens imposed on states especially in health care and pensions.

European welfare states have to work harder and harder in order to meet welfare, equity and solidarity commitments in the conditions of recent societal changes, gradual loss of policy flexibility and straining public deficits. Studies focusing on endogenous sources of the contemporary crisis reveal how welfare states designed for a previous era differ in the modality adopted and degree of success in tackling the challenges of internal origin. They point out that common post-industrial changes impose different problems on different welfare state regimes, due to heterogeneous economic development, heterogeneous social structure, differences in social policy legacies, systems of interest organization and democratic

[130] Ferrera, M. and A. Hemerijck. 'Recalibrating Europe's Welfare Regimes', in J. Zeitlin and D. Trubeck (eds.) *Governing Work and Welfare in the New Economy: European and American Experiments*. Oxford: Oxford University Press, 2003, p. 121.

institutions[131]. Countries belonging to different welfare clusters face regime-specific difficulties that go beyond the general challenge of maintaining international competitiveness.

Theories on welfare states are particularly interesting for the analysis of recent developments concerning health care and the EU. They explain why health care is safeguarded as a core competence of national social policy regimes and shielded from integration. EU Member States differ a lot in the way they organize, deliver and finance health care. Following the categorization described above, one can conclude that 'old' Member States[132] belonging to the liberal cluster (the United Kingdom and Ireland), the social-democratic cluster (Denmark, Sweden and Finland) and the Latin rim have national health systems financed by taxes. The United Kingdom and Ireland are often cited as examples for a more centralized national health system. Denmark, Sweden, Finland, Italy, Portugal, Spain and Greece have a more decentralized national health system[133]. Old Member States belonging to the corporatist-conservative model (France, Belgium, Luxembourg, Germany, the Netherlands and Austria) have social insurance systems largely funded via contributions. France, Belgium and Luxembourg are social insurance systems operating on the basis of cost reimbursement, while Germany, the Netherlands and Austria are social insurance systems providing benefits in kind[134]. **(**The categorization mentioned above did not include new CEE members. It will be shown in Chapter 4 that CEE countries have been moving since early nineties from centralized state-socialist health systems towards social insurance systems.)

[131] See also Hemerijck, A. 'The Self-Transformation of the European Social Model(s)', in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002, pp. 173-213; Esping-Andersen, G. 'Towards the Good Society, Once Again?', in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002, pp. 1-26.
[132] For the purposes of this paper, the term 'old' Member States will be used for the 15 countries that formed the European Union before the 2004 enlargement.
[133] See, for example, Palm, W. and J. Nickless. 'Access to Healthcare in the European Union'. *Eurohealth* 7(1), 2001, pp. 13-14; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 125-126.
[134] Ibid.

Efforts to develop EU-level regulatory competences in the field of health care are politically impeded by the diversity of national states' normative aspirations, institutional structures and levels of economic development[135]. Even if Member States have public health care systems (complemented and in certain cases supplemented to various degrees by voluntary and/or private insurance) that strives for universal access to services of appropriate quality, the rights of individuals in medical care and the mechanism of implementation vary a lot across countries[136]. European-level harmonization of market-correcting social regulations is impeded by deeply rooted differences. Uniform European rules attract strong national-level opposition where they require significant changes in the structures and functions of social security institutions[137]. These theories explain why European-level legislation on access to health care would be strongly opposed by national governments. The disagreement of several Member States with the Commission's proposal to include access to cross-border care in the EC Service Directive confirms this reasoning[138]. EU Member States face different challenges in health care organization, delivery, financing and meeting the standards in access to health care. They also apply different solutions, as highlighted by comparative analyses of health care reforms[139]. It is the intention of this dissertation to show that new Member States of Central and Eastern Europe face some particular challenges in this respect, as relevant from the analysis included in Chapter 4.

[135] Scharpf regards these differences as main impediments to adopting European social policies and implementing the European Social Model. Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4):645-670, 2002.
[136] Freeman, R. *The Politics of Health in Europe*. Manchester: MUP, 2000; Saltman, R.B., Figueras, J. and C. Sakallarides (eds.) *Critical Challenges for Health Care Reform in Europe*. Buckingham: Open University Press, 1998.
[137] Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4):645-670, 2002.
[138] See Chapter 3 for further details.
[139] See Chapter 4 for further discussion.

Interestingly, exogenous and endogenous factors leading to the contemporary crisis of welfare states are rarely studied as linked to each other, and there is little connection between research focusing on exogenous factors and those addressing endogenous ones. In search for a theory that could link these two types of pressures on contemporary welfare states, Flora[140] and Ferrera[141] re-interpreted Rokkan's theory on state formation and nation building in Europe[142]. In the followings, the basic premises of their theory will be summarized to highlight their relevance to the discussion on the contemporary competency gap and governance crisis that manifests itself in the field of health care regulation.

4. Linking together exogenous and endogenous sources of the competence crisis

In search for an analytical framework that is suitable for interpreting recent developments affecting the fields of welfare and social redistribution in European states, Flora and Ferrera revisited Rokkan's argument about the link between boundary building and internal structuring as the two crucial dimensions of nation building and state formation in Europe. Ferrera applies Rokkan's theoretical insights and basic conceptual elements in order to build a model that links together the exogenous and endogenous pressures challenging the sovereignty of European nation states over the field of social redistribution. This model shows that, although the pressures are largely exogenous and are mainly connected to European integration, they are reinforced by pressures that originate within the nation states[143].

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[140] Flora, P. 'Introduction and Interpretation', in P. Flora et al. (eds.) *State Formation, Nation Building and Mass Politics in Europe. The Theory of Stein Rokkan*. New York: Oxford University Press, 1999, pp. 1-91.
[141] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6): 611-652, 2003.
[142] Rokkan, S. 'Entries, Voices, Exits: Towards a Possible Generalization of the Hirschman Model'. *Social Sciences Information* 1(13):39-53, 1973.
[143] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003, on pp. 3-4.

According to Rokkan, nation and state building in modern Europe has two main dimensions: boundary building and internal structuring. Boundary building is understood in two ways[144]: 1) in a territorial sense, as a demarcation of physical space of a state and creation of a geographic space; 2) in a social sense, as a creation of forms of distinctions between insiders and outsiders, members and non-members of a collectivity, nationals and non-nationals, citizens and non-citizens. In this sense, boundary formation is the process of physical *and* social closure of a territory. Social boundary building creates the membership space that is usually much more difficult to enter for outsiders than the geographic space due to specific rights and entitlements that are only conferred upon the members of the collectivity. Rights and entitlements based on citizenship constitute a typical example illustrating that for non-members, crossing the borders of the social membership space is more difficult than crossing the borders of the physical/geographic space.

In order to explain the concept of boundary building, Rokkan elaborates on the *exit-voice-loyalty scheme* proposed by Hirschman[145]. According to this scheme, state formation in Europe included three main steps. The first step was the gradual foreclosure of exit options for actors and resources belonging to a certain territorial collectivity. The second step was the establishment of a system of institutions capable of developing domestic loyalty. At the same time, channels have been created as instruments for exercising the collectivity's internal voice through transmitting claims from social and geographic peripheries towards the central elite of the system and exercising pressures from below. The third step was the development of collectivity members' loyalty towards domestic institutions.

[144] Rokkan, S. 'Entries, Voices, Exits: Towards a Possible Generalization of the Hirschman Model'. *Social Sciences Information* 1(13):39-53, 1973.
[145] Hirschman, A. O. *Exit, Voice and Loyalty*. Cambridge: Harvard University Press, 1970.

Creation of territorial boundaries through limitation of territorial exit options for the members and resources belonging to a certain collectivity and creation of social boundaries were the main elements of boundary building. Boundary building represents one dimension of state and nation building. The other dimension is internal structuring realized through creation of center-periphery relations, social-political cleavages and differentiation of domestic institutions. Rokkan defines center-periphery structures as systems of relationships and transactions between the governing and controlling center of a collectivity and the subordinate areas. Cleavage structures are fundamental divisions within communities that originate in socio-economic and cultural differences[146].

The two major processes of internal structuring were the introduction of mass democracy based on universal suffrage and the establishment of redistributive arrangements. These two steps were crucial for connecting the members of a collectivity to state institutions. Particularly, the creation of social rights, social redistribution and entitlements to resources constituted an important element of nation building[147] and a tool for distinguishing between members and non-members. Establishment of social citizenship[148] was a major step in nation and state building (in addition to territorial delimitation, creation of cultural identity and emergence of rights related to political participation). European welfare states between the 1950s and the 1970s constitute good examples of highly integrated systems with increased level of internal structuring/differentiation and external closure.

[146] Examples for cleavage structures are church/state cleavage or the workers/owners cleavage.
[147] The idea that social rights and social citizenship were as important in the development of modern citizenship as civil and political rights was put forwarded by Marshall already in 1950. See Marshall, T. H. 'Citizenship and Social Class', in T. H. Marshall. *Sociology at the Crossroads and Other Essays*. London: Heinemann Educational Books, 1963, pp. 67-127.
[148] Ibid. The concept of social citizenship is used here in the meaning established by Marshall, T. H., 1963, pp. 67-127.

4.1. Redistributive arrangements and social citizenship: elements of state building in Europe

As seen above, Rokkan identified social redistribution as an important element in the process of state formation and nation building. He recognized that the establishment of arrangements for social redistribution constituted a crucial element in stabilizing the politico-territorial system through creation of entitlements for members to resources. Social rights linked the members of the collectivity to state institutions operating within a closed domestic geographic space.

Rokkan's insights on the role of redistributive arrangements in nation and state building have been recently completed by Ferrera's theory that focuses primarily on the social sharing component[149]. Concretely, Ferrera examines the influence of European integration on the territorial and social boundaries of national welfare systems. The cornerstone of his premise can be summarized as follows: European integration has affected the boundaries of social citizenship in Member States and have challenged the national closure of social citizenship. This process resulted in de-structuring internal constellations (institutional orders, cleavages and center-periphery relations existing at national level) and in attempts at re-structuring these constellations at European level[150].

Ferrera emphasizes the introduction of compulsory social insurance of national scope as an important element of nation formation in Europe. Compulsory social insurance schemes played an important role both in external closure (boundary formation) and internal structuring. On one hand, they made it more difficult for non-nationals to enter the solidarity

[149] Ferrera, M. *The Boundaries of Welfare: European Integration and the New Spatial Politics of Social Protection*. Oxford: Oxford University Press, 2005.
[150] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003, on p. 622.

space of other states and become members of their social redistribution programs. On the other hand, citizens became virtually locked in their national welfare programs due to compulsory membership in public schemes that limited exit options. Moreover, expansion of social redistribution programs during the second half of the 20th century and increase of the level of generosity enhanced citizens' loyalty towards their own national welfare regimes. As formulated by the author, '*welfare rights, legitimized through the electoral channel, have a fundamental contribution for nationalizing the citizenry and accentuating territorial identities*[151]'. In this sense, social security rights have become the social component of state borders. This has been enhanced by the principle of territoriality in social insurance that intends to sustain nation states' monopolistic control over social redistribution[152]. National closure of social citizenship between the 1950s and 1970s constituted an important step in the state building process in Europe through enhancing loyalty and bounding the citizen to domestic welfare programs and institutions.

Institutionalization of solidarity through the introduction of compulsory social insurance of national scope played an important role also in the process of internal structuring. It constituted a major factor in the development and strengthening of center-periphery and cleavage structures by distinguishing between the beneficiaries of different entitlements and establishing the specific institutional structures for the implementation of social rights. Following different routes of development in each state, social insurance became a major factor in strengthening the different welfare state regimes in Europe as well as in developing

[151] Ibid, p. 629.
[152] The territoriality principle will be discussed in Chapter 2 in the context of health insurance. According to the territoriality principle in health insurance, domestic sickness funds generally restrict financial coverage of health care services to those obtained from providers located and functioning within the national territory. See for further details, Cornelissen, R. 'The Principle of Territoriality and the Community Regulations on Social Security'. *Common Market Law Review* 3, 1996; Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven: Instituut Sociaal Recht, 2004-2005.

the specific institutional characteristics for each cluster. For example, social sharing institutions enhanced the loyalty of civil society by substantial, nation-wide, all-inclusive, and efficiently organized distributions of social benefits in the Northern (Scandinavian) regime. As opposed to the Northern countries, social insurance was structured on the basis of pre-existing social and cultural differences in many countries belonging to the continental cluster and strengthened further the existing cleavage structure (like in the Netherlands). Social sharing arrangements took a clientelistic dynamic in Southern Europe as a result of specific challenges such as lower economic development compared to other Member States of Western Europe, poor administrative capacities, large differences across regions as well as existence of a deep church-state cleavage and a paternalistic legacy in public administration[153].

The cross-regime differences played a role also in external boundary building by making it more difficult for members of a certain social sharing space and regime to move to another one. Regime particularities of social redistribution within Europe can act as major impediments to the harmonization of social sharing arrangements in Europe, because Member States' social protection systems are politically very sensitive national agreements constructed and safeguarded throughout decades[154]. Although there are shared values and principles in Member States' social redistribution systems, the models applied in various welfare regimes differ a lot in underlying philosophy and concrete mechanisms of provision[155]. This is a major reason why attempts to create one single European Social Model

[153] The particularities of the fourth welfare regime (the Latin rim) are discussed in Ferrera, M. 'The 'Southern Model' of Welfare in Social Europe'. *Journal of European Social Policy* 6(1):17-37, 1996.
[154] See also Begg, I. and J. Berghman. 'Introduction: EU Social (Exclusion) Policy Revisited?'. *Journal of European Social Policy* 12(3):179-194, 2002, p. 181.
[155] See for more on the differences between welfare state regimes, Esping-Andersen, G. *The Three Worlds of Welfare Capitalism*. Princeton, NJ: Princeton University Press, 1990. See also Begg, I. and J. Berghman. 'Introduction: EU Social (Exclusion) Policy Revisited?'. *Journal of European Social Policy* 12(3):179-194, 2002, p. 181.

and one common framework for European social policy face so many obstacles. As noted by Flora, '*once a population has developed some minimum level of trust in the efficiency and fairness of the territorial government, it is unlikely to favor the transfer of substantial authority from this body to agencies beyond direct electoral control*'[156]. It is indeed difficult to identify possible replacements for social rights and domestic redistributive arrangements as bases for this trust. As shown by Habermas[157], the general concept of human rights constitutes a weak candidate for this role in spite of its universal acceptance because human rights cannot replace solidarity rooted in particular collective identities with closed social borders.

4.2. Endogenous and exogenous pressures: a joint challenge to national closure of social citizenship

Ferrera applies the theoretical constructs described above to show how factors of external and internal origin are jointly responsible for weakening the monopolistic control of Member States over their social boundaries and membership spaces. The beauty of this theory is that it links together exogenous and endogenous pressures faced by contemporary European welfare states in a single explanatory framework. This framework highlights how pressures of internal and external origin have accumulated and interacted in weakening the national closure of social citizenship.

Ferrera considers that internal differentiation of social insurance schemes and particularly, the emergence of the so-called 'second pillar', supplementary schemes constitute the major endogenous sources of pressure. In the conditions of greater economic development and

[156] Flora, P., Kuhnle, S. and D. Urwin (eds.) *State Formation, Nation Building and Mass Politics in Europe. The Theory of Stein Rokkan.* New York: Oxford University Press, 1999, p. 265.
[157] Habermas, J. 'The Postnational Constellation and the Future of Democracy', in Habermas, J. (ed.) *The Postnational Constellation: Political Essays*. Cambridge Mass: Polity Press, 2001, pp. 58-112.

social mobility, certain occupational groups started to make use of different forms of supplementary insurance. This was especially characteristic to the field of pension insurance and to a lesser extent also health insurance. People who could afford extra insurance opted for it in order to gain additional benefits on the top of those provided by the compulsory schemes. The so-called 'second pillar' schemes including supplementary insurance have created a new space for redistribution. Although supplementary insurance schemes did not affect at the beginning the external social boundaries because non-nationals had no access to them, such schemes nevertheless re-shaped domestic/internal social membership spaces by giving birth to new institutions and new exit/entry opportunities *within* a country from one scheme to the other. Supplementary insurance has affected in this sense the dynamics of internal structuring[158].

The process of re-shaping the internal structuring of European welfare states runs parallel to the process of European integration. Ferrera regards the creation of the European regime for co-ordination of social security systems (Regulation 1408/71[159]) as a factor that has weakened directly the external social boundaries of national welfare states. By setting the rules of transportability of social rights from one Member State to others, the social security co-ordination mechanism has created new exit options from a given Member State and matched them by corresponding entry opportunities into other Member States. The effect of cross-border transportability of social rights has been completed by the equal treatment principle saying that Member States should not discriminate between their own citizens and citizens of other Member States legally residing on their territory in terms of access to social

[158] Ferrera, M., 2003 and 2005. Idem notes 149 and 150.

[159] Council of the European Communities. Regulation (EEC) Council No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (Consolidated version), *OJ* L 28 of 30 January 1997, pp. 0001-0147. For the latest text, see the online source of EU legislation: http://eur-lex.europa.eu/en/index.htm (Last accessed on May 26, 2009).

security benefits[160]. The outcome is that Member States have become obliged to open their social borders in front of entitlements matured in other countries and let entitlements accumulated within their own territory to be redeemed in other states[161].

At present, Member States cannot restrict anymore access to welfare programs to their own citizens only. Benefits previously restricted to the territory of the country of citizenship have become portable within the whole EU. Borders of previously closed redistributive spaces have gradually opened and it has become much easier for citizens of an EU Member State to enter the solidarity space of another Member State. In short, Member States' ability to control exits/entries of their social redistribution spaces has weakened. The notion of social citizenship limited to the territory of the state of citizenship has been strongly challenged and eventually rendered untenable. As formulated by Ferrera, '*with the creation of second tier insurance, on the one hand, and the establishment of the coordination regime on the other hand, the monopolistic control of the state over both the membership and territorial boundaries of social sharing started to be undermined from within and from outside*[162]'.

5. Relevance of the theoretical constructs identified

Rather than providing a single explanatory framework on the emerging mandate of EU law in health care, the main contribution of contemporary theories on European integration and welfare state development is that they embed this topic in the wider debate on a present-day competency crisis of European welfare states. This crisis manifests itself in the decreasing suitability of Member States to meet the pressing endogenous and exogenous challenges and

[160] See on the history of the development of EC Regulation 1408/71 and the four underlying principles, Schoukens, P. (ed.) *Prospects of Social Security Co-ordination*. Leuven: Acco, 1997.
[161] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003, on p. 631.
[162] Ibid., p. 632.

in their diminishing regulatory ability in the fields of social redistribution and social security including health care and health insurance.

Macro theories of European integration provide insights into the nature of factors determining and motivating the integration process and a number of constructs that are suitable tools for analyzing recent developments in health care governance in Europe. Examples are the neo-functionalist tenets of spill-over and self-sustaining integration. Other examples are the intergovernmentalist premise of prevalence of national self-interest and distinction between high vs. low politics that could be applied to certain elements of health care regulation[163]. Theories of European integration divide on whether they consider intergovernmental or supranational factors and actors as main determinants of integration, and this fact can turn the analysis into a dichotomous theoretical debate. The perspective of multilevel governance focusing on the interaction effects between different levels of negotiations (supranational, national, regional and local) might provide a way out of the sterile intergovernmentalism vs. neo-functionalism/supranationalism dichotomy.

Theories emphasizing endogenous pressures as sources of the contemporary crisis highlight that EU Member States differ in terms of their main challenges in organizing and regulating their health care systems. Differences are rooted in heterogeneous economic development and social structures, diverse social policy legacies and systems of interest organization. They highlight that the modality adopted and the degree of success in tackling the challenges differ across the welfare state regimes. Theories on welfare states explain why health care is regarded as a core competence of national social policy systems. Regime particularities of social redistribution within Europe act as major impediments to the cross-country

[163] Although applying it to health policy as a whole would limit the analysis as a result of a one-dimensional conceptualization of this field.

harmonization of social sharing arrangements. This is a reason why attempts to create one single European Social Model and one common framework for European health policy face so many obstacles.

Rokkan's theory on the historical process of state formation and nation building in Europe provide useful insights for the discussion on the competence loss of Member States in health care. The basic concepts are boundary formation and internal structuring. Building on these concepts, Ferrera emphasizes the importance of redistributive arrangements and social citizenship as major elements of state formation in Europe. His analysis reveals how social security rights have become the social component of state borders. Institutionalization of solidarity through the introduction of compulsory social insurance of national scope has played an important role in the process of internal structuring. National closure of social citizenship between the 1950s and 1970s constituted an important step in the state building process in Europe.

Ferrera claims that the notion of social citizenship limited to the territory of the state of citizenship has been strongly challenged and eventually rendered untenable by simultaneous developments of external and internal origin. His theoretical framework links together exogenous and endogenous pressures on contemporary welfare states and illustrates the joint role of these factors in the gradual removal of state-boundaries in the realm of social redistribution in Europe. Ferrera considers the development of supplementary social insurance schemes and the creation of the European social security co-ordination mechanism established by Regulation 1408/71 as the two main factors contributing to the competence loss of Member States in social security fields including health care.

The implications of these developments for the regulatory competence of Member States in the field of social security including health insurance have already started to unfold. At present, no Member State can lawfully limit access to social benefits to its own citizens only. Instead, these benefits must be extended to citizens of other EU Member States as well as to legally residing third-country nationals coming under the scope of Regulation 1408/71[164]. Workers, pensioners, students coming from other EU countries to a certain Member State have to be included into social security programs existing in the host state. It will be discussed in Chapter 2 that, as a result of the case law of the European Court of Justice, EU law interprets broadly the concept of 'worker'. This concept includes not only full-time employed workers and their dependants but also part-time workers, self-employed persons, unemployed persons registered as job-seekers, students and persons undergoing vocational training, pensioners. Recently, even inactive persons not actively seeking employment have been included in the scope of the social security co-ordination mechanism[165]. In addition, as a consequence of the rules applicable within the social security co-ordination mechanism, Member States must accept that the determination of the beneficiary status and the content of the right to access health services is done sometimes by institutions of other Member States. Examples are deciding in individual cases of access to cross-border care who can be regarded as 'sick' or 'disabled' as a condition for being entitled to benefits or what amounts to 'health care that becomes necessary on medical grounds' during a temporary stay in another Member State.

[164] The provisions of Regulations 1408/71 and 574/72 were extended to third country nationals in 2003. See Council Regulation (EC) 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, *OJ* L 124, 20 May 2003, 0001-0003.

[165] As shown in Chapter 2 analyzing the *ratione personae* of the social security co-ordination mechanism and recent developments brought about by the new co-ordination regulation (883/2004).

Another important consequence is that Member States cannot lawfully limit the exercise of social security entitlements to their own territory. The territoriality principle in social insurance has been affected by integration. Social benefits including health insurance benefits have become portable across borders within the EU. Moreover, there is an increasing possibility for persons insured to have access to services in other EU social systems at the cost of their home system, as relevant from the ECJ rulings on access to health services and goods in other Member States, discussed in Chapter 3 of this dissertation. These rulings also establish an obligation for Member States to allow health service providers from other Member States to enter their national welfare systems[166].

Challenges to Member States' exclusive competence in social security organization and regulation have become particularly obvious in case of 'second pillar' social security schemes, such as supplementary pensions or supplementary health insurance. As ruled by the ECJ in the landmark *Coreva*[167] judgment, in case of second-pillar schemes both providers and beneficiaries are allowed to look for best investment opportunities and beneficiaries can seek more favorable services in other Member States[168].

It is the intention of this dissertation to show that the application of the freedom to provide services has blurred the borderline between redistributive activities and market integration activities of an economic nature. Chapter 3 will analyze the ECJ rulings establishing that social security services constituted economic services within the meaning of the EC Treaty.

[166] The same holds for the provision of supplementary, second pillar insurance schemes that are common for example in the domain of pensions.
[167] Case C-244/94 *Coreva* [1995] ECR I-04013. In the *Coreva* case, the ECJ ruled that a non-profit organization that manages an old-age insurance scheme established by law as optional and intended to supplement a basic compulsory scheme is an undertaking in the light of the EC Treaty. Although the organization is non-profit making and it has some solidarity features, it still performs an economic activity.
[168] While exercising pressures on Member States, these developments have potentially positive consequences as well, such as increased market efficiency, clarification of coverage rules and possible improvements in the quality of non-compulsory, supplementary services as a result of increased competition.

The ECJ has also repeatedly ruled that Member States must comply with the freedom to provide services when exercising their regulatory powers in the field of social security. According to settled ECJ case law, that there is no general exemption for social security regulation from the application of the free movement services.

The leverage of the ECJ is particularly well illustrated by the topic of cross-border care. Focusing on access to health care, the following two chapters will examine the role of the ECJ in decreasing the sovereignty and regulatory ability of Member States. As predicted by Leibfried and Pierson, '*the health area will be a first Europe-wide testing-ground for the turf struggle between national welfare states and the Community plus the market, as represented by private insurance, producers, etc.*'[169]. Chapters 2 and 3 will shift the analysis to the level of legal developments in order to examine how national regulation of access to health care has become affected through legislation adopted at EU level and litigations based on directly effective provisions of EU law. Further on, Chapter 4 will examine the implications for Member States with particular focus on new members of Central and Eastern Europe. The theoretical concepts and premises identified in Chapter 1 will be applied as analytical tools examining the role of EU law in re-drawing the boundaries of national competences in health care. The analysis will highlight that the accumulation of EU constraints and requirements over this field has been largely court-and law-driven[170] instead of being left to traditional centers of policy making. It will discuss how European social security lawyers have entered the area of policy making and have used the judiciary for filling in the emerged competency gap in health care regulation.

[169] Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition. Oxford: Oxford University Press, 2000, pp. 267-292, on p. 283.
[170] See also Begg, I. and J. Berghman. 'Introduction: EU Social (Exclusion) Policy Revisited?'. *Journal of European Social Policy* 12(3):179-194, 2002, p. 189.

CHAPTER 2: Access to cross-border health care in EC social security co-ordination law

Cross-border health care is a field where the influence of the EU on Member States' regulatory capacity has become particularly relevant. Regulating access to health services and goods is a competence traditionally left for nation states. Nevertheless, legislation adopted at EU level and the rulings of the European Court of Justice have undermined Member States' efforts to keep this competence under exclusive national jurisdiction. Access to health care has become an issue in European law through the phenomenon of cross-border health care and patient mobility. Chapter 2 examines access to cross-border care under European social security co-ordination law.

Theories discussed in Chapter 1 conceptualize the creation of the European regime of regulatory co-ordination of national social security systems (shortly, the social security co-ordination mechanism) as an exogenous factor that has weakened the 'social boundaries' of Member States[171]. The co-ordination mechanism created exit options from the social security system of a given state and matched them by corresponding entry opportunities into the system of another state. As a result, cross-border transportability of social rights has been ensured within the EU. At the same time, the co-ordination mechanism imposed on Member States the obligation to open their social borders in front of social entitlements matured in other EU countries. It also obliged nation states to let social entitlements accumulated within their own territory redeemed in other states. As an outcome, the notion of social citizenship

[171] See the theories on welfare states development discussed in Chapter 1 and particularly, the theoretical framework established by Ferrera linking together exogenous and endogenous pressures on contemporary welfare states in Europe. Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003; Ferrera, M. *The Boundaries of Welfare: European Integration and the New Spatial Politics of Social Protection*. Oxford: Oxford University Press, 2005.

restricted to the territory of the nation state has been challenged and rendered untenable. Solidarity and social entitlements cannot be regarded anymore as exclusive national issues[172].

Chapter 2 analyzes the influence of the social security co-ordination mechanism on Member States' competence and *de facto* ability to regulate access to health care. The analysis is restricted to questions of social coverage of health care, and the focus is on the patient's perspective[173]. The analysis distinguishes between three categories of patients. The first category includes patients residing in a Member State other than the state of insurance. The second category includes patients obtaining health care that becomes necessary on medical grounds during a temporary visit to another EU country. The third category includes patients who travel to another Member State with the specific goal to receive health care there. The analysis will make recourse to theoretical concepts and premises identified in Chapter 1 in order to discuss the role of the social security co-ordination mechanism in undermining Member States' efforts to shield health care from integration.

Throughout the analysis, the relevance of the proposed European Directive on the application of patients' rights in cross-border health care (shortly, EC Directive on cross-border care) will be addressed[174]. As mentioned also in Chapter 1, the European Commission proposed in July 2008 the draft Directive in order to ensure that individuals can effectively exercise their right to access health care in cross-border settings. As an EU instrument establishing relevant

[172] This connects the discussion to the larger debate on the social dimension of the EU. The developments mentioned above show that European integration cannot move forward without social integration. Social integration is interdependent with economic and political integration. See also Mückenberger, U. (ed.) *Manifesto Social Europe*. Brussels: European Trade Union Institute (ETUI), 2001.

[173] Although issues related to free movement of health professionals are occasionally addressed, Chapter 2 does not intend to provide an exhaustive analysis of this aspect. The focus is on individuals' access to health care in cross-border settings.

[174] European Commission. 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 of 2 July 2008. Brussels: Commission of the European Communities, 2008. Relevant provisions of the proposed Directive will be analyzed at different sections of Chapters 2 and 3.

rights, entitlements and duties, the proposed Directive intends to clarify the competence-sharing rules, the quality, safety and cost-assumption issues, and strengthen European cooperation in cross-border health care [175].

1. Health and EU law: an evolving relationship

Any discussion on the emerging role of EU law in access to health care needs to take into account that the Union has limited law-making competence and it cannot lawfully act without an appropriate legal basis in the EC Treaty. Acts taken by the EU outside of its formal legal competence can be challenged judicially. At present, the EU is not formally empowered to regulate health care organization, delivery and financing. Its formal legal competence does not include the development of legal standards in the field of access to health care except for citizens moving between Member States[176]. Given this fact, the general understanding of competence-sharing between the EU and Member States is that European Union authority is limited to certain public health issues.

EU competence in public health was first stipulated in Article 129 of the Maastricht Treaty, ratified in 1992. Article 129 created a legal basis for the Union to run a public health policy of disease prevention, health promotion, information, research and education. As relevant from this article, the competences given to the EU by the Maastricht Treaty were essentially of a preventive character[177]. The Amsterdam Treaty (ratified in 1997) extended EU

[175] See the explanatory memorandum of the proposed EC Directive on cross-border care. The goals of the proposed Directive were reaffirmed by the Directorate-General for Health and Consumers of the European Commission at the EU Open Health Forum 2008 'Developing and Implementing Health in the European Union', organized in Brussels on December 10-11, 2008. All documents and presentations related to the Forum are available at:
http://ec.europa.eu/health/ph_overview/health_forum/open_2008/index_en.htm (Last accessed on May 26, 2009).

[176] See also Schoukens, P. 'The Right to Access Health Care: Health Care According to European Social Security Law Instruments'. *Medicine and Law* 27(2):501-533, p. 503.

[177] See also Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008, pp. 576-577.

competence beyond preventive measures. Article 152 created a legal basis for EU action to improve public health. Based on the Treaty of Amsterdam, the Union can take measures in setting standards of quality and safety of organs and substances of human origin, blood and blood derivatives, as well as veterinary and plant health[178].

Since the ratification of the Amsterdam Treaty, the EU has continuously developed its public health activities that got synthesized in a formal European strategy[179]. The 2007 European public health strategy reaffirms solidarity, universality, access to good quality care and equity as values and principles that are shared across Europe[180]. Equity is defined by the European Council as equal access according to need, regardless of ability to pay and other characteristics such as social status, gender, ethnicity, age, etc. Universality means that nobody is impeded in accessing health services[181].

Besides overarching values, the European Council has also identified a set of operating principles in health care that are shared across the Union. These principles include: providing good quality and evidence-based care, ensuring patient safety, promoting patient involvement, ensuring that patients have a right to redress and respecting the right to confidentiality and privacy[182]. The Council envisages the creation of structures supporting the operating principles in all health systems in the EU. The European public health strategy promotes a patient-centered health care that is responsive to individual need. It foresees an active role for patients in public health policy making as well as increasing involvement of

[178] See Article 152(4)(a)(b) of the Treaty of Amsterdam.
[179] European Commission. White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013', COM(2007) 630 final of 23 October 2007. Brussels: Commission of the European Communities, 2007.
[180] The European Council identified solidarity, universality, access to good quality care and equity as values and principles shared across Europe. See for details, Council of the European Union. Council Conclusions on Common Values and Principles in European Union Health Systems, *OJ* C 146/1, 22 June 2006, pp. 0001-0003.
[181] Ibid.
[182] Ibid.

individuals in decision-making. It also emphasizes the need to take EU-level action in reducing inequalities in health, not only between but also within Member States (although the latter has been traditionally regarded as a responsibility of states)[183].

Unlike public health, the organization, delivery and financing of health care are not defined specifically as EU competences in the EC Treaty[184]. The subsidiarity principle applies to the field of health care. The Maastricht Treaty stipulated this principle establishes as follows[185]:

"*The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only it and so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the effects of the proposed action, be better achieved by the Community.*"

The Treaty of Amsterdam makes for the first time explicit the application of the subsidiarity principle to health care. Article 152 states that *'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care.'* The European Court of Justice (ECJ) has repeatedly asserted the principle of subsidiarity in social security including health care, by stating that '*in the absence of harmonization at Community level, it is for the legislation of each Member State to determine the conditions on which social security benefits are granted*'[186].

[183] The European Commission launched in February 2009 an open consultation on the role of the European Union in reducing health inequalities within and between Member States. The open consultation process targeted a wide range of stakeholders including professional, public and private, non-profit and for-profit organizations, as well as individuals. The responses will feed into a Commission Communication on health inequalities in the European Union. See the website of the European Commission: http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=462 (Last accessed on May 26, 2009).

[184] See also Belcher, P. J. *The Role of the European Union in Healthcare*. Brussels: Zoetermeer, 1999, pp. 11-12.

[185] See Article 3B of the Maastricht Treaty. The subsidiarity principle is also stipulated in the Amsterdam Treaty (Article 5).

[186] Case C-110/79 *Coonan* [1980] ECR 1445, para.12; Case C-349/87 *Paraschi* [1991] ECR I-4501, para. 15; Joint Cases C-4/95 and C-5/95 *Stöber and Piosa Pereira* [1997] ECR I-511, para. 36; Case C-120/95 *Decker* [1998] ECR I-1831, para. 21; Case C-158/96 *Kohll* [1998] ECR I-1931, para. 17; Case C-157/99 *Geraets-Simts/*

Nevertheless, the settled case law of the ECJ also makes it clear that, when exercising their social security powers, Member States must comply with the EC Treaty provisions on free movement. These provisions prohibit the introduction and/or maintenance of unjustified restrictions on exercising the freedom to provide services in health care[187].

Although the principle of subsidiarity has been traditionally considered as the main basis in EU law for defending Member States' authority over health care, it does not rule out Union action in this field. Instead, it creates a legal basis for the EU to act wherever the proposed objective cannot be sufficiently achieved by Member States and can be better achieved by the Union, due to the scale of effects[188]. Vertical subsidiarity implies a duty for the Union to intervene and support the states and regions where policy objectives are not adequately achieved[189]. The European Commission makes use of the notion of vertical subsidiarity when asserting a legal basis for proposing the European Directive on the application of patients' rights in cross-border health care. As stated in the explanatory memorandum, '*action by Member States alone or lack of Community action would significantly undermine both the safe and efficient provision of cross-border health care, and would leave Member States without a clear capacity to manage and steer their health systems as a whole*[190]'. The Commission refers to the jurisprudence of the ECJ in *Watts*[191] when stating that the Union is empowered to ask from Member States under EC Treaty provisions (or under EU measures

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Peerbooms [2001] ECR I-5473, para. 45; Case C-385/99 *Müller-Fauré/ Van Riet* [2003] ECR I-4409, para. 100; Case C-56/01 *Inizan* [2003] ECR I-12403, para. 17; Case C-8/02 *Leichtle* [2004] ECR I-2641, para. 29; Case C-372/04 *Watts* [2006] ECR I-4325, para. 92; Case C-444/05 *Stamatelakis* [2007] ECR I-3185, para. 23.

[187] Case C-157/99 *Geraets-Simts/ Peerbooms* [2001] ECR I-5473, paras. 45-46; Case C-385/99 *Müller-Fauré/ Van Riet* [2003] ECR I-4409, para. 100; Case C-56/01 *Inizan* [2003] ECR I-12403, para. 17; Case C-8/02 *Leichtle* [2004] ECR I-2641, para. 29; Case C-372/04 *Watts* [2006] ECR I-4325, para. 92; Case C-444/05 *Stamatelakis* [2007] ECR I-3185, para. 23.

[188] For a similar interpretation of the subsidiarity principle in health care see Belcher, P. J. *The Role of the European Union in Healthcare*. Brussels: Zoetermeer, 1999.

[189] For further discussion on the role of vertical subsidiarity in creating a Social Europe see Mückenberger, U. (ed.) *Manifesto Social Europe*. Brussels: European Trade Union Institute (ETUI), 2001, pp. 381-832.

[190] See the explanatory memorandum, part 4(b) on general legal aspects.

[191] See para. 147 of the ECJ judgment in Case C-372/04 *Watts* [2006] ECR I-4325.

adopted under other EC Treaty provisions) to adjust their health care and social security systems to EU requirements[192]. The proposed Directive makes it clear that the Commission regards the ultimate aim, i.e., *'universal access to high quality health care on the basis of equity and solidarity*' as requiring European-level action that cannot be achieved sufficiently by Member States alone[193].

Despite the lack of a formal legal competence in health care, the EU can rely on several different legal bases to take action that influences health care organization at national level[194]. The free movement articles of the EC Treaty constitute a most illustrative example: they have served as grounds for the Union to take action that has an impact on Member States' competence to regulate access to health care. Policy decisions and EU law provisions meant to move forward the internal market have affected the health care competences of nation states.

1.1. Freedom of movement in the European Union

Free movement of persons, services, goods and capital represent the four cornerstones of the internal market. As stipulated in Article 14(2) of the EC Treaty, the internal market '*shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty*.' Moving forward the development of the internal market (positive integration) and removing the

[192] The Commission builds this argument on the subsidiarity provision of the EC Treaty. It relies on the *Watts* decision confirming that Article 152(5) does not exclude the possibility to require under other EC Treaty provisions such Article 49 that Member States make adjustments to their national social security systems including their health systems. See part 4(b) of the explanatory memorandum on general legal aspects.
[193] Explanatory memorandum of the Directive on application of patients' rights in cross-border health care, part 4(c), p. 9.
[194] Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 67-68.

obstacles impeding this process (negative integration) constitute major objectives of EU law and policy making[195].

Citizens of the European Union and their family members have a right to reside and move freely within its territory. This right is based on Articles 39-42 of the EC Treaty[196], Regulation 1612/68 on freedom of movement for workers within the Community[197] and EC Directive 2004/38 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States[198]. Freedom of movement can only be exercised if citizens are not constrained by lack of access to appropriate health care while moving between states and do not have to worry about loosing their health care entitlements acquired in the country of insurance.

The European social security co-ordination mechanism has been created in order to ensure that citizens exercising their freedom of movement within the EU are able to preserve their

[195] The distinction between negative and positive integration is particularly relevant to the discussion on the role of the ECJ in promoting access to cross-border care. Originally, the ECJ was meant to promote integration by eliminating national barriers to free movement (the process of negative integration). However, commentators of ECJ rulings on cross-border care argue that the Court has been successful in generating positive integration involving active harmonization of national legislations. Amendments to domestic legal norms on access to medical treatment abroad constitute an illustrative example. (A number of EU countries, notably, Belgium, Denmark and Luxembourg introduced new reimbursement rules for outpatient care obtained abroad, following the ECJ case law). The ECJ rulings will be discussed at detail in Chapter 3. Further details on the distinction between negative and positive integration can be found in Scharpf, W. F. 'Negative and Positive Integration in the Political Economy of European Welfare States', in G. Marks, F. W. Scharpf, P. C. Schmitter and W. Streeck (eds.) *Governance in the European Union*. London: SAGE Publications, 1996.

[196] See particularly, Article 39 of the Treaty Establishing the European Community (Nice consolidated version). Article 39(3(c)) stipulates that the free movement of workers within the Union shall entail the right to '*stay in a Member State for the purpose of work and employment in accordance with the provisions governing the employment of nationals of that State laid down by law, regulation or administrative action*'. The EC Treaty also establishes the general limitations on the free movement of workers. Limitations can be justified on the grounds of public security, public policy and public health. In addition, there are some limitations as to employment in the public service sector. See Articles 39(3) and 39(4) of the EC Treaty.

[197] Council of the European Communities. Council Regulation (EEC) No 1612/68 of 15 October 1968 on freedom of movement for workers within the Community, *OJ* L 257, 19 October 1968, pp. 0002-0012.

[198] European Parliament and Council of the European Union. 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 amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC, *OJ* L 158, 30 April 2004, pp. 0077-0123, p. 35.

social security rights acquired in a certain Member State by transporting them to other countries of the Union. The aim of the co-ordination mechanism is to set the framework for cross-border portability and co-ordination of social security rights[199]. Achievement of this goal is indispensible for making sure that citizens and their families exercising their freedom of movement retain their social security entitlements including the right to health care and medical treatment. If no provisions were made towards this end, then a strong chilling effect would be imposed on this fundamental freedom. At the same time, the co-ordination mechanism reflects the idea that social citizenship is not restricted anymore to the nation state, and the individual should be able to preserve his/her social citizenship while moving across borders.

The legal sources of the social security co-ordination mechanism are the EC Treaty articles dealing with the free movement of persons[200] and the legal basis for co-ordination[201]. The actual framework of the co-ordination mechanism was established by Regulation 1408/71[202] including the substantive provisions and Regulation 574/74[203] containing the implementing measures. Member States should apply directly the social security co-ordination regulations that have been repeatedly amended and updated. A new Regulation (883/2004[204]) was adopted in 2004 with the intention to simplify and modernize the co-ordination mechanism.

[199] See also Vandenbroucke, F. 'The EU and Social Protection: What Should the European Convention Propose?'. Paper presented at the Max Planck Institute for the Study of Science, Köln, 2002.
[200] See Articles 18, 39, 43 and 49.
[201] See Article 42.
[202] Council of the European Communities. Regulation (EEC) Council No 1408/71, 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (Consolidated version), *OJ* L 28 of 30 January 1997, pp. 0001-0147. Regulation 1408/71 is amended regularly**.** For the latest text, see the online source of EU legislation: http://eur-lex.europa.eu/en/index.htm (Last accessed on May 26, 2009).
[203] Council of the European Communities. Regulation (EEC) Council No 574/72 of 21 March 1972 laying down the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to their families moving within the Community (Consolidated version), *OJ* L 28 of 30 January 1997, pp. 0001-0235.
[204] European Parliament and Council of the European Union. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (Text with relevance for the EEA and for Switzerland), *OJ* L 166, 30 April 2004, pp. 0001-0123**.**

Its objectives include strengthening the exercise of free movement of persons and reinforcing the co-operation obligation between the social security systems of Member States[205]. The new implementing regulation is currently under negotiation by the Council and the European Parliament. According to the expectations of the European Commission, the new and modernized social security co-ordination mechanism will be applicable by 2010[206]. Until then, Regulation 1408/71 continues to apply[207].

The co-ordination techniques applied in Regulations 1408/71 and 574/72 intend to remove the elements of national law that might lead to under-protection or accumulation of protection for beneficiaries. There are several co-ordination techniques pursuing this end[208]. The so-called 'single–state rule' establishes that in social security matters involving more than one Member State, one competent state should be indicated that determines the rules on affiliation, liability to contribute and entitlement to benefits[209]. Guaranteeing cross-border portability of acquired social security rights and ensuring aggregation or apportionment of benefit rights constitute further techniques[210]. Last but not least, one should mention the principle of non-discrimination on the basis of nationality, equality of treatment with own nationals and promotion of a smooth collaboration between social security administrations of different states.

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[205] For an analysis of the new and modernized social security co-ordination mechanism, see also Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007, pp. 27-28.

[206] See the website of the European Commission, Employment, Social Affairs and Equal Opportunities: http://ec.europa.eu/social/main.jsp?catId=516&langId=en (last accessed on May 26, 2009).

[207] As stipulated in Article 91 of Regulation 883/1004, Regulation 1408/71 continues to apply until the entry into force of the new implementing regulation.

[208] See EC Regulation 1408/71, Articles 3; 10(1) 12(1); 18(1); 38; 45; 46(3) 64; 67; 72. For a good overview of the co-ordination techniques, see Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven: Instituut Sociaal Recht, 2004-2005.

[209] See EC Regulation 1408/71, cited above. On the co-ordination techniques see also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 113.

[210] If a Member State applies certain conditions for acquisitioning social security rights (for example, certain periods of employment, insurance or residence should be present in order to acquire these rights) then these conditions should be aggregated to the conditions fulfilled in the host Member State. See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 113.

One should note that the scope of the co-ordination mechanism is not restricted to 'workers', but includes also workers' dependants and other categories of EU citizens who can lawfully claim to benefit from freedom of movement[211]. As discussed also in Chapter 1, the ECJ has interpreted broadly the concept of 'worker', and it has extended the categories of persons that a host Member State needs to include into its social security programs. The scope of Regulation 1408/71 includes now citizens of EU countries who are either employed, self-employed or unemployed and seeking work in another Member State, as well as family members, pensioners and students. It also includes citizens of Norway, Iceland, Liechtenstein belonging to the European Economic Area (EEA) and Switzerland. (Since June 2002, the provisions of Regulations 1408/71 and 574/72 which apply between EU Member States also apply in relation to Switzerland, apart from a few exceptions[212]). Third-country nationals legally residing within the EU are also included if they have a situation '*that is not confined in all respects within a single Member State*'[213].

Regulation 883/2004 widens the *rationae personae* of the co-ordination mechanism even further. Instead of enumerating the categories of persons who come under its scope of application, it includes all citizens of EU countries. In addition, it includes also stateless persons and refugees legally residing in a Member State as well as their family members and survivors, provided that these persons have been subjected to the social security legislation of

[211] Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008.
[212] The Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons entered into force on June 1, 2002. Originally concluded for an initial period of 7 years, the agreement can be extended indefinitely. On April 1, 2006 a protocol entered into force extending the agreement to Member States that joined the EU on May 1, 2004. Starting from this date, Regulations 1408/71 and 574/72 are also applicable in relations between Switzerland and the new Member States.
[213] Council of the European Union. Council Regulation (EC) 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, *OJ* L 124, 20 May 2003, 0001-0003, Art. 1.

at least one EU country. This means that, starting with the application of Regulation 883/2004, the personal scope of the co-ordination mechanism will be extended also to the category of *inactive persons* who did not fall previously under its scope[214].

Extension of the co-ordination mechanism to inactive persons is an important development in the field of social solidarity in the EU. It ensures cross-border transportability of social entitlements even if they are not linked to a current work relationship. The rationale behind this development can be traced back to discussions around the importance of de-commodification of the labor force in European welfare states[215] and ideas of social citizenship not confined to paid employment. As defined by Esping-Andersen, '*de-commodification occurs when a service is rendered as a matter of right, and when a person can maintain livelihood without reliance on the market*'[216]. The idea to free individuals from dependence on the labour market is an important development in the field of social solidarity because it highlights that a worker is not a commodity but a person who should maintain his/her social rights even after withdrawing from the labour market. In this sense, individuals would not be continuously forced to sell their own labour force in order to safeguard their social citizenship. This approach reflects the idea that work is not confined to paid employment but encompasses other social activities that are necessary for the existence and survival of the society but are often unpaid. Examples are child care, elderly care, etc. For this reason, there is a need to ensure a legally guaranteed status for all workers including not only employees but also people who perform other activities that are socially desirable but

[214] See also Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven: Instituut Sociaal Recht, 2004-2005, p. 8.
[215] See, for further details on the importance of de-commodification of the labour force in European welfare states, Esping-Andersen, G. *The Three Worlds of Welfare Capitalism*. Cambridge: Polity Press, 1990; Esping-Andersen, G. 'Towards the Good Society, Once Again?', in G. Esping-Andersen (ed.) *Why We Need a New Welfare State*. Oxford: Oxford University Press, 2002.
[216] Esping-Andersen, G. *The Three Worlds of Welfare Capitalism*. Cambridge: Polity Press, 1990, p. 21.

not realized in the framework of a formal employment relationship. This is a precondition for social citizenship[217].

Freedom of movement has been used by the European Commission to assert a legal basis for proposing the Directive on application of patients' rights in cross-border health care. The process of spill-over discussed in Chapter 1 can be clearly traced in this instance[218]. As stated in the explanatory memorandum of the proposed Directive, Article 95 constituted for the Commission a legal basis to put in place the alternative Kohll and Decker procedure for cost assumption in cross-border health care. This alternative procedure is based on the directly effective primary law provisions of the EC Treaty (the free movement articles).

The Commission emphasizes that the Kohll and Decker procedure does not amend in any way the existing social security co-ordination mechanism. Instead, it represents an alternative mechanism for cost assumption that allows for patients to seek cross-border care and be reimbursed according to the tariff applicable for the same treatment in the state of insurance. Within the framework of this mechanism, the financial risk of additional expenses needs to be supported by the patient[219]. This implies that, if the treatment costs more abroad than in the state of insurance, then the patient has to cover the difference. The position of the

[217] See also Mückenberger, U. (ed.) *Manifesto Social Europe*. Brussels: European Trade Union Institute (ETUI), 2001, pp. 372-373.

[218] As discussed in Chapter 1, the neo-functionalist approach conceptualizes spill-over as a leading dynamic in moving forward the process of European integration. Spill-over is the process through which EU authority over one particular policy field emerges and evolves as a result of policy developments and pressures existing in other fields. Neo-functionalist views emphasize that effective conflict management between different interests of economic and political elites leads to spill-over, defined as a constant demand for more integration to satisfy further interests. Integration occurs when supranational institutions manage efficiently the conflicts between economic and political elites. The existence of such supranational activity unleashes a self-reinforcing dynamic that leads to further and deeper integration. See Haas, E. B. *The Uniting of Europe: Political, Social and Economic Forces 1950-1957*, 2nd edition. Stanford: Stanford University Press, 1968, pp. 283-317; McGowan, Lee. 'Theorizing European Integration: Revisiting Neo-functionalism and Testing Its Suitability for Explaining the Development of EC Competition Policy'. *European Integration online Papers* 11(3), 2007, p. 6. On the role of spill-over in health policy development in the EU, see also Mossialos, E. and M. McKee. *EU Law and the Social Character of Health Care*. Brussels: P.I.E. – Peter Lang, 2002, pp. 45-47.

[219] See Part (22) of the Preamble, and Article 3(20), Relationship with other Community provisions, of the proposed Directive. See also Part 3(a) of the explanatory memorandum.

Commission is very much in line with the ECJ case law, analyzed at detail in Chapter 3. The analysis will show that, as a result of the ECJ's constant jurisprudence, the application of freedom of movement to the organization and delivery of health care has become settled.

1.2.The doctrines of direct effect, supremacy and state liability

There are a number of doctrines that play a crucial role in turning EU law into a special legal order. These doctrines have been instrumental in moving forward the process of European integration. They confer upon EU law characteristics that distinguish it from ordinary international law, agreed between and binding upon sovereign states but generally not suitable for being invoked by individuals in national courts unless transposed first into domestic law.

A relevant doctrine in this respect is direct effect. The doctrine of direct effect establishes that Member States must enforce directly EU legislation that is clear, unambiguous, unconditional, and its operation is not dependent on further action on behalf of the Union or national authorities[220]. Individuals can rely on directly effective provisions of EU law in domestic courts of Member States. Courts must give effect to such EU law provisions as if they were provisions of national law[221]. On the basis of the ECJ case law, the principle of direct effect has become applicable to all primary law provisions of the EC Treaty including the free movement articles, and also to secondary EU legislation that meets the criteria mentioned above[222]. EC directives may contain directly effective provisions if they impose a

[220] Hartley, T. C. *The Foundations of European Community Law*, 4th edition. Oxford: Oxford University Press, 1998, p. 191. Also in the presentation given by Vassilios Skouris, President of the European Court of Justice at the Annual Lecture for the United Kingdom Association of European Law, London, 2005.
[221] Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 42-43.
[222] The concept of direct effect was developed by the European Court of Justice in 1963 with regard to a provision of the EC Treaty (primary legislation). See Case C-26/62 *NV Algemene Transport en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration* [1963] ECR 3. The ECJ has subsequently refined the doctrine of direct effect and extended it to secondary EU legislation. See ECJ decisions

minimum protection to be ensured by Member States, if they are clear, unconditional, and have not been transposed at all or have been transposed inadequately although the transposition period has expired[223].

