11 *Free movement of services in the EU and health care*

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1. Introduction

Throughout the European Union, health care systems traditionally have been characterized by extensive regulatory intervention. National and regional authorities intervene mainly to ensure equal access, sustainability, quality, safety, equity and efficiency of health care for the citizens residing in their territory. Given the multitude of different actors involved, they need to align these overall principles and objectives with the interests of stakeholders to ensure the stable cooperation of all the players in the system.

Increasingly, this high level of public intervention has been challenged on the part of the European Community. Regulation in the field of health care is being scrutinized with regard to its conformity with EU law, particularly Community rules on free movement (of persons, goods and services). As different forms of mobility in the EU increase and also extend to all sectors, including health care, national measures and mechanisms increasingly run the risk of being seen as unjustified obstacles to free movement, which is prohibited under the EC Treaty.[1] This chapter will focus particularly on the impact of the EC Treaty rules on free movement of services, which encompass both the principles of free provision of services (Article 49–50 EC) and of free establishment of providers (Article 43 EC).

Mainly spurred on by the jurisprudence of the European Court of Justice (the Court) and the action undertaken by the European Commission, the application of these two principles has gradually made its way into national health systems and has extended far beyond the specific cases of patient and provider mobility. This trend is followed with suspicion by many policy-makers and actors. They mainly fear the deregulatory effect that is likely to cripple steering

[1] See Chapter 2 in this volume.

instruments and may conflict with the specific objectives pursued by national health policy and its important challenges. Most policy actors also point to the legal uncertainty created by the internal market logic and its inequitable consequences. The political debate, which culminated in the exclusion of health services from the Services Directive,[2] looks at how free movement principles can be reconciled with health policy objectives, and how an acceptable balance can be found between respecting free movement principles and the need to regulate and steer the health sector. This comes at a time when there is an increased emphasis on the economic dimension of the health sector, and its potential for boosting the Lisbon agenda is acknowledged.

Very often reference is made to the specific features characterizing this sector, which warrant specific treatment and attention. Firstly, the specificity of health policy lies in the fact that health and access to health care are acknowledged as fundamental human rights by several international treaties, including the Charter of Fundamental Rights of the European Union.[3] In addition, when health care is discussed in an economic context, the existence of important market failures that could occur when health care is delivered in an unregulated setting are highlighted. Primarily, the need for government regulatory intervention follows from the asymmetry of information between health care providers and patients. Patients generally lack the necessary background knowledge to make informed decisions about the care they need, as well as the quality and effectiveness of the care they receive, whereas health care providers have the unique power to induce demand and to set prices. Moreover, health care expenditure is highly concentrated among a minority of the population, which can be identified relatively easily on the basis of risk factors such as age, education level and socioeconomic status. Even if, in the health sector, competing economic actors are involved in organizing and providing health care, it is widely accepted that their activities require regulation to bring them fully in line with the goals of public health and social policy. Others have pointed to the risk that unbridled liberalization and deregulation in health care could make health systems less

[2] Article 2(2)(f), European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2006 No. L376/36.

[3] Article 36, Charter of Fundamental Rights of the European Union, OJ 2000 No. C364/1.

effective, more costly and less equitable.[4] Since health care systems in the EU are mainly publicly financed, it is also important to take into account changes in the behaviour of both patients and health care providers that result from their awareness that the full cost or a substantial part thereof is born by a third public party/financier.[5] Given the fact that, as a consequence, patients are likely to seek to receive – and providers to seek to supply – more health care, government regulatory intervention is needed to prevent publicly funded systems from suffering losses in economic efficiency, which could undermine the entire health care system's sustainability.