Individuals can bring cases in front of domestic courts by relying on directly effective Treaty articles on free movement. The free movement provisions are enforceable not only by Member States as parties to the EC Treaty but also by individuals bringing litigations against their own Member States. According to the test applied by the ECJ in the *Dassonville* case, individuals can challenge in national courts '*all trading rules enacted by Member States that are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade*'[224]. It is also settled ECJ case law that '*the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement*'[225]. Further on, the ECJ has established that Member States need to comply with the free movement provisions of the EC Treaty and particularly, the freedom to provide services when exercising their regulatory powers in the field of social security including health insurance[226]. As a consequence, even if national rules on health care financing fall within the sphere of social security, they still come under the EC Treaty. As discussed at detail in Chapter 3, the ECJ has gradually extended this rule to all types of health systems (reimbursement, benefit-in-kind, national).

Case C-36/74 *Walgrave and Koch v Association Union Cycliste Internationale* [1974] ECR 1405 and Case C-13/76 *Gaetano Dona v Mario Mantero* [1976] ECR 1333. A good overview of the ECJ jurisprudence related to the doctrine of direct effect was presented by Vassilios Skouris, President of the ECJ since October 7, 2003, at his Annual Lecture for the United Kingdom Association of European Law, London, 2005.

[223] Although EC directives leave to Member States' discretion the means to be used in order to achieve the objectives within the respective period for transposition, they are nevertheless binding as to the result to be achieved. See the presentation given by Vassilios Skouris, President of the European Court of Justice at the Annual Lecture for the United Kingdom Association of European Law, London, 2005.

[224] Case C-8/74 *Dassonville* [1974] ECR 837, para. 5.

[225] See Case C-279/80 *Webb* [1981] ECR 3305, para. 10; Case C-158/96 *Kohll* [1998] ECR I-1931, para. 20; Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473, para. 54.

[226] Case C-158/96 *Kohll* [1998] ECR I-1931, para. 21; Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473, para. 54; Cases C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-0000, para. 39; Case C-372/04 *Watts [*2006] ECR I-4325, para. 92.

The doctrine of direct effect promotes legal integration across the EU together with other two doctrines, namely, supremacy and state liability. According to the doctrine of supremacy, European law prevails in case of conflict with national law. The doctrine of state liability creates a possibility to hold Member States liable for national-level infringements of EU law[227]. The EC Treaty creates a right and a mechanism for the European Commission to initiate infringement procedures against Member States that fail to fulfill an obligation imposed by EU law[228]. According to the infringement procedure, the European Commission may refer a matter to the ECJ when it considers that national laws and regulations are incompatible with EU law. The Commission can start this procedure without having to prove the exhaustion of national remedies or relying on a concrete individual case.

It is noteworthy that the European Commission has been making use of the mechanism of infringement procedure to ensure that Member States comply with EU law on cross-border health care. In an interview carried out in 2005 at the Directorate-General Internal Market and Services, the official emphasized the infringement procedure as the instrument applied by the Commission against Member States that do not implement the ECJ rulings[229]. By 2007, there were around twenty pending infringement procedures against ten Member States with regard to the issue of cross-border patient mobility[230].

[227] The doctrine of state liability was developed by the ECJ in the *Francovich* judgment. Case C-6/90 *Francovich* [1991] ECR I-5357.
[228] See Article 226 of the EC Treaty.
[229] Interview with Geraldine Fages, European Commission, Directorate-General Internal Market and Services. Brussels, October 15, 2005. The interview revealed that, besides making recourse to the infringement procedure, the Commission has also been urging individuals to turn to national courts with complaints related to access to cross-border care.
[230] Kostera, T. 'Europeanizing HealthCare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008, p. 12.

The doctrines of direct effect and supremacy have been established by the ECJ in cases referred to it by national courts via the procedure of preliminary reference[231]. As discussed also in Chapter 1, the procedure of preliminary reference has been instrumental in the process of integration. This procedure entrusts the ECJ with the exclusive competence to pronounce the interpretation of EU law provisions if a related question is referred to it by parties in a domestic court case. National judges may refer questions to the ECJ before the final judgment is delivered at national level whenever a doubt arises related to the compatibility of a national legal provision with EU law, and the decision delivered at national level depends on the interpretation of a specific EU law provision. If no further appeal is possible against the decision of the national court and there is a doubt related to the compatibility of a national legal provision with EU law, then the national court *must* make use of the preliminary reference procedure[232]. As confirmed by the ECJ, the justification for a reference for a preliminary ruling is that it is necessary for the effective resolution of a dispute. Therefore, the Court can only give a preliminary ruling if the question referred to it is related to the actual facts of the case[233]. This mechanism can be used by every national court concerned, even by first instance courts. Preliminary rulings delivered by the ECJ are binding, not only on the court that referred the question but also on all other parties involved (national authorities, institutions and individuals) as well as all other courts in all Member States that

[231] Streho, I. 'Regional Organizations' Judicial Systems Compared: Is the European Model Transposable and Should It Be?'. *Review of Asian and Pacific Studies* 27, 2004.
[232] Ibid. According to Article 234 of the EC Treaty, domestic courts and tribunals against whose decision there is no judicial remedy and who are confronted with questions related to the interpretation or the validity of EU law must ask the ECJ for preliminary ruling. Not respecting this obligation can trigger the infringement procedure established in Article 226 of the EC Treaty.
[233] See Case C-466/04 *Herrera* [2006] ECR I-5341, paras. 48-49. In *Herrera*, the ECJ confirmed that it could not give a preliminary ruling on a question that was hypothetical, or had no relation to the actual facts of the case, or the Court did not have the factual or legal material necessary to give an answer that was useful for the effective resolution of the dispute before the national court.

are confronted with the same question[234]. Consequently, the ECJ is able to promote a uniform interpretation of EU law across domestic legal systems[235].

Preliminary rulings have produced important systemic results in the field of social security through ensuring an ongoing legal conversation between national courts and the ECJ[236]. Other parties such as governments of Member States and the European Commission have also become involved in this legal conversation through written observations submitted to the ECJ cases pursuant to Article 23 of the ECJ Statute. Since the EU law provisions on social security were adopted, the ECJ has delivered more than 600 rulings on their interpretation, and more than ninety percent of these judgments have been delivered upon requests for preliminary ruling[237]. Chapter 3 will discuss the importance of preliminary rulings in establishing the alternative Kohll and Decker procedure in access to cross-border care. It will show how individual litigants, national courts referring cases to the ECJ and the Court itself have became actors in placing access to health services and patients' rights in cross-border care on the European agenda. It will highlight that individuals have been encouraged by the European Commission to make use of the preliminary reference procedure in order to get the ECJ involved in cases involving social security matters and obtain a binding interpretation of relevant EU law provisions on social security.[238]

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[234] As stated also on the website of the ECJ: http://curia.europa.eu/en/instit/presentationfr/index_cje.htm (last accessed on May 26, 2009).
[235] See also Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008.
[236] See also Weiler, J. H. H. 'Epilogue: The Judicial Aprés Nice', in G. De Burca and J. H. H. Weiler (eds.). *The European Court of Justice*. Oxford: Oxford University Press, pp. 215-226, on p. 215.
[237] See the website of the European Commission, Employment, Social Affairs and Equal Opportunities summarizing the social security rights of EU citizens under Union law: http://ec.europa.eu/social/main.jsp?catId=516&langId=en (last accessed on May 26, 2009).
[238] Ibid. The website mentioned at the above note shows the efforts of the European Commission to raise awareness among European citizens on the possibility available for individuals bringing a cross-border care or other social security case to a national court to suggest to the national judge to consult the ECJ in order to obtain a binding interpretation of relevant EU law provisions.

1.3. The Charter of Fundamental Rights of the European Union

In an effort to strengthen the protection of fundamental rights in the European Union, a Charter of Fundamental Rights[239] was adopted in 2000 as an instrument stipulating basic individual rights and freedoms. The Charter has been rarely invoked in legal and political debates around the issue of access to health care in cross-border settings.

Given that the issue of cross-border care has been addressed mainly from a free movement angle and not in an individual rights context, it is remarkable that the proposed 2008 Directive on cross-border health care makes explicit recourse to the Charter of Fundamental Rights. The European Commission relies on several rights stipulated in the Charter when proposing an EU-level framework for enforcing patients' rights in cross-border settings. Specifically, it recalls the right to access preventive health care and benefit from medical treatment, set forth in Article 35 of the Charter:

'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.'

The Charter establishes the importance of recognizing the health care-related rights in the EU and it stipulates the general principles of law. However, determining the precise content of these rights is left for the competence of Member States. In this sense, the wording of Article 35 confirms the general understanding of competence allocation between the EU and Member States, the latter being empowered to regulate the implementation of the health care-related rights at national level. Article 35 makes it clear that these rights are granted under conditions established by domestic law and practice.

[239] European Parliament, Council of the European Union and European Commission. Charter of Fundamental Rights of the European Union, *OJ* C 364, 18 December 2000, pp. 0001-0022.

Article 35 also makes it clear, however, that the EU is obliged to guarantee a high level of human health protection in the definition and implementation of all its policies and activities. This provision is in line with Article 95(3) of the EC Treaty stipulating that EU action aiming to move forward European harmonization should be taken in a way that ensures a high level protection of human health. The proposed Directive on the application of patients' rights in cross-border health care makes explicit recourse to these provisions when asserting its legal basis.

In addition to Article 35 on health care, the proposed Directive mentions other rights and basic principles enshrined in the Charter of Fundamental Rights. Examples include respect for private and family life[240], protection of personal data[241], the right to an effective remedy and to a fair trial[242], the principles of equality before the law[243] and non-discrimination[244]. The proposed Directive identifies these rights as particularly important in cross-border care settings, and makes recourse to them for putting forward a specific Community legal instrument dealing with concrete aspects of patients' rights in cross-border care. Such aspects include cross-border transfer of personal health data and protection of privacy, compensation and complaint mechanisms in case of harm arising from care obtained in another Member State[245], equal treatment of patients from the Member State of insurance with the patients of the Member State of treatment, and the right to challenge administrative decisions regarding the use of health care in another Member State through administrative review and also through judicial proceedings.

[240] Article 7 of the Charter of Fundamental Rights of the European Union.
[241] Article 8, op. cit.
[242] Article 47, op. cit.
[243] Article 20, op. cit.
[244] Article 21, op. cit.
[245] The proposed Directive defines 'harm' as adverse outcomes or injuries that originate in the provision of health care. See Article 4.

Particularly interesting is the European Commission's reliance on the equal access principle when proposing a regulatory power for itself to determine the criteria, conditions and procedure for establishing European reference networks of health care providers[246]. The Commission justifies the establishment of such European reference networks by the need to '*organize at European level equal access to high level shared expertise in a given medical field for all patients as well as for health professionals*'[247]. The criteria and conditions for new health care providers intending to join the European reference networks as well as the procedure for establishing these networks would be determined by the Commission.

As stipulated in Article 15 of the proposed Directive, European reference networks would provide health care to patients whose medical condition requires a particular concentration of resources or expertise, and would also act as focal points for medical training and research, information dissemination and evaluation[248]. They would help Member States lacking technology or expertise in a certain medical field to provide to their patients highly specialized services of the best quality available in Europe[249]. Such centers could be particularly useful for carrying out treatment requiring highly specialized technology and expertise and for treatment of rare diseases. Several smaller countries that cannot sustain national centers providing such treatment would have an option to refer their patients to the respective European center. An example given by the Hungarian National Health Insurance Fund (NHIF) is lung transplantation. According to the Head of the NHIF Department of International Relations and European Integration, there are around 4-5 Hungarian patients per year that need a lung transplantation. The NHIF always sends such patients to the Vienna

[246] See Article 15 of the proposed Directive on cross-border health care.
[247] Preamble, Part 40 of the proposed Directive on cross-border health care.
[248] Preamble, Part 8.3 of the proposed Directive on cross-border health care.
[249] Article 15(2)(e) and Article 15(2)(f) of the proposed Directive on cross-border health care.

transplantation center carrying out around 60 lung transplantations per year[250]. National health care systems could benefit from similar reference centers in other treatment fields.

A novelty of the proposed Directive is the idea that the European reference networks should be responsible for developing health care quality and safety benchmarks applicable throughout the EU[251]. These are clearly issues pertaining to Member States' competence to govern their health care system. The suggestion of the Commission represents a step towards harmonization in the field of health care, because it envisages the development of shared quality and safety benchmarks established at EU level. It is expected that Member States will oppose the extension of EU competence over issues of health care quality and safety benchmarks. It remains to be seen whether the articles moving towards harmonization in health care will be revised or kept unchanged[252].

The following part of Chapter 2 will analyze the legal framework of access to cross-border care as established by the European social security co-ordination mechanism. Since Regulations 1408/71 and 574/72 remain applicable to current and ongoing matters, they will constitute the framework used for the analysis. Nevertheless, significant changes brought about by Regulation 883/2004 will also be discussed.

2. The regulatory framework established by the social security co-ordination mechanism

Social security systems of EU Member States share a basic principle: access to health care is a territorial right. Health coverage is generally restricted to services and goods obtained from

[250] Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary. Budapest, May 22, 2009.
[251] Article 15(2)(e) and Article 15(2)(f) of the proposed Directive on cross-border health care.
[252] The proposed Directive passed the review of the European Parliament in April 2009. However, the text was not finalized until June 1, 2009, when this dissertation was completed.

providers established within the territory of the state of insurance[253]. Cost covering for health care obtained abroad is not automatic and granted only in specific circumstances. Until the developments brought about by the series of ECJ rulings on cross-border care, Member States have enjoyed considerable discretion in establishing the conditions of financing medical treatment obtained abroad. Traditionally, one could not speak of the existence of a genuine 'right to health care abroad', because access to medical treatment has been generally conceptualized as a right restricted to the domestic territory of a given state[254].

Although the territoriality principle is implemented in European health systems as an effort of Member States to restrict financial coverage to services obtained within the national territory[255], each State is required by the European social security coordination mechanism to allow for certain exceptions. One of these exceptions imposed by Regulation 1408/71 is medically necessary treatment received during a temporary visit to another Member State of the European Economic Area (EEA) (including also Norway, Liechtenstein and Iceland as well as Switzerland since 2002[256]). The other exception is planned medical care obtained in another Member State with the authorization of the competent (domestic) insurance fund.

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[253] See, for further details on the territoriality principle in health insurance, Cornelissen, R., 'The Principle of Territoriality and the Community Regulations on Social Security'. *Common Market Law Review* 3, 1996; Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, p. 83; Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven, Instituut Sociaal Recht, 2004-2005.

[254] See also Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, pp. 83-122.

[255] EU Member States generally follow the territoriality principle in regulating access to cross-border care. The EC social security co-ordination mechanism established by Regulations 1408/71 and 574/72 is used as the main framework. Efforts to implement these Regulations can be also detected in case of Member States that joined the EU in 2004. Examples from Hungary and Slovenia will be discussed in Chapter 4. See, for further examples, European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.

[256] The Agreement between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons entered into force on June 1, 2002. Since then, the provisions of Regulations 1408/71 and 574/72 which apply between EU Member States also apply in relation to Switzerland, apart from a few exceptions. On April 1, 2006 a protocol entered into force extending the agreement to the Member States that joined the EU on May 1, 2004. Starting from this date, Regulations 1408/71 and 574/72 are also applicable in relations between Switzerland and the new Member States.

As far as health care is concerned, the purpose of Regulation 1408/71 is threefold. First, it establishes the conditions for transporting health insurance rights across borders for persons who legally reside in a Member State other than the state of social insurance (including workers, self-employed and their dependants, students, pensioners and the unemployed[257]). Second, it specifies the conditions under which a person insured and residing in a certain Member State can be covered for medically necessary treatment received during a temporary visit to another Member State. Third, it specifies in what conditions an insured person is entitled to travel to another Member State for planned treatment covered by the insurance fund of his/her country of insurance. The co-ordination mechanism distinguishes between these three situations, and provides for each of them specific rules and instruments to ensure cross-border and cross-system exportability of acquired social security rights.

2.1. Individuals residing in a Member State other than the state of insurance

The principle of free movement of workers in the European Union[258] establishes a right to reside in any Member State for the purpose of work and employment. Regulation 1408/71 defines 'residence' as habitual residence as distinguished from temporary residence or 'stay'.[259] In such cases the state of insurance differs from the state of residence. The goal of the social security co-ordination mechanism is to ensure that individuals can access social

[257] Prior to the alignment of the rights ensured for different categories of insured persons, Articles 25, 27-29 and 34(a) of Regulation 1408/71 used to deal with students, pensioners and unemployed persons. Regulation 631/2004 amended Regulation 1408/71 in order to bring into line the different health care benefits in kind. See section 2.2.2. of Chapter 2 for further details.

[258] See Article 39 of the EC Treaty (Nice consolidated version). Article 39(3(c)) stipulates that the freedom of movement for workers within the Union shall entail the right to '*stay in a Member State for the purpose of work and employment in accordance with the provisions governing the employment of nationals of that State laid down by law, regulation or administrative action*'. The EC Treaty also establishes the general limitations on the free movement of workers, on the grounds of public security, public policy or public health, as well as some limitations as to employment in the public service sector. See Articles 39(3) and 39(4).

[259] See Article 1(h) and (i) of Regulation 1408/71.

security benefits in the state of residence based on their entitlements acquired in the state of insurance. This applies also to access to health care.

Identifying the Member State that is competent in regulating the given aspect of access to health care is a major issue addressed by the social security co-ordination mechanism. Article 19 of Regulation 1408/71 stipulates the general competence-sharing rules to be applied in such cases. The basic rule is simple: the state of insurance regulates the conditions for entitlement to health care benefits, and the state of residence regulates the provision of benefits. Insured persons and their dependants residing on the territory of a Member State other than that of insurance have the right to health care benefits that are equivalent to the benefits ensured by law for the citizens of the state of residence. In order to be able to exercise this right, insured persons must meet all entitlement conditions established in the legislation of the state of insurance[260].

2.1.1. Benefit in kind vs. cash benefit

Article 19 establishes different competence-sharing rules for regulating access to benefits in kind and for cash benefits. Benefits in kind are provided by the institution of the state of residence *'in accordance with the provisions of the legislation administered by the institution of the place of residence as though the patient were insured with it'*[261]. The rule mentioned above shows that the state of residence where health care is provided determines what kind of health services qualify as benefit in kind. Cash benefits are provided '*by the competent institution in accordance with the legislation which it administers*'. For the purposes of Regulation 1408/71, the concept of 'competent institution' means the institution with which the person is insured at the time of the application of the benefit (or the institution from

[260] As relevant from Article 19 of Regulation 1408/71.
[261] See Article 19 of EC Regulation 1408/71.

which the person is entitled or would be entitled to benefits if he/she or a family member were residents in the territory of the state where the institution is situated)[262]. While the term 'competent institution' has a fixed definition provided by Regulation 1408/71, the meaning of 'competent state' changes depending on the concrete aspect: it can be either the state of insurance or the state of residence. Different competence-sharing rules apply to 'benefit in kind' and 'cash benefit'. It is thus important how benefits in kind and cash benefits are defined and distinguished.

The ECJ case law provides some guidance for defining the scope and content of the 'benefit in kind' concept and distinguishing it from cash benefits. Already in 1965, the Court established in the *Dekker*[263] case that benefits in kind within the meaning of the social security co-ordination mechanism refer to '*benefits in respect of a specific case of sickness or maternity*', and they do not include supplementary pension payments meant for financing an individual's health insurance. In *Vaassen-Göbbels*[264]*,* the ECJ ruled that benefits in kind might take in certain conditions the form of expense reimbursement for medical treatment, medicines and nursing. This is particularly relevant for countries with health systems based on cost reimbursement. As ruled by the Court, '*the term 'benefit in kind' does not exclude the possibility that such benefits may comprise payments made by the debtor institution'*. However, allowances are required to involve the reimbursement of a well-defined treatment in order to qualify as benefit in kind in the meaning of Regulation 1408/71[265]. In the *Vaassen-Göbbels* ruling, the ECJ distinguished cash benefits from benefits in kind by establishing that '*cash benefits are essentially those designed to compensate for a worker's loss of earnings through illness'*.

[262] See Article 1(o) of EC Regulation 1408/71.
[263] Case C-33/65 *Dekker* [1965] ECR I-1135.
[264] Case C-61/65 *Vaassen-Göbbels* [1996] ECR 257.
[265] See also Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, p. 88.

The *Molenaar*[266] case provides further guidelines for distinguishing benefits in kind from cash benefits. This case concerned the problem of cross-border exportability of benefits in case of dependency on long-term care. Concretely, the issue at stake was the status of the German *Pflegegeld* consisting of a regular payment covering the costs entailed if insured persons became reliant on permanent assistance in the performance of their daily routine[267]. Cross-border transportability of insurance benefits concerning dependency on care is becoming an issue of growing attention in the European Union in the context of population ageing and increasing costs of provisions for persons dependent on long-term care. The *Molenaar* case illustrates how cross-border transportability of dependent care benefits comes into conflict with the territoriality principle, as states have traditionally restricted the export of such benefits and suspended their provision in case of residence abroad.

The ECJ ruled in *Molenaar* that benefits of the type of the *Pflegegeld* were intended to supplement sickness benefits in order to improve the health condition and life quality of a person dependent on permanent care[268]. Consequently, such benefits must be considered as health insurance cash benefits with atypical characteristics in the meaning of Article 4(1)(a) of Regulation 1408/71. The ECJ emphasized that the *Pflegegeld* had to be regarded as a cash benefit in the light of Article 19(1)(b) of Regulation 1408/71, because it was a fixed and periodical payment not dependent on the amount of actual expenditures, and its administration was left for the discretion of the recipient[269]. Two further Court decisions

[266] Case C-160/96 *Molenaar* [1998] ECR I-843. This case concerned Mr. and Mrs. Molenaar, Dutch citizens residing in France but employed and voluntarily insured in Germany. They challenged the decision of the German health insurance fund to suspend their entitlement to the German *Pflegegeld* (care allowance) due to the fact that they were living in France.
[267] The *Pflegegeld* includes the so-called 'home care' benefits that might be provided at the choice of the recipient in the form of a fixed monthly allowance.
[268] See para. 24 of the *Molenaar* judgment. Case C-160/96 *Molenaar* [1998] ECR I-843.
[269] Case C-160/96 *Molenaar* [1998] ECR I-843, para. 34.

(*Jauch*[270] and *Gaumain-Cerri/Barth*[271]) confirmed the status of the Pflegegeld as a 'sickness insurance cash benefit' in the meaning of Article 19(1)(b) of Regulation 1408/71. The Court ruled in the *Jauch* case that the care allowance provided in Austria (similar to the German *Pflegegeld*) had to be regarded as a health insurance benefit in cash that had to be provided regardless of whether the insured person resided in the country of insurance or another Member State. The *Jauch* ruling made it clear that Article 19(1) of Regulation 1408/71 precluded national legislation subjecting the provision of dependency care allowance to the condition that the person receiving it resides habitually in the state of insurance.

Several years later, the ECJ was once again confronted with the issue of distinguishing between benefit in kind and cash benefits in the *Herrera* case. In this judgment the Court confirmed its earlier reasoning in *Molenaar*[272], and defined cash benefits as '*benefits of a periodic nature which procure for persons suffering from illness an income substitute or financial support serving to maintain the overall standard of living for the sick person and members of his family*[273].' It emphasized that the concept of cash benefit did not refer to reimbursement of the costs of a well defined treatment, nor to reimbursement of travel, accommodation and subsistence costs linked to planned medical treatment abroad.

The *Molenaar* case made it clear that patient care allowances came under the scope of the co-ordination mechanism as cash benefits. As opposed to benefits in kind, in the administration of cash benefits the legislation of the state of insurance prevails. Specifically, cash benefits

[270] Case C-215/99 *Jauch* [2001] ECR I-1901.
[271] Cases C-502/01 *Gaumain-Cerri* and C-31/02 *Barth* [2004] ECR I-6483.
[272] See Case C-466/04 *Herrera* [2006] ECR I-5341, para. 32.
[273] Case C-466/04 *Herrera* [2006] ECR I-5341, para. 33.

are provided by the competent insurance institution in accordance with the legislation administered by the state of insurance[274].

With the inclusion of care allowances under the scope of the co-ordination mechanism, situations might occur when persons exercising their free movement rights can accumulate benefits. The new co-ordination mechanism introduced by Regulation 883/2004 foresees such situations and includes a rule to prevent the accumulation of benefits. Article 34 of Regulation 883/2004 specifies that in such cases, the amount of the cash benefit shall be reduced by the amount of the benefit in kind that is or could be claimed from the institution of the Member State required to reimburse the cost.

2.1.2. Pensioners retiring to a Member State other than the country of insurance

The ECJ cases on long term care and permanent care allowance highlight the importance of regulating the cross-border transportability of such benefits in the context of the increasing share of elderly people and population ageing in European Union countries. A specific but growing population group that presents a particular interest for cross-border care regulation is formed by pensioners who choose to stay over the long term in another Member State. Studies show that an increasing number of people from Member States of Northern Europe settle down in Southern Europe (typically in Spain, Portugal, Italy, Greece, France[275] but increasingly also in Central European Member States like Hungary[276]).

[274] See Article 19 of EC Regulation 1408/71. In fact, by agreement between the competent institution and the institution providing the health services in the actual state of residence, such cash benefits may be provided by the latter on behalf of the former, in accordance with the legislation of the state of insurance.

[275] Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008, p. 46.

[276] Lengyel B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztositásban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14. According to this study, the number of German, Dutch and British pensioners moving to Hungary has significantly increased following EU accession

The European social security co-ordination mechanism stipulates different rules applicable to pensioners who move their residence officially to another Member State and those who stay abroad without changing officially their original residence. Pensioners who move their residence officially transport to the targeted Member State the benefits that they acquired in their country of origin. The European social security co-ordination law ensures for them the enjoyment of health care benefits on equal footing with the residents of the targeted country[277]. The health insurance institution of the state where they settle down and transfer their residence officially becomes for them the competent institution. As ruled by the ECJ in the *Van der Duin* case[278], the competent institution located in the state where they transfer officially their residence will be in charge of issuing prior authorization for treatment obtained in any other Member State including the country of origin. This is particularly relevant for hospital care, as the *Van der Duin* case makes it clear that such pensioners will not be able to return to their country of origin for hospital treatment without a prior authorization issued in the state where they moved their residence.

Pensioners who choose to stay in another Member State without moving their official residence are entitled to health benefits in kind that become necessary on medical grounds during their stay, taking into account the nature of benefits and the expected length of stay[279]. Health benefits in kind shall be provided by the institution of the place of stay on behalf of the institution of the place of official residence. They are also entitled to cash benefits provided by the country of official residence. Article 31 of Regulation 1408/71 stipulates the

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while the number of Hungarian pensioners moving to another Member State has not changed compared to the years preceeding Hungary's EU membership.

[277] The instrument designated for the exercise of this right is the E121 form, to be submitted for registration to the health insurance institution of the Member State where they move.

[278] Case C-156/01 *Van der Duin* [2003] ECR I-7045.

[279] See Article 31(1(a) of Regulation 1408/71.

rules concerning access to health benefits in kind and cash benefits for pensioners staying in a Member State other than the country of official residence.

Studies show that many pensioners who settle down in another Member State choose not to change their residence officially[280]. This is due partly to the fact that the right to retire officially to another EU country is linked to the condition to prove that the pensioner has the necessary means of subsistence in the targeted country. The EU does not allow for movement to another Member State solely for the sake of more advantageous social benefits including pensions. Other reasons for not transferring officially the residence include concerns linked to the loss of the more advantageous social benefits that some pensioners enjoy in their country of origin and the option to return there when needing more serious medical treatment. This is most characteristic to pensioners moving from Northern Europe to the South, where social benefits are often perceived as less generous. These pensioners often choose to return to their country of origin for longer-term and more serious medical interventions and especially for hospital care[281]. The fact that they are not officially registered in the country of stay becomes a problem especially in cases when they need long-term care or treatment of chronic illnesses.

2.1.3. Rules applicable to family members

A feature of the co-ordination mechanism that is important for social solidarity considerations is extending the right to medical care in the state of residence to workers' dependents (family members supported by them). This is a right that family members enjoy as long as they have

[280] Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008, pp. 46-47.
[281] Ibid.

no other grounds for a right to health care benefits in the state of residence[282]. Thus, an important question is who should be considered a 'family member' in such cases. Article 1(f) of Regulation 1408/71 provides a complex definition of the concept of family member:

'"Member of the family" means any person defined or recognized as a member of the family or designated as a member of the household by the legislation under which benefits are provided.'

The main issue is identifying the competent legislation for determining who qualifies as a family member for the purposes of the social security co-ordination mechanism. Article 1(f) of Regulation 1408/71 says that the legislation of the state of residence determines who should be considered a family member. Although the general practice mostly follows this assumption[283], the European Court of Justice has a word to say in this matter. In the *Delavant* case,[284] the ECJ ruled that the legislation of the state of insurance could also be the competent one in this matter. Concretely, this can happen in cases when a person cannot be considered as a family member according to the legislation of the state of residence[285]. As stated by the ECJ in the *Delavant* judgment:

[282] As set forth in Article 19(2) of EC Regulation 1408/71.
[283] As shown by Jorens, Y. 'The Right to Health Care across Borders', in McKee, M., Mossialos, E. and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, p. 88, footnote 7.
[284] Case C-451/93 *Claudine Delavant v Allgemeine Ortskrankenkasse für das Saarland* [1995] ECR 257.
[285] In the *Delavant* case, the ECJ faced a rather interesting setting. The issue concerned the health benefit in kind of the children of Mrs. Delavant, a French woman working and possessing health insurance in France but residing in Germany as the spouse of a German man. Since the French and the German rules regarding health care cover for Mrs. Delavant's children were in conflict, a crucial issue of the case was which legislation prevailed: the legislation of the state where Mrs. Delavant was residing, or the legislation of the state where she was working and insured. The father's lack of public health insurance complicated the case. The German insurance institution did not accept to base the children's right to benefit on the father, because he was not affiliated with a statutory sickness fund but had private health insurance, due to his income exceeding the limit laid down in German law. The Belgian, German, Dutch and French Governments and the Commission argued for the sole competence of the state of residence in deciding who could be regarded as family member of the worker, if the worker was affiliated to the statutory health insurance fund of that state. The ECJ opposed this argument, and decided that the legislation of the state of insurance was competent in determining who should be considered a family member qualified for benefits in kind when dependants of the insured person were not entitled to those benefits under the legislation of the state of residence.

'Article 19(2) of the Regulation is to be understood as meaning that when a worker resides with the members of his family in the territory of a Member State other than the Member State in which he works, under whose legislation he is insured by virtue of the regulation, the conditions for entitlement to sickness benefits in kind for members of that person' s family are also governed by the legislation of the State in which that person works in so far as the members of his family are not entitled to those benefits under the legislation of their State of residence[286]*.'*

2.1.4. Rules applicable to unemployed persons and frontier workers

Regulation 1408/71 distinguishes two categories of individuals that constitute exceptions to the competence-sharing rules discussed above. One exception concerns the totally unemployed for whom the state of residence becomes in charge of regulating access to benefits in kind and to cash benefits, as though they had been subject to that legislation during their last employment. Also, the costs of benefits shall be met by the institutions of the state of residence. The second exception concerns frontier workers and their family members who are covered by special rules set forth in Article 20 of Regulation 1408/71.

The concept of 'frontier worker' is defined in Article 1(b) of Regulation 1408/71 as any employed or self-employed person who works in a certain Member State and resides in another state where he/she returns as a rule daily or at least once a week. If the worker is posted elsewhere in the territory of the same or another Member State, he/she will still retain the status of frontier worker for a period not exceeding four months, even if he/she is prevented from returning home daily or at least once a week. A frontier worker may obtain benefits both in the state of residence and in the state of insurance. This is an important achievement in enhancing the free movement of workers, because the bureaucracy involved in transferring the entitlements back and forth in case of people who divide their stay between two countries could be a serious impediment to cross-border mobility. This is true especially in case of persons suffering from a chronic disease that requires continuous medical attention.

[286] Case C-451/93 *Claudine Delavant v Allgemeine Ortskrankenkasse für das Saarland* [1995] ECR 257, para. 19.

As a general rule, family members of frontier workers are entitled to benefits in the state of residence, but they can also receive benefits from the state of insurance, based on agreement between the Member States concerned or, in the absence of such an agreement, a prior authorization issued by the competent insurance institution[287].

Summing up the competence-sharing rules, the legislation of the state of insurance governs the *conditions for entitlement* (based on membership in a national health system or an insurance system), the *length of the period* for which the benefit in kind is provided and the *administration of cash benefits*. In case of insurance systems, the state of insurance governs also the *rules on health insurance contributions*[288]. Once the entitlement has been determined, the state of residence prevails in governing the *administration of benefits in kind*, including applicable tariffs, co-payments, access to specialist care and referral procedures[289]. The essence of the social security co-ordination mechanism is that it integrates the patient into the social protection system of the state of residence where he/she obtains the treatment, when it comes to benefits in kind. The state of insurance has to cover the costs that the state of residence incurs in treating the patient. Costs are settled between the two social protection systems according to the tariffs of the state of residence where the treatment is delivered.

Establishing the social security co-ordination rules applicable in case of residence in a Member State other than the state of insurance is one of the objectives pursued by the co-ordination mechanism in health care. In the followings, I will discuss the other main

[287] Emergency treatment constitutes an exception when prior authorization is not necessary, as shown in section 2.2. of Chapter 2.
[288] In the light of the co-ordination mechanism, no contribution can be imposed according to the legislation of the state of residence. See also Stiemer, N. 'Sickness Insurance Viewpoint of the EU Member States', in Y. Jorens and B. Schulte (eds.), *Coordination of social security schemes in connection with the Accession of Central and Eastern European States*. 'The Riga Conference', die Keure, Brugge, 1999, pp. 227-253, p. 228.
[289] See also Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven, Instituut Sociaal Recht, 2004-2005, p. 14.

objectives: ensuring access to medically necessary health care during a temporary visit to another Member State and access to planned treatment in another EU country. Article 22 of Regulation 1408/71 is the key source of rules in both situations (read in conjunction with the relevant provisions of the implementing Regulation 574/72).

2.2. Access to health care during a temporary visit to another Member State

The social security co-ordination mechanism addresses distinctly the situations when an individual insured in an EU Member State becomes ill and in need of medical care during a temporary visit to another country of the European Union. In such cases, the state of treatment does not coincide with the state of residence/insurance. Regulation 1408/71[290] and the implementing Regulation 574/72[291] establish the conditions and procedures for access to health care in such situations.

The rule stipulated in Regulation 1408/71 can be summarized as follows: insured persons who satisfy the entitlement conditions established by the legislation of the state of insurance are entitled to health care benefits in kind that become necessary on medical grounds during a temporary visit to another Member State, taking account of the nature of the benefits and the expected length of the stay. The cost of benefits in kind shall be covered by the competent insurance institution (i.e., the state of insurance). The state of insurance regulates the length of the period during which such benefits are provided. The state of treatment governs the effective provision of the benefits in kind that become necessary on medical grounds. The state of treatment establishes the conditions on access to specialist care, referral procedures and co-payments. This framework is also applicable in Norway, Iceland, Liechtenstein and Switzerland (i.e., within the whole European Economic Area).

[290] See Article 22(1)(a)(i) on employed or self-employed persons and their family members, Article 25(1)(a) on unemployed persons and their family members and Article 31(1)(a) on pensioners and their family members.
[291] See Articles 21, 26 and 31.

Based on the social security co-ordination mechanism, the patient becomes temporarily integrated into the social security system of the Member State visited, as though he/she were insured there. The goal is to ensure equality of treatment with locals, as far as access to medically necessary health care is concerned. To be entitled to benefits, the patient has to prove that he/she has a valid health insurance in the state of insurance.

The following part of this chapter intends to show that the major goal of the social security co-ordination mechanism is to ensure that EU citizens can exercise their free movement rights without being hampered by lack of access to health care that becomes necessary during travel/stay abroad. Nevertheless, equity considerations can also be detected, especially in case of the efforts of EU institutions to bring into line the rights of all insured persons in respect of access to health care during a temporary visit to another Member State.

2.2.1. Introduction of the European Health Insurance Card (EHIC)

The European Health Insurance Card (EHIC) is currently the main instrument designated within the European social security co-ordination mechanism to be used by individuals for exercising their right to medical care during a temporary visit to a Member State other than the state of insurance/residence. The EHIC has recently replaced the previously used E111 and E111B forms that were originally established by Regulation 574/72 for this purpose[292]. Benefits in kind obtained from a provider contracted with the health system of the state of

[292] In addition to the E111 and E111B forms, EC Regulation 574/72 established several other forms to be used by EU citizens seeking treatment while on a temporary visit to a Member State other than the state of insurance or residence. The type of form required depended on the type of the beneficiary. Concretely, forms E111 and E111B were meant for tourists, E128 for students and people working temporarily in a Member State other than the state of residence, E110 for international road transporters and E119 for people registered as unemployed and seeking work in another Member State. One major purpose of the introduction of the European Health Insurance Card was the simplification of the E-forms-based procedures through replacing the different paper forms by one single, personalized, electronic card containing all relevant data.

treatment are financed by the state of insurance. The use of the EHIC is typically recommended for health services that become necessary during a holiday, a business or study trip or a short break abroad[293]. The EHIC is meant for the use of European citizens within the whole European Economic Area including Norway, Iceland, Liechtenstein, and also in Switzerland[294]. The model is identical, and it includes the same technical specifications in each country in order to enable health care providers to identify the card immediately.

According to the rules currently in force, a crucial condition that needs to be fulfilled for a legitimate use of the EHIC is the demonstrated need for medically necessary health care that occurs *during* the insured person's visit abroad. As a rule, the EHIC does not cover the costs of health care obtained abroad if the patient travels to another Member State with the specific aim to obtain treatment for an illness that he/she already had before travelling[295]. The treatment needs to be unplanned in order to be covered by the EHIC. The health care provider in the state of treatment decides in case of doubt whether it is 'medically necessary' to provide the treatment during the expected duration of the stay, meaning that it cannot be delayed until the card holder returns home.

The EHIC can be used to access both hospital and non-hospital care. However, costs are not covered if card holders obtain health services from providers not contracted with the public

[293] The European Commission recommends the use of the EHIC primarily for these types of movement. See the website of the European Commission. Employment, Social Affairs and Equal Opportunities: http://ec.europa.eu/social/main.jsp?catId=559&langId=en (last accessed on May 26, 2009).

[294] European Parliament and Council of the European Union. Regulation (EC) No 631/2004 of the European Parliament and of the Council of 31 March 2004 amending Council Regulation (EEC) No 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, and Council Regulation (EEC) No 574/72 laying down the procedure for implementing Regulation (EEC) No 1408/71, in respect of the alignment of rights and the simplification of procedures (Text with relevance for the EEA and for Switzerland), *OJ* L 100, 6 April 2004, pp. 0001-0005.

[295] As discussed further at section 2.3. of Chapter 2, health care within this category is generally called 'planned care'. The scope of the EHIC does not include such situations, as relevant from Decision 194 of the Administrative Commission on Social Security for Migrant Workers and EC Regulation 631/2004, discussed further in this chapter. See Decision No 194 of December 17, 2003 of the Administrative Commission on Social Security for Migrant Workers. *OJ* L 104/127, April 8, 2004. See also EC Regulation No 631/2994, cited above.

health insurance system. The EHIC is meant to ensure that the card holder has the same access to public sector health care (e.g., non-hospital and hospital care, pharmacies) as nationals of the Member States visited[296]. In most EU countries, the cost of treatment obtained from private doctors and facilities that are not contracted with the public insurance fund need to be fully covered by the EHIC holder. Emergency is usually treated as a special case, when the card holder can turn to the emergency service of the nearest health care facility[297].

The introduction of the EHIC is a good example for the gradually increasing involvement of EU law in the organization and administration of health care benefits. Acting as a promoter of free movement, the European Commission initiated in 2002 an Action Plan for removing the barriers to mobility of workers within European labour markets by 2005[298]. The Commission emphasized in this Action Plan the need to modernize and simplify the social security co-ordination mechanism through *'the extension of the material and personal scope of Regulation 1408/71 and by simplifying its wording and implementation'*. The declared goal of modernization was to alleviate the administrative obstacles faced by workers exercising their free movement rights within the EU. As a component of this modernization initiative, the Commission launched the idea of an 'EU-wide health card' transforming the relevant paper forms (E-forms previously used as instruments to access emergency treatment abroad) into a single, personalized electronic card[299].

[296] These rules are available for the public on the website of the European Commission. See, for further details, http://ec.europa.eu/social/main.jsp?catId=569&langId=en (Last accessed on May 26, 2009).
[297] See section 3.2. of Chapter 4 on the use of the EHIC in Hungary and Slovenia.
[298] European Commission. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Commission's Action Plan for Skills and Mobility, COM(2002) 72 final of 13 February 2002. Brussels: Commission of the European Communities.
[299] See Article 13 of the European Commission's Action Plan for Skills and Mobility, op. cit.

Further to the Commission's Communication, the Barcelona European Council of March 15-16, 2002 agreed to create the EHIC[300]. Afterwards, the effective creation of the card was left for the Administrative Commission on Social Security for Migrant Workers, the body responsible for dealing with all administrative questions arising from Regulation 1408/71 and subsequent regulations[301]. The Administrative Commission adopted in June 2003 three Decisions concerning the introduction of the EHIC starting from June 1, 2004, its technical specifications and the replacement of forms E111 and E111B by the EHIC[302].

2.2.2. Bringing into line the rights of different categories of insured persons

A closely linked initiative of the European Commission was the alignment of rights of all categories of insured persons concerning access to benefits in kind that become medically necessary during a visit to another EU country. Previously, the social security co-ordination mechanism established several different forms and procedures for different categories of insured persons/workers. In order to simplify the procedures and align the rights, the Administrative Commission on Social Security for Migrant Workers adopted in December 2003 the Decision No 194 on the uniform application of Article 22(1)(a)(i) of Regulation 1408/71. The goal of this Decision was to align the contents of Articles 22(1)(a)(i), 25(1)(a)

[300] The outcomes of the Barcelona European Council can be found on the website of the European Parliament: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20020320+ITEMS+DOC+XML+V0//EN&language=EN (Last accessed on April 17, 2009).

[301] See Article 81(a) of EC Regulation 1408/71 establishing the duties of the Administrative Commission on Social Security for Migrant Workers. The Administrative Commission includes delegates of Member States. It is responsible for assisting uniform implementation of the social security co-ordination mechanism and promoting co-operation between states in order to modernize information exchange between competent institutions and speed up cost settlement between different social security systems. See also Lengyel B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztositásban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, pp. 4-14, p. 5.

[302] See Decisions No 189, 190 and 191 of the Administrative Commission of the European Communities on Social Security for Migrant Workers, adopted on June 18, 2003.

and 31(1)(a) of Regulation 1408/71 in order to ensure that health care providers within the EU apply these provisions in a uniform way[303].

Decision 194 brought about a number of important developments. First of all, it contributed to the clarification of the content of the rights conferred upon EHIC holders. Article 1 of Decision 194 defines 'benefits in kind which become medically necessary' as treatments that are granted '*with a view to preventing an insured person from being forced to return before the end of the planned duration of stay to the competent state to obtain the treatment he/she requires*'. One can clearly notice in this reasoning the intention to facilitate free movement. Indeed, Decision 194 stipulates in Article 1 that the purpose of treatment in such cases is to '*enable the insured person to continue his/her stay under safe medical conditions, taking into account the planned length of the stay*'. This clarification became subsequently endorsed by Regulation 631/2004 as a necessary step towards ensuring the alignment of rights of all categories of insured persons with respect to access to health benefits in kind during a temporary visit to another Member State. Regulation 1408/71 used to distinguish between 'immediately necessary care' and 'necessary care'. For certain categories of insured persons, such as pensioners, students, unemployed persons, and persons staying for a longer time in another Member State without being residents or insured there, Regulation 1408/71 used to apply the term 'necessary care'[304]. For other categories, it used to apply the term 'immediately necessary care'. The 2002 Action Plan of the European Commission talked only about 'immediately necessary care' as the sole benefit that EHIC holders could

[303] See the Decision No 194 of December 17, 2003 of the Administrative Commission on Social Security for Migrant Workers concerning the uniform application of Article 22(1)(a)(i) of Council Regulation (EEC) No 1408/71 in the Member State of stay. *OJ* L 104/127, April 8, 2004.

[304] Prior to the amendment brought about by EC Regulation 631/2004, the right of these categories of insured persons to 'necessary care' while on a temporary visit abroad was established in Articles 22b, 25, 31 and 34b of Regulation 1408/71.

obtain[305]. Regulation 631/2004 abolished the distinction between 'immediately necessary care' and 'necessary care', and applied the term 'benefits in kind which become necessary on medical grounds' to all categories of insured persons. Regulation 1408/71 was subsequently amended accordingly.

Another clarification brought about by Decision 194 and subsequently endorsed by Regulation 631/2004 concerns the issue whether the scope of the EHIC covers access to treatment of chronic illnesses occurred *prior* to the patient's departure from the country of insurance/residence. In such cases, the issue is not a sudden illness but rather the need to sustain continuous care during a temporary visit abroad. In other words, are the rights of chronically ill individuals to access health care in such cases restricted to sudden and unforeseeable illnesses that occurred after their departure from the country of insurance/residence? Decision 194 states that the relevant rules set forth in the co-ordination mechanism *'cannot be interpreted in such a way that chronic or existing illnesses are excluded*'. Decision 194 motivates this standpoint by referring to the case law of the European Court of Justice and quoting directly the holding of the *Ioannidis*[306] judgment. The relevant paragraph of the *Ioannidis* ruling included also in the text of Decision 194[307] presents the following reasoning:

The concept of necessary treatment cannot be interpreted '*as meaning that those benefits are limited solely to cases where the treatment provided has become necessary because of a sudden illness. In particular, the circumstance that the treatment necessitated by developments in the insured person's state of health during his temporary stay in another Member State may be linked to a pre-existent pathology of which he is aware, such as a*

[305] See Article 13 of the European Commission's Action Plan for skills and mobility. COM(2002)72 final. Brussels, February 13, 2002, p. 16.
[306] Case C-326/2000 *Ioannidis* ECR I-1703.
[307] See Part 7 of the Preamble of Decision No 194 of the Administrative Commission of the European Communities on Social Security for Migrant Workers.

chronic illness, does not mean that the conditions for the application of these provisions are not fulfilled[308]*'*.

The ECJ emphasized in the *Ioannidis* judgment that the concept of 'health care that becomes necessary on medical grounds' cannot be interpreted as referring only to cases of sudden illness occurred after leaving the home country. This holding strengthened the ability of persons suffering from chronic illnesses to travel to another Member State under safe medical conditions. Again, one can clearly sense the free movement logic here. A very restrictive interpretation of the co-ordination mechanism and particularly, Article 22(1)(a) of Regulation 1408/71 would lead to a strong chilling effect on the free movement of persons with chronic illnesses whose health condition requires continuous and regular medical attention. Besides the free movement aspect, the decision is also important from an equity aspect, because it strengthens the right of chronically ill persons to access health care during a visit abroad on equal footing with persons who do not suffer from chronic illnesses.

2.2.3. Abolishment of needlessly restrictive formalities

Another contribution of Regulation 631/2004 is the abolishment of needlessly restrictive formalities previously imposed by the social security co-ordination mechanism on insured persons seeking health care while traveling within the EU. Formalities that needed to be completed *prior* to treatment included the obligation to submit to the health care institution of the place visited a statement certified by the competent insurance fund proving entitlement to benefits in kind. The free movement argument was crucial in abolishing this formality: Regulation 631/2004 argued that there was a need to remove such needlessly restrictive formalities of '*a nature to hamper free movement*'[309].

[308] Case C-326/2000 *Ioannidis* ECR I-1703, para. 41.
[309] See Part 6 of the Preamble of EC Regulation 631/2004.

It is important to note that Regulation 631/2004 does not exempt all types of benefits in kind from the requirement of prior agreement between the insured person and the institution providing the treatment abroad. The social security co-ordination mechanism has singled out so far two types of interventions that require such a prior agreement. These interventions are specified in Decision No 196 of the Administrative Commission on Social Security for Migrant Workers[310] as kidney dialysis and oxygen therapy. The reasoning set forth in Decision 196 and subsequently endorsed by Regulation 631/2004 combines the free movement logic with the practical spirit of Article 22(1)(a) of Regulation 1408/71. According to Decision 196, the goal of this rule is to ensure that these vital health services requiring specific infrastructure are available upon need and their lack does not hamper the insured person in exercising his/her free movement rights. In line with the rules stipulated in Decision No 196 of the Administrative Commission, EHIC holders can obtain dialysis and oxygen therapy on the basis of a preliminary agreement with a dialysis center located in the state of treatment.

The last but not least progressive development brought about by Regulation 631/2004 was the establishment of a mechanism allowing for institutions to rule on individual cases when differing interpretations of Regulations 1408/71 and 574/72 could endanger the rights of the person concerned. This mechanism includes also the option to refer the controversial matter to the Administrative Commission on Social Security for Migrant Workers.

2.3. Access to planned medical treatment in another Member State

EU citizens traveling to other Member States with the purpose to receive health services represent a particularly interesting case of cross-border care where the clash between social

[310] Decision 196 of the Administrative Commission on Social Security for Migrant Workers. *OJ* L 212/83, June 12, 2004.

security and internal market rules becomes most visible. Commentators point it out that, in economic terms, health services get imported to the Member State that authorizes travelling abroad with the explicit goal to obtain health care and exported by the Member State where the service is provided[311]. It is thus not surprising that the ECJ rulings involving planned medical care abroad have raised the most intensive debates around the economic vs. solidaristic character of health care. Furthermore, these are the judgments that reveal most spectacularly the extent to which EU law and particularly, the jurisprudence of the ECJ can influence national level regulation of access to health care.

'Planned medical treatment' is the term used by the European Commission for cases when patients travel to Member States other than the state of insurance/residence with the specific goal to obtain health care[312]. The choice for this term highlights the essential distinction between unplanned (unforeseen/unexpected) treatment covered by the EHIC and planned treatment traditionally regulated via the prior authorization procedure. Although this concept is not mentioned in the text of Regulation 1408/71, 'planned treatment' is currently used not only by the Commission but also by academics and other commentators[313].

Given the specific importance of planned treatment as a form of cross-border/transnational care, the following section will discuss the regulatory framework set by the social security

[311] Busse, R., Drews, M. and M. Wismar. 'Consumer Choice of Healthcare Services across Borders', in R. Busse, M. Wismar and P.C. Berman (eds.) *The European Union and Health Services: The Impact of the Single European Market on Member States*. Amsterdam: IOS Press, 2002.
[312] Although the term 'planned treatment' implies that the treatment is not urgent but can be postponed, this term is currently used by the Commission for defining movement of patients to other Member States with the aim to obtain health care, be it urgent or not. See the website of the European Commission. Employment, Social Affairs and Equal Opportunities: http://ec.europa.eu/social/main.jsp?catId=569&langId=en (Last accessed on May 26, 2009).
[313] See, for example, Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008; McKee, M., MacLehose, L. and T. Albreht. 'Chapter 11: Free Movement of Patients', in M. McKee, L. MacLehose and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004, pp. 157-175.

co-ordination mechanism established by Regulation 1408/71. The analysis will also refer to the changes brought about by the new co-ordination Regulation 883/2004. Further on, Chapter 3 will be dedicated to the alternative Kohll and Decker procedure (established by the ECJ rulings and based directly on the free movement principles of the EC Treaty) to examine the importance of this mechanism for accessing planned medical care in the European Union.

2.3.1. The prior authorization mechanism under the social security co-ordination law

The essence of the social security co-ordination mechanism in case of access to planned treatment is the prior authorization procedure, established by Article 22 of Regulation 1408/71. In short, the prior authorization rule says that a patient seeking treatment in a Member State other than the state of insurance is required to obtain first an authorization issued by the competent social security institution. This authorization constitutes a necessary condition for cost covering by the insurer. In the framework of the co-ordination mechanism, the prior authorization procedure is generally administered via the E112 form.

The analysis of Article 22(2) of Regulation 1408/71 reveals two legitimate reasons that the competent sickness fund can invoke when refusing an authorization for planned treatment: (1) the treatment targeted abroad is not among the benefits provided for in the state of insurance; (2) the patient can get treated in the state of insurance within the time normally necessary for obtaining the treatment in question in that country[314]. In other words, if the necessary and appropriate health care is among the benefits provided for in the state of insurance but it cannot be provided within the time normally necessary, the competent health insurance institution must authorize the treatment in another Member State and bear the

[314] Previous versions of Regulation 1408/71 included a third possible legitimate reason for the competent sickness fund for refusing prior authorization. According to the previously existing rule, health insurance institutions could refuse the requested authorization also in cases when traveling abroad was prejudicial to the patient's state of health or the receipt of medical care.

financial risk of any additional costs arising[315]. Regulation 1408/71 mentions the patient's current state of health and the probable course of the disease as the two factors that have to be taken into consideration when establishing whether the waiting time for care is still within the time normally necessary in the state of insurance.

In spite of acknowledging the issue of waiting time as a possible source of justification for claiming authorization for treatment abroad, Regulation 1408/71 does not stipulate an unconditional right to be treated in another Member State that could be individually enforceable in EU law and used by patients as a basis for jumping waiting lists existing in the state of insurance[316]. Instead, Regulation 1408/71 sustains Member States' authority to control the authorization procedure, and it grants to insurers considerable discretion in application[317].

It is obvious that a major purpose of the co-ordination mechanism is to sustain the prior authorization rule as an instrument to restrict individuals in uncontrolled cross-border and EU-wide access to medical interventions and health service providers. The competent insurance institution has thus a powerful instrument in controlling, regulating and limiting the

[315] Such an understanding of the essence of the co-ordination mechanism in case of planned care is in line with the approach of the European Commission, as relevant from the explanatory memorandum of the Directive on the application of patients' rights in cross-border health care. See Part 3(a) on regulation for coordination of social security schemes.

[316] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 116.

[317] Practice in this respect differs across Member States. Some states have been usually very restrictive in granting prior authorization, such as Sweden, France and the United Kingdom. Others grant it more often and easily, like Belgium and Luxembourg. There are also Member States that tend to grant authorization for certain types of treatment only, such as new types of treatment that are not available (yet) in the state of insurance. Examples for such practices can be found in Denmark, Germany, the Netherlands, Greece, Hungary and Portugal. See also Palm, W., Nickless, J., Lewalle, H. and A. Coheur. *Implications of Recent Jurisprudence on the Coordination of Health Care Protection Systems*. Summary Report produced for DG Employment and Social Affairs. Brussels: AIM, 2000; Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, pp. 83-122, p. 91; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 116.

insured person's access to planned treatment abroad. Cost-control reasons are clearly present among the motivation backing the establishment of this rule.

The new co-ordination mechanism established by Regulation 883/2004 confirms the conditions of individuals' access to planned treatment in another Member State. Article 20(1) makes it clear that '*an insured person traveling to another Member State with the purpose of receiving benefits in kind during the stay shall seek authorization from the competent institution*'. Article 20(2) of Regulation 883/2004 includes the conditions under which the competent insurance institution must grant authorization. There is one important difference, compared to Regulation 1408/71: when it comes to the issue of waiting time, Regulation 883/2004 applies the concept of '*medically justifiable time limit'*[318] that replaces the term '*time normally necessary for obtaining the treatment'*. One can detect the influence of the ECJ case law in the introduction of the term 'medically justifiable time limit' into the text of Regulation 883/2004[319]. Already in the *Kohll* judgment, the ECJ emphasized the importance of the patient's medical condition in determining the length of the acceptable waiting time for treatment. The recent *Inizan*[320] and *Watts*[321] rulings contributed to the interpretation of 'medically acceptable waiting time'.

What exactly qualifies as acceptable waiting time is a crucial issue that has been addressed by several ECJ cases involving access to planned treatment in cross-border settings. Frequently, the reason why patients opt for seeking treatment abroad is that they have to wait too long for

[318] See Article 22(2) of EC Regulation 1408/71.

[319] The ECJ jurisprudence will be discussed further in Chapter 3 dealing with the case law of the Court and its role in establishing the alternative Kohll and Decker procedure for accessing cross-border care. At this point, I only want to show that the new co-ordination Regulation (EC) 883/2004 attempts to include elements of the ECJ jurisprudence regarding the application of the prior authorization procedure.
[320] Case C-56/01 *Inizan* [2003] ECR I-12403.
[321] Case C-372/04 *Watts [*2006] ECR I-4325.

the necessary treatment in their state of insurance. The ECJ has established that undue delay in treatment is a legitimate reason for obtaining authorization for medical treatment abroad. The *Inizan* case and particularly, the recent *Watts* case are important in this respect, the latter challenging the use of waiting lists as a rationing system in the British NHS.

In the *Watts* case, a British citizen suffering from severe hips arthritis was placed on a waiting list for the necessary surgery in the United Kingdom, with a one-year waiting time. The British doctors considered that Mrs. Watts' health condition required urgent medical intervention, so, she applied for prior authorization to carry out the surgery in another Member State. The British authorities refused to grant the authorization on the grounds that the patient needed a 'routine' intervention and the waiting time (subsequently reduced to four months) was normal and usual within the British NHS. Further to the refusal, Mrs. Watts choose to undergo a hip replacement operation in France. She paid for the surgery herself and challenged in court the British NHS decision refusing the prior authorization. She claimed reimbursement for her surgery costs on the grounds that the authorization was unlawfully refused.

The *Watts* decision is illustrative for the patient-centered approach of the ECJ, and it is an example for strengthening the rights of the individual patient against financial and economic considerations put forward by governments and health authorities. In this judgment, the ECJ made it clear that the crucial factor in determining the acceptable waiting time should be the medical condition of the patient. When interpreting Article 22(2) of Regulation 1408/71, the ECJ emphasized that a medical assessment of the clinical needs of the patient was imperative[322]. Consequently, decisions establishing the existence of undue delay should

[322] *Watts*, para. 79.

always be taken on an individual basis, and national authorities are required to take into account all factors characterizing the medical condition of the patient. The ECJ also established the factors that should be taken into account when carrying out such assessments. Besides the patient's current state of health, these factors also include the patient's degree of suffering, medical history, type of occupation and work performed, as well as the probable course of the illness and its impact on the patient's professional activity.

The important message of the *Watts* ruling is that in determining the length of acceptable waiting time for treatment, the medical condition of the patient prevails over any other consideration of economic, financial or administrative nature[323]. Even if the waiting time is still within the limits of the administratively set waiting period in the patient's state of insurance, authorization for treatment in other Member States cannot be lawfully refused if the patient's health situation necessitates a more urgent intervention. Also, the fact that waiting lists are regarded as 'usual' in the national health care system cannot constitute a legitimate reason for refusing authorization for treatment abroad if the delay arising from such waiting lists exceeds the acceptable waiting time established through medical assessment. The medical assessment should be patient-centered, not disease-centered: the focus is on the person. Medical considerations prevail over cost-control reasons. Last but not least, the lack of specific funds for reimbursing the costs of treatment received abroad – which is typical to national health care systems operating on a benefit in kind basis such as the British NHS – is not a legitimate ground for refusing authorization[324]. As stated by the ECJ:

[323] See, for example, Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security*. Leuven: Instituut Sociaal Recht, 2004-2005, p. 17.

[324] The message of the ECJ is that the national health care systems based on benefit in kind – such as the British NHS - are not exempt of the consequences of the ECJ rulings on cross-border care. The relevance of the ECJ

"[…] the competent institution may not refuse the authorization sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State"[325].

The implementation of the prior authorization rule has raised several controversies due to the differences between Member States' practices in application. Comparative research illustrates that certain countries apply very restrictive rules in granting authorization for planned care in other Member States, while rules applied in other countries are more flexible and generous[326]. Also, the legitimacy of the prior authorization procedure has been questioned by insured patients who have repeatedly claimed that this rule constituted an impediment to the exercise of their free movement rights in the European Union[327]. This is particularly relevant for countries where the social security co-ordination mechanism constitutes in practice the only framework accessible by patients seeking planned care abroad, and the Kohll and Decker procedure has not been implemented[328]. Chapter 3 will discuss how the prior authorization rule has been challenged in a series of ECJ rulings as an impediment to the freedom to provide services within the European Union. The analysis of the ECJ jurisprudence will show that the prior authorization mechanism has been rendered untenable in case of non-hospital treatment and its application has become subject to specific conditions in case of hospital

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case law – and particularly the *Watts* decision - for the benefit in kind systems will be discussed at detail in Chapter 3.

[325] *Watts*, para. 120.

[326] Schulte, B. and Y. Jorens. *European Report*. European Observatory for the Social Security of Migrant Workers, DG Employment and Social Affairs European Commission. Brussels, 2000, p. 45.

[327] See the relevant ECJ cases on access to health care in cross-border settings. Chapter 3 will analyze the court cases initiated by patients who complained that the prior authorization scheme restricted them in exercising their fundamental freedoms in the European Union.

[328] Chapter 4 will discuss examples for countries where the prior authorization procedure constitutes in practice the only mechanism used by patients to access planned care abroad, because the implementation of the Kohll and Decker procedure is moving very slowly forward, and most patients remain poorly informed about their rights in cross-border health care settings.

treatment. Also, the ECJ has ruled in a series of cases that EU countries must ensure that the decision of the competent insurance fund to refuse authorization for planned treatment in another Member State can be reviewed in judicial or quasi-judicial proceedings.

2.3.2. The cost-assumption rules

The social security co-ordination mechanism puts a lot of emphasis on clarifying the cost-assumption rules in case of planned cross-border care. Under co-ordination law, costs are settled between the two social protection systems according to the tariffs of the state of treatment in case of planned medical care obtained through the prior authorization mechanism. As resulting from Article 36 of Regulation 1408/71, benefits in kind provided by the health care facility in the state of treatment shall be fully refunded by the state of insurance. Expenses shall be refunded either on the basis of proof of actual expenditure or lump-sum payments; the latter shall ensure that the refund is as close as possible to the actual expenditure[329]. The competent insurance fund bears the financial risk of any additional costs associated to the authorized medical care, such as additional treatment or hospitalization that could become suddenly necessary. The co-ordination mechanism allows for the possibility for two or more Member States (or the competent authorities of those countries) to provide for other methods of reimbursement or waive all reimbursement requirements between institutions under their jurisdiction[330].

The ECJ has addressed the issue of cost-assumption within the social security co-ordination mechanism in the *Vanbraekel* ruling. In this case Ms Descamps, a Belgian citizen requested authorization for orthopaedic surgery in France from her Belgian insurance institute (Alliance Nationale des Mutualités Chrétiennes, ANMC). The insurance fund refused the authorization

[329] See Article 36(2) of Regulation 1408/71.
[330] See Article 36(3) of Regulation 1408/71.

on the ground that the insured person failed to produce the opinion of a doctor practicing in a Belgian university institution. Ms Descamp decided to get operated in France in spite of the refusal. She paid the cost of the surgery and brought an action against the ANMC for reimbursement of the treatment cost. The domestic court ruled that the requirement imposed by the insurance institute, i.e., that the opinion of a Belgian university professor was necessary before authorization could be granted was excessive. An expert designated to assess the merits of Ms Descamp's request concluded that the patient's recovery required hospital treatment that could be provided in better medical conditions in France. Hence, the national court ruled that the authorization request was unlawfully refused and the cost of health care had to be reimbursed to the patient.

The question referred by the national court to the ECJ in *Vanbraekel* was related to the method of reimbursement. Concretely, the national court asked the following question: when an insured person's authorization request for treatment abroad has been refused and it is subsequently established that the refusal has been unfounded, cost reimbursement should be made according to the scheme of the state or treatment or the scheme of the state of insurance? (The two schemes differed significantly in this case.) Also, the national court asked whether the patient was entitled under Article 36 of Regulation 1408/71 to be reimbursed for all the medical costs incurred in the state of treatment once it was established that the refusal of authorization was unlawful.

The ECJ examined the question of the national court both in the light of Article 22(1)(c) of Regulation 1408/71 and Article 49 of the EC Treaty on freedom of movement. It established that Article 22(1)(c) conferred on insured persons the right to receive benefits in kind provided by the institution in the state of treatment on behalf of the competent institution of

the state of insurance. Benefits in kind should be provided to the insured person in accordance with the provisions of the legislation of the state of treatment, as if the person were insured there. Only the length of the period during which benefits in kind are provided is governed by the legislation of the state of insurance[331]. The Court emphasized the purpose of Article 22(1)(c) to facilitate the free movement of persons covered by social insurance. It stated that both the practical purpose and the spirit of Regulation 1408/71 require that the person is reimbursed directly by the competent insurance institution by an amount equivalent to the sum that would have been paid if the authorization had been granted properly in the first place[332]. As for the second question, the Court made it clear that Article 36 of Regulation 1408/71 on the cost refund between institutions concerns only benefits in kind provided in the state of treatment on behalf of the competent institution of the state of insurance[333]. Hence, the patient is only entitled to reimbursement for such benefits in kind.

The cost-assumption rule established by Regulation 1408/71 differs radically from the cost-settlement rules applied within the framework of the alternative Kohll and Decker procedure based on the free movement principles. As confirmed by the ECJ rulings[334] and the proposed EC Directive on application of patients' rights in cross-border health care[335], the cost assumption rules applied in this alternative framework establish that patients advance the expenses of treatment obtained abroad and get reimbursed *up to the amount that the same or similar treatment would have cost in the state of insurance*, without exceeding the actual expense of the care received abroad. Patients also bear the associated financial risks in this case. As discussed further in Chapter 3, this cost assumption rule renders untenable the

[331] Case C-368/98 *Vanbraekel* [2001] ECR, I-5363, para. 32.
[332] See the *Vanbraekel* judgment, paras. 34 and 53.
[333] *Vanbraekel,* para. 55-56.
[334] See, particularly, the *Kohll, Decker, Vanbraekel* cases.
[335] See Parts (21) and (24) of the Preamble, and Article 6(2) of the draft Directive. See also Part 3(a) of the explanatory memorandum.

argument of national authorities that the Kohll and Decker procedure undermines the financial balance of the domestic social security system. Nevertheless, this rule raises an equity issue, because it advantages wealthier patients (able to advance treatment expenses and to cover additional financial risks) in exercising the right to obtain health care in other Member States on the basis of the free movement principle. The specific equity issues concerning patients from Central and Eastern European Member States will be discussed further in Chapter 4.

The ECJ also addressed the issue whether the authorization granted by the competent institution for medical treatment in another Member State also confers on the patient the right to be reimbursed for the costs of travel, accommodation and subsistence that the patient and any person accompanying him/her incurred in the territory of the state of treatment. The *Herrera* judgment[336] makes it clear that the social security co-ordination mechanism (concretely, Article 22(1)(c) and (2) and Article 36 of Regulation 1408/71) does not confer on the insured person the right to be reimbursed for ancillary expenses, except for the cost of accommodation and meals in the hospital for the insured person himself[337]. Accommodation and subsistence costs are 'inextricably linked' to the health service itself and should be covered by the competent institute, together with the treatment costs[338].

[336] Case C-466/04 *Herrera* [2006] ECR I-5341**.** In this case, Mr. Herrera, a self-employed worker insured with the Spanish national health service was granted authorization to receive hospital treatment in France. The authorization form was valid for one year. Mr. Herrera travelled to France several times in order to obtain the hospital care authorized by the competent institute. He was accompanied by a family member due to his fragile health condition. He claimed reimbursement for the travel, accommodation and subsistence costs from the Spanish national health service. The health service met the cost of the hospital treatment obtained in France, but refused to reimburse the travel, accommodation and subsistence costs and the costs of the family member. The question referred to the ECJ was whether Articles 22(1)(c) and 22(2) and Article 36 of Regulation 1408/71 must be interpreted as meaning that the authorization granted by the competent institution for planned treatment in another Member State also confers on the insured person concerned the right to be reimbursed for the travel, accommodation and subsistence costs connected.

[337] See para. 39, Case C-466/04 *Herrera* [2006] ECR I-5341.

[338] In the *Leichtle* case the ECJ also ruled that accommodation and meals costs incurred during a stay at a spa were inextricably linked to the treatment itself. Case C-8/02 *Leichtle* [2004] ECR I-2641. See Chapter 3 for a detailed discussion of the *Leichtle* case.

2.3.3. Extending the right to planned treatment abroad beyond the EU boundaries

The ECJ was confronted in 2005 with the issue whether planned treatment abroad, authorized in the framework of the social security mechanism could also be obtained in a non-EU country at the cost of the Member State of insurance. The *Keller* judgment is relevant to this issue. In this case, a patient insured in Spain was authorized to obtain hospital treatment in Germany, but the German medical institution decided to refer her to a Swiss (non-EU state) private clinic, due to the special expertise required for the necessary treatment. This case is particularly interesting because, unlike all other ECJ cases on access to health care abroad, it concerns reimbursement of treatment obtained outside of the EU (the social security co-ordination mechanism was not applicable to Switzerland during the time when Ms Keller was treated in the Swiss clinic, i.e., 1994-1996). The Spanish Government emphasized that the issue in *Keller* was a matter falling in the exclusive competence of national law because the treatment was not provided in another EU Member State and the interpretation of Community law was not relevant for the outcome of the main proceedings[339]. Contrary to these arguments, the ECJ ruled that, although the territorial scope of Regulation 1408/71 and EU law in general is restricted to EU Member States, this does not exclude their applicability in cases when services are provided outside the European Union[340]. The ECJ established that EU law and Regulations 1408/71 and 574/72 were applicable in *Keller* because the patient was affiliated to a social security scheme of a Member State, and this was the decisive factor:

'It must be observed on this point, however, that the mere fact that the treatment was given outside Community territory is not enough to exclude the application of those regulations, since the decisive criterion for their applicability is that the insured person concerned is affiliated to a social security scheme of a Member State[341].'

[339] Case C-145/03 *Keller* [2005] ECR I-2529, para. 37. As discussed before in this paper, the ECJ cannot rule on questions that are not directly linked to the outcome of the main proceedings.
[340] See also Den Exter, A. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008, for a thorough analysis of the *Keller* case. Den Exter considers this rule as the essence of the *Keller* judgment.
[341] *Keller*, paras. 38-39.

The Keller case illustrates particularly well the idea discussed in Chapter 1 that the social security co-ordination mechanism weakens Member States' capacity to control their social security systems as a result of having opened up the territorial boundaries of social redistribution. As pointed out by the ECJ, in cases of treatment provided in another Member State via the social security co-ordination mechanism, the state of insurance and the state of treatment share the responsibility for providing the appropriate medical benefits to the patient who was granted authorization for obtaining planned treatment abroad. The Spanish state of insurance was bound in *Keller* by the treatment choice made by the German doctors because the Spanish insurance fund issued the authorization that placed the patient in the German doctors' hands. In the framework of the co-ordination mechanism, the German clinic became responsible not only for choosing the appropriate treatment but also for referring the patient to another clinic in a third state, if the necessary treatment could be provided in due time only there. As it was correct to assume that the German doctors acted as competent medical providers when opting to refer the patient to a third-country (Swiss) clinic[342], the fact that the chosen clinic was located in a non-EU state made no difference in terms of the patient's right to cost reimbursement. By issuing the authorization for treating the patient in Germany, the Spanish social security system and the Spanish state have become obliged to delegate the regulation of the conditions of providing the necessary care to the state of treatment (Germany) including the competence to refer the patient to a third country.

Pointing out that the essence of the co-ordination mechanism is exactly to put the patient on equal footing with the insured persons of the state of treatment, the ECJ ruled that the Spanish insurance fund had to cover the cost of treatment according to the tariffs applied in

[342] The appropriate medical competence of the German doctors could not be doubted in this case, not only because of the mutual recognition of medical doctors' professional skills within the EU, but also because the patient was granted by the Spanish sickness fund authorization to be treated by the German doctors in question.

Germany and by following the German reimbursement rules, provided that the treatment received in Switzerland was among the benefits lawfully provided and covered in the state of insurance (Spain). As ruled by the ECJ, the Spanish sickness fund was not entitled to impose on the patient the obligation to return to the state of insurance and get treated there because the German doctors considered that the medical intervention was urgent and it was impossible to provide it without undue delay elsewhere but in Switzerland. Also, the ECJ ruled that the competent insurance fund was not entitled to impose the prior authorization requirement on obtaining the necessary treatment in Switzerland. Such a requirement would have contravened the interest of the patient needing urgent and vital care, and it would have disregarded the principle of shared responsibilities between the state of insurance and the state of treatment, a cornerstone of the co-ordination mechanism[343].

While extending the scope of the social security co-ordination mechanism beyond the EU boundaries was surprising, the holding in *Keller* followed logically from the main objectives of the co-ordination mechanism, notably, facilitating the free movement of persons, cross-border transportability of acquired social security rights and strengthening the shared responsibility between the state of insurance and the state of treatment in cross-border settings. The *Keller* ruling also confirms the patient-centered approach of the ECJ because it emphasizes the patient's need for urgent care as a decisive factor overruling considerations of administrative, economic and/or financial nature. In determining the urgency of care, the rules applied in the state of treatment prevailed over the rules of the state of insurance.

[343] *Keller*, para. 57.

3. Consequences of the co-ordination mechanism for regulating access to health care

The analysis of the framework established by Regulation 1408/71 reveals that the social security co-ordination mechanism temporarily integrates the patient into the social protection system of the Member State where he/she receives the treatment. The aim of the co-ordination mechanism is to put the patient receiving health care in another Member State on equal footing with the persons insured in that state. The co-ordination framework applies when the patient:

- Legally resides for work-related purposes[344] or as a pensioner on the territory of the Member State where the treatment is provided, while being insured in his/her home country, or
- Uses the European Health Insurance Card as an instrument to access treatment that becomes necessary on medical grounds during a temporary visit to another Member State, or
- Requests and obtains authorization from the competent social security institution of the state of insurance to travel to another Member State for planned treatment.

In the framework of the co-ordination mechanism, the state of insurance and the state of treatment share the responsibility for providing the appropriate medical benefits to the patient. The state of insurance sets the rules determining the patient's entitlement to reimbursed health care abroad, and the state of treatment sets the rules of cost sharing and effective provision of services, including the conditions of access to specialist care (referrals). As a rule, the treatment provided should be allowed for/ recognized by the national law of the state of insurance, and it should be among the benefits covered by the competent insurance

[344] Besides employment and self-employment, this includes study, active search for a job, and professional development/vocational training.

fund. Shared responsibility between the state of insurance and the state of treatment is a basic principle in ensuring access to health care via this mechanism.

The analysis included in Chapter 2 reveals that the social security co-ordination mechanism has affected Member States' exclusive competence to organize their health care systems. Concretely, it has removed Member States' exclusive authority to limit health care benefits to their citizens only. At present, access to health care benefits must be extended also to citizens of other Member States. Also, Member States cannot limit anymore the application and exercise of the right to access health care to their own territory. Health insurance rights have become portable across borders within the EU and in certain cases, also to third countries, as illustrated by the ECJ ruling in the *Keller* case. Moreover, Member States cannot restrict health care providers and health insurance systems form other Member States to enter their health systems. When granting to a patient prior authorization for treatment in another Member State, the state of insurance must accept that the state of treatment sets the rules of cost sharing and effective provision of services, including the conditions of access to specialist care.

The prior authorization rule is the cornerstone of the co-ordination mechanism in case of access to planned treatment in another Member State. Although Member States have traditionally had large discretionary powers in implementing this mechanism, EU law and particularly, the case law of the ECJ have increasingly limited national states' regulatory capacity in this field. At present, it is settled case law that the application of the prior authorization rule needs to be consistent with EU law and particularly, the free movement principles. In a series of judgments, the ECJ assessed the prior authorization rule against the free movement principles, and it established that this instrument constituted an impediment to

the freedom to provide services in the European Union. Although the ECJ sustained the prior authorization mechanism as a valid and lawful instrument in case of hospital treatment, it imposed on Member States the obligation to justify its application in each case in light of the free movement rules, by proving that it is a necessary and least restrictive measure. In case of non-hospital treatment, the ECJ ruled that the prior authorization mechanism constituted an unlawful obstacle to the freedom to provide services. Chapter 3 will discuss at detail the consequences of the ECJ jurisprudence for the prior authorization mechanism and Member States' competence to regulate access to planned care in other EU countries.

Chapter 3: Access to cross-border health care under internal market rules

The European Court of Justice (ECJ) played a crucial role in placing access to health care on the EU agenda. The Court established in a series of rulings that EU law and particularly, the free movement principle apply to the provision of medical services and goods, in spite of nation states' efforts to shield health care from the Union. As a consequence, the traditional view of Member States' exclusive competence in regulating access to medical treatment has been rendered untenable. Access to treatment in other Member States under the internal market rules has become a significant topic in the discussion about the role of the EU in health care and the future of health systems in Europe.

A lot has been written about the significance of the ECJ judgments on cross-border care. Some commentators regarded these rulings as the breaking point for the nationally orientated principle of territoriality in health care[345]. Others argued that the decisions brought European health policies at a critical juncture marked by an unavoidable choice between commercialization of health services and equity in access to medical treatment[346]. Yet others regarded the ECJ rulings as the possible beginning of a process that would ultimately lead to the creation of a European health policy[347].

Chapter 3 reviews the ECJ jurisprudence on access to cross border health care under the internal market rules. The analysis is centered on the legal framework and it deals with health

[345] Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007, p. 32.
[346] See, for example, Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004.
[347] Kavanos, P. 'Health as a Tradable Service: A Prospective View of the European Union'. *EuroHealth* 5(1):18-20, 1999.

care services provided in the form of social benefits[348]. The focus is on the patient's perspective[349]. The underlying idea is the current co-existence of two alternative and distinct procedures to obtain medical care in Member States other than the country of insurance. One is the framework established by the European social security co-ordination mechanism discussed in Chapter 2. The other one is the alternative way established by the ECJ rulings, based on the directly effective free movement provisions of the EC Treaty. The alternative way is referred to as the 'Kohll and Decker procedure'[350], based on the two landmark rulings delivered by the ECJ in 1998. The particularity of this procedure is that it bases insured persons' right to obtain cross-border health services and goods on the freedom to provide services and free movement of goods[351].

It is the intention of Chapter 3 to show that the Kohll and Decker procedure has emerged as a spill-over effect[352] of the ECJ's efforts to remove the obstacles to the implementation of internal market freedoms. The chapter tracks this process by analyzing a series of ECJ rulings that address individual cases with specific and often atypical features. It examines to what

[348] The social character of a health care system shows the extent to which individuals have access to health services and goods in the form of social benefits. There are differences between European states in terms of the scope and content of health care as a social benefit, but Member States generally share a common model based on solidarity. See also Mossialos, E. and M. McKee. 'Chapter 1: A European Social Model?', in E. Mossialos and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, pp. 27-41; Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007, p. 29.

[349] Similarly to Chapter 2, issues related to cross-border movement of medical products, devices, goods and professionals are occasionally addressed but not exhaustively analyzed.

[350] See, for the use of the term 'Kohll and Decker procedure", Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, pp. 83-122; Busse, R. 'Border-crossing Patients in the EU'. *Eurohealth* 8(4):19-21, 2002. The term 'Kohll and Decker solution' has also been used. See Busse, R. 'Border-crossing Patients in the EU'. *Eurohealth* 8(4):19-21, 2002. To emphasize that the *Kohll* and *Decker* rulings established a distinct procedure that runs parallel to the European social security co-ordination mechanism, the term 'Kohll and Decker procedure' is used for the purposes of this paper.

[351] The freedom to provide services is set forth in Article 49 EC. When establishing the Kohll and Decker procedure, the ECJ constructed access to medical treatment and goods in Member States other than the state of insurance as a right based on this fundamental freedom. Nevertheless, such a right presents several limitations, as revealed by the analysis of the relevant ECJ case law in Chapter 3.

[352] The concept of spill-over effect is used here in the meaning established by the neo-functionalist theories discussed in Chapter 1.

extent the preliminary rulings delivered by the Court have produced systemic changes in rules governing access to health care. It also discusses the implications of the ECJ rulings and the need for EU-level legislative action in order to fill in the gaps and clarify the legal uncertainties. Efforts of the European Commission to implement the rulings are also addressed, with particular focus on the proposed European Directive on the application of patients' rights in cross-border health care[353].

1. The Kohll and Decker procedure: a distinct alternative in cross-border care

The ECJ plays an important role in moving forward the process of European integration by removing the obstacles to the enforcement of freedom of movement. As discussed also in Chapters 1 and 2, the procedure of preliminary reference has been instrumental in this process. Established by Article 234 of the EC Treaty, the preliminary reference procedure entrusts the ECJ with the exclusive competence to pronounce the interpretation of the EC Treaty provisions if a related question is referred to it by parties in a case brought before a national court. Preliminary rulings delivered by the ECJ are binding[354], not only on the court that referred the question but also on all other parties involved (national authorities, institutions and individuals) and all other courts in all Member States that are confronted with the same question[355]. As an outcome, the ECJ is able to promote a uniform interpretation of EU law across domestic legal systems[356].

[353] European Commission. 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. Brussels, July 2, 2008.
[354] See also Streho, I. 'Regional Organizations' Judicial Systems Compared: Is the European Model Transposable and Should It Be?'. *Review of Asian and Pacific Studies* 27, 2004.
[355] As stated also on the website of the ECJ: http://curia.europa.eu/en/instit/presentationfr/index_cje.htm (last accessed on April 16, 2009). ECJ rulings can be read in full at this website.
[356] See also Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008.

The mechanism of preliminary reference has been instrumental in establishing the Kohll and Decker procedure. Individual litigants and national courts have made use of the possibility to refer to the ECJ issues related to cross-border health care in order to obtain binding interpretations of relevant EU law provisions. The cases brought before the ECJ can be grouped in two categories. In a typical case falling in the first category, a patient's request for authorization for medical treatment in another Member State is refused by the competent institute. Nevertheless, the patient decides to obtain the necessary treatment abroad, pays for the costs up-front and claims expense reimbursement arguing that the authorization was unlawfully refused. In a typical case falling in the second category, a patient obtains the necessary treatment in another Member State *without* requesting the authorization of the competent institute, and claims expense reimbursement according to the tariffs applicable for the same treatment in the country of insurance. In both cases, patients challenge the prior authorization requirement and argue that this rule constitutes an unjustified restriction on their right to obtain health services and goods in another Member State on the basis of the free movement principle (Articles 49 and 50 EC).

A major outcome of the ECJ case law is the interpretation of the European social security co-ordination mechanism as *one possible alternative* for accessing cross-border care, and the establishment of the Kohll and Decker procedure as another, co-existing and distinct alternative based on the directly effective free movement provisions of the EC Treaty.[357] Under the Kohll and Decker procedure, patients advance the expenses of the treatment obtained abroad, and claim subsequent reimbursement from their social health care system up

[357] Such an interpretation has been repeatedly acknowledged by commentators. See, for example, Nickless, J. A. 'Kohll and Decker: A New Hope for Third-country Nationals'. *Eurohealth* 5(1):20-22, 1999; Mossialos, E. and M. McKee. 'Chapter 4: Free Movement of Patients', in E. Mossialos and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, pp. 83-104. See also Schoukens, P. 'Introduction to Social Security Co-ordination in the EU', in D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security*. Leuven: Instituut Sociaal Recht, 2004-2005, p. 61.

to the amount that the same or similar treatment would have cost in the state of insurance, without exceeding the actual cost paid abroad[358]. In case of ambulatory care, the Kohll and Decker procedure enables patients to obtain medical services and goods in another Member State without the authorization of the domestic social health care system[359]. In case of hospital care, the ECJ has acknowledged the legitimacy of the prior authorization rule but made its application subject to internal market rules[360]. This means that the EC Treaty provisions on freedom of movement apply to the rules governing coverage of health care obtained in another Member State, including the prohibition of restrictions on free movement[361] and the principle of non-discrimination on the basis of nationality[362]. The ECJ has made it clear that the EC Treaty is the primary source of law in this matter, and Article 22 of Regulation 1408/71 constitutes secondary legislation:

'It must be stated that the fact that a national measure may be consistent with a provision of secondary legislation, in this case Article 22 of Regulation No 1408/71, does not have the effect of removing that measure from the scope of the provisions of the Treaty'[363].

This is particularly important because provisions of secondary EU legislation (including the prior authorization mechanism established by Article 22 of Regulation 1408/71) cannot undercut provisions of primary EU law such as free movement of persons[364], free movement of goods and the freedom to provide services. In this sense, the ECJ has reconstructed access

[358] In other words, under the Kohll and Decker procedure costs are settled according to the tariffs applicable in the state of insurance. See, particularly, the *Kohll, Decker, Vanbraekel* cases: Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931; Case C-120/95 *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831; Case C-368/98 *Vanbraekel* [2001] ECR I-5363. As discussed also in Chapter 2, the cost assumption rule applied under the Kohll and Decker procedure differs from the rule established in the framework of the social security co-ordination mechanism, where costs are settled between health systems according to the tariff of the state of treatment.

[359] See also Nickless, J. A. 'Kohll and Decker: A New Hope for Third-country Nationals'. *Eurohealth* 5(1):20-22, 1999.

[360] Access to cross-border hospital care will be discussed further at section 4 of Chapter 3.

[361] Article 49(1) EC.

[362] As stipulated in Article 39(2) EC. The ECJ established in *Ferlini* that differential treatment in health care and particularly, discriminating billing for health services on the ground of nationality constituted a breach of EU law. Case C-411/98 *Ferlini* [2000] ECR I-8081.

[363] *Kohll*, para. 25; *Decker*, para. 27.

[364] Article 39 EC.

to cross-border health care as a right based directly on internal market rules stipulated in the EC Treaty[365].

The leverage of the ECJ in defining the scope and rules on access to cross-border health care is remarkable. Since the landmark *Kohll*[366] and *Decker*[367] rulings, it has become settled case law that health care should be considered as a service within the meaning of the EC Treaty. Consequently, the internal market freedoms apply to individual cases concerning access to medical treatment and goods in cross-border settings. Access to health care has become connected to the free movement principle and ceased to be restricted to exclusive national regulatory competence. This has resulted in the removal of health care organization, delivery and financing from the power-safeguarding boundaries of exclusive national competence by subjecting these fields to the internal market freedoms.

One should nevertheless note that the ECJ rulings have never stated that the authorization procedure set forth in Article 22 of Regulation 1408/71 violated EU law. Instead, the Court upheld the authorization procedure and emphasized that Regulation 1408/71 created one possible way to access cross-border care and have the treatment costs covered by the competent institution. A most interesting outcome of the ECJ case law is the idea that an alternative procedure can co-exist under EU law, and that the social security co-ordination mechanism established by Regulation 1408/71 is not the only lawful framework. For example, the ECJ talks in the *Watts* case about two simultaneously existing procedures and cost-assumption rules in cross-border care: '*The applicability of Article 22 of Regulation No 1408/71 […] does not mean that the person concerned may not simultaneously have the right*

[365] Nevertheless, the enforcement of this right is limited by the requirement to fulfill a number of conditions, discussed in the following parts of Chapter 3 examining the relevant ECJ case law.
[366] Case C-158/96 *Kohll v Union des Caisses de Maladie* [1998] ECR I-1931.
[367] Case C-120/95 *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831.

under Article 49 EC to have access to healthcare in another Member State under rules on the assumption of costs different from those laid down by Article 22[368].'

The co-existence of two alternative procedures was confirmed by the ECJ in the *Stamatelakis* decision delivered in 2007[369]. Insured in Greece, Mr. Stamatelakis obtained treatment in a private hospital in the United Kingdom without requesting any prior authorization from the competent Greek social security institution. He paid out of pocket the cost of private hospital treatment and requested expense reimbursement in Greece. His request was refused. The Greek social security institution argued that the national legislation excluded cost reimbursement in case of treatment provided in a *private* hospital located in another Member State to persons insured in Greece and older than fourteen. At the same time, the Greek law provided for the possibility of cost reimbursement for authorized treatment provided in a *public* hospital located abroad[370]. The question examined by the ECJ was whether Article 49 EC precluded national legislation excluding cost reimbursement for treatment provided in a private hospital in another Member State to insured persons older than fourteen. Due to the fact that the patient did not request any prior authorization in accordance with Article 22 of Regulation 1408/71, the ECJ rejected at the outset the argument of the Belgian Government[371] that the issue should be considered in the light of Regulation 1408/71. Instead, the Court held that the question referred for preliminary ruling had to be considered

[368] Case C-372/04 *Watts [*2006] ECR I-4325, para. 48. See also *Vanbraekel*, paras. 37 to 53.
[369] Case C-444/05 *Stamatelakis* [2007] ECR I-3185.
[370] The relevant Greek legislation (Article 1 of Decree F7/ik. 15 of the Minister for Labour and Social Security of January 7, 1997) stated that hospital treatment abroad had to be authorized by the decision of the competent insurance institution based on a reasoned opinion issued by a special medical board. Hospital treatment had to be authorized in cases where the illness at issue could not be treated at all or sufficiently promptly in Greece. The Decree also provided for a possibility to issue the authorization *a posteriori* when patients needed immediate treatment and travelled abroad without waiting for the authorization. An *a posteriori* authorization could also be issued when patients obtained suddenly necessary treatment during a temporary stay abroad. However, Article 4 of the Greek Decree stated that the cost of treatment obtained in a private hospital was not covered (except in situations concerning children). See paras. 4-6 of the *Stamatelakis* judgment.
[371] The Belgian, Dutch, Greek Governments and the European Commission submitted observations to the *Stamatelakis* case. Particularly, the Belgian Government argued that the questions referred for a preliminary ruling should have been considered solely in the light of the social security co-ordination rules (Article 22 of Regulation 1408/71). See para. 14 of the *Stamatelakis* judgment.

solely in the light of Article 49 EC on the freedom to provide services[372]. The ECJ's reasoning confirmed the existence of two distinct procedures for accessing cross-border care.

The proposed EC Directive on the application of patients' rights in cross-border health care confirms the co-existence of two simultaneous mechanisms for cost assumption[373]. The proposed Directive makes it clear that the co-ordination mechanism (Regulation 1408/71) is sustained as one of the mechanisms. As stated in the Preamble:

'For the patient, therefore, the two systems are coherent: either this directive applies or Regulation 1408/71. In any event, any insured person who requests an authorization to receive treatment appropriate to his/her condition in another Member State shall always be granted this authorization under the conditions provided for in Regulation 1408/71 and 883/04 when the treatment in question cannot be given within the time medically justifiable, taking account his current state of health and the probable course of the disease. The patient should not be deprived of the more beneficial rights guaranteed by Regulation 1408/71 and 883/04 when the conditions are met.'[374]

Although the ECJ rulings have caught the health insurance sector by surprise, they could have been foreseen on the basis of the Court's earlier case law[375]. The analysis of the ECJ jurisprudence reveals that the *Kohll* and *Decker* decisions were neither unexpected nor unprecedented. Several commentators[376] argue that these two judgments have not introduced anything fundamentally new but constituted a logical and foreseeable step forward in the development of EU law. As formulated by Belcher, '*while the rulings may be considered a revolution from a healthcare perspective, given the potential increases in patient mobility,*

[372] See paras. 14-17 of the *Stamatelakis* judgment.
[373] See Part (23) of the Preamble.
[374] See Part (22) of the Preamble, and Article 3(20) of the draft Directive. See also Part 3(a) of the explanatory memorandum on coherence of the proposed Directive with other community policies, notably, the co-ordination regulations.
[375] See, for example, Van der Mei, A. P. 'The Kohll and Decker Rulings: Revolution or Evolution?'. *EuroHealth* 5(1):14-16, 1999.
[376] Van der Mei, A. P. 'The Kohll and Decker Rulings: Revolution or Evolution?'. *EuroHealth* 5(1):14-16, 1999; Belcher, P. J. *The Role of the European Union in Healthcare*. Brussels: Zoetermeer, 1999, p. 69; Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E. Peter Lang, 2002, p. 93.

they could be seen merely as an evolution from the perspective of EC law development'[377]. The following parts of Chapter 3 address the major issues brought about by the Kohll and Decker procedure, and discuss their novelty in the light of the ECJ jurisprudence.

2. Medical treatment as a service within the meaning of the EC Treaty

One of the most controversial aspects of the ECJ rulings on cross-border care was the argument put forward by the Court in *Kohll* and *Decker* that the fundamental principle of freedom of movement applied to the field of health care and health insurance[378]. Consequently, the ECJ examined the prior authorization mechanism in the light of free movement of goods and freedom to provide services. Several national governments objected to the approach of the Court. They argued that the prior authorization mechanism did not fall within the scope of the EC Treaty provisions on freedom of movement, because the prior authorization rule concerned social security and had to be examined solely in the light of Article 22 of Regulation 1408/71[379].

The ECJ upheld in *Kohll* and *Decker* the application of freedom of movement to the field of social security and confirmed this rule in a number of subsequent decisions[380]. The analysis of the Court's jurisprudence reveals that this development was not unprecedented, although it caught national governments by surprise. The Court relied in *Kohll* on its earlier ruling in *Webb*[381] stating that the special nature of certain services '*did not remove them from the ambit of the fundamental principle of freedom of movement'*. The *Kohll* and *Decker* cases

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[377] Belcher, P. J. *The Role of the European Union in Healthcare*. Brussels: Zoetermeer, 1999, p. 69.
[378] See *Kohll*, para. 21 and *Decker*, para. 25.
[379] See the submissions of the Luxembourgish, Belgian, French and UK governments in *Decker* (para. 20) and the Luxembourgish, Greek and UK governments in *Kohll* (para. 16).
[380] See, particularly, Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473; Case C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-4409; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-372/04 *Watts* [2006] ECR I-4325; Case C-444/05 *Stamatelakis* [2007] ECR I-3185.
[381] Case C-279/80 *Webb* [1981] ECR 3305, para. 10.

transferred this rule to the field of social security by stating that the fact that a national rule fell within the sphere of social security did not exclude the application of the EC Treaty provisions on free movement[382]. The outcome is straightforward: although '*Community law does not detract from the powers of the Member States to organize their social security systems*[383]', EU countries must comply with the free movement provisions of the EC Treaty when exercising their regulatory powers in social security[384]. This includes the power to determine the conditions concerning the right or duty to be insured with a social security scheme and the conditions related to entitlement to benefits[385].

Once the application of freedom of movement to the field of social security was settled, the ECJ established that Article 49 EC applied specifically to health care services and the medical profession. In fact, the rule that medical activities fall within the scope of Article 49 EC is also not a novelty of the *Kohll* judgment, as it was established already in the 1984 *Graziana Luisi and Giuseppe Carbone* decision[386]. This joint ruling made it clear that persons obtaining medical treatment in another Member State should be regarded as recipients of services in the meaning of the EC Treaty. In *The Society for the Protection of Unborn Children Ireland Ltd*[387] delivered in 1991, the ECJ ruled that medical termination of

[382] *Kohll*, para. 21, *Decker,* para. 25.
[383] The ECJ has repeatedly pronounced the authority of Member States in organizing their social security systems. See the following ECJ decisions: Case 238/82 *Duphar and Others* [1984] ECR 523, para. 16; Cases 159 and 160/91 *Poucet and Pistre* [1993] ECR 637, para. 6; Case C-70/95 *Sodemare* [1997] ECR I-3395, para. 27; Case C-120/95 *Decker* [1998] ECR I-1831, para. 21; Case C-158/96 *Kohll* [1998] ECR I-1931, para. 17; Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473, para. 44; Case C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-4409, para. 100; Case C-56/01 *Inizan* [2003] ECR I-12403, para. 17; Case C-8/02 *Leichtle* [2004] ECR I-2641, para. 29; Case C-372/04 *Watts [*2006] ECR I-4325, para. 92; Case C-444/05 *Stamatelakis* [2007] ECR I-3185, para. 23.
[384] Case C-158/96 *Kohll* [1998] ECR I-1931, para. 21; Case C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473, para. 54; Cases C-385/99 *Müller-Fauré/Van Riet* [2003] ECR I-4409, para. 39; Case C-372/04 *Watts* [2006] ECR I-4325, para. 92.
[385] *Kohll,* para. 19, *Decker*, para. 23.
[386] Joined Cases C-286/82 and C-26/83 *Graziana Luisi and Giuseppe Carbone v. Ministero del Tesoro* [1984] ECR I-377, para. 16.
[387] Case C-159/90 *The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others* [1991] ECR I-04685, para. 18.

pregnancy, performed in accordance with the law of the Member State in which it is carried out, constituted a service within the meaning of Article 49 EC.

Further on, the right of insured persons to access cross-border health care on the basis of Article 49 EC was stated in the 1998 *Kohll* judgment referring to the social insurance system of Luxembourg operating on the basis of cost reimbursement[388]. The ECJ concluded that the medical service provided for remuneration to Mr. Kohll's daughter (i.e., dental treatment provided by an orthodontist) had to be regarded as a '*service within the meaning of the Article 49 (former Article 60) of the EC Treaty, which expressly refers to activities of the professions*'[389]. The EC Treaty defines services as activities that are '*normally provided for remuneration, insofar as they are not governed by the provisions related to the freedom of movement for goods, capital and persons*[390]'. Article 49 EC states that activities of the professions fall within the definition of services. This includes the medical profession. Consequently, the prohibition of restrictions on free movement[391] and the principle of non-discrimination on the basis of nationality[392] apply to medical services.

[388] Insured with the Luxembourgish Union des Caisses de Maladie, Mr. Kohll requested authorization for his minor daughter to receive treatment from an orthodontist established in Germany. The treatment in Germany was recommended by the patient's Luxembourgish doctor due to the long waiting time existing for the same treatment in Luxembourg. Mr. Kohll's request was rejected by the competent insurance institute on the grounds that the proposed treatment was not urgent and could be provided in Luxembourg. Mr. Kohll challenged the rejection and the subsequent decision of the Higher Social Insurance Council confirming the refusal; he stated that the Council considered only whether the national rules were consistent with Regulation 1408/71, and not whether they were consistent with the freedom to provide services, stipulated in the EC Treaty (Articles 59 an 60). Mr. Kohll argued that Articles 59 and 60 EC precluded national rules which made reimbursement, in accordance with the tariffs of the Member State of insurance, of the cost of dental treatment provided by an orthodontist operating in another Member State subject to prior authorization (see para. 12 of the *Kohll* judgment).
[389] *Kohll,* para. 29.
[390] See Article 50 EC.
[391] See Article 49(1) EC.
[392] As stipulated in Article 39(2) EC.

Similarly, medical goods come under the principle of free movement of goods within the EU, as ruled by the ECJ in *Decker*[393]. The ECJ reasoning in *Decker* on the application of free movement of goods to medical products is also not unprecedented. The Court refers to the earlier *Duphar*[394] judgment when stating that '*measures adopted by Member States in social security matters which may affect the marketing of medical products and indirectly influence the possibilities of importing those products are subject to the Treaty rules on the free movement of goods'*[395]. The conclusion is that freedom of movement should not be compromised when medical goods are at stake[396]. In other words, free movement of goods implies that a person insured in a Member State has a right to obtain medical goods provided in or originating from another Member State[397].

A basic message of the *Kohll* and *Decker* judgments is that social security is not exempt from the requirement to comply with EU law. Following this line of reasoning, it did not take long for the ECJ to establish in the joint *Müller-Fauré*/*Van Riet*[398] judgment that national social security systems should be adjusted so as to ensure the implementation of the freedom of movement. As stated by the Court, '*the achievement of the fundamental freedoms guaranteed*

[393] Insured in Luxembourg, Mr. Decker claimed the reimbursement of the cost of a pair of spectacles with corrective lenses purchased from an optician established in Belgium, prescribed by an ophthalmologist established in Luxembourg. The competent insurance institution rejected the reimbursement claim on the ground that the spectacles had been purchased abroad without prior authorization. Mr. Decker argued that national rules making cost reimbursement of medical products purchased in another Member State conditional upon prior authorization constituted an unjustified restriction on free movement of goods. The submission of the European Commission was in line with Mr. Decker's submission (see para. 17 of the *Decker* judgment).
[394] Case 238/82 *Duphar and Others* v *Netherlands* [1984] ECR 523, para. 18.
[395] *Decker,* para. 24.
[396] See also, Kavanos, P. 'Health as a Tradable Service: A Prospective View of the European Union'. *EuroHealth* 5(1):18-20, 1999.
[397] See also Rich, R. R. and K. R. Merrick. 'Cross Border Health Care in the European Union: Challenges and Opportunities'. *The Journal of Contemporary Health Law and Policy* 23(1):64-105, 2006.
[398] See the *Müller-Fauré/Van Riet* decision. This joint decision involved two cases challenging the Dutch benefit in kind system. Ms Müller-Fauré challenged the refusal of cost reimbursement for dental treatment obtained during her holiday in Germany without prior authorization from her sickness fund. Ms Van Riet sought reimbursement for arthroscopy carried out in Belgium in spite of the fact that her sickness fund refused to authorize the treatment. The Dutch domestic court referred these cases to the ECJ for preliminary ruling on the question whether the Dutch prior authorization rule was compatible with EU law.

by the Treaty inevitably requires Member States to make some adjustments to their national systems of social security[399]*.'*

The legal development depicted above reveals the far-reaching consequences of the idea that medical services and goods are economic services and goods in the meaning of the EC Treaty. In the *Müller-Fauré/Van Riet* ruling the ECJ imposed on Member States the duty to adapt their social security systems to the internal market requirements. This is exactly the kind of development that was feared by Member States, as reflected in the observations submitted in *Kohll* and *Decker* by European governments trying to convince the ECJ to examine the prior authorization rule solely from the point of view of Article 22 of Regulation 1408/71[400].

2.1. The concept of freedom to receive medical services

In cases concerning access to health care in another Member State, what is more relevant is the freedom to *receive* services, rather than the freedom to provide services, because these cases involve patients who travel abroad to obtain medical treatment. It is the service recipient who moves across borders, not the service provider. The EC Treaty stipulates a freedom to provide services within the EU, and it does not talk explicitly about a right of individuals to move across borders in order to get services.

[399] *Müller-Fauré/Van Riet*, para. 102.
[400] In the *Kohll* and *Decker* cases, several European governments (including Belgium, France, the UK, Greece and Luxembourg) submitted observations pointing it out that the free movement provisions of the EC Treaty were not applicable to the prior authorization rule because the latter concerned social security. See *Decker*, paras. 18 and 20; *Kohll*, paras. 13 and 16.

The ECJ has developed the concept of 'freedom to receive services' by extending the EC Treaty provisions beyond their literal wording in order to include the service recipients[401]. The *Graziana Luisi and Giuseppe Carbone* is a landmark ruling illustrating the ECJ's proactive approach in this respect. This joint ruling established that persons obtaining medical treatment in another Member State should be regarded as recipients of services, and that the freedom to provide medical services implies a right to travel to another Member State in order to receive the services. The ECJ stated that '*the freedom to provide services includes the freedom for the recipients of services to go to another Member State in order to receive a service there, without being obstructed by restrictions, even in relation to payments*[402]'. Consequently, travel across borders within the EU for the purpose of receiving medical treatment falls within the scope of services within the meaning of the EC Treaty, similarly to travel for the purposes of business or education.