This chapter provides a detailed analysis of the impact of the EC Treaty provisions on free movement of services on health systems. It particularly looks into the reasoning that EU institutions – particularly the European Court of Justice and the European Commission – have developed with respect to the provision of health care. Section two deals with the scope of free movement rules and focuses on the qualification of health care services as 'economic' activities within the meaning of the EC Treaty. The qualification as economic services is important, as it implies that national regulatory measures could be regarded as unjustified restrictions to free movement and therefore open to legal challenge by discriminated parties or the European Commission. In this way, free movement rules may affect the regulatory autonomy of Member States to organize health care and related national social security systems. It also looks at the notion of barriers to free movement in the field of health care. Here we will amplify how almost any regulatory or institutional aspect of health care provision can be challenged as a potential obstacle to free movement. In section three, we will explain that these regulatory measures will have to be justified and will flesh out how the conditions under which impediments to free movement can be justified. The section illustrates that providing good evidence to justify public intervention under the free movement rules is very challenging for health authorities.

[4] See, for example, A. Maynard, 'European health policy challenges', *Health Economics* 14 (2005), Supp: 256.

[5] In insurance-based health care systems, or more generally in insurance markets, this phenomenon is typically referred to as 'moral hazard'. For an overview of organizational responses to 'moral hazard', see C. Donaldson, K. Gerard and S. Jan (eds.), *Economics of health care financing: the visible hand* (London: Macmillan Press, 2003), p. 38.

Finally, section four will identify the relevant policy initiatives taken at a European level, will look at how Member States are dealing with the consequences of the relevant case-law, trying to reinstate legal certainty and regain control over policy in this area. More specifically, the section will discuss the Services Directive and the attempt to develop a more adapted Community framework for health services. It will also link to the discussion on social services of general interest, as it is commonly accepted that health care would qualify under this new concept in the European policy debate on positioning public service obligations. We will try to explain the complexity of the policy process and analyse why, so far, policy initiatives have not succeeded in presenting appropriate answers to the challenges at hand.

One major area of focus in this chapter is the 'creeping' application of the rules on free movement of services. However, the chapter will not address areas where specific EU legislation already has been developed. There are different scenarios that trigger free movement rules.[6] First of all, recipients of services – patients, in the first place, but also purchasers of care – can seek and contract to receive medical care abroad. This area has been mainly pushed by the European Court of Justice case-law based on Article 49 EC, which established a series of principles governing the statutory reimbursement of costs of health care provided abroad. This issue is analysed further in Chapter 12. Cross-border provision of private health insurance services is not tackled in this chapter either, as the issues are dealt with in Chapter 10 and are mainly governed by specific EU legislation. As a second dimension, the service activity itself can move across borders when the health care service is provided at a distance from another country, at the individual request of a recipient or a commissioner of services. The legal framework applicable when this service activity is provided by electronic means will be dealt with in Chapter 13 on EU law and e-health. Finally, EC Treaty rules on free movement of services also come into play when the health care provider moves across borders to deliver health care. Health care professionals can temporarily move to another country and challenge regulatory measures as unjustified restrictions to their free movement rights on the basis of Article 49 EC. But health care providers – such as health care professionals, pharmacies, clinical

[6] See also European Commission, 'Communication on the consultation regarding Community action on health services', SEC (2006) 1195/4, 26 September 2006.

laboratories or hospitals – can also move to another Member State on a more permanent basis with a view to supplying health care there. On the basis of Article 43 EC, these health care providers could argue that the regulatory barriers they face in the receiving state are a *prima facie* unlawful infringement to their freedom of establishment. The specific Community framework governing the free movement of health professionals will be analysed in more detail in Chapter 14. Our chapter will thus focus on the direct application of the free movement rules of the EC Treaty, which aim to ensure that providers can freely provide services temporarily (freedom to provide services) or permanently (freedom of establishment) in another Member State without the existence of specific secondary legislation.