2.2. Hospital treatment as a service within the meaning of the EC Treaty

National governments argued after *Kohll* that the decision could not apply to hospital care. They contested especially the application of freedom of movement to hospital services, as relevant from the *Geraets-Smits/Peerboms*[403] and the *Vanbraekel* cases[404]. Several European governments submitted observations to these cases and emphasized that hospital service

[401] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 120-121.
[402] Joined Cases C-286/82 and C-26/83 *Graziana Luisi and Giuseppe Carbone v. Ministero del Tesoro* [1984] ECR I-377. This ruling also established that travel for the purposes of medical treatment, business and education fall within the scope of services within the meaning of the EC Treaty. See also Guyot, C. and H. Dyson. 'Review of European Union Case Law in the Field of Tourism'. *International Travel Law Journal* 2004, pp. 199-209.
[403] C-157/99 *Geraets-Simts/Peerbooms* [2001] ECR I-5473. This joint decision involved two cases challenging the Dutch benefit in kind system. Mrs Geraets-Smits received multidisciplinary Parkinson treatment in a German hospital without prior authorization from her Dutch sickness fund. Ms Peerbooms, a 35 years old patient insured in the Netherlands, received special intensive coma therapy in an Austrian hospital that was available only on an experimental basis in the Netherlands, for patients under the age of 25. Both patients challenged the decision of the Dutch sickness fund to refuse cost reimbursement on the grounds that adequate treatment could have been obtained from a contracted health care provider in the Netherlands, and that the treatment obtained abroad was not regarded as 'normal' in the Dutch professional circles.
[404] Case C-368/98 *Vanbraekel* [2001] ECR, I-5363.

could not constitute an economic activity for the purposes of Article 49 EC[405]. The reasons put forward by the governments were the followings: hospital care is not provided for remuneration; hospitals do not act with a view to make profit; and patients are not in a position to choose the content, type, extent and price of intramural services[406].

In spite of Member States' arguments, the ECJ included both hospital and non-hospital treatment within the ambit of the freedom to provide services. The ruling of the Court is again not unprecedented, being backed by its earlier judgments in *Bond van Adverteerders and Others*[407] and *Deliege*[408]. These two rulings established that Article 49 EC did not require that the service be paid by those for whom it is performed. The Court made it clear in *Geraets-Smits/Peerbooms* that the only fact that mattered was that hospitals were paid for the services they provided, and it did not make any difference whether the patient paid for the services directly or the treatment cost was covered by the sickness fund on the basis of a contractual agreement and pre-set tariffs[409].

The *Geraets-Smits/Peerbooms*[410] and the *Vanbraekel*[411] judgments extended the application of the freedom to provide and receive services to hospital treatment. In *Müller-Fauré/Van Riet*[412] the ECJ confirmed that medical activity in general must be considered a service within the meaning of the EC Treaty, and there is no distinction in this respect between care

[405] Thirteen governments submitted observations in *Geraets-Smits/Peerbooms* (the Netherlands, Belgium, Denmark, Germany, France, Ireland, Austria, Portugal, Finland, Sweden, the UK, Iceland and Norway) and eleven in *Vanbraekel* (Austria, Belgium, Denmark, Germany, France, Ireland, Finland, Spain, Sweden, the Netherlands, and the UK).
[406] See the *Geraets-Smits/Peerbooms* judgment, paras. 48-51. See also Mossialos, E. and M. McKee. 'Chapter 4: Free Movement of Patients', in E. Mossialos and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, pp. 93-94.
[407] Case C-352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, para. 16.
[408] Case C-191/97 *Deliege* [2000] ECR I-2549, para. 56.
[409] *Geraets-Smits/Peerbooms*, paras. 56-58.
[410] *Geraets-Smits/Peerbooms*, para. 53.
[411] *Vanbraekel*, para. 41.
[412] *Müller-Fauré/Van Riet*, para. 38.

provided in a hospital environment and care provided outside of such an environment. This rule was upheld in *Inizan*[413] and *Watts*[414]. In the *Leichtle* decision[415] the ECJ included health cure administered for therapeutic purposes at a spa in the scope of Article 49 EC. In the *Stamatelakis* decision delivered in 2007, the Court held that Article 49 applied also to medical services obtained in a private hospital. As formulated by the Court, '*it is immaterial whether the establishment in question is public or private*'[416].

2.3. Medical treatment as a service regardless of the type of the health system

It is also remarkable how the ECJ extended to all types of health systems the rule that medical treatment is a service within the meaning of the EC Treaty. The *Kohll* case referred specifically to treatment provided in a social insurance system operating on the principle of cost reimbursement[417]. As relevant from the national reactions to the *Kohll* and *Decker* judgments, government representatives from Germany, the United Kingdom, Denmark and Italy argued that the rulings only concerned reimbursement social insurance systems (existing in Luxembourg, Belgium and France) and they saw no case for transferability to other systems such as national health services[418].

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[413] *Inizan*, para. 16.
[414] *Watts,* para. 86.
[415] *Leichtle*, para. 28.
[416] *Stamatelakis,* para. 22.
[417] In general, social insurance schemes are based on compulsory insurance, and insurance contributions are usually income related. Social insurance schemes can be reimbursement schemes, when insured persons have to pay for health services and get subsequently reimbursed by their sickness funds, and benefit in kind schemes, when sickness funds pay for the costs of health services directly to health care providers. France, Belgium and Luxembourg are reimbursement social insurance systems. Germany, the Netherlands and Austria are benefit in kind social insurance systems. See Palm, W. and J. Nickless. 'Access to Healthcare in the European Union'. *Eurohealth* 7(1):13-14.
[418] See the synopsis of the German EU Presidency preparatory meeting held in Bonn on November 23-24, 1998: Gobrecht, J. 'National Reactions to Kohll and Decker'. *Eurohealth* 5(1):16-17, 1999. In general, national health systems are benefit in kind systems funded by revenue taxation. The United Kingdom and Ireland are often cited as European examples for a more centralized national health service. Italy, Portugal, Spain, Greece, Denmark, Sweden and Finland are more decentralized national health services. See Palm, W. and J. Nickless. 'Access to Healthcare in the European Union'. *Eurohealth* 7(1):13-14, 2001.

An example for a national health service is the British NHS where hospital treatment is delivered free of charge at the point of use, on a non-profit basis[419], and treatment is financed directly by the state (mostly from general taxation revenue)[420]. The reimbursement issue is not regulated, and there is no set tariff for reimbursement in the British legislation. Government representatives attending in 1998 a working meeting organized by the German Federal Ministry of Health voiced their concerns related to a possible extension of the ECJ rulings to national health services like the British NHS[421]. The Danish representatives expressed their preference to have no further ECJ judgments and suggested to solve the issue of cross-border care by a more flexible organization of the mechanism stipulated in Regulation 1408/71. The French representatives emphasized the need to take measures to prevent the ECJ from regulating the health systems of Member States. Governments voiced their fears that further ECJ decisions would affect their competence to govern social security issues. They emphasized the tension between the internal market freedoms and the right of Member States to organize their social security systems. As concluded by the synopsis of the working meeting, government representatives agreed that Member States would '*seek to avoid the health sector being fashioned by judicial decisions that had already been taken without the political will of the Member States being reflected or endorsed*'[422].

In spite of Member States' opposition, the ECJ established the non-exemption of benefit in kind social insurance systems from the requirement to comply with internal market rules. Stated in *Geraets-Smits/Peerbooms*, this rule was confirmed later in the *Müller-Fauré/Van Riet* judgment. The *Müller-Fauré/Van Riet* cases concerned specifically the Dutch benefits in

[419] As stated in the National Health Service Act 1977 (Section 3), any budget that is allocated, but not spent, can be carried forward under certain conditions, or must be returned to the central government.
[420] See Section 3 of the National Health Service Act 1977.
[421] See the synopsis of the German EU Presidency preparatory meeting held in Bonn on November 23-24, 1998: Gobrecht, J. 'National Reactions to Kohll and Decker'. *Eurohealth* 5(1):16-17, 1999.
[422] Ibid., p. 17.

kind social insurance system. Although the observations submitted by the Netherlands and the United Kingdom emphasized that social insurance systems of benefit in kind and national health systems were non-profit-making bodies, the ECJ ruled that it made no difference whether a treatment was paid directly by a sickness fund to the provider or subsequently reimbursed to the patient. The ECJ relied on its earlier case law (cases *Bond van Adverteerders and Others*[423] and *Deliege*[424]) when stating that Article 49 did not require a service to be paid by those for whom it was performed. As pointed out by the Court in *Müller-Fauré/Van Riet*, a medical service provided and paid for in one Member State still falls within the scope of the freedom to provide and receive services, even if cost reimbursement is done under another Member State's sickness insurance legislation with a social insurance system of benefits in kind[425]. The Court confirmed this rule in *Stamatelakis* by stating that '*a supply of medical services does not cease to be a supply of services within the meaning of Article 49 EC on the ground that the patient, after paying the foreign supplier for the treatment received, subsequently seeks reimbursement of the cost of that treatment through a social security system*'[426].

The British NHS was openly challenged in the *Watts* case referred for a preliminary ruling by the Court of Appeal of England and Wales. One of the questions referred by the national court was whether the ECJ jurisprudence on cross-border care applied also to a national health system such as the British NHS. The ECJ was asked whether there was any distinction in this respect between state-funded national health services and insurance systems such as the Dutch scheme at issue in *Müller-Fauré/Van Riet*. In particular, the question was whether the NHS was obliged to pay for treatment provided for a British person in another Member

[423] Case C-352/85 *Bond van Adverteerders and Others* [1988] ECR 2085, para. 16.
[424] Case C-191/97 *Deliege* [2000] ECR I-2549, para. 56.
[425] *Müller-Fauré/Van Riet*, para. 103.
[426] *Stamatelakis*, para. 21.

State, and whether it was relevant that the patient was seeking treatment independently of the NHS, without prior authorization or notification. The second group of questions addressed to the ECJ asked whether: the provision of hospital treatment by NHS bodies amounted to provision of services within Article 49 EC; NHS bodies providing hospital treatment were service providers in the meaning of EC Treaty Articles 48 and 50; and patients receiving hospital treatment under the NHS exercised a freedom to receive services under Article 49 EC. The Court answered these questions in the affirmative. The *Watts* ruling confirmed the economic service-character of hospital treatment, this time expressly in the framework of the British NHS. The ruling made it clear that national social security rules could not be applied so as to exclude the application of the free movement principles, not even in case of hospital care provided in a national health service.

To sum it up, the ECJ interprets the concept of economic service broadly, as illustrated by its case law on access to cross-border care. The Court upheld the economic service-character of medical care not only in case of ambulatory[427] and hospital treatment reimbursed by a national health insurance fund[428] but also in case of health services funded from the state budget, via taxation[429]. As a consequence, medical care must be regarded as a service in the meaning of the EC Treaty, regardless of the type of treatment and the type of the health care system. This means that the prohibition of restrictions on free movement applies to all forms of medical care obtained in another Member State.

The extension of the ECJ rules mentioned above to all types of medical care, health facilities and health systems is confirmed by the proposed EC Directive on application of patients' rights in cross-border health care. Article 2 defines the scope of the draft Directive as

[427] *Kohll*, para. 29.
[428] *Geraets-Simts/Peerbooms*, paras. 55-58; *Vanbraekel*, para. 42; *Müller-Fauré/Van Riet*.
[429] See the *Watts* decision.

including '*provision of health care regardless of how it is organized, delivered and financed or whether it is public or private*'. The European Commission makes recourse to the ECJ rulings when asserting that neither the special nature nor the way in which they are organized or financed removes health services from the ambit of the free movement principles of the EC Treaty[430].

3. The prior authorization requirement as a restriction to the freedom to provide and receive services

Once it is settled that medical care constitutes a service within the meaning of the EC Treaty, the prohibition of restriction applies. As established by the ECJ, the EC Treaty provisions on the freedom to provide services '*prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the health care sector*'[431]. Nevertheless, restrictions on free movement are not absolute; EU law acknowledges certain conditions when restrictions can be lawful. Therefore, a crucial issue in access to cross-border care is what can be accepted as a lawful restriction on free movement under EU law. This question is particularly relevant to the issue of prior authorization for treatment abroad.

Since the 1970s, the Court has built up progressively the interpretation of the concept of restriction. The *Dassonville*[432] ruling established a test that has been applied repeatedly in cases dealing with cross-border care[433]. The *Dassonville* test says that '*all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or*

[430] See also Parts (5) and (9) of the Preamble and Part 5.2. of the explanatory memorandum on the scope of the proposed Directive.
[431] *Geraets-Smits/Peerbooms*, paras. 44-46, *Watts*, para. 92, *Stamatelakis*, para. 23.
[432] Case C-8/74 *Dassonville* [1974] ECR 837, para. 5.
[433] See paragraph 31 of the *Decker* ruling, when the ECJ refers concretely to the *Dassonville* case as the source of the test applied.

potentially, intra-Community trade' go against free movement[434]. The ECJ applied the *Dassonville* test to medical goods in *Decker* and ruled that the requirement of prior authorization for obtaining health care goods in another Member State constituted an impediment to free movement. As formulated by the Court, '*such rules must be categorized as a barrier to the free movement of goods, since they encourage insured persons to purchase those products in Luxembourg rather than in other Member States, and are thus liable to curb the import of spectacles assembled in those States*[435]*.'*

When dealing with restrictions on the freedom to provide and receive services, the ECJ assesses first whether the given restriction has a potentially chilling effect on the provision of services across borders. The test applied by the ECJ in *Kohll*[436], *Geraets-Smits/Peerbooms*[437], *Vanbraekel*[438] and confirmed in subsequent cases is whether the application of a national rule makes the provision of services between Member States more difficult than the provision of services within one State. This test was developed and applied by the Court in its earlier ruling in *Commission* v. *France*[439]. The outcome of its application in cross-border care is straightforward: the prior authorization rule deters, or even prevents, insured persons from seeking medical services from health care providers established in another Member State. Consequently, the prior authorization scheme constitutes both for insured persons and for health service providers a restriction on the freedom to provide services[440]. The ECJ followed

[434] *Dassonville*, para. 5.
[435] *Decker*, para. 36.
[436] *Kohll*, para. 33.
[437] *Geraets-Smits/Peerbooms*, para. 61.
[438] *Vanbraekel*, para. 44.
[439] Case C-381/93 *Commission v France* [1994] ECR I-5145, para. 17.
[440] *Kohll,* para. 35; *Vanbraekel*, para. 45; *Geraets-Smits/Peerbooms*, para. 69. The ECJ backs this reasoning by referring to the previously mentioned *Graziana Luisi and Giuseppe Carbone* cases (para. 16 of the *Luisi and Carbone* judgment) and the *Bachmann* case: Case C-204/90 *Bachmann v Belgium* [1992] ECR I-249, para. 31.

the same reasoning in its subsequent judgments, notably, *Inizan*[441], *Müller-Fauré/Van Riet*[442], *Leichtle*[443] and *Stamatelakis*[444].

It is thus crucial to clarify what amounts to a justifiable restriction under EU law. The general principle of non-discrimination on the basis of nationality applies. Accordingly, limitations on free movement that discriminate on the basis of nationality (citizenship) are not justifiable[445]. Nevertheless, restrictions that are equally applicable to citizens and non-citizens of a given Member State are still untenable under Article 49 EC unless appropriately justified. The burden of proof is on Member States. The question is what exactly constitutes an appropriate justification for restriction. Article 55 EC (referring to Article 46(1)) stipulates the possibility to restrict the freedom to provide services on three grounds: public policy, public security and public health[446].

Establishment of the elements of appropriate justification has been left largely for the ECJ's jurisprudence. The ECJ permits restrictions on the freedom to provide services if they can be justified by 'overriding reasons of general interest'. Although the Court has not established yet an exhaustive list of 'overriding reasons of general interest', it acknowledged a number of interests that can in principle constitute legitimate justifications for restricting freedom of movement[447]. Examples include protection of the financial viability of social security systems, maintaining a rationalized, stable, accessible and balanced supply of hospital services, controlling expenditures and planning health services in order to maintain treatment

[441] *Inizan*, para. 18.
[442] *Müller-Fauré/Van Riet,* para. 44.
[443] *Leichtle*, para. 30.
[444] *Stamatelakis,* para 25.
[445] See, for the application of the non-discrimination rule in health care, Case C-411/98 *Ferlini* [2000] ECR I-8081.
[446] The EC Treaty also mentions these three grounds as justifications for restricting the free movement of persons. See Article 39(3) EC.
[447] The relevant overriding general-interest reasons accepted by the Court will be discussed further at section 4.2.

capacity and/or medical competence on the national territory that is essential for public health.

The Court established four conditions that Member States must meet in pursuance of overriding general-interest reasons[448]. The first condition is the general principle of non-discrimination on the basis of citizenship. The second condition is the presence of mandatory requirements, meaning that imperative reasons relating to the public interest must be present. The third condition is that the public interest pursued is not already protected by other means. The forth condition is proportionality, meaning that the measure or rule applied should be the least restrictive necessary to achieve the proposed goal. The burden of proof is on states. The ECJ also established that protection of national interests from competition from other Member States does not constitute a justified exemption.

The ECJ case law has also made it clear that interpretation of grounds for restrictions on free movement is a matter of EU law, not national law, and it falls under the competence of the European Court of Justice[449]. This means that the Court has the competence to decide whether national regulatory rules that restrict the freedom to provide and receive services are appropriately justified in the light of EU law. In the followings, I will analyze the ECJ case law concerning restriction on cross-border medical care.

4. The prior authorization rule in case of hospital care

An analysis of the ECJ case law following *Kohll* and *Decker* makes it clear that the Court upheld the prior authorization requirement within the framework of the social security co-

[448] See for an extensive analysis of the ECJ jurisprudence on overriding reasons of general interest, Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 122-123.
[449] See Case C-36/75 *Rutili* [1975] ECR 1219. See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 122.

ordination mechanism. Nevertheless, the Court also established that national authorities had to fulfill a number of conditions when applying the authorization rule. This is particularly relevant to hospital care. At this point, the distinction between hospital and non-hospital treatment and the special character of hospital care become crucial issues. The *Geraets-Smits/Peerbooms* joint cases and the *Vanbraekel* case involved hospital treatment, and confronted for the first time the ECJ with the question whether prior authorization could be justified in case of intramural care. Later on, the ECJ addressed the issue of prior authorization in hospital care also in *Watts* and *Stamatelakis*.

4.1. Definition of hospital care

A basic question is how to define hospital treatment, i.e., how to distinguish it from non-hospital (extramural, ambulatory) treatment. There is no clear consensus across Member States on what constitutes hospital care. The most commonly used definition is that of health care that requires at least one night of stay (or, at least 24 hours admission) in a hospital or clinic[450]. In the *Müller-Fauré/Van Riet* judgment, the ECJ mentioned the importance of distinguishing between hospital and non-hospital treatment, but it did not provide further clarifications or guidance on how to distinguish between them[451].

The importance of defining hospital treatment has been recognized by the European Commission[452], and the task to put together a comprehensive definition was assigned to a

[450] Den Exter, A. 'Patient Mobility in European Union: Health Spas in Ischia, Italy'. *Croat Medical Journal* 46(2):197-200, 2005, p. 199.
[451] *Müller-Fauré/Van Riet*, para. 75.
[452] Establishing a clear definition for hospital care is also necessary because the lack of clarity in distinguishing between hospital and non-hospital care can delay the national-level implementation of the ECJ case law on cross-border care. This is the case for example in Slovenia, where the Health Insurance Institute (HIIS) in charge of implementing the cost-assumption rules under the Kohll and Decker procedure claims that the lack of clarity in defining hospital care hinders implementation. Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, Health Insurance Institute of Slovenia. Ljubljana, October 14, 2008.

special working group in 2005[453]. As no European consensus has been achieved since then, the proposed EC Directive on the application of patients' rights in cross-border health care calls for a minimum Community definition for hospital care. Although distinguishing intramural from extramural care is a matter pertaining to health care organization and falls as such within Member States' competence, the Commission uses a free movement argument to justify EU-level action in this field. According to the argument set forth in the proposed Directive, cross-country differences in the definition of hospital care lead to differences in the application of the ECJ rulings and patients' rights in cross-border settings, and this is a potential obstacle to free movement[454]. Also, the Commission emphasizes the necessity to introduce a minimum harmonized definition of hospital care so that there is no distortion of competition among health systems[455]. For the purposes of reimbursement rules applicable in cross-border settings, the basic definition set forth by the Commission in Article 8(1) of the proposed Directive is in line with the most commonly used version, i.e., treatment requiring overnight accommodation in a health care facility. However, the proposed Directive extends the definition of hospital care also to other types of treatment that do not require overnight hospital accommodation, but do require the use of highly specialized and cost-intensive medical infrastructure or equipment, and to treatment that presents a particular risk for the patient or the population (for example, highly contagious infectious diseases). The proposed Directive calls for EU-level action in establishing and regularly updating the list of such treatments, and confers this responsibility upon the Commission[456].

A further elaboration of the difference between hospital and non-hospital care remains necessary. For example, there is a need to establish the status of combined treatments and the

[453] Interview with Roland Bladh, European Commission, Directorate-General Internal Market and Services. Brussels, October 10, 2005.
[454] See Part (30) of the Preamble and Part 7.3 of the explanatory memorandum.
[455] Ibid.
[456] See Article 8(2) of the proposed Directive on the application of patients' rights in cross-border health care.

so-called 'policlinic treatments' that are in practice carried out in a hospital, although that is not necessary[457]. Drawing a distinction between hospital and non-hospital medical care is particularly important because the ECJ case law established different elements of justification for the prior authorization requirement. In the followings, the elements of justification in case of hospital care are discussed.

4.2. Criteria for justifying the prior authorization rule in case of hospital treatment

The ECJ distinguishes between contracted and non-contracted hospitals in its case law on cross-border care. Contracted hospitals are hospitals (located in-country or in another Member State) that have a contractual agreement with the patient's sickness fund. In such cases, there is no need of prior authorization due to the existence of a contractual arrangement on the provision of services, the applicable tariffs, etc. In case of non-contracted hospitals, the prior authorization requirement might be justified only if Member States prove the existence of overriding reasons of general interest that are capable of lawfully limiting the freedom to provide services[458]. The EC Treaty allows for restrictions on free movement on the grounds of public policy, public security and public health[459].

In *Geraets-Smits/Peerbooms,* the ECJ assessed the prior authorization rule in hospital treatment in the light of the freedom to provide services. The Court acknowledged that medical services provided in a hospital infrastructure presented certain characteristics that made the prior authorization requirement for cost assumption both necessary and reasonable[460]. The ECJ accepted three overriding general-interest reasons that were capable of legitimizing prior authorization in case of non-contracted hospital treatment. The first one

[457] See also Steyger, E. 'National Health Care Systems under Fire (but not too heavily)'. *Legal Issues of Economic Integration* 29, 2002, p. 97. Policlinics are common in some countries of Central and Eastern Europe.
[458] See Case C-353/89 *Commission V. Netherlands* [1991] ECR I-4069.
[459] See Articles 46 and 55 of the EC Treaty.
[460] *Geraets-Smits/Peeroboms*, paras. 76-81.

is protecting the financial balance of social security systems with the aim to ensure cost control in the condition of scarcity of resources. The second reason is maintaining a rationalized, stable, accessible and balanced supply of hospital services. The third one is controlling expenditures and planning health services in order to maintain treatment capacity and/or medical competence on the national territory that is essential for public health[461]. The Court noted that no planning would be possible if patients were at complete liberty to obtain hospital treatment from non-contracted facilities, whether located in the country of insurance or abroad[462]. Consequently, EU law does not in principle preclude a system of prior authorization in case of hospital treatment. Nevertheless, it is the responsibility of the competent institution to justify the conditions attached to the application of the prior authorization rule with regard to overriding reasons of general interest[463]. This means that the competent institution has the burden of proof in justifying refusal of authorization for hospital treatment in another Member State.

It should be noted that the ECJ rejected the argument that public health (as an overriding general-interest reason) required that social security institutions checked the quality of hospital care provided abroad before authorizing it. In *Stamatelakis*, the Court emphasized that public and private hospitals located in other Member States were subject to quality controls in those countries, and medical professionals established within the EU provided professional guarantees equivalent to those of doctors in the Member State of insurance[464]. It based this argument on Council Directive 93/16/EEC of 5 April 1993 to facilitate the free

[461] See *Kohll*, paras. 41, 50 and 51; *Geraets-Smits/Peerbooms*, paras. 72-74. See also Mossialos, E. and M. McKee. 'Chapter 4: Free Movement of Patients', in E. Mossialos and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, p. 94.
[462] *Geraets-Smits/Peerbooms*, para. 81.
[463] *Geraets-Smits/Peerbooms*, para. 82.
[464] See *Stamatelakis,* para. 37. See also *Keller,* para. 50.

movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications[465].

The ECJ assumption that mutual recognition of diplomas and the coordinating and harmonizing directives ensure similar quality standards within the EU has attracted a lot of criticism[466]. As pointed out by Jorens, the Court relied on an entirely hypothetical assumption when holding that quality standards were uniform across Europe and protecting treatment quality was therefore no acceptable justification for the prior authorization requirement. The Council Directive 93/16/EEC mentioned by the Court refers to quality standards for licensing of medical professionals, not for actual medical practice. Also, there are no quality standards for clinics and hospitals that are applicable across the EU. Quality standards differ a lot across Member States and remain an issue of concern in cross-border care. In order to cope with this challenge, the proposed EC Directive on the application of patients' rights in cross-border health care envisages the development of European reference networks of health care providers that would provide quality and safety benchmarks applicable across Europe[467].

In addition to the responsibility to justify the application of the prior authorization rule with regard to the overriding reasons of general interest, the ECJ also made it clear that the application of the prior authorization rule had to satisfy the requirement of proportionality. According to the proportionality requirement, national rules imposing a restriction on freedom of movement should not be more restrictive than what is objectively necessary for the overriding general-interest goal pursued, and they can only be applied if the same result

[465] Council of the European Communities (1993), Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications, *OJ* L 165, 7 July 1993, pp. 0001-0024.
[466] Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, pp. 83-122, on pages 96-97.
[467] See Article 15(2)(e) of the proposed Directive. See Chapter 2 for further discussion on the proposed European reference networks.

cannot be achieved by less restrictive rules. If the goal pursued by the national authorities can be met by a less restrictive measure under the same conditions as the measure that is challenged, then the less restrictive measure should be applied[468].

In *Geraets-Smits/Peerbooms* and in other subsequent cases[469], the ECJ applied the proportionality test to assess the prior authorization rule. What makes the application of the proportionality test peculiar in this case is that the ECJ assesses a whole regulatory mechanism against the goal pursued. In other words, the Court does not assess the size/extent of a restriction, which is usually the idea behind a proportionality test[470]. Instead, it examines whether the mechanism established by EC social security co-ordination law for regulating access to planned treatment abroad constitutes or not the least restrictive measure in a given case. As an outcome, the prior authorization mechanism can be upheld as the least restrictive measure in one case and as a disproportionately restrictive and therefore unjustified measure in another case.

Moreover, the prior authorization mechanism can sometimes constitute a *less restrictive* measure that should be chosen by authorities instead of the measure currently applied, as illustrated by the *Stamatelakis* judgment. As discussed earlier, this case concerned treatment obtained by a Greek patient in a private hospital located in the United Kingdom. The national law prohibited the reimbursement of private hospital care obtained abroad from a non-contracted facility. The Greek government argued that the balance of the national social security system could be endangered if insured persons were allowed to obtain treatment in

[468] See also the following ECJ rulings for the application of the proportionality test: Case C-205/84 *Commission v Germany* [1986] ECR 3755, paras. 27 and 29; Case C-180/89 *Commission v Italy* [1991] ECR I-709, paras. 17 and 18; Case C-106/91 *Ramrath* [1992] ECR I-3351, paras. 30 and 31.
[469] See particularly, the *Müller-Fauré/Van Riet* and the *Stamatelakis* judgments.
[470] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004.

non-contracted private hospitals located in other Member States due to the significantly higher treatment costs charged by private hospitals abroad, compared to public hospitals in Greece. The outcome of the proportionality test was here in the favor of the patient: the ECJ ruled that the prohibition of reimbursement of treatment obtained in non-contracted private hospitals located abroad was not the least restrictive measure. In the opinion of the Court, the prior authorization mechanism constituted a less restrictive measure that took greater account of the freedom to provide services[471]. Also, the Court emphasized that Member States were permitted under EU law to establish reimbursement rates to which patients obtaining health care abroad were entitled[472], provided that the rates were set on the basis of objective, transparent and non-discriminatory criteria.

Besides the proportionality requirement, the ECJ established in *Geraets-Smits/Peerbooms* a set of conditions that Member States had to meet in the application of the prior authorization mechanism. Paragraph 90 of the judgment makes it clear that the prior authorization mechanism '*cannot legitimize discretionary decisions taken by the national authorities which are liable to negate the effectiveness of provisions of Community law, in particular those relating to a fundamental freedom*'. Therefore, the prior authorization mechanism must be based on '*objective, non-discriminatory criteria which are known in advance*' and safeguard the patient against arbitrary measures of national authorities[473]. Authorization requests should be dealt with objectively, impartially and within a reasonable time (regrettably, the Court has not provided any further clarification on how the reasonable procedural length should be determined). The Court also established that Member States had to ensure the possibility to challenge authorization refusals in judicial or quasi-judicial proceedings. In addition, it

[471] See para. 35 of the *Stamatelakis* judgment.
[472] As relevant from the *Stamatelakis* ruling, para. 35.
[473] See also Case C-205/99 *Analir and Others* [2001] ECR I-1271, para. 38.

settled that aims of purely economic nature could not justify the prior authorization mechanism[474].

In *Geraets-Smits/Peerbooms,* the Court considered two conditions that had to be satisfied under the Dutch rules in order to authorize medical treatment in another Member State. One of the conditions was that the treatment had to be considered 'normal in the professional circles concerned'. The other condition was that the treatment had to be 'medically necessary'. The following sections examine these two conditions in the light of the ECJ jurisprudence.

4.2.1. The 'normality' condition

The 'normality condition' is one of the novelties of the ECJ cases on access to cross-border care. In *Geraets-Smits/Peerbooms,* the Dutch sickness fund justified refusal of authorization for treatment abroad by stating that the medical service obtained (i.e., multidisciplinary treatment for Parkinson's disease) was not regarded as 'normal within the professional circles concerned' and it was therefore not part of the benefits covered by the applicable Dutch rule[475]. 'Professional circles concerned' meant in practice professional circles in the Netherlands. The Dutch sickness fund applied the 'normality condition' to cost-assumption in general, regardless of whether the treatment was provided by a contracted or a non-contracted medical facility, within the country or abroad. The 'normality condition' resulted in the establishment of a limitative list excluding certain treatments from reimbursement.

[474] The rule saying that aims of purely economic nature cannot justify a restriction on the freedom to provide services was already formulated in the *SETTG* case and then applied in *Kohll* to the issue of cost reimbursement in health care. See Case C-398/95 *SETTG* [1997] ECR I-3091, para. 23.
[475] *Geraets-Simts/Peerbooms,* para. 29.

The ECJ upheld the 'normality' rule as a possible ground for refusing prior authorization. Relying on its earlier judgment in *Duphar and Others*[476], the Court confirmed that it was within Member States' regulatory competence to determine the conditions governing entitlement to benefits within domestic social security systems. This means that EU law cannot in principle require Member States to extend the list of health services included in the domestic social insurance package. Therefore, it is in principle compatible with EU law for a Member State to establish limitative lists excluding certain products from reimbursement under its social security scheme, even if the same products are covered in other Member States[477]. However, it is also settled case law that Member States have to comply with EU law when taking such decisions. The list of medical services excluded from reimbursement must be established in compliance with the EC Treaty provisions and in accordance with objective criteria that are independent of the origin of the service provider[478]. Putting in place objective and non-discriminatory guidelines that are known in advance and not used arbitrarily was emphasized by the ECJ as a requirement that had to be met in determining 'normality' of treatment. Only such guidelines could safeguard patients from arbitrary application of the prior authorization rule and be therefore compatible with the ECJ case law.

An analysis of the relevant case law reveals that the Court left the concept of 'normal' treatment open to interpretation. It only established that deciding what is 'normal in the professional circles concerned' is not an exclusive matter of national law and practice. A focus on national conceptions of 'normal' would favor domestic health care providers[479] and constitutes therefore a restriction on the freedom to provide services. So, the ECJ made it

[476] Case 238/82 *Duphar and Others* v *Netherlands* [1984] ECR 523, para. 17.
[477] *Geraets-Simts/Peerbooms*, para. 85.
[478] *Duphar and Others* v *Netherlands*, para. 21; *Geraets-Simts/Peerbooms*, para. 86.
[479] *Geraets-Simts/Peerbooms*, para. 96. See also Den Exter, A. P. 'Claiming Access to Health Care in the Netherlands under International Treaty Law'. *Medicine and Law* 27(2):569-595, 2008, p. 581.

clear that authorization could not be refused on the 'normality' ground if the treatment was sufficiently tried and tested by international medical science[480]. As stated by the Court,

'*Member States must take into consideration all the relevant available information, including, in particular, existing scientific literature and studies, the accepted opinions of specialists and the fact that the proposed treatment is covered or not covered by the sickness insurance system of the Member State in which the treatment is provided*'.

The 'normality' rule suggests that Member States and sickness insurance institutions have to guarantee for all insured persons health care that satisfies the standards of international medicine[481]. However, the problem with this approach is that it is entirely unclear what the ECJ means by criteria based on international medical science, as there is no common international medical paradigm to rely on. It is noteworthy that the ECJ talks about international medical science, not European. This implies that medical science outside the EU should also be considered. As highlighted also by Mossialos et al., such an approach disregards existing evidence on the high diversity of national treatment practices and the cultural contingency of health care[482]. Also, the 'normality' rule suggests that it is not enough anymore to aim at the respective national standards of medicine. If treatment of international standards cannot be provided in the insured person's home country, then the domestic insurance fund must cover the costs of treatment obtained in another Member State[483]. This could impose particularly challenging requirements for domestic health systems, especially because patients are likely to make use of the differences among medical opinions in order to

[480] *Geraets-Simts/Peerbooms*, para. 98.
[481] Karl, B. 'The Future of Cross Border Care', in *Yearbook of European Medical Law*. Lidingö: The Institute of Medical Law, 2005, pp. 73-89, on pages 77-78.
[482] Mossialos, E., McKee, M., Palm, W., Karl, B. and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union. Brussels, 19 November 2001, p. 52; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 137.
[483] See also Karl, B. 'The Future of Cross Border Care', in *Yearbook of European Medical Law*. Lidingö: The Institute of Medical Law, 2005, pp. 73-89, on pages 77-78.

steer reimbursement-related disputes according to their own interest, as suggested by the *Geraets-Smits/Peerbooms* and *Vanbraekel* cases[484].

4.2.2. The 'necessity' condition

The necessity condition is one of the most debated issues within the topic of cross-border care. The ECJ addressed this rule for the first time in a comprehensive way in the *Geraets-Smits/Peerbooms* case. The Dutch sickness fund argued in this case that the treatment for which authorization was required had to be necessary for the patient in terms of time and quality/adequacy[485]. The authorization for treatment in another Member State was refused on the ground that satisfactory and adequate treatment was available without undue delay in the state of insurance, at an establishment with contractual arrangements with the sickness fund, and the treatment received abroad provided no additional advantage. In other words, there was 'no medical necessity' justifying treatment abroad.

The main question analyzed by the ECJ at this point is whether appropriate and equally effective treatment can be provided without undue delay in the patient's state of insurance. The Court interprets the concept of 'undue delay' in the favor of the patient. The *Geraets-Smits/Peerbooms* ruling states that, if the same or equally effective treatment cannot be obtained without 'undue delay' from a contracted establishment, then the patient should be able to get reimbursed for the costs of treatment obtained from a non-contracted provider. This condition applies both to non-contracted located in the state of insurance and in other Member States. In other words, if the necessary treatment cannot be obtained in due time from contracted providers, then national sickness funds cannot favor contracted providers

[484] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 137.
[485] See also Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007, p. 34.

over non-contracted providers situated in the state of insurance or in other Member States[486]. Also, the fact that a country has a system of waiting lists is a consideration of a 'purely economic nature' that cannot appropriately justify a restriction on free movement[487]. As a result, the sole fact that there are waiting lists within the country does not constitute an appropriate justification for refusing authorization for treatment in another Member State.

Regarding the interpretation of the concept of 'undue delay', the contribution of the ECJ is most relevant from the *Geraets-Smits/Peerbooms*, *Inizan* and *Watts* rulings. In *Inizan* and *Watts,* the ECJ talks about medically acceptable waiting time. As discussed also in Chapter 2, the ECJ establishes that decisions concerning the acceptable waiting time need to be taken on a case-by-case basis, taking into account each patient's medical condition, medical history, degree of suffering, the nature of his/her disability and its impact on the patient's ability to carry out a professional activity[488]. Decisions should be individual and patient-centered. National authorities cannot establish general rules stipulating standard waiting times based on the type of medical intervention (for example, they cannot claim that a six months waiting period for hip replacement is accepted in the light of the national practice). As discussed also in Chapter 2, the comprehensive medical assessment of the patient's condition is the defining factor in determining the medically acceptable waiting time, and the medical condition of the patient prevails over considerations of economic, financial or administrative nature, regardless of the type of the health system. As emphasized by the ECJ:

'A refusal to grant prior authorization cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness,

[486] *Geraets-Simts/Peerbooms*, para. 107.
[487] *Müller-Fauré/Van Riet*, para. 92.
[488] *Geraets-Simts/Peerbooms*, para. 104; *Müller-Fauré/Van Riet*, para. 90; *Inizan*, para. 46.

the degree of pain he is in and/or the nature of his disability at the time when the request for authorization was made or renewed.[489]'

It is important to note that the ECJ talks in the *Geraets-Smits/Peerbooms* decision about 'the same or equally effective treatment'. This implies that the treatment provided abroad does not have to be the same as the one available in the home country; it is enough if the treatment is equally effective. However, the concept of 'equally effective treatment' is open to interpretation. The vagueness of the term is likely to lead to disputes and further litigation. Once can expect that the Court follows a similar approach like in case of 'undue delay': 'equally effective treatment' needs to be defined on a case-by-case basis, following a comprehensive evaluation of the patient's medical condition.

Summing up the ECJ jurisprudence concerning the prior authorization requirement, one can state that it is settled case law that the prior authorization rule constitutes an impediment to the freedom to provide services. Article 49 EC precludes any national rule making cost reimbursement subject to a system of prior authorization where such a system deters, or prevents, insured persons from approaching health care providers located in another Member State, except for cases when the impediment on the freedom to provide services is justifiable under one of the derogations permitted by the EC Treaty. In case of cross-border hospital treatment, the prior authorization rule is in compliance with EU law only if its application is justified by overriding reasons of general interest. The prior authorization rule should be applied in a manner that is objective, non-discriminatory, non-arbitrary, foreseeable and impartial. It should be the least restrictive measure and the restriction imposed by it should not exceed what is objectively necessary for the overriding general-interest reason pursued. Member States should ensure that refusals can be challenged by judicial or quasi-judicial

[489] *Watts*, para. 25.

proceedings. The burden of proof is on Member States; they should make sure that the refusal is preceded by an analysis of the decision in the light of the criteria mentioned above. The prior authorization rule cannot be justified simply by the existence of waiting lists in the state of insurance. The application of the prior authorization rule should be patient-centered, and the medical condition of the patient should prevail over any other considerations of economic, financial or administrative nature, regardless of the type of the health system. 'Normality' of treatment as a condition for cost coverage should be determined with reference to the international scientific literature, research and practice.

It is very important to note, however, that the ECJ has never pushed aside the prior authorization rule as unlawful in the EU! This is relevant from the *Inizan* case, when the ECJ was asked specifically whether Article 22 of EC Regulation 1408/71 was valid in the light of the application of Article 49 EC to access to health care in other Member States. The answer of the ECJ was that Article 22 of Regulation 1408/71 remained valid EU law[490], having the intention to facilitate free movement of persons by granting additional rights to those ensured under Article 49 EC[491]. Towards this end, Article 22 confers an entitlement to medical treatment provided by a host Member State on behalf of the Member State of insurance, in accordance with the legislation of the host State. In this respect, Article 22 attaches conditions to the free movement rights, and the Community legislature is competent to do so[492]. This view is confirmed in *Watts*, where the ECJ states that:

'The obligation of the competent institution under both Article 22 of Regulation No 1408/71, as amended and updated by Regulation No 118/97 and Article 49 EC to authorize a patient registered with a national health service to obtain, at that institution's expense, hospital treatment in another Member State, where the waiting time exceeds an acceptable period having regard to an objective medical assessment of the condition and clinical requirements of the patient concerned does not contravene Article 152(5) EC'[493].

[490] *Inizan*, para. 26.
[491] *Inizan*, para. 22.
[492] *Inizan*, para. 23.
[493] *Watts*, para. 26.

5. The prior authorization rule in case of non-hospital care

The overriding general-interest arguments legitimizing prior authorization in case of hospital care were tested in case of non-hospital care in the *Müller-Fauré/Van Riet* joint cases. As opposed to hospital care, the ECJ was not convinced that access to non-hospital care in another Member State without prior authorization would undermine the financial balance of social security systems. As pointed out in paragraph 95 of the *Müller-Fauré/Van Riet* judgment:

'There was no evidence that indicated that the removal of the prior authorization requirement for that type of care would give rise to patients travelling to other countries in such large numbers, despite linguistic barriers, geographic distance, the cost of staying abroad and lack of information about the kind of care provided there, and that the financial balance of the social security system would be seriously upset.'

The ECJ relied in *Müller-Fauré/Van Riet* on the *Kohll* judgment that concerned non-hospital medical services (dental care). It is worthwhile noting that the ECJ did not exclude in principle the legitimate concern for the financial balance of the social security system in case of non-hospital treatment. However, it pointed out both in *Kohll* and in *Müller-Fauré/Van Riet* that there was no evidence in the EU that patients would travel abroad in large numbers threatening the balance of the domestic social security systems[494]. The ECJ admitted that a large cross-border flow of non-hospital patients that reached dangerous proportions would in

[494] Studies show that the current share of patients obtaining health care services in other Member States is very small, also in case of non-hospital treatment. See Busse, R. 'Border-Crossing Patients in the EU'. *Eurohealth* 8(4):19-21, 2002; Busse, R., Drews, M. and M. Wismar. 'Consumer Choice of Healthcare Services across Borders', in R. Busse, M. Wismar and P.C. Berman (eds.) *The European Union and Health Services: The Impact of the Single European Market on Member States*. Amsterdam: IOS Press, 2002. Nevertheless, the extent of cross-border patient mobility for non-hospital care becomes higher when considering also patients seeking health care in another Member State on their own initiative, based on individual arrangements (i.e., outside of the pre-authorized context). Since such patients often target private health care providers and cover the costs out-of-pocket, the magnitude of this type of patient mobility is still unexplored. See, for examples from Southern Europe, Albrecht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience,* pp. 9-21. Copenhagen; European Observatory of Health Systems and Policies, 2006. Chapter 4 dealing with Hungary and Slovenia will discuss the relevance of individually-driven patient mobility taking place outside of any pre-authorized context and will highlight the main incentives and hindering factors.

principle justify prior authorization. Yet, existing statistics show that this is unlikely to happen, and it is extremely hard for Member States to prove the opposite. In addition, the reimbursement rules applied in case of non-hospital treatment obtained abroad via the Kohll and Decker procedure (i.e., covering the costs up to the level that the same or similar treatment would cost in the domestic health system) made it impossible for national authorities to claim that this procedure would undermine their capacity to control expenditures.

Nevertheless, it remains unclear what amounts to a sufficiently high number of patients moving across borders that could justify the authorization requirement in case of non-hospital care. The outcome of the quantitative criteria applied by the Court is that the elements of justification can change as a function of the actual cross-border mobility of patients and related financial implications. This implies that at a certain point, prior authorization might become justified in case of non-hospital treatment if the cross-border flow of patients reaches sufficiently high proportions. There is a need for further clarification on the elements of justification in case of non-hospital care in order to prevent related disputes.

The proposed EC Directive on the application of patients' rights in cross-border health care proposes to solve this issue by establishing a general rule that Member States shall not make the reimbursement of non-hospital treatment costs provided in another Member State subject to prior authorization, if the same treatment is lawfully available and covered in the state of insurance. As pointed out in the explanatory memorandum, the proposed Directive intends to codify that the prior authorization mechanism constitutes an obstacle to free movement that is not justified in case of non-hospital care. One should note that the proposed Directive also mentions that Member States may impose limitations on the choice of provider or may

establish other domestic planning mechanisms including conditions, criteria of eligibility and other administrative rules. The conditions that are applied at domestic level may in principle also be applied in cross-border settings. However, the rules established by Member States will be subjected to EU scrutiny in cross-border settings: they will have to be in accordance with the free movement principles and restrictions applied should be necessary, proportionate and non-discriminatory[495]. This is again an illustrative example for the additional scrutiny that Member States' rules on access to health care get subjected to, once patients cross borders. It shows how the cross-border setting extends EU scrutiny over health care organization, delivery and financing by testing indirectly the domestic access rules.

Although in *Müller-Fauré/Van Riet* the ECJ did not rule explicitly that the prior authorization requirement in case of non-hospital treatment was unlawful, the decision made it extremely difficult for national authorities to justify the necessity of such a requirement. The ECJ concluded in *Müller-Fauré*/*Van Riet* that the Dutch government failed to prove that the prior authorization rule was the least restrictive measure that could be applied to achieve the goal pursued, i.e., maintaining a balanced medical and hospital service open to all insured persons. It should be mentioned, however, that the ECJ overlooked here an important argument in favor of the prior authorization requirement non-hospital treatment, namely, the objective of effective rationing of use of medical services. Seeking specialist non-hospital treatment abroad on the basis of the Kohll and Decker procedure (without prior authorization) might result in an easy way to escape the gatekeepers in the home country. This might be relevant for patients seeking health services in new CEE Member States such as Hungary and Romania where the role of general practitioners as gatekeepers is less developed than in

[495] See Part 7.2. of the explanatory memorandum.

many Western states, and patients can see a range of specialists without referral[496]. In the conditions of the often-mentioned overuse of health care systems, the rationing of medical interventions is an important goal that seems to be underestimated by the ECJ.

The ECJ also dismissed the arguments related to the impossibility to control the quality of non-hospital services obtained in other Member States outside of the prior authorization mechanism. While recognizing the importance of quality control, the ECJ ruled that concerns for the quality of medical services provided in another Member State could not limit the freedom to provide services. Already in *Kohll* the Court stated that the conditions for taking up and pursuing a medical profession have been addressed by coordinating and harmonizing EC Directives and are subject to mutual recognition between Member States[497]. According to the Court, in the light of the European directives applied to medical profession '*it follows that doctors established in other Member States must be afforded all guarantees equivalent to those accorded to doctors established on national territory, for the purposes of freedom to provide services*'[498]. Consequently, the ECJ concluded in *Kohll* and *Müller-Fauré/Van Riet* that the prior authorization requirement could not be justified on grounds of public health by the overriding reason to protect the quality of medical services provided[499]. As discussed

[496] See Chapter 4 on further details on referral rules applied in Hungary.
[497] The Court referred in the *Kohll* ruling to the following EC Directives: Council Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services. *OJ* 1978 L 233, p. 1; Council Directive 78/687/EEC of 25 July 1978 concerning the coordination of provisions laid down by law, regulation or administrative action in respect of the activities of dental practitioners. *OJ* 1978 L 233, p. 10; and Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications. *OJ* 1993 L 165, p. 1.
[498] *Müller-Fauré/Van Riet*, para. 48. See also *Kohll*, para. 48.
[499] As discussed earlier, the ECJ applied a similar reasoning in case of access to cross-border hospital care. In *Stamatelakis*, the Court rejected the argument of national authorities stating that public health as an overriding reason of general interest requires that social security institutions check the quality of hospital treatment provided abroad before authorizing it. The ECJ emphasized that public and private hospitals located in other Member States were also subject to quality controls in those countries, and medical professionals established within the EU provided professional guarantees equivalent to those of doctors in the Member State of insurance. The Court based its argument on Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement

earlier, the ECJ has been criticized for assuming that mutual recognition of diplomas and the coordinating and harmonizing directives ensure similar quality standards within the EU[500].

The currently existing dual system for covering the costs of non-hospital care provided in another Member State brings about several uncertainties. For example, what happens if during a non-hospital treatment or a day admission, longer-term hospital admission becomes suddenly necessary?[501] If a patient chooses the Kohll and Decker procedure and seeks non-hospital care in another Member State without prior authorization, is it legitimate to make him/her responsible for covering the costs of a suddenly necessary hospital care linked to the non-hospital treatment received? According to the proposed Directive, the patient has to bear all additional financial risks if choosing the Kohll and Decker procedure.[502] As pointed out by Den Exter, the general Dutch practice is to make the patient fully responsible for the costs of hospital care in such cases, since he/she did not ask for prior authorization[503]. This shows that a decision to avoid the prior authorization scheme could have in certain cases serious financial consequences for patients, in addition to the requirement to advance the costs of treatment. The cost assumption rule is the one generally applied in the Kohll and Decker procedure: the patient advances the treatment expenses and gets reimbursed up to the level of costs that would have been covered had the same or similar care been provided in the state of insurance. The amount reimbursed should not exceed the actual cost of the treatment received. This cost assumption rule exists simultaneously with the framework of the EC social security co-ordination mechanism, and the patient is free to choose which mechanism

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of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications. *OJ* 1993 L 165, p. 1. See *Stamatelakis*, para. 37. See also *Keller*, para. 50.

[500] See section 4.2. of Chapter 3. See also Jorens, Y. 'The Right to Health Care across Borders', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: Peter Lang, 2002, pp. 83-122, on pages 96-97.

[501] See also Den Exter, A. P. 'Patient Mobility in European Union: Health Spas in Ischia, Italy'. *Croat Medical Journal* 46(2):197-200, 2005, p. 199.

[502] See Part 3(a) of the explanatory memorandum.

[503] See also Den Exter, A. P. 'Patient Mobility in European Union: Health Spas in Ischia, Italy'. *Croat Medical Journal* 46(2):197-200, 2005, p. 199.

he/she wants to follow when seeking cross-border non-hospital care. While the possibility to choose between the two mechanisms is now open to patients seeking non-hospital care, the Kohll and Decker procedure presents disadvantages in terms of increased financial risks.

6. Ancillary costs related to cross-border health care

The issue of cost assumption for additional expenses (travel, accommodation, visitors' tax, medical reports associated with the treatment) was addressed by the ECJ in *Leichtle* and in *Herrera*. In *Leichtle*, a patient insured in Germany requested the reimbursement of expenses related to health cure that he intended to obtain at a spa in Italy. As the request was rejected by the competent institution, Mr. Leichtle brought an action before the German Administrative Court and travelled to the Italian spa before his case was decided. He challenged the refusal to reimburse his additional costs including travel, accommodation and visitor's tax charged at the spa. According to the German rule, the reimbursement of these costs was only granted if it was established in a report prepared by a medical officer or consultant, that the health cure was absolutely necessary outside Germany on account of the significantly increased prospects of success, and the targeted spa was listed in the Register of Health Spas.

Due to the fact that the reimbursement conditions concerning ancillary expenses were set only for treatment obtained abroad and not for treatment obtained in the state of insurance, the ECJ held that the German reimbursement rule constituted an impediment to the freedom to provide services. As stated by the Court,

'The fact that a Member State's rules subject the reimbursement of the other expenditure incurred in respect of such a cure to conditions different from those applicable to cures taken in that Member State is capable of deterring those covered by social insurance from

approaching providers of medical services established in Member States other than that in which they are insured'[504].

The ECJ ruled in *Leichtle* that accommodation costs formed an integral part of the health cure itself: just as hospital treatment involves a stay in hospital, a health cure includes a stay at a spa[505]. Similarly, the medical report prepared at the end of the health cure falls directly within the scope of medical activity[506]. As for travel and visitors' tax costs, although such expenses are not medical in character, they are inextricably linked to the health cure itself, because the patient is required to travel to the spa.

Therefore, the Court tested the conditions set by German law for reimbursing expenditure on board, lodging, travel, visitors' tax and expenses linked to preparing a final medical report against the overriding general-interest reasons and the proportionality requirement. Subjecting the prior authorization rule applied to ancillary, travel-related costs to the same tests that are applied to treatment expenditures is a remarkable novelty of the *Leichtle* decision. The Court was not convinced by the argument put forward by German authorities, i.e., that the applied restriction was necessary to maintain treatment capacity or medical competence necessary for safeguarding public health[507]. The ECJ did not accept the argument that allowing for insured persons unrestricted access to spas throughout Europe would endanger the financial equilibrium, the medical and hospital competence and the medical standards of the German health cure system[508]. Instead, the Court agreed with the observation submitted by the European Commission that the German rule could have limited the amount of reimbursement to the level that would have been recognized in case of obtaining equally effective cure in Germany. This would have been a less restrictive measure

[504] *Leichtle*, para. 32.
[505] *Leichtle*, para. 33.
[506] *Leichtle*, para. 34.
[507] *Leichtle*, para. 46.
[508] *Leichtle*, para. 13.

based on objective, non-discriminatory and transparent criteria, in accordance with the settled case law[509]. The ECJ emphasized that Member States were permitted under EU law to establish reimbursement rates to which patients obtaining health care abroad were entitled[510], provided that the rates were set on the basis of objective, transparent and non-discriminatory criteria.

The ECJ ruled in *Leichtle* that Articles 49 EC and 50 EC precluded national rules under which reimbursement of ancillary expenses linked to health cure provided in another Member State was conditional on obtaining a prior report from a medical officer that the cure was absolutely necessary in the targeted state due to significantly increased prospects of success. At the same time, the requirement that the targeted health spa should be listed in the Register of Health Spas is not in principle in contradiction with Articles 49 EC and 50 EC. It is, however, the responsibility of national courts to ensure that the conditions that health spas need to fulfill in order to get registered are objective and do not make the provision of services between Member States more difficult than the provision of services within one state.

Nevertheless, it does not follow from the *Leichtle* decision that all ancillary costs must always be reimbursed when a patient travels to another Member State for treatment. The ECJ distinguishes between different types of ancillary costs. As relevant from *Leichtle* and the subsequent *Herrera* decisions, the Court regards the costs of accommodation and meals in hospital for the insured person as inextricably linked to the treatment that must be always covered. On the other hand, the *Herrera* judgment makes it clear that insured persons cannot claim under social security co-ordination law (Article 22(1)(c) and (2) and Article 36 of

[509] *Leichtle,* para. 48.
[510] The ECJ confirmed this rule also in the *Stamatelakis* ruling, para. 35.

Regulation 1408/71) a right to be reimbursed for travel costs and for the travel, accommodation and subsistence costs of an accompanying person[511]. Nevertheless, EU law does not prevent national legislation from covering such costs as benefits additional to those provided for in Regulation 1408/71.

7. Implications of the extension of internal market rules to access to health care

A major outcome of the ECJ rulings is the extension of freedom of movement to access to health services and goods by establishing the Kohll and Decker procedure. The judgments create for insured persons a right to obtain health care in another Member State at the cost of the competent institute of the state of insurance. This right is based on the directly effective primary law provisions of the EC Treaty. Although not unlimited and not straightforward to exercise due to a number of uncertainties that still persist in the legal framework, this right represents an important extension of insured persons' entitlements in access to health care. The Kohll and Decker procedure is most relevant for planned care.

7.1. Consequences of the ECJ rulings promoting the Kohll and Decker procedure

The ECJ rulings have enhanced access to cross-border care under the free movement principles and outside of the social security co-ordination mechanism. In the light of the ECJ jurisprudence, the main rules can be summarized as follows, from the patient's perspective:

Insured persons may seek in any other Member State without prior authorization non-hospital care to which they are entitled in their state of insurance. They have to advance the treatment costs and have the right to be subsequently reimbursed up to the level provided in their domestic health system for the same or equally effective treatment. Insured persons may seek

[511] See Chapter 2 for a detailed discussion of the *Herrera* case.

in any other Member State hospital care to which they are entitled in their domestic Member State, provided that they obtain first the prior authorization of their competent health insurance fund. The domestic health insurance system cannot deny prior authorization for the same or equally effective hospital treatment in another Member State if the necessary treatment cannot be provided in the state of insurance within a medically acceptable time limit. The medically acceptable time limit is established on the basis of a complex evaluation of the patient's medical condition. Application of the prior authorization requirement in case of hospital treatment should be non-discriminatory, objective, non-arbitrary, proportional and capable of being subjected to judicial review. Domestic health authorities must provide to insured persons seeking health care in other Member States information on prior authorization procedures, reimbursement conditions and procedures of appeal against decisions of the competent institution.

The analysis of the ECJ case law has revealed that in many respects the Court's jurisprudence on access to health care in cross-border settings was neither unexpected nor unprecedented. What is nevertheless new is establishing that Regulation 1408/71 does not constitute an exclusive framework for access to cross-border care. The ECJ has made it clear that the co-ordination mechanism is one possible alternative, and it co-exists with the Kohll and Decker procedure based on the directly effective EC Treaty provisions on free movement. In this sense, EU law provides at present for a dual system of social coverage for cross-border care. The Kohll and Decker procedure creates opportunities for at least some individuals to opt out of treatment options available in the state of insurance and look for better, faster and more adequate health services available in other EU countries. This is particularly relevant to non-hospital care.

Nevertheless, the Kohll and Decker procedure presents a number of limitations and pitfalls. A potentially restrictive rule is the requirement that patients pay up-front for the costs of treatment obtained abroad, which advantages those who can afford doing so. Another restriction is that reimbursement is provided up to the tariff applicable for the same treatment in the country of insurance. Yet another restriction is that patients have to bear all additional financial risks if choosing the Kohll and Decker procedure, as confirmed also by the proposed European Directive on cross-border care[512]. This means that patients need to make a co-payment if the treatment obtained abroad is more expensive than the same treatment in the state of insurance. It is also unclear whether patients need to cover the costs of hospital treatment that becomes necessary during a non-hospital care obtained abroad without prior authorization[513]. Such co-payments burden disproportionately patients insured in CEE Member States and seeking health care in Western countries, because tariffs applied in Western states are generally higher, but patients can only claim reimbursement up to the amount applied in the state of insurance. There is a clear equity issue here, especially if we consider also that the average income of citizens of 'new' CEE members is significantly lower, so, they are less likely to be able to cover co-payments for treatment obtained in the West on the basis of the Kohll and Decker procedure. Such co-payments and subsequent equity issues do not occur in case of treatment obtained on the basis of prior authorization, where costs are generally settled between health systems according to the tariff applied in the state of treatment.

The case law of the ECJ illustrates the increasing role of EU law in regulating access to health care. Even if the rulings left for Member States the prerogative to organize their health

[512] See Part 3(a) of the explanatory memorandum.
[513] At least in some member states, the general practice is to make the patient fully responsible for the costs of hospital care in such cases, since he/she did not ask for prior authorization. An example is the practice in the Netherlands, discussed by Den Exter, A. P. 'Patient Mobility in European Union: Health Spas in Ischia, Italy'. *Croat Medical Journal* 46(2):197-200, 2005, p. 199.

systems and determine the scope and content of entitlement to health care, they established that nation states had to comply with EU law and particularly, the free movement principle when exercising this power. Although Member States can still impose restrictions on access to cross-border care in order to protect an 'overriding reason of general interest' (such as the financial balance of the domestic health system), they can only do so if meeting the requirements of equivalence[514] and proportionality[515]. Although harmonization of health care legislation has never constituted an explicit goal of the ECJ, the decisions analyzed illustrate the progressive extension of EU law over issues pertaining to access to health care. The system of preliminary reference has been instrumental in this process, as all cases dealing with cross-border care were referred to the Court with a request for an authoritative interpretation of relevant EU law. Through the mechanism of preliminary reference, the ECJ has promoted across domestic legal systems a uniform interpretation of EU law on access to health care in cross-border settings. While access to treatment in an in-country context remains an issue of national law, access to treatment in a cross-border context is now an EU-law issue.

An important contribution of the ECJ case law is shifting the focus in health care from the supply side to the beneficiary (patients) side. This is a significant development because health care has been traditionally looked at from the supply side, with emphasis on cost control and budgetary balance[516]. By shifting the emphasis on the beneficiary side, the ECJ decisions have raised the controversial issue whether patients could have an active and even proactive

[514] As discussed at section 2.2 of this chapter, the requirement of equivalence means that the overriding reason of general interest pursued by the state is not already protected in the other Member State where the service is provided.
[515] The requirement of proportionality means that the national measure or rule imposing restrictions on freedom of movement do not restrict it more than is necessary to meet the overriding general-interest objective pursued.
[516] See, for example, Berghman, J. 'Concluding Observations', International Symposium "Health Care without Frontiers within the European Union". Ministry of Social Security of the Grand Duchy of Luxembourg, Association Internationale de la Mutualite, European Institutie of Social Security, Luxembourg, 1999, p. 69.

role in deciding whether to obtain health services in another Member State instead of relying entirely on their competent insurance fund for such decisions[517]. The ECJ rulings put into focus the consumer choice aspect in health care[518]. While consumer choice across borders remains quite restricted under the social security co-ordination mechanism due to the prior authorization rule, it has been enhanced under the Kohll and Decker procedure.

7.2. Critics of the ECJ rulings: concerns related to the application of market rules to health care

The idea that patients are entitled to look for the most convenient health services and providers within the EU brought about strong reactions and controversies. Commentators argued that patients are not well-informed consumers and the health sector is not a commercial market. Concerns have been voiced about the dangers of the commercialization of the health care sector and the necessity to maintain the regulatory authority and ability of public authorities in this field[519]. These arguments were based on the specific characteristics of the health care sector and the substantial differences between medical services and services within a commercial market.

The specific nature of the health care sector stems from a series of characteristics. One is the information asymmetry between patients and health care providers[520]. It is a generally known

[517] As illustrated further in Chapter 4, patients have been traditionally very dependent on their competent health insurance fund in cases when treatment abroad was necessary, and it has been hardly possible for them to take the lead in seeking opportunities for cross-border health care.

[518] Busse, R., Drews, M. and M. Wismar. 'Consumer Choice of Healthcare Services across Borders', in R. Busse, M. Wismar and P. C. Berman (eds.) *The European Union and Health Services: The Impact of the Single European Market on Member States*. Amsterdam: IOS Press, 2002. See also Busse, R. 'Border-crossing Patients in the EU'. *Eurohealth* 8(4):19-21, 2002.

[519] Baeten R. 'The Proposal for a Directive on Services in The Internal Market Applied to Healthcare Services'. Paper presented for the public hearing in the European Parliament. Brussels, November 11, 2004; Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004.

[520] See, for example, Vandenbroucke, F. 'The EU and Social Protection: What Should the European Convention Propose?'. Paper presented at the Max Planck Institute for the Study of Science, Köln, 2002; Nickless, J. 'The Internal Market and the Social Nature of Health Care', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E. - Peter Lang, 2002; Mihályi, P. *Bevezetés az Egészségügy Közgazdaságtanába* (Introduction to Health Economy). Veszprém: Veszprémi Egyetemi Kiadó, 2003; Baeten

fact that patients do not have the necessary knowledge and information to assess properly their medical needs; nor can they assess the quality and appropriateness of the treatment they receive. Consequently, patients are heavily dependent on the decisions of health professionals and care providers, and this distinguishes them from other service consumers. Health care providers have thus an overwhelming role in determining demand for medical services. They might have other interests than patients, and can influence the demand according to their own interests. Therefore, public authorities must be able to step in and compensate for the effects of the information asymmetry.

Another specific feature of the health care sector that distinguishes it from commercial markets is the large share of public money involved in the financing of most health systems[521]. Member States share the goal to ensure universal and equitable access to at least a core package of services as a state responsibility[522]. Equitable access to appropriate health care is considered a right in several European states. Therefore, most countries use public money to finance health service delivery. In order to achieve the state promises, public authorities need to be able to regulate the use of available budgets so that they ensure efficient use, control the prices charged for services and guide choices between treatments of comparable effectiveness but different price. The public financier is a third party in the health

R. 'The Proposal for a Directive on Services in The Internal Market Applied to Healthcare Services'. Paper presented for the public hearing in the European Parliament. Brussels, November 11, 2004; Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004.

[521] Nickless, J. 'The Internal Market and the Social Nature of Health Care', in M. McKee, E. Mossialos and R. Baeten. *The Impact of EU Law on Health Care Systems*. P.I.E.-Peter Lang, Brussels, 2002, pp. 79-81. See also Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004; Baeten R. 'The Proposal for a Directive on Services in The Internal Market Applied to Healthcare Services'. Paper presented for the public hearing in the European Parliament. Brussels, November 11, 2004.

[522] Equity in access to health care, appropriate quality of services and financial sustainability are core principles shared by health care systems in Europe and promoted also by the EU. See also European Commission. *Communication from the European Commission. Modernizing Social Protection for the Development of High-quality, Accessible and Sustainable Health Care and Long-term Care: Support for the National Strategies Using the 'Open Method of Coordination'*. COM(2004) 304 final. Luxembourg: European Communities, 2004.

care sector and it needs to maintain its regulatory powers, such as the ability to conclude contracts with providers and impose cost-effectiveness on them[523].

Commentators of the ECJ rulings feared the risk that EU trade policies would compromise Member States' de facto capacity to guarantee the social rights of their citizens[524]. They highlighted the controversies in applying competition rules to the organization of social security schemes that are meant exactly to compensate for inequalities created by competition[525]. Pessimistic scenarios predicted that the promotion of single market logic in health care would inevitably lead to problems. For example, a growing movement of patients towards countries that provide faster and/or better quality care at a wider choice and more advantageous price could lead to a decrease in accessibility for persons insured in those countries, due to an increase in waiting lists and/or preference for foreign patients[526]. Foreign patients could make use of the capacity of health care facilities located in these countries at the detriment of accessibility for locals[527]. Also, an increased movement abroad of patients from certain geographic regions could lead to a drop in the standards at the health care

[523] Idem note 519 above.
[524] See, for example, Baeten, R. 'European Integration and National Healthcare Systems: a Challenge for Social Policy'. *Infose* 8, 2001. Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004, p. 21; Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, pp. 267 – 292.
[525] Hatzopoulos, V. G. 'Do the Rules on Internal Market Affect National Health Care Systems?', in M. McKee, E. Mossialos and R. Baeten (eds.) *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E.-Peter Lang, 2002, pp. 123-160, on p. 156.
[526] An anecdotic example for the effects of care providers' preference for better paying foreign patients comes from the town of Szeged located in Hungary near to the border with Romania. The increasing number of Romanian patients treated in this hospital resulted in complaints submitted by local Hungarian patients to the Health Insurance Fund. Local Hungarians complained about differential treatment that advantaged Romanian patients willing to pay market prices and even informal charges for hospital services in Szeged in order to secure better attitude and quality of care on behalf of medical staff. Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary (NHIF). Budapest, May 22, 2009.
[527] Worst case scenarios predict a decrease in the quality of care provided in the host country. See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 139.

facilities located in those regions and even endanger their functioning. That would jeopardize access to quality care for people remaining in those regions.

Governments of several Member States emphasized that enhancement of cross-border care endangered the financial balance of national social security systems and complicated health care planning and co-ordination[528]. As a result, an increased cross-border movement of patients was predicted to affect nation states' ability to control both the quality of medical services and health care expenditure[529]. Fears have been expressed that unregulated patient mobility could overburden certain hospitals, facilities and providers, and the access of locals to such 'overburdened' providers would be negatively affected. Governments also argued that reimbursement of less urgent treatment for patients who were willing and able to travel abroad would result in either diverting resources from more urgent treatments needed by patients who cannot or are not willing to cross borders for health care, or increasing costs for the system[530]. Particularly the interpretation of the 'normality condition' in *Geraets-Smits/Peerbooms* has been criticized due to the loss of national control in determining what is 'normal' treatment: following the ECJ ruling, 'normality' has to be established in the light of the standards of international medicine[531]. This means that it is not enough anymore to aim at respective national standards of medicine. Given that it is completely unclear what international standards are, the 'normality' rule causes uncertainty and creates a basis for further disputes.

[528] See Member States' submissions in *Geraets-Smits/Peerbooms, Müller-Fauré/Van Riet, Watts*, discussed earlier in this chapter.
[529] See the government statements at the German EU Presidency preparatory meeting held in Bonn on November 23-24, 1998: Gobrecht, J. 'National Reactions to Kohll and Decker'. *Eurohealth* 5(1):16-17, 1999.
[530] See the argument of the UK Secretary of State in *Watts*, para. 42(3)(c).
[531] See the analysis of the 'normality condition' at section 4.2.1. of this chapter. See also Karl, B. 'The Future of Cross Border Care', in *Yearbook of European Medical Law*. Lidingö: The Institute of Medical Law, 2005, pp. 73-89, on p. 78.

7.3. Enhancement of cross-border care under internal market rules: a danger to equity?

Although most of the scenarios depicted above seem excessively pessimistic in the light of the limited cross-border movement of patients, the promotion of single market logic in health care without equity safeguards will surely lead to equity problems. The rulings are more advantageous for individuals who have the means to afford paying up-front for treatment abroad and cover co-payments. They put in a better position individuals living closer to borders not only because of the geographic and sometimes also linguistic and cultural proximity but also because of lower travel costs (if the treatment is targeted in a neighboring country). Individuals who have better access to information benefit more from the enhancement of cross-border care. It is a common argument that certain population categories always benefit more from the EU market freedoms than others. Nevertheless, insured persons have a right to expect that decisions in health care organization are made on the basis of the principle of equitable access to quality care for everyone, rather than on the basis of internal market freedoms and equal treatment of service providers within the EU[532]. If the EU commits itself to promote high quality, equitable, accessible and sustainable health care[533], then cross-border care should not be left solely to market forces.

There are also interest groups who welcome the extension of the freedom to provide services to medical treatment. Examples are health service providers, private insurance companies and certain categories of patients and employers. Indeed, the enhancement of cross-border patient mobility and extension of internal market rules to health care can also have positive

[532] See also Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004, p. 21

[533] Equity in access to health care, appropriate quality of health services and financial sustainability of health care systems have been emphasized by the European Commission as basic principles of health care governance in Europe. These principles also serve as a basis for extending the Open Method of Co-ordination to the field of health care and represent pillars of mutual learning and peer evaluation of Member States. European Commission. Modernizing social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the "open method of coordination". COM(2004) 304 final. Brussels, April 20, 2004.

outcomes. One of the good aspects is that the ECJ rulings prevent Member States from discriminating against foreign health care providers and sickness funds. Also, the rulings promise opportunities for accessing health care of better quality in other Member States and reducing waiting lists[534]. The European Union provides financial incentives to support cross-border co-operation of health care providers, sickness funds and other stakeholders for better use of resources in order to enhance access to health care and patient mobility. Several co-operation initiatives in health care have been launched in the framework of Euregios; some of them focus explicitly on increasing accessibility and promoting better use of complementary capacities in neighboring Member States[535]. Examples for such initiatives are discussed in Chapter 4 of this paper. They reveal that enhancement of cross-border care can also have positive outcomes for accessibility, especially in the border regions and for highly specialized treatments that are not available locally. The challenge is how to make use of opportunities brought about by the extension of internal market rules to medical services and goods, and safeguard at the same time the social character of health care.

[534] In fact, the idea to make use of cross-border care opportunities for easing waiting lists is not a novelty brought about by the *Kohll* and *Decker* rulings. Such initiatives existed already before the ECJ judgments on cross-border care. One interesting example comes from the Netherlands, where private sector employers and insurance companies joined forces in concluding contracts with hospitals in the neighboring countries for treating their employees so that they can 'jump' Dutch waiting lists for specialty treatment. Employers were particularly affected by long waiting times because a law obliged them to continue paying their sick employees during the period when they were awaiting treatment. The Dutch government and public organizations opposed and stroke down the initiative. The official governmental discourse put forward an equity argument emphasizing that priority treatment provided abroad for employees of certain companies contravened the basic principles of equity and justice in health care due to the discriminatory distinction drawn between employees of different companies. See, for further details, Brouwer, W. B. F. and H. E. G. M. Hermans, 'Private Clinics for Employees as a Dutch Solution for Waiting Lists: Economic and Legal Arguments'. *Health Policy* 47, 1999.

[535] See, for a review of cross-border health care initiatives in the EU, Glinos, I. A., and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union*. Brussels: Observatoire Social Européen, 2006; GEIE Luxlorsan LLS. *Le Systeme de Prise en Charge des Urgences Médicales dans l'Espace Wallonie-Loraine.* Luxembourg: GEIE Luxlorsan LLS, 2006; LIGA.NRW. *Evaluation of Border Regions in the European Union (Euregio)*. Düsseldorf: LIGA.NRW, 2008. The report is available at: http://www.euregio.nrw.de/files/final_report_euregio_en.pdf (Last accessed on May 7, 2009).

8. Cross-border care under the internal market rules: the way forward

The particularity of the legal developments discussed in this chapter is that they extended the role of EU law in health care via a series of court decisions, not through direct legislative action. Extension of internal market rules to health care has been criticized because it has been done through litigation[536]. Member States cannot veto ECJ decisions like they can veto direct legislative action by the EU in social policy fields. As a result, nation states have witnessed an infiltration of internal market rules in health care. The competence loss in health care regulation has not been compensated yet by adequate competences formalized at EU level. So, the competence gap persists, and it continues to allow for a leaking of EU law into the area of health care.[537]

European states have been quite reluctant to acknowledge the legitimacy of the Kohll and Decker procedure, and have delayed its implementation in national law[538]. They have blamed the legal uncertainties and particularly, the difficulty to reconcile the consequences of the Kohll and Decker procedure with the principle of territoriality in health care[539]. They have requested clarifications from European institutions on pending legal questions. This has raised the issue of the necessity and appropriateness of a legislative response at EU level. It is clear that an EU-level legislative response should go beyond an adjustment of the social security co-ordination mechanism by amending Regulation 1408/71, because the Kohll and

[536] See particularly, Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, pp. 267 – 292.

[537] Berman and Nickless use the concept of Euro-creep to define this competency gap. See, for details, Berman, P. 'The effects of Euro-creep on Health Care: 'Ostrich Policies or Anticipation''. Speech delivered at the Fifth Workshop on European Legislation and National Health Policies, organized by the Dutch Ministry of Health, Welfare and Sport. Oostende, February 19-20, 1998, cited by Nickless, J. 'The Internal Market and the Social Nature of Health Care', in M. McKee, E. Mossialos and R. Baeten (eds.) *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E.-Peter Lang, 2002, p. 79.

[538] See, for example, the case of Hungary and Slovenia, discussed in Chapter 4 of this paper.

[539] Interview with the Director-General of the Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV). Brussels, October 10, 2005. See also Sieveking, K. 'ECJ Rulings on Health Care Services and Their Effects on the Freedom of Cross-Border Patient Mobility in the EU'. *European Journal of Migration and Law* 9:25-51, 2007.

Decker procedure is a distinct alternative based on the directly effective EC Treaty provisions that constitute primary law. Consequently, the adoption of the new co-ordination Regulation 883/2004[540] is not sufficient, in spite of the simplification and modernization of the co-ordination procedure. The necessity of EU-level legislative action remained an open issue after the adoption of Regulation 883/2004.

EU institutions have been facing contradictory pressures from different stakeholders. Some prompted a legislative response that filled in the gaps and removed unlawful restrictions on the freedom to provide and receive cross-border care. The ECJ encouraged the Community legislature to make it more difficult for Member States to refuse prior authorization for treatment abroad. In *Decker*, the Court stated that '*Community legislature should at least act, and do so promptly, to broaden the range of circumstances in which authorization may not be refused. There is no doubt that it would be advantageous in many respects for authorization to be granted in all cases in which the insured persons could receive more effective treatment in another Member State.*'[541] Patients have turned repeatedly to the European Commission with complaints about national-level infringements of their right to access cross-border care[542]. Health ministers and sickness funds' managers asked the Commission to explore how to improve legal certainty concerning the rights of patients in cross-border care[543].

[540] European Parliament and Council of the European Union. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (Text with relevance for the EEA and for Switzerland), *OJ* L 166, 30 April 2004, pp. 0001-0123.
[541] *Decker*, para. 60.
[542] Interview with Geraldine Fages, European Commission, Directorate-General Internal Market and Services. Brussels, October 10, 2005.
[543] Interview with the Director-General of the Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV). Brussels, October 10, 2005. See also European Commission. *Communication from the Commission. Follow-up on the High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union,* COM(2004) 301 final of 20 April 2004. Brussels: Commission of the European Communities.

The European Commission has been particularly active in the legal dialogue around access to cross-border care. This is relevant from the observations submitted to the cross-border care cases brought before the ECJ and notably, in *Decker, Kohll, Geraets-Smits/Peerbooms, Leichtle, Watts*. The submissions of the Commission were generally in favor of free movement and enhancement of the freedom to provide services in the health sector, as relevant especially in *Decker*[544] and *Kohll*[545]. Also, the Commission has encouraged individuals to turn to the judiciary when their access to cross-border care is impeded by national legislation[546] and make use of the preliminary reference procedure in order to get the ECJ involved in their individual case[547].

At present, the Commission applies several instruments to enhance the implementation of freedom of movement in health care. It makes use of the mechanism of infringement procedures against Member States that do not comply with EU law on cross-border care[548]: in 2007, there were around 20 pending infringement procedures against 10 Member States with regard to the issue of cross-border patient mobility[549]. Also, it has been responsive to Member

[544] In *Decker,* the European Commission submitted the same argument as the patient: national rules under which reimbursement of the cost of products obtained in another Member State is subject to prior authorization constitute an unjustified barrier to free movement of goods if the same products are reimbursed when purchased within the country. See para. 17 of the judgment.
[545] In *Kohll*, the European Commission submitted that the prior authorization rule constituted a barrier to the freedom to provide services but could be justified, under certain conditions, by overriding reasons of general interest. See para. 14 of the judgment.
[546] Interview with Geraldine Fages, European Commission, Directorate-General Internal Market and Services. Brussels, October 10, 2005.
[547] See the website of the European Commission, Employment, Social Affairs and Equal Opportunities summarizing the social security rights of EU citizens under Union law: http://ec.europa.eu/social/main.jsp?catId=516&langId=en (last accessed on May 26, 2009).
[548] Interview with Geraldine Fages, European Commission, Directorate-General Internal Market and Services. Brussels, October 10, 2005.
[549] Kostera, T. 'Europeanizing HealthCare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008, p. 12.

States' request for more legal certainty and initiated in 2002 the high level reflection process on patient mobility and health care[550].

Bringing together fourteen 'old' EU Member States, the high level reflection process has been portrayed by the Commission as means to recognize the value of European co-operation in meeting health objectives of Member States[551]. The initiative presented the ECJ judgments as opportunities to improve health care for all in Europe. The Commission expressed the intention to develop a European vision of health systems, promote European co-operation for better use of resources and enhance accessibility and quality of health care services[552]. It created a High Level Group on Health Services and Medical Care with a specific objective to reach European-level agreement on patients' rights, entitlements and duties in cross-border settings[553]. In addition, it commissioned a number of external studies and analyses on the impact of enhancing cross-border care. Examples are the independent expert analysis provided by the European Observatory on Health Systems and Policies[554] and a research project called 'The Future for Patients in Europe'[555]. These studies provided information for improving co-ordination of legal, contractual and regulatory issues, based on the hypothesis

[550] In December 2001, the Belgian EU presidency organized a conference in Ghent on the impact of EU law on access to health care. A second conference followed under the Spanish presidency in 2002 in Malaga. In June 2002 the Health Council called for the creation of a high level reflection process on patient mobility and health care. The high level process included a specific objective to develop a better understanding of the rights and duties of patients in cross-border health settings.

[551] See the Conclusion of the EC report on the high level reflection process. COM(2004) 301 final, note 543 above.

[552] Ibid.

[553] Ibid., pp. 6-8. Besides the actions meant to clarify insured persons' rights in cross-border health settings, improve legal certainty around the prior authorization rules and simplify the social security co-ordination mechanism, the Commission also set the objectives to facilitate cross-border mobility of patients, improve information about patient mobility and health care developments, and facilitate European-level co-operation towards this end.

[554] Wismar, M., Palm, W., Figueras, J., Ernst, K. and E. Van Ginneken. *Cross-border Healthcare: Mapping and Analyzing Health Systems Diversity.* European Observatory on Health Systems and Policies, 2007.

[555] Funded by the European Community and implemented between February, 2004 and January, 2007, the research project entitled *The Future for Patients in Europe* (acronym *Europe for Patients* (e4p)) provides a Europe-wide mapping of existing, practical obstacles to greater cross-border co-ordination of health systems. The research project brought together a multi-disciplinary team in order to reveal the challenges met in enhancing patient mobility within an enlarged Europe, drawing on legal, health policy and health services research perspectives. Further details are available online at: http://www.iese.edu/en/events/Projects/Health/home/home.asp (Last accessed on May 26, 2009).

that enhanced patient mobility would bring benefits for patients, health care providers and health systems[556].

In addition, the Commission has attempted two times to codify the ECJ rulings. In 2004, it proposed to include an article on health care in the 2006 Directive on services in the internal market[557]. The proposed article intended to clarify the reimbursement rules and harmonize patients' rights in cross-border settings. In particular, it intended to establish for EU citizens a right to reimbursement of non-hospital care obtained in other Member States without prior authorization. This initiative was, however, not accepted by the European Parliament and Council, and health care was excluded from the scope of the Directive on services. Opposing arguments emphasized that certain specific characteristics of health services such as their technical complexities and dependence on public financing, were not sufficiently considered[558].

Having in mind these concerns, the Commission launched a nearly two years-long public consultation process with regard to possible Community action on health services[559]. The open consultation resulted in 280 answers from various stakeholders including national and regional governments, health care providers, patients, insurers, health professional organizations and the health care industry. As an outcome, the Commission the launched in 2006 the 'Europe for Patients' campaign proposing ten health policy initiatives with the

[556] See also Rosenmöller, M., McKee, M., Baeten, R. and I. A. Glinos. 'Patient Mobility: the Context and Issues', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006, p. 4.
[557] Directive 2006/123/EC on services in the internal market. *OJ* L 376, December 27, 2006, p. 36.
[558] See also the Explanatory Memorandum of the European Commission's proposal for a Directive on the application of patients' rights in cross-border healthcare. COM(2008) 414 final, Brussels, July 2, 2008.
[559] The open consultation started formally with the publication of a Commission Communication inviting relevant stakeholders to express their views: European Commission. Communication, Consultation regarding Community action on health services. SEC 1195/4. Brussels: European Commission, September 2006. A report summarizing the responses to the open consultation is available on the website of the European Commission: http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm (Last accessed on May 26, 2009).

common goal to achieve better health care for all in Europe[560]. Within the framework of the Europe for Patients campaign, the Commission adopted the proposed Directive on the application of patients' rights in cross-border health care. As discussed also in Chapter 2, the Directive intends to establish a Community-level legal framework for the provision of cross-border health care within the European Union. Towards this end, it proposes to clarify patients' entitlements and Member States' duties in cross-border care, establish the competence-sharing rules in quality and safety issues and strengthen European cooperation in cross-border health settings[561].

As illustrated by the developments analyzed in this chapter, European Union institutions, particularly, the Court of Justice and the Commission have embarked on a journey leading to the ultimate goal to create a clear legal framework of access to cross-border care. This is a difficult journey undertaken on the background of large differences between Member States' social security systems, diverse and sometimes conflicting national rules, and cumbersome administrative procedures that make cross-border co-ordination particularly challenging. The court cases that have started this process came from a few 'old' EU Member States, and the patients whose stories have became well known through the ECJ decisions represented a very small and often atypical selection of European patients. In order to have a Europe-wide legal framework of cross-border patient mobility, it is important to find out how other Member States and particularly, new members of Central and Eastern Europe have responded to European-level developments. There is a need to explore the particular aspects of patient

[560] The 'Europe for Patients' campaign was launched in Brussels on September 30, 2006. See, for details, the 'Europe for Patients' campaign's webpage: http://health.europa.eu/efp (Last accessed on May 26, 2009).
[561] See the explanatory memorandum of the draft Directive. The goals of the proposed Directive were openly declared by the Directorate-General for Health and Consumers of the European Commission at the EU Open Health Forum 2008 'Developing and Implementing Health in the European Union', organized in Brussels (Belgium) on December 10-11, 2008. All documents and presentations related to the EU Open Health Forum 2008 are available at: http://ec.europa.eu/health/ph_overview/health_forum/open_2008/index_en.htm (Last accessed on May 26, 2009).

mobility that exist in these countries and examine what aspects have been addressed so far, what are the challenges and the means applied to cope. Chapter 4 will focus on two 'new' EU members of Central and Eastern Europe with the purpose to analyze the regulatory framework of cross-border health care, the broader context determined by relevant characteristics of the health care system, and the different reasons, forms, pull and push factors of patient mobility.

Chapter 4: Hungary and Slovenia: a comparative analysis of the implications of EU law on cross-border health care

Regulation of health care organization, delivery and financing has been safeguarded by EU Member States as a core competence of national social policy regimes. Contemporary national systems of social protection are the result of historical developments linked to state and nation building in European countries[562]. In the context of exogenous and endogenous pressures on their social systems, Member States differ from each other in their responses to often similar challenges. The diversity of solutions is rooted in the diversity of legacies, systems of interest organization and institutional structures in social redistribution[563]. Health systems are part of social policy systems closely linked to the nation state, and organization of health care is largely determined by the characteristics of the welfare regime. Consequently, any attempt to harmonize in the field of health care faces significant political impediments.

Nevertheless, European integration has affected health care through a spill-over process originating in efforts to promote the internal market and implement the freedom of movement[564]. European social security co-ordination rules on cross-border medical care and particularly, the case law of the European Court of Justice are illustrative for this process. As discussed in Chapters 2 and 3, these legal developments have undermined Member States'

[562] See Chapter 1 for the relevance of Rokkan's theory on state and nation building in Europe and Ferrera's application of Rokkan's concepts as analytical tools in examining the role of European integration in weakening the social boundaries of welfare states.
[563] See also Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4): 645-670, 2002.
[564] See Chapter 1 on the importance of the spill-over process in health care. See also Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, 2000, pp. 267–292; Mossialos, E., McKee, M., Palm, W., Karl, B. and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union, Brussels, 2001, p. 19; Kostera, T. 'Europeanizing Health Care: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008.

efforts to shield health care regulation from European integration and keep it as an exclusive national competence. Despite the intention of states to safeguard their health systems from European harmonization, it has become settled that Member States have to adjust health care regulation and organization of their health systems to EU law requirements. The traditional view of exclusive national competence in this field has become untenable.

The previous two chapters of the dissertation analyzed EU-level legal developments that are relevant to access to health care. Chapter 4 shifts the analysis from the European level to the level of countries in order to examine how health care systems of nation states have been affected. The focus is on new Member States of Central and Eastern Europe (CEE). Building on theoretical considerations on welfare state development discussed in Chapter 1, the analysis will show first why health care is safeguarded by European states as a core national competence shielded from the European Union. Next, the discussion will address the effects of the EU law developments analyzed in Chapters 2 and 3 on nation states in general and new members of CEE in particular. It will highlight the specific challenges that CEE countries face in health care organization, delivery and financing and will discuss the effects of EU rules on cross-border care in the context of these challenges.

Afterwards, the analysis will zoom into specific country situations. It will compare legal and institutional contexts, the regulatory framework as well as incentives, impediments, practices and potential for cross-border care in two new Member States of the CEE region: Hungary and Slovenia. The comparative country-level analysis will examine first the broader legal and institutional context and the relevant characteristics of the two health care systems under review. Particular attention will be paid to health care reforms initiated right before and after EU accession and the consequences of reforms for access to health care. The regulatory

framework of cross-border care will be analyzed next in order to explore whether and how the relevant EU rules have been transposed into national legislation. Afterwards, the chapter will highlight the main enhancing and hindering factors of cross-border patient mobility. It will also discuss the current extent and perspectives for institutionalized cross-border co-operation in health care, with specific attention paid to opportunities brought about by EU accession. Throughout the analysis, examples from other, old and new Member States will be used for comparison[565].

1. Health systems as core elements of national social policy regimes in EU countries

European states aim at universal and equitable access to health care. Solidarity, universality, access to appropriate quality care and equity constitute values shared by European health systems[566] that have committed themselves to safeguard the social character of health care[567]. Nevertheless, the scope and content of rights that individuals have in medical care and the mechanisms of implementation vary considerably across countries[568]. Each Member State has the authority to establish the benefit packages and conditions of social coverage applicable within the national territory[569]. States apply diverse solutions in health care organization,

[565] For the purposes of this paper, the term 'old Member States' refers to the fifteen countries that formed the EU before the 2004 enlargement. The term 'new Member States' refers to the countries that joined the EU in 2004 and 2007.

[566] As discussed also in Chapter 3, the social character of health care shows the extent to which individuals have access to health services and goods in the form of social benefits. Although European Member States differ in terms of the social character of health care, they generally base the organization of their health systems on social solidarity. See also Mossialos, E. and M. McKee, 2002, pp. 27-41; Sieveking, K., 2007, p. 29.

[567] The Council of the European Union and the European Commission have acknowledged these core values as shared by health systems throughout the EU. Council of the European Union. Council Conclusions on Common Values and Principles in European Union Health Systems, *OJ* C 146/1, 22 June 2006, pp. 0001-0003; European Commission. *Communication from the European Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Modernizing Social Protection for the Development of High-quality, Accessible and Sustainable Health Care and Long-term Care: Support for the National Strategies Using the 'Open Method of Coordination'*, COM(2004) 304 final of 20 April 2004. Brussels: Commission of the European Communities.

[568] Freeman, R. *The Politics of Health in Europe*. Manchester and New York: Manchester University Press, 2000; Saltman, R.B., Figueras, J. and C. Sakallarides (eds.) *Critical Challenges for Health Care Reform in Europe*. Buckingham: Open University Press, 1998.

[569] This competence of Member States has been repeatedly confirmed by the European Court of Justice. See Chapter 3 for further discussion.

delivery and financing and specifically, in ensuring equitable access to services. Health services and goods are delivered and funded in different ways.

Public health care systems in the European Union can be broadly categorized as national health systems and social insurance systems, with a further subdivision between reimbursement and benefit in kind systems[570]. In general, national health systems are benefit in kind systems funded by revenue taxation, with health services provided for free at the point of delivery and to everyone residing in the country. Social insurance systems are largely based on compulsory insurance, with income-related insurance contributions administered by various bodies. They can be reimbursement schemes, when insured persons have to pay up-front for (at least part of) health services and get subsequently reimbursed by their respective insurance institutions. Social insurance systems can also be benefit in kind schemes, when insurance institutions pay for the costs of health services directly to health care providers.

It is important to note that the 'social insurance vs. national health system' dichotomy is a simplification because public health systems often present mixed features such as mixed models of financing[571] and/or reliance on voluntary and private health insurance besides the compulsory scheme. For example, private health insurance can play substitutive, complementary or supplementary roles[572]. In case of a substitutive role, it covers people excluded from some or all aspects of public cover (for example, foreigners temporarily residing in the country) or people who can afford a private cover instead of a public one (for

[570] See also European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007, p. 1.
[571] In certain EU countries, funds raised via mandatory health insurance contributions are completed by funds from taxation. See, for example, the Hungarian health insurance system, discussed further in this chapter. Other systems use a mix of public and private funds.
[572] See the typology established by Thomson, S. and E. Mossialos, in 'Regulating Private Health Insurance in the European Union: The Implications of Single Market legislation and Competition Policy'. London: LSE Health, the London School of Economics and Political Science, 2006, pp. 6-7.

example, citizens with higher income in the Netherlands before 2006 had to have a private insurance). Private insurance with a complementary role is meant to cover services that are excluded or only partially covered by the public scheme (for example, voluntary health insurance in Slovenia plays a predominantly complementary role, as discussed further in this chapter). Private insurance with a supplementary role is meant to ensure an increased choice of treatment providers, higher standard of services and/or faster access to health care. Despite the over-simplification, interventions submitted by governments and the approach of the European Court of Justice in cases dealing with cross-border health care have generally followed the social insurance vs. public taxation division[573].

The binary division between social insurance systems and national health systems is also reflected in the classification of European welfare states, discussed in Chapter 1. Theories on welfare state development include each old Member State in one of the four welfare regimes. Accordingly, the liberal cluster includes the Anglo-Saxon countries, the social-democratic cluster includes the Scandinavian states, the corporatist–conservative cluster includes countries of Continental Europe except Spain, Italy, Portugal and Greece, which belong to the Latin (South-European) rim[574]. Following this categorization, one can conclude that old Member States belonging to the liberal cluster (the United Kingdom and Ireland), the social-democratic cluster (Denmark, Sweden and Finland) and the Latin rim have national health systems financed by taxes[575]. Old members belonging to the corporatist-conservative model

[573] See the analysis of the ECJ case law in Chapter 3. See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 126.
[574] See Esping-Andersen, G. *The Three Worlds of Welfare Capitalism*. Princeton, NJ: Princeton University Press, 1990; Leibfried, S. 'Towards a European Welfare State? On Integrating Poverty Regimes into the European Community', in Z. Ferge and J. E. Kolberg (eds.) *Social Policy in a Changing Europe.* Frankfurt/Main and Bouldcr, Colo.: Campus and Westview, 1992; Ferrera, M. 'The 'Southern Model' of Welfare in Social Europe'. *Journal of European Social Policy* 6(1): 17-37, 1996.
[575] The United Kingdom and Ireland are often cited as examples for a more centralized national health system. Denmark, Sweden, Finland, Italy, Portugal, Spain and Greece are more decentralized national health systems. See, for example, Palm, W. and J. Nickless. 'Access to Healthcare in the European Union'. *Eurohealth* 7(1),

(France, Belgium, Luxembourg, Germany, the Netherlands and Austria) have social insurance systems largely funded via contributions[576]. The categorization mentioned above did not include new CEE members. It will be shown in section 2 of Chapter 4 that CEE countries have been moving since early nineties from centralized state-socialist health systems towards social insurance systems.

Choices in health care organization and financing are determined by the institutional features of the systems and influenced by underlying social philosophies and legacies. This is illustrated by the different solutions that national health systems and social insurance systems apply in health care reform. A comparative analysis of health care reforms adopted by old Member States since the seventies and eighties identified a number of systematic differences between the two types of health systems[577]. According to the findings, national health systems attempted to achieve cost reduction by a series of measures including: reducing the benefit packages and excluding certain types of treatment from coverage; limiting access to specialist care by strengthening the gatekeeper role of general physicians; using waiting lists as a means of rationing access to non-emergency treatment. Social insurance systems limited the possibilities of patients to choose the health care provider and increased the share of co-payments. The analysis concluded that organizational characteristics determined not only the specific challenges and strengths of a given health system but also the solutions applied.

2001, pp. 13-14; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 125-126.

[576] France, Belgium and Luxembourg are social insurance systems operating on the basis of cost reimbursement. Germany, the Netherlands and Austria are social insurance systems providing benefits in kind. See also Palm, W. and J. Nickless. 'Access to Healthcare in the European Union'. *Eurohealth* 7(1), 2001, pp. 13-14; Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, pp. 125-126.

[577] Kostera, T. 'Europeanizing HealthCare: Cross-Border Patient Mobility and Its Consequences for the German and Danish Health Care Systems'. *Bruges Political Research Papers* No 7, Bruges: College of Europe, 2008, p. 5.

It is important to remember, however, that health care organization is not only an economic and technical issue but also a political one. Health systems of most EU countries are characterized by a strong public role in organization, financing and in some states, also in the provision of services. Although there are exceptions[578], a high degree of government intervention in health care characterizes even countries where privatization is high on the agenda[579]. As formulated by Freeman, '*the health system is coterminous with public (state) intervention: health policy problems are problems of and for the state*'[580]. Health systems also aim at social solidarity, besides economic efficiency. In order to achieve the state promises of solidarity, equity and universal access, public authorities must maintain their regulatory role in health care in order to compensate for inequalities created by competition, market forces and attempts of various stakeholders to influence organization and provision of medical services according to their own interests[581]. Public authorities must be able to regulate the use of available budgets so as to ensure efficient use, control the prices charged for services and guide choices between treatments of comparable effectiveness but different price. They must compensate for the effects of information asymmetry between patients and health care providers[582]. They must be able to reconcile the often contradictory interests of various stakeholders such as patients, treatment providers, insurers and the pharmaceutical industry. Given the role played by the state, health care governance has been traditionally regarded as a national competence. European-level harmonization in health care is impeded by cross-country differences grounded in different normative aspirations and social policy

[578] One of the notable exceptions is the Netherlands, where the private sector has a predominant role, especially in health insurance. See, for example, Hamilton, G. J. 'Private Insurance for All in the Dutch Health Care System?'. *European Journal of Health Law* 10(1):53-61, 2003.
[579] This is true also for a number of CEE countries (examples include Hungary, Slovenia, Estonia, Latvia, Romania and Bulgaria), where government intervention in funding, organizing and delivering health care remains strong although privatization is emphasized.
[580] Freeman, R. *The Politics of Health in Europe*. Manchester and New York: Manchester University Press, 2000.
[581] See section 7.2 of Chapter 3 for discussion on the specific features of the health care sector that distinguish it from regular markets.
[582] See section 7.2 of Chapter 3 for further discussion and reference on the concept of information asymmetry in health care (note 521).

legacies. Uniform European rules would attract strong opposition in Member States where they require significant changes in the organization and functioning of the health system[583].

2. Health care systems in new CEE Member States: similar challenges, diverse solutions

Existing research on the influence of European integration on Member States' health systems has mainly focused on old EU members[584]. There is little research dealing specifically with new CEE members that joined the EU in 2004 and 2007[585]. The few studies available explore the existing trends in patient mobility to and from a number of new members including the Czech Republic and Poland[586], Slovenia[587] and Estonia[588]. These case studies involve field research exploring the current extent of patient mobility, its underlying pull and push factors and treatment providers' incentives to seek foreign patients. There is very little research focusing specifically on questions pertaining to health care and EU enlargement. Apart from a few but noteworthy exceptions[589], enlargement-related questions do not constitute the

[583] See also Scharpf, W. F. 'The European Social Model: Coping with the Challenges of Diversity'. *Journal of Common Market Studies* 40(4): 645-670, 2002.
[584] See, for example, Den Exter's analysis on the consequences of the ECJ rulings for the Dutch social health insurance system, Kostera's research on the implications of cross-border patient mobility for the German and Danish health care systems and Sieveking's legal analysis focusing on the implementation of the ECJ rulings in Germany mentioned also in the introduction (notes 41, 42 and 43 of the Introduction).
[585] See the Introduction (section 3) for an overview on the literature on health care and the EU focusing on new Member States of CEE.
[586] Vallejo, P., Sunol, R., Van Beek, B., Lombarts, M.J.M.H., Nruneau, C. and F. Vlcek. 'Volume and Diagnosis: An Approach to Cross-Border Care in Eight European Countries'. *Qual Saf Health Care* 2009, 18(Suppl l):i8-i14; European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.
[587] Albreht, T., Pribakovic Brinovec, R., and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006.
[588] Jesse, M. and R. Kruuda. 'Cross-border Care in the North: Estonia, Finland and Latvia', in M. Rosenmöller, M. McKee and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization, 2006.
[589] One notable study was carried out by Österle on access to health care in the neighboring regions of Austria, the Czech Republic, Slovakia, Hungary and Slovenia. The study discusses perspectives for cross-border health care activities in the region following the 2004 enlargement. Österle, A. 'Health Care Across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007. See also Österle, A. and J. Delgado. 'Dental Care Migration in Central Europe', in R. Burger and M. Wieland (eds.) *Economic and Sociopolitical Perspectives for Health Services in Central Europe.* Vienna, 2006; McKee, M., MacLehose, L. and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004.

explicit focus of the analysis. Yet, it has been recognized that EU accession of CEE states imposes significant challenges on their health care systems[590].

New CEE members inherited a centralized health system from the state socialist years, and have been struggling since with challenges in moving towards a more decentralized and cost-efficient system. These changes have been carried out in the context of major economic and social transformations: since the end of the eighties, these countries have experienced first the transition from state-socialist to market economy and then the transformation from EU membership candidate status to EU membership. Health care systems in CEE have generally gone through a development process that is different from the path followed by old members.

2.1. Legacies of the state-socialist years

Since early nineties, health care systems in several new CEE members have been trying to cope with the legacies of the state-socialist years such as outdated management systems and particularly, inefficient management of resources available for health care[591]. The situation was worsened by a fall in health care expenditure as a share of GDP between 1995 and 2000: a decrease in health care expenditure occurred in the second half of the nineties in most CEE countries including Bulgaria, Hungary, Slovenia, Slovakia, Estonia, Lativa and Bulgaria[592]. Although resource allocation in health care is a sensitive issue in most EU countries, this challenge has become even more severe in case of new CEE members in the context of

[590] See the discussions on the implications of Eastern enlargement for new members' health care systems, included in McKee, M., MacLehose, L. and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004.
[591] During the state socialist years there was no separate budget for health care funding in several Member States including Hungary and Romania. As pointed out by Kornai, the soft budget constraint that characterized health care funding resulted in wastage of resources and inefficient management. Kornai, J. *Economics of Shortage*. Amsterdam: North Holland Press, 1980.
[592] WHO Regional Office for Europe. *Health Status Overview for Countries of Central and Easter Europe That Are Candidate for Accession to the European Union*. European Communities and World Health Organization. Copenhagen: WHO Regional Office for Europe, 2002.

limited resources and decreasing expenditures. With the exception of Slovenia[593], CEE countries spend at present a smaller proportion of their national income on health care than old members. As shown by OECD data, health care expenditure as a share of GDP is below the EU and OECD average in most CEE countries. In 2006, the latest year for which comparable OECD data are available, the average for health care expenditure as a share of GDP was 7.1% in CEE Member States, while for old members it was 9.1% and the OECD average was 8.9%[594]. At the same time, there has been a general tendency to increase out-of-pocket payments required from patients[595].

Most CEE health systems present a number of similar features inherited from state-socialist years. They generally remain very clinically orientated[596] and characterized by a predominantly hospital-focused structure, high specialist referral rates and high use of specialist care. The gate-keeper role of general practitioners is not accomplished, and it is relatively easy for patients to see a specialist, without or with referral[597]. Especially the hospital-orientated character of these health care systems has been identified as a source of inefficiencies[598]. In the context of limited resources allocated for health care, the need for cost-containment and improvement of resource management is even more pressing in CEE countries than in old Member States.

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[593] In Slovenia, health expenditure as a share of GDP is the closest in the CEE region to the EU average but remains below it.

[594] According to data published by OECD, in CEE this share was the lowest in Poland (6.2%), followed by the Czech Republic (6.8%), the Slovak Republic (7.1%) and Hungary (8.3%). See for further information, OECD Health Data 2008, available at www.oecd.org/health/healthdata (Last accessed on May 26, 2009).

[595] Dubois, C. A. and M. McKee. 'Chapter 4: Health and Health Care in the Candidate Countries to the European Union: Common Challenges, Different Circumstances, Diverse Policies', in M. McKee, M, L. MacLehose and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004, pp. 43-63.

[596] Rosenmöller, M. 'Health and Enlargement: Half Way There'. *EuroHealth* 6(5): 9-11, 2000-2001.

[597] One example is Hungary, where patients can see without referral a range of specialists within the public health care system (including oncologists, otolaryngologists, ophthalmologists, dermatologists, gynaecologists and urologists). While a GP referral is officially required for seeing other specialists, informal (unofficial) payments can sometimes secure direct access.

[598] Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007, on p. 115.

As a particular heritage of the state-socialist years, informal payments represent a significant challenge shared by several CEE health systems. Informal payments are unofficial out-of-pocket payments for health services and goods that should be provided free of charge at the point of delivery[599]. Informal charges for health services are a product of the state-socialist system: although the socialist state proclaimed free and equal access to health care for all, it was unable to accomplish its promises. As a result, many people started to pay informal charges in order to secure better and faster services. After a short while, more and more people paid such charges and less and less received anything extra. The phenomenon of informal payments has become entrenched in the system and survived the state-socialist period. At present, patients continue to pay informal charges to health care providers in the public health system for a number of reasons, such as obtaining better quality services delivered in better conditions, securing proper attitude and better information on the part of health professionals and decreasing waiting time for treatment.

Although there is a general lack of quantitative data, informal payments are estimated to account for a significant proportion of health care financing that is often not reflected by official statistics[600]. According to World Bank estimates, up to 60 percent of health services in Slovakia are related to informal payments[601]. In Romania, informal payments are estimated to account for over 40 percent of total out-of-pocket health expenditure, and they are more prevalent in the health system than in other sectors, such as the judicial system or public

[599] Informal charges are sometimes called 'gratitude payments' (*parasolventia*). Nevertheless, the meaning of the term 'gratitude' payment is slightly different because informal payments also function as unofficial fees and means to secure access to better and faster treatment.