2. Health care as an economic activity and its consequence

A. The economic nature of health care

The specificity of health care has for a long time dominated the European debate on the application of free movement principles in this sector. Since the development of health and social protection systems has been largely determined by the historical, social and economic background of individual countries, and national welfare states have drawn quite some legitimacy from the organization of these systems, traditionally some reluctance can be observed when it comes to sharing this competence with other administrative levels. Moreover, in legal terms, health care has long been considered to be 'an island beyond the reach of Community rules'.[7]

However, the only determining criterion to establish whether a service falls under the scope of the fundamental principles of free establishment (Article 43 EC) or free service provision (Article 49 EC) is its economic character. Services within the meaning of the EC Treaty are defined by Article 50 EC as any activities 'where they are normally provided for remuneration, insofar as they are not governed by the provisions relating to freedom of movement for goods, capital and persons'. The qualification of 'social' – or statutorily

[7] See Opinion of the Advocate General Tesauro in Case C-120/95, *Decker* v. *Caisse de Maladie des Employés Privés* [1998] ECR I-1831; and Case C-158/96, *Kohll* v. *Union des Caisses de Maladie* [1998] ECR I-1931.

covered – health care[8] as services under the meaning of Article 50 EC has raised quite some discussion. The constitutive element of remuneration is particularly contentious for services that are of a public nature or linked to the general interest.

Long before the application of EU free movement rules to the health care sector was put on the political agenda by the well-known cases of *Kohll* and *Decker*, the economic nature of (private) health services was acknowledged by the Court in the cases *Luisi and Carbone*, and *Grogan*.[9] The *Kohll* and *Decker* rulings of 1998 established for the first time the link with statutory reimbursement and social security.[10] Even if the Court accepted the specific nature of health care that is provided within the context of a social security scheme, it did not agree to remove it from the ambit of the fundamental principle of free movement.[11] In its consecutive judgements, the Court further clarified that the specific type of statutory cover – be it reimbursement, benefit-in-kind or national health service – nor the specific type of health service – hospital or non-hospital – does not alter the economic nature of the health service in question.[12]

> Article 49 EC applies where a patient … receives medical services in a hospital environment for consideration in a Member State other than her State of residence, regardless of the way in which the national system with which that person is registered and from which reimbursement of the cost of those services is subsequently sought operates.[13]

To challenge this reasoning, often the comparison is made with courses under national systems of public education, which were not considered

[8] J. Nickless, '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: PIE-Peter Lang, 2002), p. 64.

[9] Joined Cases 286/82 and 26/83, *Luisi and Carbone* v. *Ministero del Tesoro* [1984] ECR 377; Case C-159/90, *The Society for the Protection of Unborn Children Ireland Ltd* v. *Grogan* [1991] ECR I-4685.

[10] V. G. Hatzopoulos, 'The ECJ case law on cross-border aspects of the health services', DG Internal Policies of the Union Briefing Note, IP/A/IMCO/FWC/2006–167/C3/SC1, January 2007, p. 2, www.europarl.europa.eu/comparl/imco/studies/0701_healthserv_Ecj_En.pdf.

[11] Case C-158/96, *Kohll*, above n.7, para. 21. See also Case 279/80, *Webb* [1981] ECR 3305, para. 10.

[12] Case C-157/99, *Geraets-Smits and Peerbooms* [2001] ECR I-5473, paras. 53–5; Case C-385/99, *Müller-Fauré and Van Riet* [2003] ECR I-4509, para. 103.

[13] Case C-372/04, *Watts* [2006] ECR I-4325, para. 90.

by the Court to be economic activities.[14] To exclude public education from the scope of the free movement of services, the Court mainly referred to the fact that: (a) the price is not agreed upon between the service provider and the recipient; (b) the state, when establishing and maintaining a national education system, is not seeking to engage in any gainful activity but is fulfilling its duties towards its own population in the social, cultural and educational fields; and (c) the service is essentially financed from the public purse.[15] Despite obvious similarities and the fact that Member States as well as the Advocate General have referred to it, the Court has never been required to test whether these conditions have been fulfilled in the health care cases. The reason why the link with the public education cases has never been made seems to lie in the fact that, in the patient mobility cases, the persons concerned have always paid directly for the treatment received from the provider established in another Member State. Only subsequently has reimbursement for the costs incurred been sought from the statutory social security system in the home state. Therefore, the patient seems to have received the treatment in a private capacity and the supplier of the service could hardly be considered to be an agent of a public health service, at least not one to which the patient was affiliated.