[600] Dubois, C. A. and M. McKee. 'Chapter 4: Health and Health Care in the Candidate Countries to the European Union: Common Challenges, Different Circumstances, Diverse Policies', in M. McKee, M, L. MacLehose and E. Nolte (eds.) *Health Policy and European Union Enlargement*. Maidenhead: Open University Press, 2004, pp. 43-63, on page 49.

[601] Lewis, M. *Who Is Paying For Health Care in Eastern Europe and Central Asia?*. Washington DC: The World Bank, 2000. See also Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007, on p. 115.

administration[602]. In Hungary, informal payments are estimated to account for 7-16 percent of total out-of-pocket health expenditure[603]. In Bulgaria, a nationally representative survey carried out in 2001 concluded that about 25 percent of hospital patients in Sofia were asked to pay informal charges for health care services including tests, check-ups, treatment and surgeries[604]. Informal payments also persist in the Czech Republic[605] and in Latvia, mostly in case of specialized care. A recent Latvian study concluded that such payments were underreported; although there was a general awareness of the problem, 62 percent of patients declared that they were unwilling to report a health professional who had received an informal payment[606].

Persistence of informal payments is detrimental in several ways. It constitutes an impediment to access to health care and a source of differential treatment on behalf of care providers. This hits especially population groups who face higher poverty rates, such as the Roma minority[607] and the elderly. As pointed out by Dubois and McKee, informal charges reduce the effectiveness of health policies especially in social insurance systems because the existence

[602] Vlădescu, C., Scintee, G., Olsavszky, V., Allin, S. and P. Mladovsky. 'Romania: Health System Review'. *Health Systems in Transition*, 2008; 10(3): 1-172, p. 58.

[603] The figures are based on statistics published by the National Health Accounts and the Hungarian Central Statistical Office for the years 1992-2000. See also Gaál, P. *Health Care Systems in Transition: Hungary.* Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004; Mihályi P. *Egészségügy: A Halogatott Reform*. (Health Care: the Postponed Reform). Budapest: Professzorok az Európai Magyarországért, 2006.

[604] Georgieva, L., Salchev, P., Dimitrova, S., Dimova, A. and O. Avdeeva. 'Bulgaria: Health System Review'. *Health Systems in Transition*, 2007; 9(1): 1-156, p. 57. See also Delcheva, E. 'What Do Consumers Pay for Bulgarian Health Care?'. *Journal of Health Economics* 4:18-35, 1999.

[605] Rokosová, M., Háva, P., Schreyögg, J. and R. Busse. *Health Care Systems in Transition: Czech Republic.* Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2005.

[606] Tragakes, E., Brigis, G., Karaskevica, J., Rurane, A., Stuburs, A., Zusmane, E., Avdeeva, O. and M. Schafer. 'Latvia: Health System Review'. *Health Systems in Transition*, 2008; 10(2): 1-253, pp. 87-88.

[607] Vulnerable groups disproportionately hit by poverty and unemployment suffer even more from the entrenched phenomenon of informal payments. The European Roma Rights Centre, an international public interest law organization that works to combat anti-Roma racism and human rights abuse of Roma documented several cases when Roma people were denied health care due to their inability to pay informal charges. For example, during a 2005 field research carried out in Hungary, the European Roma Rights Centre found that doctors forced Roma people to pay informal charges for assistance with childbirth, and refused such services in case of inability to pay. See, for details, European Roma Rights Centre. *Ambulance not on the Way: The Disgrace of Roma in Health Care*. Budapest: European Roma Rights Centre, 2006, pp. 53-54.

of a shadow economy in health care is incompatible with a system based on insurance contributions[608]. Informal payments have also been regarded as an obstacle to the development of the private health insurance market[609]. Their persistence decreases the transparency of the health care system and it generally makes the enforcement of patients' rights in health care conditional on the ability and willingness to pay informal charges. In this sense, the problem of informal payments is also relevant to the application of patients' rights in cross-border care, particularly in cases when EU citizens seek health care in a state where informal charges are common and widespread. Such charges are unofficial and cannot be documented in a form that entitles the foreign patient to cost reimbursement in the state of insurance. In addition, unwillingness or inability to pay informal charges might impede access to services or result in lower quality care and inappropriate attitude on behalf of treatment providers.

Several CEE countries are confronted with complex challenges that make their health care reform attempts more comprehensive. While old Member States tend to go through repeated reform cycles that explicitly focus on increasing equity and accessibility and are less likely to aim at changing at the same time the whole organization and structure of the health system[610], health care reforms in several CEE countries aim at more radical changes. They intend to solve everything at the same time, such as reducing expenditure, improving cost-containment and transparency, and strengthening the quality, delivery and rationing of services[611]. At the

[608] Dubois, C. A. and M. McKee. 'Chapter 4: Health and Health Care in the Candidate Countries to the European Union: Common Challenges, Different Circumstances, Diverse Policies', in M. McKee, M, L. MacLehose and E. Nolte (eds.) *Health Policy and European Union Enlargement.* Maidenhead: Open University Press, 2004, pp. 43-63, pp. 49-50.

[609] Kornai, J. 'Hidden in an Envelope: Gratitude Payments to Medical Doctors in Hungary', in R. Darendorf and and Y. Elkana (eds.) *The Paradoxes of Unintended Consequences*. Budapest: CEU Press, 2000.

[610] Rich, R. R. and K. R. Merrick. 'Cross Border Health Care in the European Union: Challenges and Opportunities'. *The Journal of Contemporary Health Law and Policy* 23(1): 64-105, 2006, p. 13, footnote 30.

[611] See, for example, the Hungarian health care reform started in 2006, discussed further in Chapter 4. The aims of health care reforms in CEE countries and factors explaining why some reforms are implemented successfully and others not, are examined in Figueras, J., McKee, M., and S. Lessof. 'Ten Years of Health Sector Reform in

same time, the population remains poorly informed about undergoing health care reforms, and also about changes and opportunities opened up by EU accession.[612] On this background, the double burden faced at present by all Member States, i.e., catching up with evolving EU requirements and safeguarding at the same time the social character of health care becomes particularly challenging for new members of CEE.

It is important to note that new members of CEE differ not only from old members but also among each other in terms of their reactions to exogenous and endogenous pressures on health systems. Although one might expect that shared challenges promote converging development patterns, these challenges manifest themselves in different circumstances and CEE countries have been experimenting with a variety of solutions in order to cope. For example, comparative studies show that the Czech Republic has followed a more liberal approach allowing for more spending in health care, while Slovakia has opted for a stronger role for the state in interventions aiming at cost control[613]. Another example is related to the role of the market in health insurance.

The role played by the market in health insurance differs across CEE countries, although most of them emphasize privatization in health care. The role of the market has been increased in Slovakia with the introduction of a system of multiple private insurance funds. In Slovenia, there is a national health insurance fund that provides compulsory public health insurance, and the public system is complemented and to some extent also supplemented by

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CEE and NIS: An Overview', Background paper for the USAID Conference *Ten Years of Health Systems Transition in Central and Eastern Europe and Eurasia,* held in Washington, DC on July 29-31, 2002.

[612] See also Rosenmöller, M. 'Health and Enlargement: Half Way There'. *EuroHealth* 6(5): 9-11, 2000/2001. As discussed further in this chapter, information of the population on possibilities and conditions for access to cross-border health care is still weak in several CEE countries, particularly in case of planned treatment.

[613] Potucek, M. 'Health Policy Reform in the Czech and Slovak Republics as a Political Process', in J. M. Kovács (ed.) *Small Transformations. The Politics of Welfare Reform – East and West*. Münster: LIT Verlag, 2003, pp. 62-71. See also Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007, on p. 115.

voluntary insurance provided by for-profit and non-profit, mutual and commercial insurers, besides the public insurance fund. In Romania, the recently adopted 95/2006 Health Reform Act introduced the possibility for private insurance companies to offer complementary and supplementary voluntary health insurance. Similarly to Slovenia, complementary health insurance in Romania is intended to cover (fully or partially) the co-payments required in the public, compulsory scheme. Supplementary insurance covers the health services that are not included at all in the public scheme, as well as second medical opinion and hospital accommodation of higher comfort[614]. Voluntary health insurance with a complementary role is also present in Latvia, being offered by commercial insurance companies to employer organizations[615]. At the same time, a commercial market for voluntary health insurance has not taken root in the Estonian system[616]. The situation is similar in Hungary: although the legal framework for non-profit voluntary health insurance with a complementary role was created in 1993[617], few voluntary funds have been established so far. Existing voluntary funds operate less as real insurance funds and more as individual medical saving accounts that can be used by the account holders only. Private health insurance is even more limited[618]. Co-payments are covered almost exclusively out-of-pocket and they burden the patient together with informal payments, a persistent and wide-spread phenomenon. The diversity of paths

[614] Romanians are only eligible for voluntary health insurance if they pay the contributions in the public system. Premiums are based on pre-established individual risk and they are currently not regulated. See also Vlădescu, C., Scintee, G., Olsavszky, V., Allin, S. and P. Mladovsky. 'Romania: Health System Review'. *Health Systems in Transition*, 2008; 10(3): 1-172, p. 60.

[615] Tragakes, E., Brigis, G., Karaskevica, J., Rurane, A., Stuburs, A., Zusmane, E., Avdeeva, O. and M. Schafer. 'Latvia: Health System Review'. *Health Systems in Transition*, 2008; 10(2): 1-253, p. 83.

[616] Koppel, A., Kahur, K., Habicht, T., Saar, P., Habicht, J. and E. van Ginneken. 'Estonia: Health System Review'. *Health Systems in Transition*, 2008; 10(1): 1-230.

[617] See the Hungarian Act XCVI/1993 on Voluntary Mutual Insurance Funds.

[618] In 2000, private health insurance accounted for 1 percent of private and 0.2 percent of total health care expenditure in Hungary. Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 48.

and solutions illustrated above also characterizes the reactions of CEE Member States to the challenge that European integration represents for health care[619].

2.2. Challenges brought about by EU accession

In the context of similar challenges but diverse solutions applied, new CEE Member States are currently facing the common requirement to meet EU standards that are themselves changing[620]. Following accession, new members have been confronted with the fact that health care organization and financing was no longer a matter reserved exclusively for national competence. As discussed at detail in the previous chapters, health care regulation ceased to be under exclusive national control as a result of the growing influence of EU law and particularly, the extension of free movement rights to health services following the case law of the European Court of Justice (ECJ). The influence of the EU has developed through a spill-over procedure[621] originating in the dynamics of the creation of a single internal market and the implementation of the basic economic freedoms, particularly the freedom to provide services.

ECJ rulings require the implementation of internal market freedoms in the organization of Member States' health care systems and particularly, in access to health care. At the same time, the European Social Model continues to embody the principle that health care is a social good, and leaving its implementation solely for markets leads to inequalities in accessibility and violation of equity. Universal and equitable access to health services is generally a core objective of new CEE Member States even if most of them attempt to expand co-payment

[619] Potucek, M. 'Accession and Social Policy: The Case of the Czech Republic'. *Journal of European Social Policy* 2004; 14(3); 253-266.
[620] See Chapters 1-3 for a detailed discussion on the emerging role of the EU in health care.
[621] See Chapter 1 for the discussion on the importance of the spill-over process in extending EU role in health care.

schemes and strengthen competition in health care[622]. As a result, they are required to organize their health care systems so as to achieve economic efficiency, implement the free movement principle *and* safeguard at the same time the basic values of solidarity and equity. They are confronted with the clash between efforts to ensure the social character of health care and the conceptualization of medical treatment as an economic service[623].

Upon accession, EU law – including the ECJ case law on cross-border care and the EC social security co-ordination mechanism – became applicable in new CEE Member States. Consequently, these states are required to ensure the normative and practical conditions for access to cross-border care. Following accession, patients from CEE should be able according to EU law to benefit from the ECJ jurisprudence on cross-border health care, and claim a right to access medical treatment in another Member State at the cost of the domestic health insurance fund. In case of non-hospital treatment and sometimes also in hospital treatment, patients should be able to choose between the cost-assumption framework of the EC social security co-ordination mechanism and the Kohll and Decker procedure based on the directly effective free movement provisions of the EC Treaty.

Enhancing access to cross-border care and promoting patient mobility through legal instruments at EU level affects both old and new Member States. On one side, these developments open up new opportunities. Available studies focusing on the impact of relevant EU rules on new member states have predicted a number of possible scenarios. One

[622] See also Schlesinger, M. (ed.) 'Legacies and Latitude in European Health Policy', *Journal of Health Politics, Policy and Law*. Special Issue 30 (1-2), 2005; European Commission. *Communication from the European Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Modernizing Social Protection for the Development of High-quality, Accessible and Sustainable Health Care and Long-term Care: Support for the National Strategies Using the 'Open Method of Coordination'*, COM(2004) 304 final of 20 April 2004. Brussels: Commission of the European Communities, 2004.

[623] See also Mossialos, E., M. McKee, W. Palm, B. Karl and F. Marhold. *The Influence of EU Law on the Social Character of Health Care Systems in the European Union*. Report submitted to the Belgian Presidency of the European Union, Brussels 19 November 2001, p. 5.

possibility is that the health system performance of old and new members gets closer through increasing resource and information sharing[624]. Enhanced mobility of patients and services puts health system performance under a closer scrutiny especially where discrepancies exist in different Member States' practices in determining reimbursement and access rules. Another possibility is that new CEE members will benefit from an increase in the transparency of medical practices at domestic level, broader opportunities for seeking specialist care abroad and improvements in health service quality (which needs to be kept competitive). At least a certain group of CEE patients will be likely to benefit from better and/or faster treatment available in other European Union countries[625].

However, increased opportunities to seek treatment abroad could also bring about pitfalls. Concerns have been voiced about emerging inequities in access to health care as a likely consequence[626]. Studies predict that opportunities to access health care in cross-border settings are more likely to be used by certain categories of citizens/residents of CEE countries, such as people living closer to borders with other Member States, people who have better access to information, and those who are able to advance the costs of treatment abroad and opt for the Kohll and Decker procedure[627]. Differences in access to information, geographic location and ability to pay up-front for the costs could grow the discrepancies in access to health services and transform cross-border care into a privilege enjoyed by certain societal groups only.

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[624] See also Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007.
[625] Mossialos, E. and M. McKee with W. Palm, B. Karl and F. Marhold. *EU Law and the Social Character of Health Care.* Brussels: P.I.E. Peter-Lang, 2002, p. 104.
[626] Ibid.
[627] See, for example, Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17: 112-124, 2007. According to the ECJ jurisprudence and the rules derived from the court cases, insured persons who decide to seek cross-border care on the basis of the Kohll and Decker procedure have to advance the cost of the treatment and get subsequently reimbursed according to the tariffs applicable for the same treatment in the country of insurance. The Kohll and Decker procedure is extensively analyzed in Chapter 3.

The following part of this chapter examines these predictions in the light of the current situation existing in two new CEE members: Hungary and Slovenia. The comparative country-level analysis addresses first the broader environment by highlighting the relevant characteristics of the two health care systems under review. Particular attention is paid to health care reforms initiated before and after EU accession and the consequences of reforms for access to health care. Legal norms and the institutional framework of access to cross-border care are analyzed next, to explore the extent to which relevant EU rules have been transposed into national legislation. Afterwards, the chapter discusses the main enhancing and hindering factors of cross-border care, as well as the current extent and perspectives for institutionalized cross-border co-operation in health care, with specific attention to opportunities brought about by EU accession.

3. The Hungarian and Slovenian health care systems: organizational structure and relevant features

At present, both Hungary and Slovenia have a system of public, compulsory health insurance. The Slovenian compulsory system is complemented and to some extent supplemented by voluntary health insurance. The two countries share roots of work-related social insurance schemes from the mid-nineteen century when they were part of the Austro-Hungarian monarchy. Having started from common roots, the development of the two systems presents a number of distinctive features. The following section will provide an overview of previous health system models and the paths followed until the establishment of the present-day health system.

3.1. Previous health system models

The first sickness funds created in Hungary and Slovenia date back to the Austro-Hungarian Monarchy. These funds were based on the Bismarckian model of mutual assistance for members of professional groups. They provided mandatory health insurance covering short-term support for workers and disciples in case of sickness and occupational accidents[628]. Encompassing at the beginning only workers, the insurance schemes were gradually extended to other population categories.

In Hungary, voluntary self-help funds for industrial workers became legitimized already in 1840, through Act XVI/1840[629]. Further on, a General Fund of Sick and Disabled Workers was created in 1870. Act XIV of 1891 introducing mandatory health insurance for factory workers is regarded as the first step towards the development of the current social security system[630]. This law established the beneficiary categories, the types of benefits as well as the rules on financing and the institutions in charge of governing these funds. At the beginning of their functioning, sickness funds were managed at the local level. Their centralization started in 1907 as an effort to increase efficiency and reduce administrative costs. The XIX/1907 Act established two national funds for assistance of workers in case of illness and accidents. This law extended the circle of beneficiaries and the possibility of voluntary health insurance[631]. Also, a national insurance fund for agricultural workers and a national fund reimbursing health costs for the poor were established at the turn of the century[632]. The National Social

[628] See for a description of the first sickness funds in Hungary, Czúcz, O. *Szociális Jog I*. Budapest: Unió Kiadó, 2002 ; Mihályi, P. *Bevezetés az Egészségügy Közgazdaságtanába* (Introduction to Health Economy). Veszprém: Veszprémi Egyetemi Kiadó, 2003. See for Slovenia, Albreht, T., Cesen, M., Hindle, D., Jakubowski, E., Kramberger, B., Petric, V. K., Premik, M. and M. Toth. *Health Care Systems in Transition: Slovenia*. Copenhagen, European Observatory on Health Systems and Policies, 2002.
[629] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 6.
[630] Czúcz, O. *Szociális Jog I*. Budapest: Unió Kiadó, 2002, pp. 66-71.
[631] Ibid., pp. 66-71.
[632] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 6.

Insurance Institute was established in 1927[633]. Until the 1940s, the private sector played a major role in health care delivery besides some state hospitals. Health care facilities were owned by insurance funds that also employed the health professionals[634].

In Slovenia, the adoption of the Miners Act in 1854 is generally seen as the first step towards the development of a health insurance system[635]. This law established fraternal funds for miners and foundry workers that subsequently got extended to railway workers also. Similarly to Hungary, the first sickness funds operating on the territory of Slovenia followed the German social insurance model and provided mandatory health insurance to members of professional associations. The first sickness fund for compulsory health insurance was established in Ljubljana in 1889, based on the Bismarckian social insurance model, followed also by the subsequently established funds throughout the country[636]. These sickness funds operated until the collapse of the Austro-Hungarian monarchy, but social insurance for workers was reintroduced in 1918, when Slovenia became a member of the Kingdom of Yugoslavia. An association of health insurance funds was created one year later.

The state-socialist years of the twentieth century strongly influenced the development of the health care system in both countries, although the two systems followed slightly different paths during these years[637]. Common features include the general shift of health care delivery and funding under public responsibility and the abolishment of private health enterprises. Health care facilities became state-owned in both countries. Management and financing of

[633] Országos Társadalombiztosítási Intézet (OTI). See Czúcz, O. *Szociális Jog I*. Budapest: Unió Kiadó, 2002.
[634] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 6.
[635] Albreht, T., Cesen, M., Hindle, D., Jakubowski, E., Kramberger, B., Petric, V. K., Premik, M. and M. Toth. *Health Care Systems in Transition: Slovenia*. Copenhagen, European Observatory on Health Systems and Policies, 2002, p. 7.
[636] Ibid., p. 8.
[637] Slovenia became a part of the Socialist Federal Republic of Yugoslavia in 1945. The communist regime was established in Hungary in 1948.

health care was shifted under state competence and state budget for at least a part of the state-socialist period (for a few years only in Slovenia[638] and a longer time in Hungary). Nevertheless, certain elements of social insurance were preserved in both countries. This was particularly characteristic to Slovenia who preserved the main features of social health insurance throughout the state-socialist period[639]. Elements preserved by the Slovenian system include financing through contributions shared by employees and employers, autonomy and self-government of health insurance institutions. Hungary also preserved some elements, such as collection of payroll-related contributions and administration of cash benefits[640]. Nevertheless, the revenue from contributions did not constitute a separate budget for health care and became part of the integral national budget.

In Hungary, the state-socialist health care system was essentially a benefit in kind system that followed the centralized, soviet model. Capacity was determined and resources were allocated on the basis of planning ahead for several years, directed by central authorities and imposed on health service providers[641]. The system was struggling with difficulties originating in the inflexibility of central planning and political pressures on resource allocation that resulted in inequalities in services provision in terms of geographic locations and specialties[642]. Salaries of health care professionals were low compared to remunerations enjoyed by other professional categories. A feature shared by several CEE countries, the insufficient remuneration of health care professionals is considered as one of the factors

[638] As discussed further in this chapter, for a few years between the end of the eighties and 1992, the management of the Slovenian health care system was entirely under state competence, and the system was funded from the state budget.
[639] Such features included financing through contributions, shared contributions by employers and employees and self-government of funds in health insurance decision-making.
[640] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004.
[641] Losonczi, Á. *A Kiszolgáltatottság Anatómiája az Egészségügyben*. (The Anatomy of Dependency in Health Care) Budapest: Magvető, 1986.
[642] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 7.

leading to the emergence and stubborn persistence of informal payments for health services. Another factor leading to the entrenchment of informal payments in the system was the inability of the socialist state to fulfill the proclaimed free and equal access to health care for all and subsequent attempts of patients to secure better and faster health care for unofficial payments. Although health care was stipulated in Hungarian law as a right linked to citizenship and free of charge at the point of use[643], the reality of state-socialist times was not in line with the state promises. Geographic inequalities in accessibility, differences in quality and informal payments contributed to the distortion of equity in access to health care.

In Slovenia, the model of social insurance prevailed in health care until 1954, with insurance schemes administered by regional social insurance branches financed via contributions collected from employees and employers. Until the mid-1950s, the mandatory social insurance scheme included workers, pensioners and family members but left out farmers, craftsmen, self-employed persons and other professionals. After 1955, health insurance got separated from social security and separate types of insurance were established for different population categories. Insurance was provided by community health insurance institutions governed by representatives of employers and insured persons[644]. In early seventies, equality between workers and farmers in terms of health insurance rights was proclaimed[645]. Health insurance legislation adopted after 1974 conferred upon 'self-managing communities of interest in health' an important role in health care[646]. The self-management community was a model promoted by the Yugoslav ideological system that left more autonomy for

[643] See Act II/1972 on Health.
[644] Albreht, T., Cesen, M., Hindle, D., Jakubowski, E., Kramberger, B., Petric, V. K., Premik, M. and M. Toth. *Health Care Systems in Transition: Slovenia*. Copenhagen, European Observatory on Health Systems and Policies, 2002, p. 9.
[645] Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*. Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 11.
[646] Markota, M. and T. Albreht. 'Slovenian Experience on Health Insurance (Re)introduction'. *Croatian Medical Journal* 42(1):18-23, 2001, on p. 19.

communities in defining their own needs and determining the ways to satisfy them. Publicly owned regional health centers were established as the main pillars of preventive and curative health service delivery, including hospitals, primary care centers, pharmacies and regional public health institutes[647]. Although no official data were available on informal payments, this phenomenon did not become entrenched in the Slovenian system preserving the main features of social health insurance throughout the state-socialist period.

At the end of the 1980s, the management of the Slovenian health care system was transferred entirely into state competence and financing became part of the integral national budget[648]. This shift did not last long because it resulted in serious financial difficulties. The severe financial instability constituted a strong incentive for the comprehensive reform of the health care system[649]. The reform was started at the beginning of the nineties, right after Slovenia's independence from the Socialist Federal Republic of Yugoslavia[650]. The Health Care and Health Insurance Act[651] and the Health Services Act[652] adopted in 1992 laid down the main principles for reforming the system. The Health Care and Health Insurance Act created the basis for the present model of health insurance by reinstating mandatory insurance for all residents and introducing voluntary health insurance. Voluntary health insurance engaged public and private resources and introduced a public-private mix in financing[653]. In addition, this act legitimized the process of privatization in the health care system and introduced a

[647] Ibid.
[648] Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*. Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 11.
[649] Ibid, p. 11.
[650] Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 11.
[651] Health Care and Health Insurance Act 1992 (Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju). Official Gazette of the Republic of Slovenia, 1992; 9:577-90.
[652] Health Services Act 1992 (Zakon o zdravstveni dejavnosti). Official Gazette of the Republic of Slovenia, 1992; 9:601-5.
[653] The system of voluntary health insurance was introduced in Slovenia in 1993. See for a thorough presentation of the Slovenian health insurance system, Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*. Ljubljana: Health Insurance Institute of Slovenia, 2007.

public-private mix also in health care delivery. It strengthened primary care and established the gatekeeper role of primary care providers. At present, the Health Care and Health Insurance Act is also the main source of law in Slovenia on access to health care within the national system and across borders.

3.2. Relevant characteristics of the Hungarian and Slovene health insurance systems

Following the end of the state-socialist period, a comprehensive process of health system reform has been started in both countries. The reform has been carried out in the context of the political, economic and social transition from the state socialist system. Since the early nineties, Hungary and Slovenia have been moving away from the centralized, state-socialist model towards a more decentralized health system based predominantly on social insurance[654]. Solidarity, universal coverage, comprehensive and quality care constituted the main principles of the reform programs launched in early nineties.[655] Solidarity has been proclaimed as the guarantee of access to appropriate health care services for all members of society irrespective of financial status.

At present, the Hungarian and Slovenian health insurance systems have a number of similar features. Both are social health insurance systems providing benefits in kind and cash benefits. Both rely on a public insurance fund for providing compulsory health insurance to the population. This fund is called the Health Insurance Fund (HIF) in Hungary[656] and the Health Insurance Institute (HIIS) in Slovenia[657]. They have regional units. Among a series of

[654] Kornai, J. and K. Eggleston. *Welfare, Choice and Solidarity in Transition. Reforming the Health Sector in Eastern Europe.* Cambridge: Cambridge University Press, 2001.
[655] Hungarian Ministry of Welfare. *Program of Health Services Modernization*. Budapest: Ministry of Welfare of the Republic of Hungary, 1995; Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007.
[656] Egészségügyi Pénztár. Official website of the National Health Insurance Fund: www.oep.hu (Last accessed on April 30, 2009).
[657] Zavod za zdravtsveno zavarovanje Slovenije. Official website: http://www.zzzs.si/zzzs/internet/zzzseng.nsf (last accessed on June 10, 2008). The Slovenian HIIS is a strong and autonomous body managed by a governing

responsibilities related to the provision of compulsory public health insurance, these funds are responsible for authorizing coverage for medical treatment abroad for Hungarian/Slovene insured persons at the cost of the compulsory scheme.

The share of health insurance contributions collected within the public, compulsory system is at present similar in the two countries, although somewhat higher in Slovenia. In 2008, this share amounted to 6.25 percent of employees' gross salary in Slovenia and 6 percent in Hungary. The contributions collected from employers amounted to 6.75 percent in Slovenia and 6 percent in Hungary. In addition to health care contributions calculated as a percentage of the insured person's income, Hungarian employers also pay a small lump sum after each employed person (the amount is established by law on a yearly basis[658]). None of the two systems allows for opting out of the compulsory scheme. If medical services are obtained from non-contracted doctors and treatment facilities, the costs must be fully covered by the patient. Although the Hungarian and Slovenian health systems aim at universal and comprehensive coverage, co-payments are present in the compulsory scheme and can be substantial in case of non-emergency treatment and certain pharmaceutical products.

Besides the similarities, the Slovenian and Hungarian systems also present significant differences. One important difference is rooted in the way they deal with the issue of co-payments required in the compulsory scheme. As established by the Health Care and Health Insurance Act, the Slovenian system of compulsory public health insurance ensures coverage

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assembly including representatives of employers and insured persons. The most relevant responsibilities of HIIS include: defining the narrower scope of the right to health care services, establishing the standards and norms for the implementation of the compulsory health insurance scheme, defining the conditions of individuals' entitlement to health care, providing voluntary health insurance besides the compulsory scheme, establishing the financial plan and the guidelines for negotiations with partners in the health care sector for implementation of the programs, setting the prices of services and reimbursement rates for pharmaceuticals and contracting with health care providers on annual basis.

[658] Tételes Egészségügyi Hozzájárulás, EHO. See the LXVI/1998 Parliamentary Act. In 2008, the amount of this lump sum was 1950 HUF/month (3% of the gross monthly minimum salary established by law).

only within the scope or to the extent established by this Parliamentary Act. Only certain population groups and specific diseases listed in this act have full cost coverage under the compulsory public scheme[659]. Groups fully covered include preschool and school children, students enrolled full time, women obtaining health services in connection with childbirth and other adults in accordance with actual health programs. Full cost coverage is ensured for urgent medical assistance including emergency ambulance transport, early sickness detection and prevention in accordance with programs, mandatory vaccinations, advice on family planning, contraception, pregnancy and maternity care, malign diseases, infectious diseases including HIV and other diseases listed in Article 23(1) of the Health Care and Health Insurance Act[660]. Else, co-payments are required and patients need to cover from 5 to 75 percent of the total value of the medical service or appliance[661].

The solution applied in Slovenia for co-payments is voluntary health insurance based on the idea of cost-sharing and coinsurance. Persons insured in the public, compulsory system may opt for voluntary insurance for all services that are not fully covered by the compulsory scheme as well as for a higher standard of services and additional rights[662]. Introduced in 1993 as a new concept and the biggest novelty of the post-socialist reform, voluntary health insurance has become well rooted in the Slovenian system. At present, it is provided by the

[659] See Article 23 of the Slovenian Law on Health Care and Health Insurance.

[660] Other diseases fully covered by compulsory insurance include advanced diabetes, muscular and neuromuscular diseases, paraplegia, tetraparaplegia, cerebral palsy, epilepsy, haemophilia, mental disorders, multiple sclerosis and psoriasis, treatment and rehabilitation for professional illnesses and injury at work, treatment and home nursing and in social care institutes, home visits, health care in connection with the donation and exchange of tissue and organ transplantation. See Article 23(1) of the Slovenian Law on Health Care and Health Insurance.

[661] See Articles 23(2-6) of the Slovenian Law on Health Care and Health Insurance. The law leaves it at HIIS's discretion to establish the exact share of co-payment required for the given service. A specialized commission of the HIIS decides on the list of medicinal products covered by compulsory health insurance and the reimbursement rates. The European Committee of Social Rights supervising the implementation of the Social Charter noted that the range of reimbursement rates covered by compulsory health insurance was between 75% and 0%. The non-reimbursed part was covered either by voluntary insurance or out-of-pocket. See European Committee of Social Rights. European Social Charter (revised) Conclusions 2003, Slovenia. Strasbourg: Council of Europe, 2003.

[662] See Article 61 of the Slovenian Law on Health Care and Health Insurance.

HIIS[663] and also by competitive mutual and commercial insurers[664]. Based on the typology established by Thomson and Mossialos[665], one can conclude that voluntary health insurance has a complementary role in Slovenia because it provides coverage for services that are either completely excluded or only partially covered in the compulsory scheme. At the same time, it also fulfills a supplementary role because it can be used by insured persons to obtain services of higher standard. The compulsory/public and voluntary/mutual or commercial schemes are closely linked. Voluntary health insurance has introduced a public-private mix in health care financing. According to 2006 HIIS data, private funding coming from voluntary health insurance companies covered a total of 12.3% of all health care expenditure[666]. The Law on Health Care and Health Insurance establishes that the HIIS must administer the resources for voluntary insurance separately from resources for compulsory insurance[667].

Apart from the HIIS, the largest fund providing voluntary insurance in Slovenia is a mutual association called Vzajemna[668]. Established in 1999, Vzajemna has at present over one million subscribers (i.e., more than half of the population of the country). Vzajemna provides complementary insurance for co-payments required in the public scheme, supplementary insurance for higher standard services and substitutive insurance for foreigners not included in the compulsory scheme. It also has a product for medical assistance abroad that covers emergency care becoming necessary during a short visit to EU and non-EU countries[669].

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[663] Ibid.
[664] As stipulated in Article 62 of the Slovenian Law on Health Care and Health Insurance, voluntary insurance may also be provided by insurers other than the HIIS.
[665] See, for details, Thomson, S. and E. Mossialos. 'Regulating Private Health Insurance in the European Union: The Implications of Single Market legislation and Competition Policy'. London: LSE Health, the London School of Economics and Political Science, 2006, pp. 6-7.
[666] Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 13.
[667] See Article 61 of the Slovenian Law on Health Care and Health Insurance.
[668] Official website: http://www.vzajemna.si/ (last accessed on May 26, 2009).
[669] Vzajemna zdravstvena zavarovalnica. *Be Active*. Ljubljana: Vzajemna, 2005. Available at the official website of the insurance institution: http://www.vzajemna.si/default_ENG.asp?lang_eng=true (last accessed on May 26, 2009).

Besides Vzajemna, there are also commercial insurance companies that provide complementary and supplementary insurance as well as health insurance for emergency treatment that becomes necessary during a short stay abroad[670]. One of these companies called Adriatic Slovenica[671] launched in 1993 the first insurance product (CORIS) on the Slovenian market for emergency treatment abroad[672]. This product only covers emergency care that becomes necessary during a visit to EEA and non-EEA states; it does not cover planned treatment that is foreseen before departure and constitutes the objective of the travel[673].

As opposed to Slovenia, efforts to introduce a mixed, private-public health insurance system have been put on hold in Hungary since the first half of 2008[674]. As discussed earlier in this chapter, voluntary health insurance has not established itself in the Hungarian system as yet, although the legal framework for non-profit voluntary health insurance with a complementary role has existed since 1993[675]. The few voluntary funds established so far operate less as real insurance funds and more as individual medical saving accounts that can be used by the account holders only. Private health insurance has not taken root in the Hungarian system, and it is even more limited than non-profit voluntary health insurance[676]. In reality, co-payments are covered almost exclusively out-of-pocket and include substantial informal payments.

[670] For example, Adriatic Slovenica, Triglav, Mariborska.
[671] Official website: http://www.adriatic-slovenica.si/ (last accessed on May 26, 2009).
[672] Adriatic Slovenica 2006 report. http://www.adriatic-slovenica.si/bin?bin.svc=obj&bin.id=20602, pp. 15-16 (last accessed on May 26, 2009).
[673] Interview with the Director of Market Support Sector, Adriatic Slovenica. Ljubljana, October 14, 2008.
[674] Efforts of the Hungarian government to introduce a private-public health insurance system will be discussed at section 3.3 of this chapter dealing with the consequences of recent reforms on access to health care.
[675] See Act XCVI/1993 on Voluntary Mutual Insurance Funds.
[676] Gaál, P. *Health Care Systems in Transition: Hungary*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004, p. 48.

Hungarian citizens have often raised their voices against the burden of co-payments that they need to cover out-of-pocket, especially in case of pharmaceuticals. Individuals have repeatedly turned to the Hungarian Ombudsman claiming that the high share of co-payments required for certain pharmaceutical products constrains their access to medical treatment and violates therefore their constitutional right to health[677]. The Ombudsman has repeatedly acknowledged that high co-payments curtail the exercise of the right to health set forth in the Hungarian Constitution. However, not much improvement has been achieved as yet. In determining the minimum amount of action required from the state, the Hungarian Constitutional Court has only established general principles referring to extreme cases (for example, the complete lack of health care facilities and medical supply in a certain region of the country[678]). In fact, the constitutional right to health has very rarely served so far as a basis for litigation in Hungarian courts.

The constraint imposed by high co-payments on access to treatment has also been emphasized by the European Committee of Social Rights of the Council of Europe. When evaluating Hungary's performance under Article 11 of the European Social Charter (the right to protection of health)[679], the Committee has repeatedly criticized the state for high co-payments related to income and for depriving individuals of essential medical care in case of

[677] Several complaints have been filed with the Ombudsman related to high co-payments required in case of pharmaceutical products. One example is a medicine used for treatment of chronic migraine. Hungarians have repeatedly complained that, although this medicine is indispensable for sustaining an acceptable quality of life and for alleviating suffering, the high co-payment represents an unacceptable obstacle in access to this medication and constitutes therefore an unlawful limitation on the constitutional right to health.

[678] See also Mihályi P. *Bevezetés az Egészségügy Közgazdaságtanába* (Introduction to Health Economy). Veszprém: Veszprémi Egyetemi Kiadó, 2003.

[679] Council of Europe. European Social Charter of 18 October 1961, ETS 35. Strasbourg: Council of Europe. Hungary ratified the European Social Charter in 1999, which was also the year of its entry into force. The country became signatory to the Revised Social Charter in 2004. See the website of the Council of Europe: http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=035&CM=&DF=&CL=ENG. (Last accessed on May 26, 2009).

inability to pay[680]. Hungary's 2003 country report submitted to the Social Rights Committee stated that people needing constant medical care were entitled to public medical aid including medicines granted for free whenever the cost of treatment endangered their means of subsistence. Nevertheless, the Committee was not convinced and has repeatedly asked since then for more concrete data in order to assess the share of co-payments and its impact on access to health care[681].

Health services are provided on the basis of a personal identification number ('TAJ-number') in Hungary and an electronic health insurance card in Slovenia[682]. At present, both countries have a system that requires health care providers to check at each patient-doctor meeting whether insurance contributions have been paid. Since the 2000 introduction of the Slovenian electronic health insurance card, services are provided only if contributions are paid. The card holds electronic records of compulsory insurance and voluntary insurance validity data. As a result, effective payment of contributions can be easily checked. According to the HIIS[683], compliance has become high in Slovenia after the introduction of the electronic card[684],

[680] See European Committee of Social Rights. European Social Charter Conclusions XVI-2, 2003, Hungary. Strasbourg: Council of Europe, 2003.
[681] In order to determine whether the cost of health care impedes access, the Social Rights Committee has called upon Hungary to report on measures taken to prevent health care costs from becoming an excessive burden on people with low income and to identify population categories that are completely exempted from the requirement of co-payment. Also, the Committee asked for an extensive list of medical services provided for free within the mandatory insurance scheme and for information on financing the costs of long-term hospital care (i.e., exceeding one year) including care provided for people with disabilities. See European Committee of Social Rights. European Social Charter Conclusions XVI-2, 2003, Hungary. Strasbourg: Council of Europe, 2003.
[682] Information on card data is available at the website of the Slovenian HIIS: http://www.zzzs.si/ZZZS/INTERNET/zzzseng.nsf/o/FE0F77E424C1C9EEC1256EC8002A345C (Last accessed on May 26, 2009).
[683] Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, HIIS. Ljubljana, October 14, 2008.
[684] Before the 2000 introduction of the electronic health insurance card, there were problems with compliance and the Revenue Office did not manage to enforce regularity of payments. Markota, M. and T. Albreht. 'Slovenian Experience on Health Insurance (Re)introduction'. *Croat Medical Journal* 42(1):18-23, 2001, p. 20.

especially in case of employees and employers. The lowest compliance can be observed in case of small entrepreneurs and self-employed persons[685].

Lack of compliance in contribution payment has generated a lot of attention and public debate in Hungary. Prior to 2007, there was no system allowing health care providers to check whether contributions had been paid by patients seeking treatment. Enforcement of contribution payments was one of the explicit objectives of the health insurance system reform initiated in 2007, when statistics of the Hungarian State Audit Office revealed that approximately one-tenth of the Hungarian population used the public health care system without paying the contributions[686]. Since 2007, Hungarian health care providers have been obliged by law to check at each patient-doctor meeting whether the health insurance contributions are paid. At present, the Hungarian tax office is empowered to collect overdue contributions from individuals.

3.3. Reforms and their consequences for access to health care

Although the two countries are confronted with a number of similar challenges, these challenges manifest themselves in different circumstances and result in different reactions. The reforms initiated after 2000 illustrate the differences. In Slovenia, there has been explicit focus on reducing inequalities in access to health care and improving quality. Priority has been given to decreasing regional disparities and improving access to services for people

[685] Interview with Rade Pribakovic Brinovec, Researcher, Ljubljana Institute for Public Health. Ljubljana, October 13, 2008.

[686] The State Audit Office of Hungary reported in 2007 that the number of Hungarian residents who used health services in 2006 without paying the health insurance contributions exceeded 1,1 million (i.e., 10 percent of the total population and almost 30 percent of the active population). See for details, the 2007 report of the State Audit Office of Hungary: Állami Számvevőszék. *0707. számú Jelentés az Állami és Önkormányzati Kórházak Gyógyszergazdálkodásának Ellenőrzéséről* (Report No. 0707 on monitoring the management of pharmaceuticals in state and local government hospitals) May 2007, at:
http://www.asz.hu/ASZ/jeltar.nsf/0/AF464157C359F344C12572D5004E9F25/$File/0707J000.pdf
(Last accessed on February 21, 2008). More refined data collection showed that the share of people using health services without paying insurance contribution was in fact lower than first estimated (although still surprisingly high). The alarming first statistics were partly the result of the inaccuracy of the registration system.

without health insurance and for the most disadvantaged groups[687]. At the same time, the system has been moving towards a more service-centered and market-focused structure with increasing emphasis on consumers' choice[688].

A specific objective of health care reform started in Slovenia after 2000 has been strengthening the role of voluntary health insurance and particularly, private insurance. Recognizing that voluntary health insurance plays an important role in social protection, particular attention has been paid to increasing the access of the population and especially, the more vulnerable groups such as the elderly and minorities to this form of coverage. Adopted in 2000, the National Health Care Program of the Republic of Slovenia included measures to tackle inequalities and abolish risk selection in voluntary insurance[689]. In addition, private insurance funds have become obliged since 2005 to offer open enrolment and community-rated policies accompanied by a risk equalization scheme[690]. Especially strengthening the substitutive role of voluntary health insurance is important in the Slovenian context in order to ensure coverage for groups left out of the compulsory scheme, such as foreigners legally residing in the country. For example, the European Social Rights Committee monitoring the implementation of the Social Charter considered in 2006 that Slovenia did not manage to demonstrate that coverage of legally residing foreigners applied also to temporary residents. Leaving out the temporary residents was considered by the

[687] A notable effort towards this end was the establishment of outpatient departments that include counseling for the most disadvantaged persons. European Committee of Social Rights. European Social Charter (revised) Conclusions 2004, Slovenia. Strasbourg: Council of Europe, 2004.
[688] Albreht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in Rosenmöller, M., McKee, M., and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization, 2006, pp. 9-21, on p. 11.
[689] World Health Organization. *Country Cooperation Strategy at a Glance: Slovenia*. Geneva: World Health Organization, 2007. The reform of hospital care constituted another priority area. Concrete measures included the introduction of new hospital standards for accreditation and quality management systems. Continuous improvement of organization and quality of public health and primary care constituted further priority areas.
[690] Thomson, S. and E. Mossialos. 'Regulating Private Health Insurance in the European Union: The Implications of Single Market Legislation and Competition Policy'. LSE Health, London: the London School of Economics and Political Science, 2006, p. 13.

Committee a form of discrimination. As a result, the Committee concluded that the Slovenian situation was not in conformity with Article 12(4) of the Revised Social Charter[691].

The Slovenian reform process has shifted the system towards a more service-centered and market-focused structure with increased emphasis on consumers' choice[692]. The system has become favorable for the development of smaller, more flexible private practices[693]. Especially in fields such as dental care, ophthalmology and plastic surgery, these small private practices have incentives to attract patients from neighboring Member States like Italy and Austria, where out-of-pocket expenditures for such treatments have been expanding[694]. Dental treatment and certain hospital interventions (such as cosmetic surgery and eye surgery) are still performed at a lower price in Slovenia compared to the charges applied (and covered out-of-pocket) in the neighboring Austrian and Italian regions[695].

Although high on the agenda in health insurance and service delivery, privatization of the Slovenian health care system has not been as far reaching as originally planned. The majority of hospitals remain publicly owned (by the central government and by local municipalities). Ambulatory care presents a more diverse picture, with private providers being more numerous especially in certain specialties such as dental care[696]. Doctors working in private

[691] See the Council of Europe Conclusions on Slovenia's report on the implementation of the Revised European Social Charter. European Committee of Social Rights. European Social Charter (revised) Conclusions 2006, Slovenia. Strasbourg: Council of Europe, 2006.
[692] Albreht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in Rosenmöller, M., McKee, M., and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006, pp. 9-21, on p. 11.
[693] Albreht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. And E. Turk. *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria, 2005.
[694] Ibid., p. 7.
[695] Albreht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in Rosenmöller, M., McKee, M., and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization 2006, pp. 9-21.
[696] According to 2002 data, about 70 percent of Slovenian dentists were private providers and about 15 percent of them provided services for direct payers only. Albreht, T., Delnoij, D. M. J. and N. Klazinga. 'Changes in Primary Health Care Centres over the Transition Period in Slovenia'. *The European Journal of Public Health* 16(3):237-242, 2006.

practice are mainly dentists in primary care, specialists at secondary level and general practitioners[697]. Nevertheless, private practice has been made an option for all major health areas. Only a few fields have been excluded[698].

Privatization of health care facilities and strengthening primary care has also been present among the objectives of Hungarian health care reforms. During the years preceding EU accession a number of reform elements were introduced[699]. The three major strands were: large scale privatization of health care facilities, raising the remuneration of health care professionals and developing home care and outpatient facilities[700]. These measures were paralleled by efforts to strengthen the role of general practitioners in limiting the use of specialty care and in prevention and health education[701]. The Social Rights Committee of the Council of Europe welcomed Hungary's efforts to prioritize primary care and strengthen the role of general practitioners[702]. In practice, however, patients continued to be able to see a range of specialists without referral. Given the existence of a very large hospital system, shifting the focus on primary care remained an unaccomplished plan.

In Hungary the major focus of health system reforms launched since 2006 was on increasing cost-containment and reducing budgetary pressures. Early 2007, the Ministry of Health

[697] Svab, I., Vatovec Progar, I., and M. Vegnuti. 'Private Practice in Slovenia after the Health Care Reform'. *The European Journal of Public Health* 11:407-412, 2001.
[698] Ibid.
[699] These reform elements were acknowledged in 2005 by the European Social Rights Committee of the Council of Europe and commented in the recommendations following Hungary's report on the implementation of Article 11 of the European Social Charter (the right to protection of health). European Committee of Social Rights (2005), European Social Charter Conclusions XVII-2, 2005, Hungary. Strasbourg: Council of Europe, 2005, pp. 43-45.
[700] See, for further details on the reforms preceding Hungary's accession to the European Union, European Commission. Staff Working Paper 'Social Inclusion in the New Member States: Synthesis of the Joint Memoranda on Social Inclusion'. Commission Staff Working Paper SEC(2004) 848 of 22 June 2004. Brussels: Commission of the European Communities, 2004.
[701] See, for details on the pre-accession reforms of the Hungarian health care system, European Commission. *Comprehensive Monitoring Report on Hungary's Preparations for Membership*. Brussels: Commission of the European Communities, 2003.
[702] European Committee of Social Rights. European Social Charter Conclusions XVII-2, 2005, Hungary. Strasbourg: Council of Europe, 2005.

launched a package of reform measures that has become the target of vehement public criticism. This reform package intended to bring substantial changes in the structure and vision of the Hungarian health care system by involving private capital and market competition in financing, combined with the introduction of a series of cost-decreasing measures. Cost-reducing measures included decreasing the capacity and number of hospitals and introducing a system of waiting lists for hospital care, limiting the possibilities of free choice of health care providers, restructuring the scope of health insurance, increasing further the share of co-payments for health care provision and pharmaceuticals[703], and strengthening the market logic in the supply of health care and pharmaceutical products. The government proposed to restructure the scope of health insurance by differentiating between three insurance packages: a basic package containing health services ensured for all persons legally residing in Hungary regardless of insurance status; an insurance package with entitlement based on payment of contributions, and a third, optional package, covered out-of–pocket[704]. The cost-reducing measures were not preceded by an assessment of their possible consequences for access to health services. The most contested measures were reducing hospital capacity and increasing co-payments together with health insurance contribution rates.

[703] The share of co-payment for medicines has been substantially increased since 2007 (with the exception of some medicines used for treatment of chronic illnesses). The Ministry of Health justified these measures as means to increase responsibility of patients in use of pharmaceuticals and to combat over-use. See Egészségügyi Minisztérium. *Az Egészségügy Átalakitásának Programja.* Reform Tájékoztató Előadások 2007, február 7-16. Presentations by the Hungarian Ministry of Health on goals of the 2006-2007 health care reform, accessed on the website of the Ministry of Health, at http://www.eum.hu/index.php?akt_menu=5098 (Last accessed on January 20, 2008).

[704] Ibid. The basic health care package was meant to include only a limited range of services, such as life-saving interventions, public health services (defined as state interest and duty) and protection of mother and child. The second, so-called insurance package was meant to cover services for insured persons paying their contributions. The third package was intended to cover services left out of the first two, such as aesthetic surgery, non-mandatory vaccinations, certain occupation-related health examinations, health services provided for persons practicing extreme sports and detoxification. Additional costs of comfort-increasing services in hospitals also fall within this category, as well as services of providers that do not have contracts with the National Health Insurance Fund.

In an effort to strengthen the referral system and control the use of services, the government has restricted the possibilities to choose the health service provider, particularly in case of hospital treatment. It introduced a non-refundable co-payment of 30 percent (but a maximum of 100,000 Hungarian forint) in case of non-emergency hospital treatment obtained without a referral, or choosing a health care provider other than the one specified in the referral, or choosing a doctor who is not on duty at the time of the treatment[705]. Currently, this rule applies also to EEA residents seeking hospital treatment in Hungary with the European Health Insurance Card (EHIC).

The reform of the Hungarian health insurance system culminated in February 2008 with the adoption of a Parliamentary Act on Health Insurance Funds. This law intended to introduce a private-public mixed insurance system involving private capital in health care financing[706]. The proposed model included a National Health Insurance Center and several sickness funds located in different regions of the country. The National Health Insurance Center was designed to function as a government institution with autonomous management; among a series of planning, monitoring and governing responsibilities, it was designated to supervise the implementation of EC Regulation 1408/71 on social security co-ordination and other international agreements[707]. The sickness funds were envisaged to operate as closed joint-stock companies founded by the Hungarian State as the controlling shareholder in case of

[705] Between 2007 and 2008, the Hungarian Ministry of Health experimented with a series of co-payment schemes. Besides the 30 percent co-payment mentioned above for hospital care, other co-payments introduced in this period were visit fees and daily fees for hospital treatment. The very unpopular co-payments were abolished following a referendum initiated by the opposition in the spring of 2008. The referendum questions targeted expressly the visit fee, the daily fee for hospital treatment and the issue of privatization in health care. A record number of referendum participants expressed their disagreement. Given the strong public disapproval, the government put on hold the whole health care reform in May 2008.

[706] In fact, the introduction of a multiple insurers system was not a completely new idea in Hungary: it was suggested already in 1999 by the State Secretariat responsible for social security. See, for further details, Mihályi P. *Egészségügy: A Halogatott Reform* (Health Care: The Postponed Reform). Budapest: Professzorok az Európai Magyarországért, 2006.

[707] Articles 51-53 of the 2008 Parliamentary Act on Health Insurance Funds included the complete list of responsibilities.

each fund[708]. The ownership of the remaining stocks of each sickness fund would have been open to private investors from Hungary and other EU countries[709].

From the perspective of access to cross-border care it is notable that the 2008 Parliamentary Act on Health Insurance Funds included a reimbursement rule based on the Kohll and Decker procedure running in parallel to the rules established by Regulation 1408/71. Article 72(4) established an obligation for Hungarian sickness funds to reimburse the costs of treatment obtained in EU states according to the tariff applicable for the same treatment in Hungary. The rule was vaguely formulated and did not specify, for example, whether this reimbursement procedure applied to ambulatory care only, or also to hospital care, and in what conditions. The 2008 Parliamentary Act on Health Insurance Funds envisaged the adoption of subsequent legal norms regulating access to planned health care abroad. However, this law has not been implemented as yet[710]. The proposed health insurance model turned out to be an unfinished experiment.

4. Regulation of access to cross-border health care in Hungarian and Slovenian legislation

The May 2004 accession marked the moment when European Union rules on access to cross-border care became subject to implementation in the new members of CEE including Hungary and Slovenia. The following part of this chapter examines and compares the current legal framework on cross-border care in these two countries, in the light of EU requirements. The analysis will focus first on rules applicable to persons insured in the Hungarian/Slovenian compulsory scheme who obtain medical treatment in other EU countries. Two main cases will be distinguished: unplanned, medically necessary health care during a short visit abroad and planned care. The analysis will also address the rules on

[708] Fifty-one percent of the stocks were envisaged to belong to the State treasury assets.
[709] See Articles 3-4 of the 2008 Parliamentary Act on Health Insurance Funds.
[710] Meaning, until May 2009, when the writing of this dissertation was completed.

treatment of foreign EU citizens in Hungary and Slovenia. Particular attention will be paid to the influence of the EU on the development of the domestic rules.

As discussed also in Chapter 2, health insurance funds usually restrict financial coverage to services and goods obtained within the territory of the state where they function[711]. This is generally known as the territoriality principle in health insurance. Cost covering for health care obtained in other countries is not automatic and granted only in specific circumstances. This approach reflects the efforts of states to close up health care financing within the territory of their national health systems. Although the territoriality principle is generally dominant in European health care systems[712], each Member State is required by the EC social security co-ordination mechanism to allow for certain exceptions. The relevant exceptions imposed by co-ordination law include medically necessary treatment received during a short visit abroad and planned health care obtained with the authorization of the competent insurance fund. The EU encourages Member States to allow for further exceptions. One example is promoting access to cross-border care as part of Euregional co-operation initiatives involving stakeholders from neighboring EU states. Such initiatives can be launched by various stakeholders including insurance institutions, health care providers and/or local governments[713].

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[711] See Chapter 2 for details on the territoriality principle in health insurance. See also Schoukens, P. 'Introduction to Social Security Co-ordination in the EU'. In D. Pieters and P. Schoukens (eds.) *International and European Social Security Law. Study Materials Master in Arts of European Social Security.* Leuven: Instituut Sociaal Recht, 2004-2005.

[712] For example, in the Czech Republic the prior authorization scheme is the general procedure for obtaining planned care abroad; however, non-hospital care can also be obtained without the prior authorization of the Czech insurance fund, with subsequent reimbursement. This illustrates the country's effort to implement the case law of the European Court of Justice. See, for an analysis of the Czech regime on access to cross-border care, European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.

[713] As discussed further in this chapter, the EU uses financial incentives in order to promote cross-border co-operation in health care. The INTERREG Community initiative has been particularly instrumental in supporting such initiatives. Examples of cross-border co-operation initiatives funded through EU mechanisms can be found in several Euregios. In 2008, an evaluation of cross-border co-operation initiatives in health was published by LIGA.NRW (Landesinstitut für Gesundheit und Arbeit des Landes Nordrhein-Westfalen). LIGA.NRW.

The European social security co-ordination regulations must be directly implemented in Member States and have priority over domestic rules. Currently, both the Hungarian and Slovenian systems allow for the above-mentioned exceptions to the territoriality approach. The basic source of law on access to covered health care abroad is the LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance in Hungary[714] and the Law on Health Care and Health Insurance in Slovenia[715].

4.1. Access to health care during a temporary visit to other Member States of the EEA

Together with EU accession, the EC social security co-ordination mechanism became applicable to access to treatment that becomes medically necessary during a temporary stay abroad and not planned before travelling. In line with EU requirements, the European Health Insurance Card (EHIC) was introduced in both countries as an instrument that should be used to access medically necessary health care during a temporary visit to the states of the European Economic Area (EEA)[716]. The EHIC is issued upon request for individuals insured in the Hungarian/Slovenian compulsory health insurance system.

The rules currently applicable in Hungary and Slovenia stipulate that health care obtained on the basis of the EHIC is financed by the domestic public health insurance system. The rules make it clear that the EHIC only covers health care obtained from providers that are contracted with the health insurance fund of the given Member State. When issuing the

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Evaluation of Border Regions in the European Union (Euregio). Düsseldorf: LIGA.NRW, 2008. The report is available at http://www.euregio.nrw.de/files/final_report_euregio_en.pdf (Last accessed on May 7, 2009).

[714] Article 27 deals with medical treatment abroad. The LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance is regularly amended.

[715] Health Care and Health Insurance Act 1992 (Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju). Official Gazette of the Republic of Slovenia, 1992; 9:577-90.

[716] In Hungary, the EHIC was introduced in November, 2005 and it replaced the previously used E111 form in January, 2006. It is generally issued for 12 months. In case of pensioners the validity of the EHIC can be extended to maximum 36 months. In Slovenia, the EHIC was introduced in June, 2004.

EHIC, the insurance fund undertakes cost coverage for treatment that might become necessary during a temporary visit in the EEA. The card does not provide an entitlement to planned medical care abroad; for such purposes, the prior authorization mechanism remains the applicable framework[717]. The EHIC stops being valid when the card holder looses his/her entitlement to health insurance within the domestic public system. If the card holder tries to use an invalid EHIC to access treatment, he/she becomes fully responsible for covering the treatment costs. If the patient cannot show the EHIC to the foreign treatment provider, he/she has to pay for the costs and can claim reimbursement after returning to the state of insurance. However, the patient will be only reimbursed for the amount that the sickness fund would need to cover on the basis of the EHIC. In such cases the amount of reimbursement can be significantly lower than the price actually paid, because treatment providers may charge market prices when the patient is not able to present an EHIC[718].

The EHIC-related rules adopted in the two countries reflect a practical logic, a free movement logic and a social security co-ordination logic. Technically, the EHIC serves the practical objective to simplify administrative procedures and prove that the card holder has a valid health insurance in the state where he/she lives. In this sense, it is an instrument proving entitlement. The free movement logic is reflected in the EHIC's role to ensure that card holders exercising their free movement rights do not have to interrupt their visit to other EU states because of reasons linked to access to health care. The social security co-ordination logic is reflected in putting the Hungarian/Slovene EHIC holder on equal footing with insured persons living in the state visited (i.e., the state of treatment). The health care

[717] This is in accordance with the EC rules, because the EHIC has never intended to replace the prior authorization scheme for planned treatment in other Member States. The E112 form is the main instrument designated by the EC social security co-ordination mechanism for accessing planned care.

[718] See also Lengyel B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztosításban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14, on p. 6.

provider treating an EHIC holder is under the obligation to refrain from discrimination based on citizenship. As a result, the EHIC temporarily integrates the patient in the social security system of the state of treatment. The rules applicable in the state of treatment determine what health benefit in kind will be provided to the card holder according to what is available by law in that particular country. Also, the health care provider decides (in case of doubt) whether it is medically necessary to provide the treatment during the expected duration of the stay, meaning that it cannot be delayed until the patient returns to the home country. In general, the rules and conditions applicable to persons insured in the state of treatment are also applicable to EHIC holders. This includes the referral rules and co-payments.

Since the relevant rules on health service provision can differ from state to state, the card holder might face situations when a certain treatment is lawfully available in one EEA country and not in another one. The Hungarian National Health Insurance Fund (NHIF) foresees such situations and explicitly encourages EHIC holders to be aware, informed and prepared[719]. However, besides informing actual and potential card holders about the possibility that they might encounter such situations, the NHIF cannot do much more because each Member State is entitled to define what services can be lawfully provided within its territory. By temporarily integrating the card holder in the health system of the state of treatment, the EHIC submits the Hungarian/Slovene insured persons to the treatment provision rules applicable in that state and obliges the Hungarian/Slovenian health insurance system to accept those rules.

The rules linked to the EHIC provide a concrete example for the effect of the EC social security co-ordination mechanism on Member States' health care systems: although Hungary

[719] See the website of the Hungarian National Health Insurance Fund: http://www.oep.hu/oepdok/fajlok/e.pdf (Last accessed on May 26, 2009).

and Slovenia are the states where the EHIC holders are insured, they must accept that the state of treatment sets the rules of effective provision of services, including the conditions of access to specialist care. The state of treatment prevails also in terms of cost-settlement rules: costs are settled among the two states according to the tariffs applicable in the state of treatment. This is a concrete illustration of the developments discussed in Chapter 1 at theoretical level: as a result of EC co-ordination law, Member States cannot limit anymore the application and exercise of the right to access health care to their own territory; nor can they restrict health care providers and health insurance systems from other Member States to interfere with their own system. Health care rights acquired in a Member State have become portable across borders within the EU.

Another example illustrating the influence of EU law on regulating access to medical treatment is the development of Hungarian rules on health care benefits that can be obtained during a temporary visit abroad at the cost of the domestic health insurance system. Prior to accession, the Hungarian Health Insurance Fund was only obliged to cover the cost of health care obtained during a temporary visit to the EEA if the treatment qualified as emergency care. Prior to accession, Article 27(1) of the LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance stipulated that treatment obtained during a temporary visit to the EEA countries was only reimbursed if the lack of care severely endangered the physical integrity or the life of the patient and caused lasting health damage. Such services were reimbursed up to the cost applicable for the same treatment in Hungary. This rule still applies to health care obtained in non-EEA states. The rule set forth in Article 27 is very much in line with the definition of urgency as included in the Hungarian Health Care Act Nr. CLIV/1997, Article 3(i):

i) Urgent need: a change occurred in the state of health when the lack of immediate care results in imminent danger of life or causes serious or lasting damage in the health condition.

Following the amendment of Regulation 1408/71, Hungary removed the emergency requirement in case of EHIC holders. The current rules include in the scope of the EHIC health care that becomes 'necessary on medical grounds during a temporary stay in an EEA Member State, taking into account the nature of the benefits required and the expected length of stay'. This rule follows the current wording of Regulation 1408/71: instead of urgent need and immediate necessity, it talks about medical necessity. This enlarges the scope of the EHIC because the coverage of service is not conditional anymore on the presence of a sudden change in the state of health that represents an imminent danger for life or causes serious and lasting health damage. This is particularly important for persons suffering from chronic illnesses that might require sudden treatment during their travel within the EEA. Their health care needs are not linked to a sudden change in the state of health but a need to sustain the continuity of medication/treatment. Especially in their case it becomes obvious that the new rule fulfills better the goal of the EHIC, i.e., making it possible for insured persons – including patients suffering from chronic diseases - to stay in the Member State visited as planned and under proper medical care[720]. This is in line with the developments in the EC social security co-ordination mechanism rules and the amendment of Regulation 1408/71 (discussed also in Chapter 2).

There is no exact definition for medically necessary treatment, neither in EU law nor in the domestic legislation. Member States agreed to leave this decision largely to the medical professional providing the treatment. They have been reluctant to accept more detailed

[720] It also illustrates that limiting the scope of the EHIC to emergency treatment defined according to the Hungarian Health Care Act Nr. CLIV/1997 would result in a chilling effect on free movement in case of certain groups of insured persons. This would be contradictory to the goal of the social security co-ordination mechanism.

harmonized guidelines on the interpretation of this concept[721]. Consequently, determining what amounts to medically necessary treatment remains a predominantly medical decision and rules of administrative and/or financial nature cannot overrule it.

4.2. Access to health care for EHIC holders in Hungary and Slovenia

In line with the European social security co-ordination mechanism, Hungary and Slovenia created the possibility for EEA residents to access medically necessary care during their visit to these countries. According to the general rule, an EEA resident with a valid European Health Insurance Card (EHIC) is entitled to obtain health care that becomes 'necessary on medical grounds during a temporary visit, taking into account the nature of the benefits required and the expected length of the stay', as set forth in Regulation 631/2004[722]. The idea is to put the EHIC holder on equal footing with the Hungarian/Slovenian residents insured in the public, compulsory system.

The framework is similar in the two countries[723]. For EHIC holders, the state of insurance governs entitlement and the state of treatment (i.e., Hungary/Slovenia) governs the effective provision of health care including the available benefits in kind, referral rules and co-payments. The cost of care is covered by the state of insurance (i.e., the competent insurance institution in that state). The state of insurance covers the services that are legally available in

[721] See also Lengyel B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztosításban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14, on p. 6.

[722] If an EEA resident cannot present an EHIC while seeking medically necessary treatment during a temporary stay in Hungary, the health care provider can accept a retroactively issued Provisional Replacement Certificate submitted within 15 days. Should the patient fail to submit the Provisional Replacement Certificate in due time, the health care provider will charge a fee that cannot be refunded in Hungary. It is up to the patient to seek subsequent reimbursement from his/her competent insurance institution in the home country. Information for EU residents is available in English, French and German on the website of the National Health Insurance Fund: www.oep.hu (Last accessed on May 26, 2009).

[723] The public compulsory health insurance fund (HIIS in Slovenia and NHIF in Hungary) puts together and publishes the rules applicable to EHIC holders including the conditions of access to treatment. The information is available on the website of the HIIS in Slovenia (http://www.zzzs.si/zzzs/internet/zzzseng.nsf) and NHIF in Hungary (http://www.oep.hu/oepdok/fajlok/e.pdf, (Last accessed on May 26, 2009).

the home country. The EHIC proves that the card holder is insured in his/her home country and entitled to health care within the national health system or mandatory health insurance scheme (depending on the system existing in the state of insurance). The EHIC can be used to access both non-hospital and hospital care.

The Hungarian/Slovenian health care provider decides whether it is 'medically necessary' to provide the treatment during the expected duration of the stay, meaning that it cannot be delayed until the card holder returns home. Dialysis, oxygen therapy, pregnancy and childbirth constitute exceptions when all treatments should be considered as medically necessary[724]. EHIC holders can only obtain dialysis and oxygen therapy on the basis of a preliminary agreement with a treatment facility[725]. The online English-language information published by the Slovenian HIIS for EHIC holders includes the list and contact details of dialysis centers contracted in the public, compulsory insurance scheme. EHIC holders can contact these centers in advance for securing the preliminary agreement already before departure from the home country[726]. There is no similar foreign language information available on the website of the Hungarian NHIF; patients have to contact the NHIF in order to get preliminary information on available dialysis centers.

Generally, the necessary treatment is provided to EHIC holders free of charge at the point of use. However, only health care obtained from a provider contracted with the Hungarian/Slovenian public, compulsory health insurance fund comes under the scope of the

[724] The rules follow the Decision No 196 of the Administrative Commission of the European Communities on Social Security for Migrant Workers. Decision 196 of 23 March 2004 of the Administrative Commission on Social Security for Migrant Workers pursuant to Article 22(1)(a) (Text with relevance for the EEA and for the EU/Switzerland Agreement), *OJ* L 160, 30 April 2004, 0135-0137.
[725] This is in line with Decision No 196, op. cit.
[726] See the HIIS website: http://www.zzzs.si/zzzs/internet/zzzseng.nsf (Last accessed on May 26, 2009). The HIIS regional units can be contacted for further information on the providers of health services that necessitate a preliminary agreement.

EHIC. Emergency is a special case, when the card holder can turn to the emergency service of the nearest health care facility. EHIC holders usually need a referral provided by a general practitioner in order to obtain specialized non-hospital and hospital treatment. Emergency hospital care and certain types of ambulatory care can be obtained without referral. In Hungary, these are non-hospital treatments related to dermatology, gynecology, urology, otolaryngology, ophthalmology, oncology and general surgery not necessitating hospital care[727]. EHIC holders can also obtain dental care from dentists contracted with the NHIF if the dentist decides that it is medically necessary to provide the treatment during the expected duration of the stay[728]. The referral rules are similar in Slovenia[729]: EHIC holders seeking medically necessary treatment may go directly to a public health institution (health care center, hospital or pharmacy) or to a general practitioner contracted with the HIIS. Primary level care and diagnostic services can be obtained in these facilities. For specialist or hospital treatment, patients must have a referral from a general practitioner (except in emergency cases, when they can go directly to the emergency unit of the nearest hospital). Dental care is available from dentists in public health centers and by private dentists contracted with the HIIS.

Co-payments may be required from EHIC holders for pharmaceutical products and for health care services. The same co-payments apply to local residents and EHIC holders. Patients have to cover the full cost of health care obtained from providers who are not contracted with the public health insurance fund. In Slovenia, only urgent medical treatment and services

[727] As listed on the website of the Hungarian NHIF: http://www.oep.hu/oepdok/fajlok/e.pdf (Last accessed on May 26, 2009).
[728] Dental treatment available for EHIC holders includes emergency care, dental surgery, dental hygienic treatment and treatment of gum diseases, as well as tooth preserving treatments for adults above 18. Children under 18, adults above 60, day-time students and women during their pregnancy and for a period of 90 days following childbirth are fully covered for basic and specialist care, excluding technical expenses. Regardless of age, treatment of dental and mouth diseases that are linked to other illnesses are covered. These are the dental care services covered also for Hungarians by the public health insurance scheme. See Article 12 of the LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance.
[729] See the website of the HIIS: http://www.zzzs.si/zzzs/internet/zzzseng.nsf ((Last accessed on May 26, 2009).

listed in Article 23(1) of the Law on Health Care and Health Insurance[730] are free upon the presentation of the EHIC. For other, non-emergency services, a varying degree of non-refundable contribution - between 5%-75% of the total cost - has to be made by EHIC holders, similarly to locals.

In Hungary, co-payments are required for extra services that hospitals can provide upon the patient's request (such as higher quality rooms and meals) and for dental treatment materials and technical costs. Also, a non-refundable co-payment of 30 percent (a maximum of 100,000 Hungarian forint) is required from EHIC holders in case of non-emergency hospital treatment obtained without a referral, or choosing a health care provider other than the one specified in the referral, or choosing a doctor who is not on duty at the time of the treatment[731]. This rule has been introduced recently as part of the Hungarian health care reform launched in 2007. One of the objectives of the reform was to limit the possibility to choose freely the health provider, particularly in case of hospital care. Although this rule has been introduced with the aim to limit free choice of providers for Hungarians, EHIC holders have become equally affected. This example illustrates that the effects of national-level reforms in health care are not restricted anymore to persons insured within the national system; they will also have an impact on other EEA citizens exercising their right to free movement. On the other hand, this example also illustrates that EHIC holders cannot exercise the same rights in the same way in each visited EEA state, because the concrete content of the

[730] As discussed before, full cost coverage is ensured for urgent medical assistance including emergency ambulance transport, as well as early illness detection and prevention in accordance with programs, mandatory vaccinations, advice on family planning, contraception, pregnancy and maternity care, malign diseases, infectious diseases including HIV and other diseases listed in Article 23(1) of the Slovenian Health Care and Health Insurance Act. See note 641 above.

[731] Other co-payment rules introduced in 2007 and applied to patients insured within the Hungarian public system – such as non-refundable visit fees and daily fees for hospital treatment – used to apply also to EHIC holders until their general abolishment following the referendum organized in the spring of 2008. The website of the National Health Insurance Fund provides updated information for EHIC holders on obtaining health care during a temporary stay in Hungary: http://www.oep.hu/oepdok/fajlok/e.pdf. (Last accessed on May 26, 2009).

rights guaranteed by the EHIC is determined by the specific conditions existing in the state of treatment.

The rules discussed above reveal that, as a result of the social security co-ordination mechanism, Hungary and Slovenia have opened their health systems to EEA residents exercising their freedom of movement within the EU. The states do not have anymore exclusive authority to decide what types of health care benefits to provide to citizens of other European countries who seek treatment during a temporary visit. Instead, domestic health care systems must put EHIC card holders on equal footing with their own insured persons. Health care providers contracted with the public insurance funds have to treat other EEA citizens as if they were their own nationals. This is relevant for public sector health care in both countries as well as for private providers contracted with the public health insurance fund. Only non-contracted private providers are exempt from this requirement. Although Hungary and Slovenia are responsible for organizing their health care systems, they have to ensure the conditions for freedom of movement as required by EU law. They have to enable EEA citizens to continue their temporary stay under appropriate medical care.

The influence of the EU is well illustrated by comparing the benefits provided to EHIC holders to benefits provided to non-EEA residents. Citizens and permanent residents of non-EEA countries that concluded with Hungary/Slovenia bilateral agreements on health care can obtain services on the basis of these agreements[732]. While EHIC holders are entitled to medically necessary care in the same conditions as locals, citizens of countries with bilateral agreements can only receive health care for free at the point of use in 'immediately necessary' cases. As illustrated before by the Hungarian example, the concept of immediately

[732] In 2009, Hungary had bilateral agreements on the provision of health care with the following countries: Angola, Bosnia and Herzegovina, Cuba, Iraq, Jordan, Kosovo, Kuwait, Macedonia, Mongolia, North Korea, Serbia, Montenegro, Russia, Ukraine and other countries of the Commonwealth of Independent States.

necessary care is more restrictive than the concept of medically necessary care applied to EHIC holders because the former includes the idea of imminent life danger and health damage[733]. Citizens/residents of countries that are not part of the EEA and do not have bilateral agreements with Hungary/Slovenia on the provision of health care need to cover the total cost of treatment except for emergency assistance[734]. Prices applicable in such cases are not regulated by the Hungarian law and the NHIF has no influence on the charges. The only rule imposed on health care providers is to apply consequently the same fee for the same service. Although the NHIF calls it a non-discrimination rule, this rule only includes the requirement to apply fees in a consistent way; else, the health care provider is free to establish any fee he/she wants. Equality of treatment with persons insured in the domestic system is not at all mentioned. The advantage of EHIC holders is thus obvious.

Distinction between planned treatment and treatment that becomes medically necessary during a temporary visit is another issue where the influence of EC co-ordination law on Member States' *de facto* capacity to regulate access to health care becomes obvious. It is important to note that neither Hungarian, nor Slovenian health care providers are allowed to accept the EHIC as an instrument to access planned medical treatment. The rules make it clear that the prior authorization mechanism should be applied to cases when EEA residents travel to Hungary/Slovenia with the explicit purpose to receive planned medical treatment at the cost of their state of insurance. However, it is not the state of insurance but the Hungarian/Slovenian health care provider who decides whether it is 'medically necessary' to provide the treatment during the expected duration of the stay (i.e., the treatment cannot be

[733] Hungarian Health Care Act No. CLIV/1997, Article 3(i).
[734] This rule is stated on the website of the Hungarian NHIF: http://www.oep.hu/oepdok/fajlok/e.pdf. (Last accessed on May 26, 2009). For Slovenia, see Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 54. Pursuant to the Law on Health Care and Health Insurance, Slovenia covers from the budgetary funds emergency assistance in such cases.

delayed until the EHIC holder returns to the home country). This means in practice that, in case of doubt, the opinion of the doctor providing the treatment is decisive in distinguishing planned treatment from treatment that becomes medically necessary during the visit. The treatment provider cannot be held responsible for a 'wrong' decision regarding medical necessity, as doctors are usually not in a position to examine the patient's intention behind the journey abroad[735]. Especially in case of non-hospital treatment it can be difficult to prove that a health service obtained by an EHIC holder was in fact planned. But this works both ways: if a doctor wants to defer an EHIC holder, he/she might rely on the argument that the treatment could be postponed until the patient's return home and is not 'medically necessary' during the expected stay. Such cases can be predicted especially in health systems where informal charges for health services provided in the public system are wide-spread and patients' access to treatment might depend on their willingness and ability to pay such charges (like in certain cases in Hungary).

Regarding the implementation of EHIC holders' rights in Hungary and Slovenia, one can conclude that the basic framework applied in the two countries is similar and it follows the EU rules. However, the details of implementation differ. Existing differences are rooted in the specific features of the health system including some entrenched legacies from the previous systems. The influence of co-payment rules and out-of-pocket payments on access to health care constitutes an illustrative example. In Slovenia, co-payments are substantial for certain forms of non-emergency treatment but persons insured in the compulsory scheme can opt for voluntary insurance to cover them. Such co-payments are official and can be documented. Informal (unofficial and undocumented) charges are not common. Although an

[735] Doctors cannot be held responsible for not determining correctly whether the patient came to the country with the explicit goal to receive treatment. See also Lengyel B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztosításban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14, p. 6.

EHIC holder cannot make use of the Slovenian voluntary health insurance system to cover co-payments for services that become medically necessary during a temporary visit, he/she might rely on the home insurer to get reimbursed for official co-payments. In Hungary, the complementary role of voluntary insurance is not as developed as in Slovenia, and co-payments are mostly covered out-of-pocket. A significant share of out-of-pocket expenditures in Hungary is made up by informal charges that are unofficial and not documented. EHIC holders are therefore confronted with the legacy of informal payments that cannot be claimed back from the home insurer. The lower transparency of the Hungarian system is felt also by EEA residents trying to exercise their right to access medically necessary care within the European Union.

4.3. Access to planned medical treatment in cross-border settings

Planned medical treatment refers to cases when patients travel abroad with the explicit goal to obtain health care. As opposed to the cases covered by the EHIC, planned medical care abroad is foreseen and often requires specific institutional arrangements before departure from the home country. The prior authorization mechanism is the instrument designated by EC social security co-ordination law to govern access to planned treatment within the EU. As a result of the ECJ case law, patients can also opt for the Kohll and Decker procedure grounded on the directly effective primary law provision of freedom to provide services (Article 49 EC) and obtain in certain conditions planned cross-border care outside of the prior authorization mechanism[736]. This is typically relevant to non-hospital care.

Both the Hungarian and Slovenian legislation stipulates a right to treatment abroad covered by the compulsory insurance scheme. Article 27 of the Hungarian LXXXIII/1997

[736] See Chapter 3 for an analysis of the Kohll and Decker procedure.

Parliamentary Act on Mandatory Health Insurance stipulates the conditions on access to planned treatment in EEA and non-EEA states. This law was amended following EU accession and it currently stipulates the direct applicability of Regulation 1408/71 for access to treatment abroad[737]. Governmental Decree No. 227/2003. (XII. 13) establishes the detailed rules. The Slovenian Law on Health Care and Health Insurance mentions medical examination and treatment abroad as a right guaranteed to persons insured in the compulsory system. The detailed rules are established by the Health Insurance Institute of Slovenia (HIIS). Before EU accession, this right was mainly realized within the framework of bilateral agreements[738]. Since May 2004, the EC social security co-ordination mechanism has become directly applicable.

Both countries apply prior authorization as the main mechanism governing access to planned medical treatment abroad. Authorization for cost coverage is issued by the public health insurance fund (the NHIF in Hungary and the HIIS in Slovenia). It can be requested by the insured person, his/her relatives and medical doctor. The request is evaluated by a professional commission which rules on the merits of the application. In Slovenia the professional commission is nominated by the management board of the HIIS assembly (it is called first degree commission)[739]. The first degree HIIS commission decides whether treatment abroad is justified[740].

[737] See Article 27(3).
[738] Bilateral agreements constituted an important factor promoting the movement of patients across Hungarian and Slovenian borders before EU accession and paved the way for cross-border co-operation in health care. These agreements existed with all neighboring countries. They used to offer coverage that was, in its effect, similar to that provided by the EC social security co-ordination mechanism. Upon EU accession, the co-ordination mechanism took over the role of social security bilateral agreements concluded with EU countries. See also Albrecht, T., Pribakovic Brinovec, R. and J. Stalc. 'Cross-border Care in the South: Slovenia, Austria and Italy', in Rosenmöller, M., McKee, M., and R. Baeten. *Patient Mobility in the European Union: Learning from Experience.* Copenhagen: World Health Organization, 2006, pp. 9-21.
[739] As stipulated in the Law on Health Care and Health Insurance.
[740] See also Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 55.

In Hungary, the commission is formed independently of the NHIF. Its members are nominated either by the competent national health institute supervised by the Minister of Health[741] or by the National Centre for Healthcare Audit and Inspection[742]. It is a professional commission whose members are specialists in the given medical field. In case of a positive decision, the commission recommends to the NHIF to grant financial support for the treatment abroad as well as a medical facility that is able and available to provide the necessary treatment. It is the responsibility of the professional commission to inform the NHIF and the patient about the availability of treatment at the institution targeted abroad, the date of admission, the expected duration of care and expenses. In case of refusal, the commission must provide a justification and recommend a domestic health care facility where the necessary treatment can be obtained. This professional commission is the main decision-maker in case of a prior authorization request, as proven by the tendency of the NHIF to authorize the necessary financial support for all recommended applicants[743].

Mechanisms to appeal decisions on prior authorization requests are available for patients both in Hungary and Slovenia. Article 3(2) of the Hungarian Governmental Decree 227/2003 sets forth that insured persons and their relatives can appeal to the Health Scientific Council for review, a body that is independent of the NHIF[744]. The Slovenian Law on Health Care and Health Insurance also sets forth an appeal procedure. Article 82 stipulates that insured

[741] The competent national health institute is the main treatment-prevention, management-methodology, training and scientific research institution in the given medical field in Hungary. ('A megbetegedés és a szükséges gyógykezelés jellege szerinti, az egészségügyi miniszter irányítása alá tartozó, az adott orvosi szakmában gyógyító-megelőző, illetve szervezési-módszertani, továbbképző és tudományos-kutató alapintézményként működő, országos feladatkört teljesítő intézmény'). See Article 2(1)(a) of Governmental Decree No. 227/2003. (XII. 13).

[742] Országos Szakfelügyeleti Módszertani Központ (OSZMK). More information on the role of this institution is available at: http://www.oszmk.hu/ (Last accessed on May 26, 2009). The competent national health inspector (szakfelügyelő) is responsible for nominating the members of the professional committee.

[743] Interview with three officials at the Department of International Relations and European Integration, National Health Insurance Fund. Budapest, June 6, 2007 and May 22, 2009. As relevant from its yearly reports, the NHIF authorized in 2002-2008 the necessary financial support for each applicant recommended by the professional committee for undergoing medical treatment abroad.

[744] Egészségügyi Tudományos Tanács. Official website: http://www.ett.hu/index.htm (Last accessed on May 7, 2009).

persons wanting to appeal the decision of the first degree HIIS commission can turn to a second degree HIIS commission[745]. In case of a second appeal, a unit at the seat of the HIIS shall issue a decision that is final in administrative procedures[746] and can only be appealed in the Court of Social Affairs, where insured persons have standing[747]. The HIIS is in charge of defining the tasks and organizing the work of health commissions of first and second degrees.

Once entitlement to treatment abroad is established, the competent institution decides on financial coverage. In Hungary, the general rule on planned treatment abroad is that the NHIF has full competence to assess the circumstances of the individual case and decide on the extent of financial coverage in case of requests already approved by the professional commission. In fulfilling this responsibility, the NHIF has to take into account the yearly budget for authorized health care in other countries[748]. However, Governmental Decree No. 227/2003 makes it clear that treatment in the EEA obtained on the basis of Regulation 1408/71 constitutes an exception to this general rule[749]. In such cases the NHIF must reimburse the expenses that competent insurance institutions are obliged to reimburse under Regulation 1408/71 in case of authorized planned treatment. The NHIF discretion remains upheld only for costs that competent institutions are not obliged to cover under the co-ordination Regulation[750].

[745] See Article 81 of the Slovenian Law on Health Care and Health Insurance.
[746] See Article 83 of the Slovenian Law on Health Care and Health Insurance
[747] Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, HIIS. Ljubljana, October 4, 2008.
[748] See Article 4(2) of Governmental Decree No. 227/2003. (XII. 13).
[749] See Article 10 of Governmental Decree No. 227/2003. (XII. 13).
[750] Besides stipulating the general applicability of Regulation 1408/71 to treatments obtained in EEA states, the Decree does not include any further specifications.

The Slovenian Law on Health Care and Health Insurance sets forth that compulsory insurance guarantees to insured persons and their family members[751] coverage of at least 95 percent of the cost of treatment obtained abroad[752]. Within this rule, the exact percentage of the coverage is defined by the HIIS in agreement with the Slovenian government; percentages for individual types of service or for individual illnesses may vary[753]. Nevertheless, persons insured in the Slovenian compulsory system may opt for voluntary insurance in order to cover the difference to the full value of treatment obtained abroad[754]. Voluntary insurance can be used for this purpose. In terms of financial coverage, the Slovenian Law on Health Care and Health Insurance does not differentiate between treatment obtained within and outside of EEA; the 95 percent rule applies equally.

4.3.1. Implementation of the ECJ rulings establishing the Kohll and Decker procedure

EU law establishes a right for insured persons to access planned treatment abroad on the basis of the Kohll and Decker procedure grounded on the directly effective free movement provisions of the EC Treaty[755]. The difference between the framework established by Regulation 1408/71 and the Kohll and Decker procedure is particularly relevant for the issue of cost assumption, as confirmed by the ECJ rulings[756] and the proposed EC Directive on application of patients' rights in cross-border health care[757]. This procedure creates a right for

[751] As defined by Article 14 of the Slovenian Law on Health Care and Health Insurance, the concept of insured persons includes the insurees and also their family members. This law does not specify whether the concept of 'family members' includes all first degree relatives or only those who are dependents of the insuree.
[752] See Article 23 of the Slovenian Law on Health Care and Health Insurance.
[753] Ibid.
[754] See Article 61 of the Slovenian Law on Health Care and Health Insurance.
[755] See Chapter 3 for a detailed analysis of access to health care abroad under internal market rules.
[756] See, particularly, the *Kohll, Decker, Vanbraekel* cases.
[757] As discussed in Chapters 2 and 3, the cost assumption rules applied under the Kohll and Decker procedure establish that patients advance the expenses of treatment obtained abroad and get reimbursed up to the amount that the same or similar treatment would have cost in the state of insurance, without exceeding the actual expense of the services received abroad. Patients also bear the associated financial risks in this case. Under the social security co-ordination regulations, costs are settled between the two systems according to the tariffs of the state of treatment in case of planned treatment obtained in other Member States through the prior authorization mechanism. The competent insurance fund bears the financial risk of any additional costs associated to the authorized medical care (such as additional treatment or hospitalization that becomes suddenly necessary). See

insured persons to obtain non-hospital care and in certain conditions, also hospital care in another Member State without prior authorization, and be subsequently reimbursed up to the level reimbursed for the same treatment in the country of insurance (without exceeding the actual amount paid abroad).

European states differ in terms of national-level implementation of ECJ rulings establishing the Kohll and Decker procedure. As relevant from a 2007 study commissioned by the European Parliament, some Member States have amended their national rules in order to implement the relevant ECJ rulings. Examples mentioned by the report come from old and new Member States: Sweden, Germany, France and the Czech Republic.

In Sweden, prior authorization is not a requirement for reimbursing the cost of cross-border non-hospital care obtained in the EEA, following the two judgments delivered by the Supreme Administrative Court in 2004[758]. Costs are reimbursed to the patient if the treatment obtained is related to a disease or health condition treated within the Swedish public health system and corresponds in several aspects to a treatment method used in Sweden for the same disease[759]. Another example is Germany. The 2003 German Modernization Act for the Public Health System included a right for insured persons to reclaim the cost of cross-border care obtained from providers who are qualified to treat public health insurance policyholders in the respective health system. Cost reimbursement can be claimed in general up to the amount reimbursed for the same treatment in Germany. Full cost reimbursement can be claimed only

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the proposed EC Directive, Parts (21) and (24) of the Preamble and Article 6(2). See also Part 3(a) of the explanatory memorandum.

[758] European Parliament, DG Internal Policies of the Union, Policy Department Economic and Scientific Policy. 'The Impact of the European Court of Justice Case Law on National Systems for Cross-Border Health Service Provision'. Briefing note PE 382.184. Brussels: European Parliament, 2007.

[759] Ibid., p. 5.

in cases when the treatment obtained is not available at all in Germany[760]. In France, a 2005 Decree modified the French Social Security Code and introduced the principle of reimbursement of cross-border care. At present, no authorization is needed for reimbursing non-hospital care obtained in another EU country. In the Czech Republic, the ECJ decisions were taken into account when introducing the EU rules on cross-border care upon accession. Persons insured in the Czech Republic can obtain non-hospital care in another Member State without prior authorization and get subsequent reimbursement. Hospital cross-border care can only be obtained with the authorization of the respective Czech insurance fund.

Although not mentioned by the 2007 report commissioned by the European Parliament, Hungary also belongs to the group of EU countries that created the necessary legal framework for cost-reimbursement under the Kohll and Decker procedure. Upon accession, an amendment to Article 27 of the LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance entered into force[761]. As stipulated in Article 27(6), the Health Insurance Fund shall reimburse under the Kohll and Decker procedure the treatment expenses up to the level reimbursed for the same treatment in Hungary, without exceeding the amount actually paid abroad. Articles 11(1)(b), 11(1)(c), 12(1),13(a) and 13(b) of the LXXXIII/1997 Parliamentary Act on Mandatory Health Insurance list the health services that come under this cost-assumption rule. These are in general non-hospital treatments and related medical examinations including also medical examination and treatment provided by GPs, examination by specialists upon referral and dental treatment covered by the mandatory health insurance scheme.

[760] Sec. 13 para. 4 SGB V of the Gesundheitssystemmodernisierungsgesetz 'GMG' (Modernization Act for the Public Health System) of November 14, 2003. Ibid., p. 30.
[761] It is interesting to note that neither the Hungarian nor the Slovenian legislation mentions the ECJ rulings as a source of law.

Despite the existing legal framework, Hungarian patients have not made much use of the Kohll and Decker procedure as yet. The National Health Insurance Fund explains under-use as a result of the high co-payments associated to this mechanism. The NHIF points out that the cost of health care is significantly higher in Western EU countries than in Hungary[762]. Since the NHIF only reimburses the costs up to the amount covered when the same treatment is obtained in-country, Hungarian patients need to cover the difference, which can be substantial especially in case of treatment obtained in old Member States. The NHIF bases this argument on data concerning the cost of emergency health care: available figures show that the average cost per medical service[763] is four times higher in Germany and Austria than in Hungary. According to the NHIF, the difference is of similar magnitude in case of non-emergency care that can be obtained on the basis of the Kohll and Decker procedure.

While the cost-assumption rule applied under the Kohll and Decker procedure ensures that Member States maintain control over cross-border care expenditures by limiting reimbursement to the tariffs applied in the state of insurance, it creates a clear disadvantage for Hungarian patients compared to their Western counterparts. The disadvantage becomes particularly obvious when comparing the situation of a Hungarian patient seeking treatment in a Western state to a Western patient seeking treatment in Hungary. Although it is a common argument that certain population categories always benefit more from the EU market freedoms than others, in this case the disadvantage of Hungarian patients is systemic due to the cost-assumption rules applied under the Kohll and Decker mechanism combined with the significantly lower cost of health care in Hungary.

[762] Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary. Budapest, May 22, 2009.
[763] See Lengyel B., 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztosításban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14, on p. 10.

The 2007 report commissioned by the European Parliament also includes examples for Member States that have not implemented the relevant ECJ judgments as yet. One example is Spain, where the authorization issued by the Sub-Directorate General of Health Inspection is always required for access to cross-border care. The British NHS also sticks to the prior authorization rule as the only possible mechanism to access cross-border care. Prior authorization remains the only possible framework also in Poland.

Although not mentioned by the report, the analysis of the Slovenian rules reveals that the situation is similar: the prior authorization mechanism constitutes a powerful instrument to control, manage and limit cross-border movement of patients. Although the Slovenian HIIS is aware of the EU requirement to implement the Kohll and Decker procedure, the current practice has not incorporated this mechanism as yet. As confirmed by the HIIS management in an interview conducted in October 2008[764], the Slovenian authorities have been experiencing increasing pressures by the European Commission to implement the ECJ case law. At the time of the interview, the HIIS management was expecting that the rules would need to be adapted following the entry into force of the draft EC Directive on the application patients' rights in cross-border health care. While the HIIS could not predict when this would happen and with what consequences for the extent of cross-border patient mobility, the interview revealed that the HIIS had not yet faced significant pressures from patients or patient organizations for treatment in other EU countries. The HIIS management argued that patients were not interested to travel abroad for treatment because they had confidence in and were satisfied with the domestic health system.

[764] Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, HIIS. Ljubljana, October 14, 2008.

4.3.2. Waiting time as a reason for seeking planned treatment in other Member States

Access to health services without undue delay is an important benchmark used in comparative performance evaluation of health care reforms[765]. Waiting time for non-emergency treatment is an indicator of accessibility of health services[766]. Long waiting time in non-emergency treatment generally indicates the inappropriate functioning of the system.

Although there is no international consensus on what exactly amounts to undue delay in access to treatment, the European Commission[767] and the Council of Europe consider long waiting time as a barrier to access to health care. The Council of Europe's Social Rights Committee considers that long waiting time for specialist care is an obstacle in access to treatment and it recommends series of indicators for assessing waiting list management. These indicators include non-discrimination in admission, access to treatment irrespective of the patient's ability to pay, and regular efforts to validate and review waiting lists, reduce waiting time and improve access[768]. As discussed in Chapters 2 and 3, EU law recognizes waiting time of medically unacceptable length as a basis for a right to obtain the necessary health service in another Member State at the cost of the state of insurance.

Chapters 2 and 3 discussed the ECJ rulings[769] addressing the concepts of undue delay and medically acceptable waiting time. The judgments have strengthened the role of medical

[765] Daniels N., Light D. W. and R. Caplan. *Benchmarks of fairness for health care reform*. Oxford: Oxford University Press, 1996.
[766] Committee of Ministers. Recommendation No. R (99) 21 of the Committee of Ministers to Member States on criteria for the management of waiting list and waiting times in health care, of 30 September 1999. Strasbourg: Council of Europe, 1999.
[767] European Commission. *Communication from the European Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Modernizing Social Protection for the Development of High-quality, Accessible and Sustainable Health Care and Long-term Care: Support for the National Strategies Using the 'Open Method of Coordination'*, COM(2004) 304 final of 20 April 2004. Brussels: Commission of the European Communities, 2004.
[768] Committee of Ministers. Recommendation No. R (99) 21 of the Committee of Ministers to Member States on criteria for the management of waiting list and waiting times in health care, of 30 September 1999. Strasbourg: Council of Europe, 1999.
[769] See, particularly, the *Inizan* and *Watts* cases.

considerations in decision making as opposed to economic, financial and administrative arguments. The rulings emphasized that the concept of medically acceptable waiting time should be determined on an individual basis, based on a complex and comprehensive medical evaluation of the patient's health condition. In this sense, the sole fact that standard waiting times exist in a health system cannot justify the refusal of authorization for obtaining the necessary treatment in another EU country[770].

From the perspective of access to cross-border health care it is crucial how the medically acceptable waiting time is determined. The ECJ has repeatedly emphasized that reliance on standard waiting times for granting authorization is not compatible with EU law because such decisions should be centered on the individual patient. Nevertheless, national authorities tend to establish standard waiting times on the basis of the type of the medical service. In some Member States, competent institutions in charge of authorizing treatment abroad use pre-established standard waiting times as references in assessing prior authorization requests (as illustrated by the *Watts* case coming from the United Kingdom, discussed in Chapters 2 and 3). The Slovenian HIIS follows this approach[771].

The situation related to waiting time is unclear in Slovenia, as pointed out by the European Social Rights Committee monitoring the performance of states under the European Social Charter.[772] In 2003, the Social Rights Committee concluded that there was a lack of

[770] As highlighted by the *Watts* case, the European Court of Justice does not accept justifications for denial of prior authorization that are based on arguments putting forward standard waiting times established by health authorities or sickness funds on the basis of the type of medical intervention (such as one year in case of hip replacement). According to the ECJ, the key aspect that needs to be considered when deciding what amounts to undue delay is the health condition of the individual patient, determined by a complex medical assessment.

[771] Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, Health Insurance Institute of Slovenia. Ljubljana, October 14, 2008.

[772] Slovenia ratified the Revised European Social Charter in 1999; it has accepted so far 95 of the Revised Charter's 98 paragraphs including Article 11 on the right to protection of health, Article 12 on the right to social security and Article 13 on the right to social and medical assistance. See the website of the Council of Europe on signatures and ratifications of the European Social Charter, its Protocols and the Revised European Social

information on the average waiting time for admission to hospitals and it was unclear how waiting lists were managed[773]. According to the HIIS, the length of waiting time differs a lot from hospital to hospital[774]. Certain success stories - such as eliminating the previously existing waiting list for cataract eye surgery - are mentioned as notable achievements[775]. Existing studies show that waiting time for non-emergency treatment is shorter in Slovenia than in its immediate Western neighbors and this constitutes a potential incentive for movement of patients to Slovenia[776]. However, the clarification of the overall pattern remains necessary. During the October 2008 interview the HIIS confirmed the plans to create a national level monitoring system for waiting time for hospital treatment through waiting lists and rely on this system in granting authorization for planned treatment abroad.

Lack of official data on management of waiting lists and waiting time for access to health services has also been an issue in Hungary, as pointed out by the Council of Europe's Social Rights Committee.[777] Waiting time for treatment has become an important public issue following the cost-reducing measures[778] initiated since 2006. The government introduced in 2006 the system of waiting lists for non-emergency treatment as an instrument to 'achieve

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Charter: http://www.coe.int/t/dghl/monitoring/socialcharter/Presentation/SignaturesRatifications_en.pdf (last accessed on May 26, 2009).

[773] European Committee of Social Rights. European Social Charter (revised) Conclusions 2003, Slovenia. Strasbourg: Council of Europe, 2003, p. 56.

[774] Interview with the Assistant Director, responsible for health care and health insurance legislation in Slovenia, Health Insurance Institute of Slovenia. Ljubljana, October 14, 2008.

[775] Interview with Rade Pribakovic Brinovec, Researcher, Institute for Public Health. Ljubljana, October 13, 2008.

[776] Ministry of Health of Italy. Analysis and proposal on the subject of waiting lists, Italian Ministry of Health's Commission for the formulation of operative proposals and study of the problematic related to managing waiting time. Rome: Ministry of Health, 2001. Cited by Albreht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. and E. Turk (2005), *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria.

[777] European Committee of Social Rights. European Social Charter Conclusions XVII-2, 2005, Hungary. Strasbourg: Council of Europe, 2005.

[778] As part of the reforms launched in 2006, hospital capacity has been reduced in Hungary by restructuring the hospital system and reducing the number of beds. Some hospitals were completely closed, which raised objections especially in rural areas where inhabitants' access to intramural care got reduced. The Ministry of Health motivated these measures by the need to reduce the oversized and inefficient hospital system and strengthen instead the system of non-hospital care. See, for details, Egészségügyi Minisztérium. *Az Egészségügy Átalakitásának Programja.* Reform Tájékoztató Előadások 2007, február 7-16.
Available at http://www.eum.hu/index.php?akt_menu=5098. (Last accessed on January 24, 2008).

transparency, control the public character, enforce fairness, strengthen trust and ensure equitable access and resource allocation in non-emergency health care'[779]. Waiting lists were introduced both at central level (organ-specific lists) and at local, hospital level[780].

Upon accession, the EU rules on medically acceptable waiting time have become subject to implementation in Hungary including the directly applicable Regulation 1408/71 and the relevant ECJ case law. A 2004 amendment to Governmental Decree 227/2003 establishes the general applicability of EC Regulations 1408/71 and 574/72[781] and states that access to health care abroad cannot be denied if the conditions stipulated in the social security co-ordination mechanism are met[782]. Nevertheless, long waiting time has rarely served so far as a basis for authorizing the necessary treatment in another Member State. The NHIF management argues that waiting time is not an issue in Hungary[783].

The yearly reports prepared by the NHIF on authorized treatment abroad do not mention waiting time as a reason for granting authorization. The reports reveal that the prior authorization rule is interpreted as allowing for treatment abroad in cases when the conditions of recovery are not present in Hungary and the patient has a demonstrably better chance to recover if treated abroad. This is in line with the rule stipulated in Article 2(5) of Governmental Decree 227/2003 that was applicable to treatment in the EEA prior to Hungary's accession and is still applicable to treatment in non-EEA states. Although Article 10(5) states that this rule should not be applied to treatment targeted in EEA states, the yearly

[779] Ibid.
[780] In addition to central and local-level waiting lists, the 2008 Parliamentary Act on Health Insurance Funds envisaged the introduction of waiting lists also at the level of financing. Article 65(2) stipulated an obligation for sickness funds to create their own waiting lists for certain types of hospital treatment. As the implementation of the health care reform was put on hold following the 2008 referendum, this law has not been implemented.
[781] See Article 10 of Governmental Decree No. 227/2003. (XII. 13), entered into force together with Hungary's accession to the EU in May 2004.
[782] See Article 10(1) of Governmental Decree No. 227/2003. (XII. 13).
[783] Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary. Budapest, May 22, 2009.

reports do not reflect this exemption. The most common medical interventions authorized abroad include expensive surgeries that are not available in Hungary and related control examinations[784]. According to NHIF data, between 2002 and 2008 the most frequently financed interventions included: lung, liver and stem cell transplantation, special backbone, orthopedic, oral and eye surgeries, extra-corporal photo-chemotherapy, special isotope radiotherapy and genetic examinations not available in Hungary. After EU accession, most of the interventions have been carried out in EEA states and in Switzerland. The number of Hungarian patients authorized to receive treatment abroad increased from 179 in 2002 to 473 in 2008[785]. The numbers show a yearly increase during this time period.

The number of patients authorized to obtain treatment abroad also shows a yearly increase in Slovenia. In 2006, 212 authorization requests were approved out of 493 and this number represented an 18 percent increase compared to 2005[786]. The rules established by the HIIS are very restrictive: insured persons have the right to examination and treatment abroad only when all treatment possibilities have been depleted within the country[787]. As a general rule, long waiting time does not constitute a justification accepted by the HIIS to authorize treatment abroad. Exceptions concern very specific cases and trigger special procedures. An example mentioned by the 2007 report of the HIIS is in vitro fertilization reimbursed in 14 cases up to the amount covered in Slovenia[788]. In vitro fertilization was the only medical service in 2006 for which the HIIS accepted the waiting time justification. The report does not clarify how the HIIS determined that waiting time was extensively long; it only mentions

[784] Yearly reports issued by the Hungarian NHIF on authorized treatment abroad, 2002-2008.
[785] Ibid.
[786] Health Insurance Institute of Slovenia. *Compulsory Health Insurance in Slovenia: Today for Tomorrow*, Ljubljana: Health Insurance Institute of Slovenia, 2007, p. 55.
[787] Ibid., p. 55.
[788] Ibid., p. 56.

that a special decision of the Board of Directors of the HIIS authorized cost reimbursement, limited to the tariff applied in Slovenia for the same intervention.

According to 2006 data of the Slovenian HIIS, the only medical services authorized abroad were diagnostics of tissue and blood samples and eye prostheses. The HIIS argues that Slovenian patients trust the domestic health system and are not interested in general to get treated abroad[789]. The management illustrates this argument by a recent example: Slovenian patients placed on the waiting list for cardiac surgery were reluctant to undergo the necessary intervention that was supposed to be carried out by a well-known specialist, in a Swiss or a Serbian hospital. In spite of the long waiting list and the lack of the language barrier that was notable in case of the Serbian specialist, less than 10 percent of patients accepted such an option[790]; the others preferred to wait for treatment in Slovenia. While the specific reasons for refusal have not been documented, the low interest noticed in this case was an additional argument used by the HIIS to back up unwillingness to modify the existing prior authorization scheme. The HIIS argues that Slovenian patients' interest is even lower in cross-border non-hospital care. It remains to be seen how the HIIS reacts to an increased demand that might occur as a result of the information campaign recently launched by the European Commission and the proposed EC Directive on the application of patients' rights in cross-border care.