Remarkably, the Court has always carefully avoided qualifying as a 'service' health services provided to a patient under the health system to which he or she is affiliated. In *Watts*, the Court clearly indicated that there was 'no need in the present case to determine whether the provision of hospital treatment in the context of a national health service such as the NHS is in itself a service within the meaning of those provisions [of Article 49]'.[16] It is established case-law that the Treaty provisions on free establishment and free provision of services do not apply to purely internal situations in a Member State.[17]

[14] Case 263/86, *Humbel* [1988] ECR 5365; Case C-109/92, *Wirth* [1993] ECR I-6447.

[15] The Court specified that the fact that pupils or their parents partly contribute to the operating expenses of the system does not alter the nature of the service within the meaning of the EC Treaty.

[16] Case C-372/04, *Watts*, above n.13, para. 91.

[17] For instance, Joined Cases C-54/88, C-91/88 and C-14/89, *Criminal proceedings against Eleonora Nino and Others* [1990] ECR I-3537, para. 12. However, recent case-law shows that freedom of establishment within the meaning of Article 43 EC even applies in the case of rules that lack a specific cross-border element. See below.

However, looking at the competition cases related to health care, where the economic nature of the activity – and the operator engaged in it – also needs to be acknowledged, it seems as though the Court has applied a more narrow approach to statutory health services delivered to domestic patients. In the *FENIN* case, the Court confirmed the judgement of the Court of First Instance, which held that the Spanish national health service management bodies should not be considered to be undertakings when purchasing goods, since this activity should not be dissociated from the subsequent use to which the goods are put – that is, in the provision of services free of charge to its members on the basis of universal cover and according to the principle of solidarity.[18]

It seems doubtful whether this classification as a 'non-economic' health service could be extended to all situations and all health systems.[19] Moreover, as the Advocate General in this case, Poiares Maduro, highlighted, the scope of freedom of competition and that of the freedom to provide services are not identical. There is nothing to prevent a transaction involving an exchange being classified as the provision of services, even where the parties to the exchange are not undertakings for the purposes of competition law.[20]

B. Barriers to free movement of services

The fact that the provision of health care is a service activity within the meaning of the EC Treaty implies that health care providers established in one Member State are granted a 'fundamental freedom' to establish themselves or provide their services in another Member State. Originally, the rationale behind the EC Treaty free movement rules was to eliminate discriminatory provisions and guarantee that service providers, including health service providers, established in one Member State and operating in the territory of another Member State – either

[18] Case C-205/03, *FENIN* [2006] ECR I-6295.

[19] S. A. de Vries, 'Patiëntenzorg in Europa na *Watts*: Wiens zorg?', *SEW – Tijdschrift voor Europees en Economisch Recht* 55 (2007), 136.

[20] Opinion of Advocate General Maduro in Case C-205/03, *FENIN*, above n.18, para. 51. See also E. Szyszczak, 'Competition law and services of general economic interest', Paper presented at the ERA Conference 'European Economic Integration and National Social Protection Systems: Towards a New Form of Internal Market', Brussels, 31 May-1 June 2007, p. 2.

temporarily or more permanently through an establishment – would enjoy the same conditions as the nationals of the state in which they operate (the principle of non-discrimination or national treatment). The interpretation of what constitutes a barrier to free movement has gradually extended to measures that in themselves are not directly discriminatory.

Articles 49–50 EC set out the principle of non-discrimination or national treatment in the case of temporary cross-border service provision. However, this principle was gradually abandoned from the Court's early jurisprudence onwards.[21] Indeed, the Court has interpreted Articles 49 and 50 EC to require that the host Member State refrain from imposing on health service providers established in another Member State other or additional rules that also do not apply to providers established in the host Member State. Apart from directly discriminatory rules, under Article 49 EC the Court also scrutinizes, on a case-by-case basis, measures that apply without distinction and that, although not in themselves discriminatory, would eventually have the same effect – in that existing conditions would make it easier for domestic providers to comply with these measures (so-called 'indistinctly applicable' or 'indirectly discriminatory' measures).[22] This applies when the measures are 'liable to prohibit or otherwise impede the activities of a provider of services established in another Member State'.[23] The judgment in *Commission* v. *France* provides a perfect illustration of this. The Court considered that the French requirement to have a business seat in France in order for biomedical analysis laboratories to obtain a license and to be authorized to work under the French statutory health insurance constituted a restriction to the freedom to provide services because 'it de facto precludes laboratories established in