4.4. Cross-border co-operation initiatives in health care

European countries have been experimenting since the nineties with different solutions to ease waiting lists and overcome capacity shortage. One of them is making use of cross-border

[789] Interview with the Assistant Director responsible for health care and health insurance legislation in Slovenia, Health Insurance Institute of Slovenia. Ljubljana, October 14, 2008.
[790] Albrecht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. and E. Turk. *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria, 2005, p. 41.

co-operation opportunities. Initiatives implemented with the financial support provided by the EU can be found in several Euregios. Some of these initiatives focus specifically on increasing accessibility and reduce waiting time for treatment. Examples include the ZOM and IZOM programs implemented in the Meuse-Rhine Euregio with Belgian, Dutch and German participation[791]. These initiatives include co-operation agreements between hospitals and insurance institutes in order to promote patient mobility and improve access to health care. They include the development of a shared database providing information on free capacity existing in hospitals located in the region. Another example is the TRANSCARD initiative implemented in the Tiérarche region where Belgian and French hospitals and insurance institutes co-operate in order to improve access to hospital treatment and reduce administrative impediments to patient mobility[792]. The LUXLORSAN initiative implemented in the Wallonie-Lorraine-Luxembourg Euregio puts specific emphasis on cross-border co-operation in care provided to the elderly and people with special needs[793]. Evaluations of these cross-border co-operation initiatives in health care identified a number of factors promoting successful collaboration[794]. These include appropriate and complementary character of services[795], simplification of administrative procedures, geographic, linguistic

[791] Empirica GMBH. *Case-study: Cross-border Co-operation for Health Care Provision in Euregio Meuse-Rhine*. Bonn: The European e-Business Market Watch, 2004, pp. 6-7.
[792] See the website of the TRANSCARD initiative: http://www.sesam-vital.fr/transcards/tcd_historique_eng.htm (Last accessed on May 7, 2009).
[793] GEIE Luxlorsan LLS. *Le Systeme de Prise en Charge des Urgences Médicales dans l'Espace Wallonie-Loraine.* Luxembourg: GEIE Luxlorsan LLS, 2006.
[794] Also in Földes, M. E. and A. Földes. 'Gyógyításra Várva: Európai Szabályok és Határokon Átnyúló Együttműködési Lehetőségek a Várólisták Csökkentésében (Waiting for Treatment: European Norms and Cross-border Co-operation Possibilities in Reducing Waiting Lists in Medical Care)'. *Orvostudományi Értesítő* 81(3):203-207, 2008.
[795] See the website of the TRANSCARD initiative: http://www.sesam-vital.fr/transcards/tcd_historique_eng.htm (Last accessed on May 7, 2009).

and cultural proximity, information[796] and involvement of local and regional governments as well as patient organizations[797].

The initiatives mentioned above reveal that solutions for easing waiting lists and overcoming capacity problems are worth to be explored not only at national level but also in the light of cross-border/regional collaboration. Co-operation might involve several health-related areas. Examples include taking advantage of geographic and linguistic proximity for promoting cross-border health service provision, collaboration in diagnostics, emergency care and specialty care, mutual recognition of health insurance entitlements, common purchase and use of expensive medical instruments and equipment, co-operation in medical research, training, exchange of best practices and mutual learning and joining efforts in fundraising for quality development.

Preconditions for cross-border co-operation initiatives exist both in Slovenia and in Hungary. Movement of persons, services and goods in the border areas is encouraged by several factors. Drives of mobility originate partly in the specific characteristics of these regions: multitude of borders, geographic, cultural and sometimes linguistic proximity, experiences based on pre-accession existence of bilateral social security co-operation agreements concluded with the neighboring states. Together with EU accession, the conditions for mobility of persons, services and goods across borders have improved.

Hungary and Slovenia have already created the legal framework for launching co-operation initiatives in the Euregios involving their territories. Existing co-operation frameworks are in

[796] Glinos, I. A., and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union*. Brussels: Observatoire Social Européen, 2006. See also Carnotensis, P. and A. Coheur. *Projet Interreg II – soins de santé sans frontiers dans l'Eurégio Meuse-Rhine*. Brussels: Projet expérimentale IZOM, 2002.
[797] Empirica GMBH. *Case-study: Cross-border Co-operation for Health Care Provision in Euregio Meuse-Rhine*. Bonn: The European e-Business Market Watch, 2004, pp. 6-7.

principle also suitable for initiatives focusing on health care provision. Such Euregional initiatives can benefit from several forms of EU support[798].

Studies show that Slovenia has been actively exploring the possibilities to attract patients from the neighboring states[799]. The following Euregios and similar cross-border structures have involved health-related co-operation: Euregio Steiermarkt – Nord-East Slovenia, a co-operation framework with a neighboring Austrian region, and the cross-border region of CARSO including a neighboring Italian territory. In addition, Slovenia was involved between 2001 and 2006 in two INTERREG IIIA programs with Austria and six INTERREG IIIA programs with Italy that included health-related initiatives[800].

Available Slovenian studies talk about possibilities for co-operation expansion in a number of medical fields such as orthopedics, spa treatment, as well as cardiac, gynecological and plastic surgery where demands of patients from other EU countries could be met[801]. Considering the health-related co-operation initiatives implemented together by Slovenia and Austria, one can notice the emphasis on spa and wellness services. Austria, Slovenia and Hungary implemented together a wellness education initiative between December 2001 and

[798] See also Balogh, T. 'A Magyar-Román Közös Határszakasz Mentén Zajló Egészségügyi Tárgyú Együttműködések Fejleszthetőségéről és Közösségi Támogatásáról, Magyar-Román Közös Tervezési Gyakorlat és Közös Projektek Megvalósításának Lehetőségéről' (On existing possibilities for development and European Community support for health care co-operation initiated along the Hungarian-Romanian border. Common Hungarian-Romanian planning practice and possibilities for implementing common projects). *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006.

[799] Albreht, T. 'Opportunities and Challenges in the Provision of Cross Border Care. View from Slovenia'. *Eurohealth* 8(4), 2002; Albrecht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. And E. Turk. *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria, 2005, p. 7.

[800] LIGA.NRW. *Evaluation of Border Regions in the European Union (Euregio)*. Düsseldorf: LIGA.NRW, 2008. The report is available at http://www.euregio.nrw.de/files/final_report_euregio_en.pdf (Last accessed on May 7, 2009).

[801] Albreht, T. 'Opportunities and Challenges in the Provision of Cross Border Care. View from Slovenia'. *Eurohealth* 8(4), 2002.

January 2003, supported by INTERREGIII[802]. Another initiative implemented in partnership with Austrians between 2002 and 2006 in the Euregio Steiermark – North-East Slovenia also focused on co-operation related to spa treatment[803]. Such a focus is not a surprise, given that Austrians have traditionally made use of spa treatment and rehabilitation services available in Slovenian spa resorts, on the cost of the Austrian social insurance system[804]. Studies show that rehabilitation and medically supervised spa treatments are among the health services that currently offer the most opportunities for attracting foreign patients to Slovenia and have had the greatest international experience so far[805]. Health-related cross-border co-operation is also present in the border area with Italy. Six common initiatives have been started since 2002, one of them focusing specifically on cross border co-operation for health service delivery (implemented between 2004 and 2006, supported by INTERREGIII). The other initiatives involved co-operation in medical research[806].

Interest for cross-border co-operation seems lower in Hungary than in Slovenia. Hungarian health care providers have rarely used so far the opportunities for co-operation in the fields of health care delivery and specifically, hospital care[807]. Existing co-operation focuses on exchange of experts and professional experience, health promotion, research and professional

[802] LIGA.NRW. *Evaluation of Border Regions in the European Union (Euregio)*. Düsseldorf: LIGA.NRW, 2008. The report is available at http://www.euregio.nrw.de/files/final_report_euregio_en.pdf (Last accessed on May 7, 2009).
[803] Ibid. This initiative was entitled 'Health Destination Oststeiermark – European Spa World'.
[804] Albreht, T., Pribakovic Brinovec, R, Stalc, J., Martinez, G. And E. Turk. *Cross-border Care in the South: Slovenia, Austria and Italy. Preliminary report*. Ljubljana: WP 10 Case Study 4: Slovenia/ Austria, 2005, p. 6.
[805] Albreht, T. 'Opportunities and Challenges in the Provision of Cross Border Care. View from Slovenia'. *Eurohealth* 8(4), 2002, p. 9.
[806] Studies focused on the activity of TRAIL anticancer protein on human normal and neoplastic cells, as well as mapping the risk for Lyme borreliosis and tick-borne encephalitis in the trans-border area between Italy and Slovenia as a tool for preventive public health measures to be implemented by local authorities. LIGA.NRW. *Evaluation of Border Regions in the European Union (Euregio)*. Düsseldorf: LIGA.NRW, 2008. The report is available at http://www.euregio.nrw.de/files/final_report_euregio_en.pdf (Last accessed on May 7, 2009).
[807] Balogh, T. 'A Magyar-Román Közös Határszakasz Mentén Zajló Egészségügyi Tárgyú Együttműködések Fejleszthetőségéről és Közösségi Támogatásáról, Magyar-Román Közös Tervezési Gyakorlat és Közös Projektek Megvalósításának Lehetőségéről' (On existing possibilities for development and European Community support for health care co-operation initiated along the Hungarian-Romanian border. Common Hungarian-Romanian planning practice and possibilities for implementing common projects). *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006.

development. Initiatives targeting health care delivery are at a very early stage of implementation. Attempts for common and systematic needs- and capacity assessment are very rarely present, although this is a basic precondition for developing efficient cross-border partnerships for improving access to health care[808].

Nevertheless, there are some examples for pioneering initiatives started with Hungarian participation. One is the 'Health Insurance without Borders' initiative launched along the Hungarian-Romanian-Serbian borders (DKMT Euregio)[809]. This initiative proposes the development of a Euregional Health Insurance Card. The initiative carried out an assessment of the actual extent of patient mobility in the region, the capacity of health care facilities located in the region as well as existing health insurance rules and possibilities to overcome administrative impediments to cross-border patient mobility. A theoretical agreement has been concluded between health insurance providers but the actual implementation has not started yet. Other plans for cross-border co-operation have been developed in spa treatment[810] and stroke intervention. The latter proposes a cross-border stroke network with the participation of university centers located in the DKMT Euregio[811].

These initiatives are at a very early stage of implementation. Although there is a legal empowerment, the details of regulation need to be worked out. This could be done most

[808] Common and systematic needs assessment has been identified as a crucial precondition for successful cross-border and regional co-operation initiatives in access to health care. See, for details, the evaluation of cross-border initiatives concluded with the participation of Belgium: Glinos, I. A., and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union*. Brussels: Observatoire Social Européen, 2006. See also Carnotensis, P. and A. Coheur. *Projet Interreg II – soins de santé sans frontiers dans l'Eurégio Meuse-Rhine*. Brussels: Projet expérimentale IZOM, 2002.

[809] See the website of Euroregio Duna-Körös-Maros-Tisza (DKMT): http://www.dkmt.net/hu/index.php (Last accessed on October 28, 2008).

[810] Ponta, R. 'Egészség és Gyógyfürdőkezelés a DKMT Eurorégióban' (Health and Balneotherapy in the DKMT Euroregio). *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 52-53.

[811] Nanu, P. D., Deme-Ioncu, S., and R. M. Chenderes. 'Stroke-egységek, Tele-stroke Hálózat a DKMT Eurorégióban - Határon Átnyúló Egyetemi Együttműködés'. (Stroke Units, Tele-stroke Network in Euroregio DKMT – Cross-border Co-operation of Universities). *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 56-62.

efficiently on the basis of a concrete example. The NHIF has repeatedly encouraged health care providers to move forward with such initiatives and ensured them that the details of regulation could be worked out during implementation[812]. Nevertheless, there is still a lack of common and systematic need- and capacity-assessment and planning, which is a prerequisite of effective and sustainable regional co-operation in health care delivery. National borders still work as frontiers in such planning processes, and the nationally focused health care organization does not include co-operation and contracting across borders.

4.5. Individually-driven planned cross-border care outside of pre-authorized contexts

The literature on cross-border care distinguishes a form of patient mobility that takes place outside the European co-ordination rules, bilateral agreements or any pre-authorized context[813]. This includes patients who decide to seek health services abroad on their own initiative and outside any institutional arrangements. This represents the least documented, least studied and probably the most heterogeneous group of mobile patients[814]. Decisions to seek medical care abroad in such conditions are usually individually-driven.

Patients have various reasons for seeking health care abroad on their own initiative. Price, quality, waiting time, access to information, proximity (geographic, cultural and linguistic), illegality of the targeted medical intervention in the home country and the patient's ability to

[812] Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary. Budapest, May 22, 2009. See also Lengyel, B. 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztosításban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, pp. 4-14, 2006.

[813] Glinos, I. A., and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union.* Brussels: Observatoire Social Européen, 2006; Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17:112-124, 2007; Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008.

[814] Legido-Quigley, H., McKee, M., Nolte, E. and I. A. Glinos. *Assuring the Quality of Health Care in the European Union. A case for action.* Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008, p. 49.

travel abroad and advance the costs have been identified as potential factors[815]. Price matters especially when patients have to either advance the cost of the treatment or cover it entirely out-of-pocket. Available studies show that mobility is limited when the targeted medical treatment is (almost) fully covered in the home country and when quality levels are similar[816]. Perceived difference in quality constitutes an important incentive to travel abroad for treatment even if the same medical service is fully covered in the home country[817].

Although this type of patient mobility takes place outside of the EC social security co-ordination mechanism, EU rules and particularly the Kohll and Decker procedure are very much relevant. Following EU accession, patients seeking cross-border care on their own initiative are entitled to cost reimbursement according to the tariffs applicable for the same treatment in the state of insurance. As discussed in Chapter 3, this rule applies to all forms of cross-border non-hospital care, whether provided in a public or a private medical facility. In certain conditions it also applies to hospital care. The proposed Directive on the application of patients' right in cross-border health care intends to codify the applicable cost-assumption rules.

Individually-driven, planned patient mobility taking place outside any pre-authorized context existed across Hungarian and Slovenian borders also before accession. This type of mobility is not brought about by the EU and its magnitude is unexplored. There are big obstacles to systematic data collection because many patients receive treatments outside the public system

[815] Ibid., pp. 49-50. See also Palm, W., Nickless, J., Lewalle, H. and Coheur, A. *Implications of Recent Jurisprudence on the Co-ordination of Health Care Protection Systems*. Brussels: AI, 2000.
[816] Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17:112-124, 2007, p. 120; Glinos, I. A., and R. Baeten. *A Literature Review of Cross-border Patient Mobility in the European Union*. Brussels: Observatoire Social Européen, 2006.
[817] Ibid.

and remain unreported. Statistical evidence is very hard to obtain and there is very little research in this field. Evidence is largely anecdotal and comes mainly from the press.

Nevertheless, a number of cases have been documented and suggest that the share of these mobile patients might be higher than expected. One example is movement of EU patients to Hungary and to a smaller extent to Slovenia for dental treatment, aesthetic interventions and ophthalmology. Hungarian towns situated near the Austrian border present a high concentration of health care providers specialized in the medical interventions mentioned above that are typically not reimbursed or not entirely covered by the Austrian health system. For example, the city of Sopron is characterized by one of the EU's highest concentrations of dentists per residents: according to the grey literature, it is estimated that Sopron has somewhere between 150 and 400 dentists for 50,000 inhabitants (for a population of this size 20 dentists would be common)[818]. A European Commission survey reported that 58,000 individuals claimed reimbursement for health care obtained abroad without prior authorization and the majority of reimbursement claims were related to dental treatment obtained in Hungary[819]. Given that many patients obtaining dental treatment in Hungary cover the cost out-of-pocket, the actual numbers are not reflected by official data[820].

There is a lack of research systematically examining the characteristics of individually-driven cross-border patient mobility for dental care in the Austro-Hungarian border region. Official figures are not available but the grey literature presents some interesting data. For example,

[818] Picard, M. and F. Schmidt. 'A L'Est, les nouvelles dents sont moins cheres'. *L'Hebdo*, 2004. The article is available at http://poussieresdempire.blogspot.com/2004_07_01_archive.html. (Last accessed on February 19, 2008). See also Glinos, I. A. and R. Baeten. 'A Literature Review of Cross-Border Patient Mobility in the European Union'. *Europe for Patients Project*, Observatoire Social Européen, 2006, p. 71.
[819] Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy*17:112-124, 2007, p. 120.
[820] Interview in Budapest on July 2, 2007 with M.G., foreign agent working on commission basis for Hungarian private dental clinics in patient recruitment from Western Member States.

according to the French newspaper *Le Figaro*, the Austro-Hungarian frontier region has been witnessing in the last twelve years a real cross-border flux of dental care patients and one out of three Austrian residents has traveled at least one time to Hungary for dental treatment[821]. The situation is similar (although less impressive in terms of numbers) for opticians and aesthetic surgery clinics[822].

Facts reported so far suggest that treatment quality and more advantageous prices are important incentives, besides geographic proximity. A recent exploratory study carried out by Österle and Delgado[823] concluded that price constituted the decisive factor: 27 out of 30 respondents indicated relative cost advantage as the decisive incentive. Tariffs applied in Hungary are generally lower. Although patients can claim to be reimbursed also for treatment provided in other Member States if the respective medical intervention is included in the benefit package in Austria, coverage for dental services is more limited than for many other health care services (both in terms of the type of service covered and the contributions made)[824]. In case of treatments that are not or are only partly covered by the Austrian health insurance system, patients having to pay out-of-pocket become interested to look for the financially most attractive offers.

[821] Picard, M. and F. Schmidt. 'A L'Est, les nouvelles dents sont moins cheres'. *L'Hebdo*, 2004.
[822] Interview with Rita Baeten and Irene Glinos, researchers at Observatoire Social Européen. Brussels, October 17, 2005.
[823] Österle, A. and Delgado, J. 'Dental Care Migration in Central Europe', in R. Burger and M. Wieland (eds.) *Economic and Sociopolitical Perspectives for Health Services in Central Europe.* Vienna, 2006. See also Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17:112-124, 2007.
[824] The Austrian reimbursement regime distinguishes between doctors contracted and those not contracted by the insurance institute. Treatment provided by contracted doctors is covered according to the tariffs agreed in the contract. Treatment provided by a non-contracted doctor is reimbursed at a rate of 80 percent of the fee that is established in the contract for those doctors that have an agreement with the insurance institute. This rule equally applies to doctors practicing on Austrian territory and those in other EU Member States. See, for further details, Hofmarcher, M. M. and Rack, H. *Health Care Systems in Transition. Austria.* Copenhagen: European Observatory of Health Care Systems and Policies, 2001; Österle, A. 'Health Care across Borders: Austria and Its New EU Neighbors'. *Journal of European Social Policy* 17:112-124, 2007.

Physical proximity is an important factor especially when patients need to return repeatedly for treatment and check-ups. According to respondents included in the study carried out by Österle and Delgado, the most important secondary incentives include geographic proximity, recommendations from relatives and friends and overall service quality. The issue of linguistic proximity is also important. This has been recognized also by the Hungarian health care providers who advertise their services in German and/or English[825]. The press also mentions the patient-friendly attitude of Hungarian dental care providers and the complexity of services offered (patients often receive assistance with travel and accommodation arrangements[826]). Additional incentives include shorter waiting time and treatment duration.

The most important means applied by Hungarian dentists to reach out to foreign patients are internet and press advertisements and co-operation with agents located in the targeted countries[827]. Their means are effective, as shown not only by regular visits of foreign patients but also by the dissatisfaction of Austrian dentists. Austrian dentists have initiated and won several court cases against Hungarian dental care providers on the basis of illegal advertising, as the Austrian law prohibits medical publicity in the press[828]. In addition, Austrian dentists and their association (ZAEK) have started counter-campaigns trying to convince their

[825] Most of the Hungarian clinics situated in this border area use multi-lingual internet advertisements as means to reach out to foreign patients. For example, the information on the website of the Rosengarten clinic is available in four languages. The clinic takes care of accommodation and other travel-related arrangements. http://www.rosengarten.hu/php/index_dent.php?lang=english&section=main&id=0. (Last accessed on February 19, 2008).

[826] Ibid. The declared goal of the clinic is '*to offer a full range of services in dental tourism and to turn treatment into a pleasant experience*'.

[827] Interview in Budapest on July 2, 2007 with M.G., foreign agent working on commission basis for Hungarian private dental clinics in patient recruitment from Western Member States. Agents recruiting patients from foreign EU countries advertise on the internet, in local newspapers and airline magazines.

[828] Glinos, I. A. and R. Baeten. 'A Literature Review of Cross-Border Patient Mobility in the European Union'. *Europe for Patients Project*, Observatoire Social Européen, 2006, p. 71. See also Picard, M. 'Tourisme Dentaire en Pays Magyar (Les Voyages pour Raison Medical se Developpent)'. *Le Figaro,* 2004.

patients to drop the idea to seek dental care in Hungary because of the low quality of services[829].

Clinics in Budapest have also been successful in attracting foreign patients by combining competitive prices with high quality of care. In an interview, the owner and manager of a private dental clinic located in Budapest provided data on foreign patients, their main incentives to travel to Hungary and the strategy of the clinic to attract them[830]. Patients generally cover treatment costs out-of-pocket. Upon request, the clinic issues an invoice and it is up to the patient to try to get reimbursed in his/her country of insurance[831]. The clinic applies the same comprehensive, full-service approach that characterizes the providers located in the Hungarian-Austrian border area[832]. Yet, the manager emphasizes that the key to success is the comparatively low price combined with high quality and efficient organization of the patient's time. Long waiting times in the patient's home country are also an important incentive. The success of the clinic has been echoed in the press of several EU states. Newspaper articles entitled 'Patients are saving thousands on top-notch dental work[833]', 'Hungarian dentists have a longstanding reputation[834]', 'NHS shortage driving sufferers to Hungary[835]', 'Foreign dentists take a bite out of Irish market[836]', 'Irish dental tourists fly to

[829] Ibid.
[830] Interview with the owner and manager of a private dental clinic located in Budapest. Budapest, March 12, 2008. Patients come to this clinic mainly from the United Kingdom, Ireland, Denmark, Norway, Switzerland, and recently also from the Netherlands and Belgium. They are recruited by agents located in these countries and working for the clinic on commission. Due to the high demand the clinic operates with a waiting time of 2-3 months for treatment; there is no waiting time for consultations and priority is given to complicated and costly interventions such as dental surgery and implants, bridge work, etc.
[831] For example, patients from Ireland and Denmark successfully claimed reimbursed for a small share of the cost (up to 15 percent) based on their membership in the public health insurance system. Danish patients with private insurance were reimbursed up to 50 percent for crowns and bridges. Interview with the owner and manager of the private dental clinic located in Budapest. Budapest, March 12, 2008.
[832] The clinic provides for patients free transport from the airport, accommodation arrangements, free consultations, English and German-speaking doctors and nurses, long opening hours including weekends if needed and tourist programs upon request.
[833] Daily Record, August 16, 2004, Scotland.
[834] Le Monde, August 20, 2005, France.
[835] The Herald, August 14, 2004, England.
[836] Sunday Times, September 20, 2005, England.

Budapest[837]' were published in British, Danish, French and Irish newspapers. These articles reveal the stories of individual patients and provide information on patient recruiting mechanisms, reactions of domestic health care authorities and incentives for traveling to Hungary for health care.

Patient mobility towards Hungary outside any institutional context can also be detected at the Romanian-Hungarian border. Here the main incentives are different from those noticed in case of Austrians. Better quality of care seems to be a major incentive in case of patients coming from Romania, combined with geographic and linguistic proximity. One interesting example is crossing the border for childbirth. This has been detected by Romanian health authorities as an increasing form of patient mobility that is not backed by institutional arrangements. During an interview carried out in January 2008, a local government official of the city of Oradea[838] mentioned that women living in Romanian regions bordering with Hungary increasingly preferred to travel to nearby Hungarian hospitals for childbirth[839]. The same phenomenon has been noticed by the Hungarian NHIF[840]. As explained by the Romanian local government official, women usually agree with a Hungarian doctor on a date when they arrive to the country. The doctor initiates childbirth and registers it as an emergency intervention[841]. The main incentive for women to travel abroad for childbirth and subsequent maternity care is perceived higher quality of care compared to that available in

[837] The Sunday Times, January 25, 2004, Ireland.
[838] Oradea is a city of approximately 230,000 inhabitants. It is located in Romania (Bihor county) at 8 km from the Hungarian border.
[839] As shown by the official statistics published by the Office for Population Statistics in Bihor county (Romania), in 2007 more than 8 percent of the registered births for the county with approximately 640.000 inhabitants occurred in Hungary. The rate has doubled since 2006. Source: Directia de Evidenta Persoanelor a Municipiului Oradea. Informare Privind Situatia Statistica pe Judetul Bihor pentru Perioada 2006-2007 (Statistical Information on the Population of Bihor County for 2006-2007). Oradea, 2008.
[840] Interview with the Head of the Department of International Relations and European Integration, National Health Insurance Fund of Hungary (NHIF). Budapest, May 22, 2009. There has been anecdotal evidence on the dissatisfaction of Hungarian women due to the differential treatment of Romanians willing to pay higher informal charges.
[841] Interview with A.F., local government representative in charge of social issues of the city of Oradea. Oradea, January 25, 2008.

Romania. For the sake of higher quality, Romanian women are willing to cover additional costs related to travel and even informal payments to health care professionals. Besides better quality of care, geographic and linguistic proximity constitute additional incentives, as Romanian regions bordering Hungary have a higher incidence of ethnic Hungarian inhabitants.

Crossing the border with Hungary for childbirth can also be detected in case of Ukrainian and Serbian women. According to data published by the Hungarian NHIF, childbirth and maternity care represent the most common type of services obtained by Serbians, Ukrainians and Romanians in Hungary (in 2002, it represented 30.64 percent of medical interventions provided for Romanians, 42.2 percent for Ukrainians and 19.7 percent for Serbians)[842].

The data available at the NHIF confirm that geographic proximity, higher quality and linguistic proximity are important incentives for Romanians and other Eastern neighbors to travel to Hungary for health care. During the years preceding EU accession, the majority (70 percent) of foreign patients treated in Hungary came from four countries: Romania, Serbia, Ukraine and Germany. Childbirth/obstetrics, gynecology, internal medicine, elective surgeries and traumatology are the most common fields targeted by Romanians, Serbians and Ukrainians. Medical interventions provided for Romanian, Ukrainian and Serbian patients are evenly spread throughout the year. As opposed to them, Germans obtain health care in Hungary mostly in holiday seasons and in tourist areas and the most common interventions are traumatology and rheumatology care provided in spas.

[842] Balogh, T. 'A Magyar-Román Közös Határszakasz Mentén Zajló Egészségügyi Tárgyú Együttműködések Fejleszthetőségéről és Közösségi Támogatásáról, Magyar-Román Közös Tervezési Gyakorlat és Közös Projektek Megvalósításának Lehetőségéről' (Possibilities for development and European Community support for health care co-operation initiated in the Hungarian-Romanian border area. Common Hungarian-Romanian planning practice and possibilities for implementing common projects). *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006.

The EU has indirectly facilitated individually-driven patient mobility by easing transnational movement in Europe in general. (Following the 2004 EU enlargement, low-cost airlines started to fly also to Central and Eastern Europe. At present, people can travel long distances at an affordable cost.) Nevertheless, equity concerns remain. Individuals who live closer to borders, are better informed and are able to afford advancing the costs of treatment are more likely to benefit of possibilities to access and get reimbursed for cross-border care. This brings back the discussion to the initial consideration that predominance of market logic and instruments in health care can substantially increase inequity in access to medical services.

5. Access to health care: a national competence?

The comparative analysis on Hungary and Slovenia reveals that, as a result of the EC social security co-ordination mechanism, the two countries cannot limit anymore the application and exercise of the right to access health care to their own territory; nor can they restrict health care providers and health insurance systems form other Member States to interfere with their own system. The two countries have opened their health systems to EEA residents exercising their free movement rights within the EU. Similarly to other Member States, they do not have anymore exclusive authority to decide what types of health care benefits to provide to citizens of other European countries who seek treatment during a temporary visit.

Resistance of states to the effect of EU-level developments in cross-border care is most obvious in the field of planned care. Especially the Slovenian HIIS has been considerably restrictive in the application of the prior authorization mechanism for planned treatment abroad. In both countries under review the general practice is to authorize treatment that is not available in the home country. Long waiting time very rarely serves as a justification for

authorization. Although the public health insurance funds argue that waiting time is not (yet) an issue within the country, the situation in this respect is not clear. Waiting times differ from hospital to hospital and there is a need for further clarification in this field.

Although official statistics show a low-level patient mobility across Hungarian and Slovenian borders, the current magnitude of patient mobility is not systematically explored. Particularly, the extent of individually driven mobility not backed by institutional and pre-authorized context is unknown. EU law and especially the Kohll and Decker procedure established on the basis of the ECJ case law is relevant for this type of mobility because it creates a right for patients to claim cost reimbursement according to the tariff applicable in the state of treatment. If entering into force, the proposed EC Directive on the application of patient's rights in cross-border health care will impose an obligation on Hungary and Slovenia to implement the Kohll and Decker procedure. This will have important consequences especially for this category of patients who will be able to claim reimbursement for costs that they currently cover out of pocket. A systematic analysis of factors behind spontaneous mobility is needed to predict what could be expected following further enhancement of mobility. Especially in case of Hungary there is a significant difference between prices charged within the country and in the Western neighbors, so, Hungarian citizens will be less likely to benefit of this type of mobility than their Western counterparts.

Although there have been some attempts to develop cross-border co-operation initiatives in health care, these initiatives are at a very early stage of implementation. There is a lack of common and systematic need- and capacity-assessment and planning in health care, which is a precondition for effective and sustainable regional co-operation. Nevertheless, EU accession brings about important opportunities by providing support (including financial

incentives) for cross-border co-operation in health care. Such opportunities and successful models from other Euregios should be explored together with the possibilities of their application in the Hungarian and Slovenian context.

Conclusions

Health care has been predicted to become a 'first Europe-wide testing-ground' in the competence-struggle between Member States and the EU[843]'. Organization, delivery and financing of health care constitute regulatory competences formally reserved for nation states. Nevertheless, EU legislation and particularly, the judgments of the European Court of Justice on cross-border care undermined Member States' efforts to keep these fields under exclusive national jurisdiction. Access to health services and goods has become an issue in European law.

The dissertation addressed the emerging role of the EU in access to health care and its consequences on Member States with particular focus on two new members of Central and Eastern Europe, Hungary and Slovenia. The analysis was centered on questions of social coverage of health care[844] and the patient's perspective[845]. It revealed that the central issue in cross-border care was the clash between Member States' efforts to safeguard health care as a national competence unaffected by market integration and efforts of the EU to promote free movement and the internal market. It showed that cross-border care was an illustrative example for the gradual infiltration of policy fields traditionally reserved for Member States by EU law promoting the internal market. The analysis demonstrated that the European social security co-ordination mechanism and particularly the case law of the European Court of Justice reduced Member States' discretion in deciding who has under what conditions access

[843] Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition. Oxford: Oxford University Press, 2000, pp. 267-292, on p. 283.
[844] As discussed in Chapters 2 and 4, the social character of a health care system illustrates the extent to which individuals have access to health services and goods in the form of social benefits.
[845] Issues related to cross-border movement of medical products, devices, goods and professionals were occasionally addressed but not exhaustively analyzed.

to health services within the national territory and who and under what conditions can claim social coverage for health care obtained outside of the national borders.

The first chapter appealed to theories on European integration and welfare state development in order to identify analytical tools suitable for anchoring the developments and debates around the emergence of an EU role in health care. The analysis was centered on the premise of a currently existing competency gap in social policy governance. According to this premise, Member States' authority and de facto regulatory ability in the field of social policy have been gradually limited through constraints imposed by a series of exogenous and endogenous pressures. As a result, a competency gap has emerged since no adequate regulatory competence has been formalized yet at EU level.

Macro theories of European integration provided insights into the nature and impact of exogenous pressures on contemporary welfare states. The neo-functionalist tenets of spill-over and self-sustaining integration and the intergovernmentalist premise of prevalence of national self-interest turned out to be useful analytical tools. The emerging role of EU law in governing access to health care was conceptualized as a spill-over effect of the Union's efforts to move forward the internal market. Pursuing the goal to remove the obstacles to free movement, the European Court of Justice (ECJ) has played a significant role in extending internal market rules to health care. The development of relevant rules has been moved from the highly visible political arena where it is difficult to reach consensus, to the judicial arena[846]. All these created the conditions that were necessary and sufficient for the ECJ to become an important actor in extending EU law to health care.

[846] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 43; Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*. 4th edition, Oxford: Oxford University Press, pp. 267 – 292, 2000.

The intergovernmentalist premise of prevalence of national self-interest and the theories on welfare state development explained why health care is safeguarded by Member States as a core competence of national social policy regimes and shielded from the Union. They highlighted that national health systems were part of social policy regimes constituting the result of historical developments linked to state and nation building in European countries. In the context of exogenous and endogenous pressures, Member States have worked out different responses to often similar challenges. The diversity of solutions is rooted in the diversity of social policy legacies, normative aspirations, systems of interest organization and institutional structures. Health systems are part of social policy systems closely linked to the nation state, and organization of health care is largely determined by the characteristics of the welfare regime. Consequently, any attempt of European harmonization in the field of health care faces significant political impediments.

Ferrera's theoretical framework based on Rokkan's insights on state and nation building in Europe has been applied to illustrate how factors of external and internal origin are responsible together for weakening the monopolistic control of Member States over their social boundaries[847]. Ferrera considers the development of supplementary social insurance schemes as the main endogenous factor and the creation of the European social security co-ordination mechanism established by Regulation 1408/71 as the main exogenous factor bringing about the gradual removal of state boundaries in the realm of social redistribution in Europe. The result is the competence loss of Member States in social security fields including health care.

[847] Ferrera, M. 'European Integration and National Social Citizenship: Changing Boundaries, New Structuring?'. *Comparative Political Studies* 36(6):611-652, 2003; Ferrera, M. *The Boundaries of Welfare: European Integration and the New Spatial Politics of Social Protection*. Oxford: Oxford University Press, 2005.

Chapters 2 and 3 examined how national regulation of access to health care has become affected through legislation adopted at EU level and litigations based on directly effective provisions of Community law. Chapter 2 addressed access to cross-border care under European social security co-ordination law. The analysis revealed that the European social security co-ordination mechanism had affected Member States' exclusive competence to organize their health care systems. As a consequence of the application of the co-ordination regulations, Member States must guarantee health care benefits to all EU citizens and even third country nationals coming under the scope of the regulations. In such cases nation states must apply the principles of non-discrimination and equal treatment with their own citizens. Also, Member States cannot limit anymore the application and exercise of the right to access health care to their own territory. Health insurance rights have become portable across borders within the EU and in certain cases, also to third countries[848]. Moreover, Member States cannot restrict health care providers and health insurance systems form other Member States to enter their health systems. When granting to a patient prior authorization for treatment in another Member State, the state of insurance must accept that the state of treatment sets the rules of cost sharing and effective provision of services including the conditions of access to specialist care. As relevant from the *Keller* ruling, in certain cases the state of insurance must even accept that the health care providers located in the state of treatment and authorized to treat the patient decide to refer him/her to a third country to be treated there at the cost of the competent insurance fund (i.e., at the expense of the state of insurance).

Chapter 3 examined the outcomes of the application of the freedom to provide and receive services to health care. Through the analysis of the relevant case law it highlighted the crucial

[848] See the analysis of the ECJ ruling in the *Keller* case (Chapter 2).

role of the European Court of Justice in placing access to health care on the EU agenda. Even if the rulings left in principle for Member States the organization of health systems and establishment of the scope and content of entitlement to health care, they made it clear that nation states had to comply with free movement when exercising these powers. The ECJ judgments have established a distinct mechanism to access cross-border care that runs parallel to the co-ordination mechanism. Grounded on the directly effective primary law provisions of the EC Treaty, this mechanism entitles insured patients to seek non-hospital care in another Member State without the authorization of the competent institution. The rulings have also established a series of conditions that Member States have to meet when applying the prior authorization rule in case of hospital care. They established the rule of sector-neutral financing in cross-border care meaning that sickness funds have to reimburse treatment obtained in public *and* private facilities located in other Member States on the basis of the internal market rules (even if they do not reimburse treatment obtained from domestic non-contracted private care providers)[849]. Moreover, the ECJ case law requires Member States to look at international standards when determining what types of treatment to include in their domestic benefit packages[850]. As a result, it is not enough anymore to consider respective national standards of medicine, as the ECJ has made it clear that there is a need to look beyond the individual Member State when determining the appropriate standards[851]. Although harmonization of health care legislation has never constituted an explicit goal of the ECJ, the decisions analyzed illustrate the progressive extension of EU law over issues pertaining to medical treatment.

[849] See the *Stamatelakis* judgment discussed in Chapter 3 and the proposed Directive stipulating that the cost-assumption rules under the Kohll and Decker procedure equally applies to services obtained from public and private providers. In fact, the rule of sector-neutral financing in cross-border care discriminates private providers located in the state of insurance, as pointed out also by the Head of Department of International Relations and European Integration of the Hungarian National Health Insurance Fund during the interview carried out in Budapest on May 22, 2009.
[850] See the analysis of the normality of treatment on the basis of the *Geraets-Smits/Peerboms* judgment.
[851] See also Hervey, T. K and J. V. McHale. *Health Law and the European Union*. Cambridge: Cambridge University Press, 2004, p. 157.

Extension of internal market rules to health care has been done through litigation, not through direct legislative action. The ECJ-driven legal developments are not constrained by the limited legal basis of EU action in health care. Member States cannot veto ECJ decisions and case law like they can veto direct legislative action by the EU in social policy fields. As a result, nation states did not manage to stop the infiltration of the sovereign national competence of health care governance by EU law and internal market rules. The ECJ judgments addressed individual, specific and sometimes atypical situations, and the rules have been developed on a case-by-case basis.

The legal uncertainties have raised the issue of the necessity of a legislative response at EU level. As pointed out by commentators, '*it is better to let the internal market in through the front door than close one's eyes and let it creep through the back one*'[852]. Some national governments expressed their preference for legislative response in order to prevent that further litigation and case law continues to affect their authority to organize their health systems[853]. However, it has become clear that an effective EU-level legislative response needs to go beyond an amendment and modernization of the co-ordination regulations because the ECJ rulings base the right to cross-border care on the directly effective primary law provisions of the EC Treaty. In spite of Member States' strong preference to solve the issue of cross-border care through an amendment of Regulation 1408/71 and keep it within the framework of the social security co-ordination mechanism, such a solution turned out to be insufficient. It has become clear that EU legislation coordinating, along the lines established by the ECJ rulings, the conditions of access to cross-border care should run

[852] Nickless, J. 'The Internal Market and the Social Nature of Health Care', in M. McKee, E. Mossialos and R. Baeten (eds.) *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E.-Peter Lang, 2002, pp. 57-82, on p. 81.
[853] See the synopsis of the German EU Presidency preparatory meeting held in Bonn on November 23-24, 1998: Gobrecht, J. 'National Reactions to Kohll and Decker'. *Eurohealth* 5(1):16-17, 1999.

parallel to the mechanism established by Regulation 1408/71[854]. Ironically, Member States' reluctance to implement the rulings and their repeated complaints about persisting legal uncertainties prompted the European Commission to codify the elements of the ECJ case law.

The first attempt of the Commission to codify the elements of the ECJ case law failed when the European Parliament and the Council did not accept to include the health care article in the 2006 EC Directive on services in the internal market. The 2008 proposed EC Directive on the application of patients' rights in cross-border care constitutes the Commission's second attempt to codify the elements of the ECJ rulings. Besides the principles established in the judgments, the Directive includes some additional elements, notably, patients' rights to accountability and transparency[855]. These rights would apply not only to patients crossing borders but to all patients within the EU. Also, the proposed Directive envisages the development of minimum quality standards, an EU-wide definition of hospital care and European reference networks providing highly specialized health care to patients whose medical condition requires a particular concentration of resources or expertise. It also codifies the rule of sector-neutral financing in cross-border care. These elements represent a step towards positive integration (harmonization) in health care[856].

The application of internal market rules to the health care sector presents several pitfalls. The health sector is not a commercial market and patients are not well-informed consumers. Health and health care are not economic commodities or tradable goods. The specifics of the

[854] Commentators have raised the question whether such legislation could be based solely on the EC Treaty provision of freedom of movement, or whether recourse should be made also to the Treaty provisions on social policy. See Hatzopoulos, V. G. 'Do the Rules on Internal Market Affect National Health Care Systems?', in M. McKee, E. Mossialos and R. Baeten (eds.) *The Impact of EU Law on Health Care Systems*. Brussels: P.I.E.-Peter Lang, 2002, pp. 123-160, on p. 156.
[855] See also the analysis of Sauter, W. 'The Proposed Patient Mobility Directive and the Reform of Cross-Border Healthcare in the EU.' Tilburg Law and Economics Center (TILEC): Discussion Paper No. 2008-034, 2008.
[856] Ibid.

health care sector stems from a series of characteristics, such as information asymmetry between patients and health care providers and the large share of public money involved in the financing of most health systems. Moreover, European states generally commit themselves to ensure the social character of health care and aim at guaranteeing universal and equitable access to at least a core package of services as a state responsibility[857]. Governments feared the risk that EU trade policies would compromise Member States' de facto capacity to guarantee the social rights of their citizens[858]. Pessimistic scenarios predicted that the promotion of single market logic in health care would undermine equity in access to services, endanger the financial balance of national social security systems, complicate health care planning and co-ordination, and affect nation states' ability to control both the quality of medical services and health care expenditure. Such effects were predicted to take on a particular pattern in new members of CEE where allocation of scarce resources in health care and the necessity of cost-containment are even more pressing than in case of old members. In the context of resource scarcity and wastage, CEE Member States have to cope with the need to improve efficiency in health care organization, ensure the social character of health care and catch up simultaneously with EU standards that are themselves evolving.

Chapter 4 moved the analysis from the European level to the level of countries in order to examine how health care systems of nation states had been affected. The chapter included a comparative analysis of regulation of cross-border care in two CEE countries, Hungary and

[857] Equity in access to health care, appropriate quality of services and financial sustainability are core principles shared by health care systems in Europe and promoted also by the EU. See also European Commission (2004), *Communication from the European Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions. Modernizing Social Protection for the Development of High-quality, Accessible and Sustainable Health Care and Long-term Care: Support for the National Strategies Using the 'Open Method of Coordination'*, COM(2004) 304 final of 20 April 2004. Brussels: Commission of the European Communities.

[858] See, for example, Baeten, R. 'European Integration and National Healthcare Systems: a Challenge for Social Policy'. *Infose* 8, 2001; Koivusalo, M. 'European Health Policies – Moving towards Markets in Health?'. *Eurohealth* 9(4):18-21, 2003/2004, p. 21; Leibfried, S. and P. Pierson. 'Social Policy – Left to Courts and Markets?', in H. Wallace and W. Wallace (eds.) *Policy Making in the European Union*, 4th edition. Oxford: Oxford University Press, 2000, pp. 267 – 292.

Slovenia. It examined the premise that new members of CEE differed not only from old members but also among each other in terms of their reactions to EU-level pressures to open up their social borders and ensure the freedom to provide and receive cross-border health care. Towards this end, it compared first the organizational structure and relevant characteristics of the Hungarian and Slovenian health systems, with specific focus on health insurance and social coverage of health care. Afterwards, it compared the legal framework on access to cross-border care, distinguishing between treatment that becomes necessary during a temporary visit to other Member States and planned treatment abroad. Finally, it looked at current extent and characteristics of patient mobility across the borders of these countries.

The comparative analysis on Hungary and Slovenia reveals that the territorial focus in the organization of health care and health insurance persists in both countries. This is most obvious in case of planned treatment abroad, where the prior authorization rule still constitutes an efficient mechanism to control and restrict access. Particularly in Slovenia the application of the prior authorization rule has been restrictive. In both countries the general practice is that authorization for treatment abroad is granted if the necessary treatment is not available at all within the country, and the treatment cannot be provided by inviting a specialist from abroad. The types of treatment authorized are mostly highly specialized and expensive surgeries and specific examinations in Hungary, and in-vitro fertilization, eye prostheses, cardiac surgeries and diagnostics of the tissue and blood samples in Slovenia that cannot be carried out at home at all or without extensive delay. In fact, long waiting time very rarely serves as a justification for authorizing treatment abroad. National public health insurance institutes argue in both countries that waiting time is not (yet) an issue, except for

very few exceptions[859]. Nevertheless, the actual situation regarding waiting time for intramural treatment differs from hospital to hospital and is far from clear, especially in Slovenia where improvement of waiting lists management has been a recurrent issue on the agenda of health care reforms.

Access to cross-border care under internal market rules is quite restricted in Slovenia. The Health Insurance Institute argues that more clarification on relevant EU rules are expected before implementing the rules on cross-border care grounded on the free movement provisions of the EC Treaty (the Kohll and Decker procedure). In this sense, Slovenia has been slower in creating the conditions for access to planned cross-border care and has waited for the negotiations around the proposed European Directive on the application of patients' rights in cross-border health care. The proposed Directive and pressures on behalf of the Commission might result in speeding up the implementation of the relevant ECJ rules. In Hungary, the possibility to access cross-border care on the basis of the free movement provisions (i.e. outside of Regulation 1408/71) has been stipulated in national law since the 2004 EU accession. Nevertheless, Hungarian patients do not make much use of this opportunity.

The Hungarian National Health Insurance Fund explains that the under-use of the Kohll and Decker procedure by Hungarian patients is a result of the high co-payments associated to this mechanism. The NHIF points out that the cost of health care is significantly higher in Western EU countries than in Hungary[860]. Since the NHIF only reimburses the costs up to the amount covered when the same treatment is obtained in-country, it does not fear a substantial

[859] The few exceptions include backbone surgeries in Hungary and cardiac surgeries and in-vitro fertilization in Slovenia.
[860] Interview with the Head of Department of International Relations and European Integration, National Health Insurance Fund of Hungary. Budapest, May 22, 2009.

movement of Hungarian patients towards Western neighbors because patients would need to cover significant costs out-of-pocket. The NHIF bases this argument on its data regarding the cost of emergency health care: available figures show that the average cost per care[861] is four times higher in Germany and Austria than in Hungary. According to the NHIF, the difference is similar in case of non-emergency care that can be obtained on the basis of the Kohll and Decker procedure. This reveals that a German or Austrian insured person is fully covered for health services obtained in Hungary, because the costs are much lower than the amount charged for the same treatment in Austria/Germany. On the other hand, a Hungarian obtaining treatment in Austria/Germany needs to cover out-of-pocket around 75 percent of the actual cost paid.

The Hungarian case illustrates that the price differences in health services between old and new Member States impose on CEE patients a clear disadvantage when it comes to the real possibility to make use of the Kohll and Decker procedure. In this respect, CEE patients benefit much less of the ECJ rulings and extension of internal market rules to health care than their Western counterparts. Although it is a common argument that certain population categories always benefit more from the EU market freedoms than others, in this case the disadvantage of CEE patients is systemic, due to the cost-assumption rules applied under the Kohll and Decker mechanism combined with the significantly lower cost of health care in CEE.

The current magnitude of movement of patients across the Hungarian and Slovene borders is not systematically explored. Available data suggest that the movement of Hungarian and Slovenian patients abroad remains low. National frontiers still work as borders in terms of

[861] See Lengyel B., 'Külföldi Betegek Ellátása és a Csatlakozásunk Eddigi Tapasztalatai az Egészségbiztositásban (Treatment of foreign patients and accession-related experiences in health insurance)'. *Egészségünk az Eurorégióban Szakkonferencia*, DKMT Kht., Szeged, 2006, pp. 4-14, on p. 10.

health care organization and service delivery. The prior authorization rule constitutes an efficient mechanism to control cross-border movement for planned treatment. The Kohll and Decker procedure is less attractive due to significant financial burdens and additional financial risks compared to the co-ordination mechanism. In addition, available experiences reveal that health care remains a special service, due to its cultural and language contingency, and patients prefer to obtain health services in the home country unless strong incentives determine them to cross the border.

Nevertheless, the number of Hungarian and Slovene patients obtaining health care in other EU countries increases slowly but steadily. An increase can be noticed in case of planned care and particularly in case of treatment that becomes medically necessary during a temporary visit to another Member State. The latter is a natural consequence of increasing mobility of persons: European citizens are living now in an era when national frontiers very rarely act as obstacles to mobility, many Member States use the same currency and low-cost airlines make it possible to commute weekly between different countries without a big financial effort. The European Health Insurance Card (EHIC) is an instrument ensuring access to medically necessary care within the EU. Health care providers contracted with the public insurance funds have to treat the card holders as if they were their own nationals. Although the EHIC cannot be used for obtaining planned care, its wide-spread application increases the interactions between health systems of EU Member States. This can lead to an increase in transparency at domestic level, and it is likely to bring health systems closer to each other. In the best case scenario this can result in improvements in quality standards of services that need to be kept competitive, and impose more scrutiny on domestic practices impeding access to treatment (such as informal charges for services that should be provided for free at the point of delivery).

The extent of individually-driven mobility across Hungarian and Slovenian borders that takes place outside of the pre-authorized context is unexplored. Existing research suggests that the magnitude of this type of mobility is larger than suggested by the few available data. Available studies suggest that there is a significant mobility of patients from the neighboring Austria and other Western countries towards Hungary for certain types of health services, particularly, dental care, aesthetic surgery, eye surgery, cure and rehabilitation in spas. To a lower extent, this is also true for Slovenia. At present, individually-driven patient mobility is mainly taking place in the private sector and most of these patients remain unregistered. Systematic analysis of the extent and pull and push factors of this type of mobility is necessary because, following the extension of internal market rules to health care, such patients can claim reimbursement of costs up to the level reimbursed by their domestic insurance fund for the same treatment provided in the state of insurance. This is also relevant to medical services obtained from private providers located in other EU countries due to sector-neutral financing applicable in cross-border care. The rule of sector-neutral financing imposes on the competent sickness fund the obligation to reimburse the cost of private treatment obtained abroad up to the amount that the same treatment would be reimbursed in the state of insurance. The lower health service costs in the CEE countries favor Western patients and could lead to an increasing mobility towards Hungary and Slovenia. Growing patient information (pursued by the European Commission's 'Europe for Patients' campaign and the proposed Directive) could lead to an increase in reimbursement claims submitted by patients who currently cover such costs out-of-pocket.

EU accession has opened up new opportunities for health care providers located in Hungary and Slovenia. Public and private providers contracted with the public health insurance fund

can benefit of an enhancement of cross-border patient mobility in several ways. They can claim financing for treatment provided to EHIC holders and patients authorized by foreign sickness funds to obtain planned treatment in Hungary and Slovenia (E112 form holders). The costs of these treatments will be covered by the domestic health insurance funds and expenses will be settled subsequently between the health systems of the state of treatment and the state of insurance. Health care providers can claim co-payments from EU citizens for services for which Hungarian/Slovene patients also need to make co-payments. This includes medical treatment and extra hospital services (such as higher quality rooms) that are not covered by the Hungarian/Slovene public health insurance system. Care providers can claim the full cost of services from foreign patients who arrive for planned treatment to Hungary/Slovenia without an authorization from their sickness funds and inform patients that, in certain conditions, they are entitled to reimbursement of treatment costs in the state of insurance on the basis of the Kohll and Decker procedure. They can follow the same procedure in case of EHIC holders for treatment that is not medically necessary given the expected length of their stay and therefore not covered by the EHIC. In addition, they can conclude contracts with foreign health care providers in order to make better use of existing complementary capacities. This could be useful for reducing waiting lists and compensate for capacity shortages. They can attract with more favorable offers patients from EU countries where certain health services are covered by supplementary insurance operating on a for-profit basis, such as dental care, health cure provided in spas, rehabilitation, aesthetic surgery, eye surgery. This can also be attractive for insurance institutions located in other Member States that provide supplementary insurance for such services on a for-profit basis. Finally, health care providers, insurance funds and other stakeholders can initiate cross-border co-operation agreements in medical service provision. Towards this end, they can make use of

the financial incentives provided by the EU and other advantages of border areas such as geographic and sometimes also linguistic and cultural proximity.

Although there have been some attempts to develop cross-border co-operation initiatives in health care, these initiatives are at a very early stage of implementation. Currently, there is still a lack of common and systematic need- and capacity-assessment and planning, which is a prerequisite of effective and sustainable regional co-operation. National borders still work as frontiers for such planning processes, and the nationally focused health care organization rarely includes ideas for co-operation and contracting across borders. Given that EU accession has brought about important opportunities by providing support (including financial incentives) for cross-border co-operation in health care, such opportunities and successful models from other Euregios should be explored, together with the possibilities of their application in the Hungarian and Slovenian context.

A number of provisions of the proposed EC Directive suggest that the EU will be likely to move forward with promoting cross-border patient mobility. This tendency seems unlikely to reverse and Member States have to accept the idea that the role of the EU in access to health care will continue to extend. As health care is not left unaffected by integration, old and new Members States need to figure out how to make use of opportunities brought about by the extension of internal market rules to medical services and goods, and safeguard at the same time the social character of health care. A major challenge of the coming years is coping with a growing role of the EU in health care so as to safeguard the interests of patients.

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