[21] See, for instance, Case 107/83, *Klopp* [1984] ECR 2971; Joined Cases 154/87 and 155/87, *Wolf* [1988] ECR 3897; Case 143/87, *Stanton* [1988] ECR 3877.

[22] See also Case 120/78, *Cassis de Dijon* [1979] ECR 649.

[23] Case C-76/90, *Säger* v. *Dennemeyer* [1991] ECR I-4221, para. 12, and confirmed in recent case-law: 'Article [49] of the Treaty requires … the abolition of any restriction, even if it applies without distinction to national providers of services and to those of other Member States, when it is liable to prohibit or otherwise impede the activities of a provider of services established in another Member State where he lawfully provides similar services'. See also, in the framework of patient mobility, Case C-157/99, *Geraets-Smits and Peerbooms*, above n.12, para. 69.

another Member State from being able to provide services to insured persons established in France'.[24]

A typical feature of temporary cross-border service provision under Articles 49 and 50 EC is that the health service provider that operates in another Member State does not cease to be regulated by its Member State of establishment. As a consequence, under Articles 49–50 EC, as interpreted by the Court, the host Member State is not entitled to restrict cross-border entry of health service providers into its market, where this would imply that the provider faces a double regulatory burden.[25] Thus, as soon as health service providers are established in a Member State and lawfully provide services similar to the ones that they intend to provide abroad they automatically acquire a right to provide their services in other Member States.[26] This position is based on the principle of mutual recognition, which is one of the corner-stones of the single market, as it guarantees free movement without the need to harmonize Member States' legislation.[27] However, as we will discuss below, this mutual recognition principle, according to which the rules of the Member State of origin prevail, is applied in a conditional manner.

When health service providers move (or wish to move) to another Member State on a more permanent basis in order to operate there, they are caught by the principle of freedom of establishment under Article 43 EC. Given the fact that most health care providers moving to another Member State in order to provide their services there are

[24] Case C-496/01, *Commission* v. *France* [2004] ECR I-2351, para. 91. The fact that the Court recognizes that it is for the Member State in which the patient is affiliated to decide which medical treatments are covered by sickness insurance and to establish the extent to which sickness coverage is made available to its insured patients does not change this conclusion. Case C-385/99, *Müller-Fauré*, above n.12, para. 98.

[25] E. Spaventa, 'From Gebhard to Carpenter: towards a (non-)economic European Constitution', *Common Market Law Review* 41 (2004), 743–73, at 748; K. A. Armstrong, 'Mutual recognition', in C. Barnard and J. Scott (eds.), *The legal foundations of the single European market* (Oxford: Hart, 2002), p. 226.

[26] V. G. Hatzopoulos, *Le principe communautaire d'équivalence et de reconnaissance mutuelle dans la libre prestation de services* (Brussels: Bruylant, 1999), p. 192.

[27] European Commission, 'Communication from the Commission to the Council and the European Parliament on mutual recognition in the context of the follow-up to the action plan for the single market', COM (1999) 299 final, 16 June 1999.

likely to require some form of establishment in that Member State, the EC Treaty provisions on freedom of establishment have a potentially greater impact on Member States' regulatory autonomy. The notion of establishment, as interpreted by the Court, can be considered to include the setting up or running of a clinical laboratory, a pharmacy, a hospital facility or even the private practice of a self-employed health care professional, provided that, in accordance with the Court's case-law, the presence of a stable and continuous participation in the economic life of the host Member State is proven.[28]

From a regulatory point of view, the situation of a health care provider operating under Article 43 EC differs from the scenario under Article 49 EC because, in the former case, the service provider ceases, for most purposes, to be governed by the Member State of previous establishment, with the result that the application of the host Member State's rules will not imply a double regulatory burden.[29] Although the text of Article 43 EC does not only target national restrictions that are discriminatory on the basis of nationality, the European Court of Justice has traditionally adopted a rather narrow approach to its interpretation. Admittedly, Article 43(2) mentions 'the conditions laid down for its own nationals', referring to the host state, but this is 'included' within the idea of freedom of establishment, not determinative of it. For instance, with regard to the refusal under the Belgian social security scheme to reimburse the services of clinical biology laboratories whose members, partners or directors are not all natural persons[30] authorized to carry out medical analyses, the Court argued that equality of treatment was still respected and that 'each Member State is, in the absence of Community rules in this area, free to lay down rules for its own territory governing the activities of laboratories providing clinical biology services'.[31] The Court concluded that the refusal was not an infringement of Article 43 EC (formerly Article 52 EC) since the measures applied without distinction to Belgian nationals and those of other states and that 'the Belgian law does not prevent doctors or pharmacists who

[28] See, for example, Case C-55/94, *Gebhard* [1995] ECR I-4165, para. 25; Case C-70/95, *Sodemare* [1997] ECR I-3395, para. 24.

[29] Spaventa, 'From Gebhard to Carpenter', above n.25, 748.

[30] 'Natural persons' is a legal term meaning individual human beings, as opposed to 'legal persons', which are firms, companies and so on.

[31] Case 221/85, *Commission* v. *Belgium* [1987] ECR 719, para. 9.

are nationals of other Member States from establishing themselves in Belgium and operating there a laboratory to carry out clinical analyses qualifying for reimbursement under the social security system'.[32] Moreover, in the *Sodemare* case, which concerned a Luxembourg profit-making company that was denied permission to run elderly care homes through subsidiaries in Italy because Italian legislation reserved private participation in the state social welfare system only for non-profit operators, the Court adopted a similar reasoning.[33] Contrary to the Opinion of the Advocate-General, who argued that the Italian law was indirectly discriminatory,[34] the Court suggested that the fact that profit-making companies were automatically excluded from participating in the running of a statutory social welfare system could not be regarded as a breach of the principle of freedom of establishment, as this would not place profit-making companies from other Member States in a less favourable factual or legal situation to profit-making companies from the Member State in which they are established.[35]

However, the European Court of Justice has gradually broadened the application of Article 43 EC from covering only directly discriminatory rules towards covering rules that are only liable to create discrimination (indistinctly applicable or indirectly discriminatory measures), in particular through a series of cases linked to national legislation establishing a single-practice rule, preventing health professionals from maintaining their registration or practice in one Member State when trying to establish themselves in another Member State. According to the Court, such rules are not compatible with the principle of freedom of establishment, as they constitute a restriction that is liable to create discrimination against practitioners established in another Member State or to raise obstacles to accessing the profession that go beyond what is necessary to achieve the intended objectives.[36] The Court observed that single-practice rules were applied

[32] *Ibid*., para. 11. [33] Case C-70/95, *Sodemare*, above n.28.
[34] *Ibid*., Opinion of Advocate General Fennelly. [35] *Ibid*., paras. 33–4.
[36] Case C-96/85, *Commission* v. *France* [1986] ECR I-1475; Case C-351/90, *Commission* v. *Luxembourg* [1992] ECR I-3945. See also Case 107/83, *Klopp*, above n.21 (on the legal profession). V. G. Hatzopoulos, 'Killing national health and insurance systems but healing patients? The European market for health care services after the judgements of the ECJ in *Vanbraekel* and *Peerbooms*', *Common Market Law Review* 39 (2002), 683–729, at 703.

more severely to health professionals from other Member States and concluded that the measures were unduly restrictive.[37]

From 1993, the European Court of Justice progressively expanded the prohibition mentioned in Article 43 from (directly and indirectly) discriminatory rules to all 'national measures liable to hinder or make less attractive the exercise of fundamental freedoms guaranteed by the Treaty'[38] and made these measures subject to justification. In the landmark *Gebhard* case, a German lawyer, qualified as a '*Rechtsanwalt*' in Germany but working in Italy and using the title of '*avvocato*' without being registered with the local Italian bar, successfully argued before the Court that this registration requirement was an obstacle to freedom of establishment that needed justification.[39]

The impact on health care of the expansion of Article 43 towards *indistinctly applicable* measures is even more substantial than in the case of Article 49 EC. Whereas (health) service providers can challenge certain national regulatory measures as barriers to Article 49 EC because they essentially constitute a double regulatory burden, (health) service providers can now also lawfully rely upon Article 43 EC to challenge the very existence of regulatory measures, even if these measures lack any specific cross-border element.[40] This is particularly important for the field of health care, as it is characterized by a vast array of regulatory interventions, such as rules on professional behaviour, patient access, quality and effectiveness, taxation, and payments and pricing, etc., which do not specifically relate to cross-border situations.[41]

The measures that are subject to scrutiny under the principle of free movement not only include regulation directly governing access to a national health care services market; they also include regulation that governs the exercise of the health care activity itself.

[37] Case C-96/85, *Commission* v. *France*, above n.36, paras. 12–3; Case 351/90, *Commission* v. *Luxembourg*, above n.36, paras. 15 and 19.

[38] Case C-55/94, *Gebhard*, above n.28, para. 37.

[39] *Ibid*., para. 37. This was confirmed in two health care cases that concerned national regulatory measures reserving the exercise of certain medical activities for doctors: Case C-8/96, *Mac Quen* [2001] ECR I-837; and Case C-294/00, *Deutsche Paracelsus Schulen* v. *Gräbner* [2002] ECR I-6515.

[40] Spaventa, 'From Gebhard to Carpenter', above n.25, 749.

[41] This has also been analysed by Y. Jorens and M. Coucheir 'The European legal framework in relation to provider mobility', Europe for Patients Project, Deliverable to the European Commission, WP 2, unpublished (2005), p. 74.

In addition to the purely quantitative restrictions that limit the number of health care providers entitled to provide their services in a Member State's territory (for example, territorial planning rules restricting the number of health service providers (such as pharmacies) according to the number of inhabitants and the minimum distance between them, or quota systems limiting the number of health professionals working within the statutory health system),[42] qualitative measures that limit access to a certain activity and that can even result in restricting the number of service providers can also be targeted. These categories can cover a broad range of requirements, as illustrated in the list below, which includes examples from case-law and policy documents:

- ownership rules for clinics and pharmacies;[43]
- bans on operating more than one entity;[44]
- bans on enterprises active in the distribution of medicines (or having links with companies active in this area) acquiring holdings in private pharmaceutical companies or community pharmacies;[45]
- limits on the choice of legal form for clinics or pharmacies;[46]
- bans on opening a pharmacy in areas without a doctor's surgery;[47]
- refusals under a national social security scheme to reimburse services of clinical biology laboratories whose members, partners or directors are not all natural persons authorized to carry out medical analyses;[48]

[42] Case C-456/05, *Commission* v. *Germany* [2007] ECR I-10517.

[43] Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes and Others* (not yet reported) (prohibition of foreign ownership of pharmacies); Case C-531/06, *Commission* v. *Italy* (not yet reported) (national rules reserving the ownership of pharmacies for pharmacists or legal entities consisting of pharmacists).

[44] European Commission's reasoned opinions to Spain (No. 2001/5261) and Austria (No. 2004/4468). See European Commission, 'Internal market: infringement proceedings concerning Italy, Austria and Spain with regard to pharmacies', Press Release No. IP/06/858, 28 June 2006, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/858&format=HTML&aged=1&language=EN&guiLanguage=en.

[45] Case C-531/06, *Commission* v. *Italy*, above n.43.

[46] Case C-171/07 and C-172/07, *Apothekerkammer des Saarlandes*, above n.43.

[47] European Commission, 'Internal market', above n.44.

[48] Case C-221/85, *Commission* v. *Belgium* [1987] ECR 719.

- prohibitions on the enrolment in a professional register of any doctor or dental surgeon who is still enrolled or registered in another Member State;[49]
- national rules reserving the task of carrying out certain medical activities to a category of professionals holding specific qualifications, to the exclusion of health providers who are not qualified medical doctors;[50]
- requirements to obtain an authorization to set up a private outpatient clinic for dental medicine[51] or requirements to have a place of business within a national territory in order to obtain the requisite operational authorization and to work under the statutory health insurance system;[52] and
- rules on minimum staff levels.[53]

All of these elements remain subject to scrutiny under the EC Treaty provisions for as long as they are not replaced by any harmonizing, secondary EU-level rules, which would then become the only framework of judicial review,[54] as is the case, for instance, for minimum training requirements for service providers.[55]

In light of this broadened interpretation of what is to be considered an obstacle to free movement, the Court's earlier assessment of measures that were not seen as discriminatory is likely to be called into question again.

Indeed, this is what happened with the Court's judgment in the above-mentioned Belgian case regarding the refusal to reimburse for services provided by clinical biology laboratories whose members, partners or directors are not all natural persons authorized to carry

[49] Case C-96/85, *Commission* v. *France*, above n.36.
[50] Case C-108/96, *Mac Quen*, above n.39.
[51] Case C-169/07, *Hartlauer Handelsgesellschaft mbH* v. *Wiener Landesregierung and Oberösterreichische Landesregierung* (not yet reported).
[52] Case C-496/01, *Commission* v. *France*, above n.24.
[53] Article 15(2)(f), European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2006 No. L376/36. The original proposal of the European Commission also applied to health and health care services, see European Commission, 'Proposal for a Directive of the European Parliament and of the Council on services in the internal market', COM (2004) 2/3 final, 5 March 2004, Article 4(1), Juncto Recital 14.
[54] Case C-37/92, *Vanacker and Lesage* [1993] ECR I-4947, para. 9; Case C-324/99, *DaimlerChrysler* [2001] ECR I-9897, para. 32; Case C-322/01, *DocMorris* [2003] ECR I-14877, para. 64.
[55] See Chapter 14 in this volume.

out medical analyses. Where the Court initially did not consider this an infringement of Article 43 EC, since the measures applied without distinction to Belgian nationals and those of other states, fifteen years later the European Commission started to question very similar rules. On 18 July 2002, a formal request was sent inviting Belgium to modify certain provisions of the Royal Decree laying down conditions in relation to clinical analysis.[56] The Commission was of the opinion that Belgium imposed conditions that were too restrictive on medical laboratories in order to qualify for reimbursement by the sickness insurance scheme. Apart from the requirement that clinical laboratories had to be run by doctors, pharmacists or chemical science graduates, these conditions also included a ban on operators running more than one laboratory within a specific geographical area and a ban preventing operators from having links with other entities active in the medical profession. Belgium subsequently modified its national legislation. On 13 December 2006, in a reasoned opinion, the European Commission requested that France modify its legislation on ownership of biological analysis laboratories. According to the Commission, the legislation restricted non-biologists from owning a stake in a firm operating biological analysis laboratories and prohibited an individual or a legal entity from owning stakes in more than two firms set up to jointly operate one or more medical biological analysis laboratories, both of which were alleged to be incompatible with Article 43 EC.[57]

Moreover, the status of the *Sodemare* landmark ruling has become more uncertain today. In that judgment, the Court took for granted that a Member State, in exercising its power to organize its social security system, may indeed consider it necessary to achieve the exclusively social aims of the system by limiting the scope of contracting to non-profit-making private operators,[58] despite the obvious restrictive nature of this rule. This almost gives the impression that the Court considered activities performed within social welfare systems to be non-economic in nature, falling outside the scope of Treaty rules on free movement altogether. However, this position would contradict

[56] Royal Decree No. 143 of 30 December 1982.

[57] European Commission, 'Free movement of services: infringement proceedings against France', Press Release No. IP/06/1793, 13 December 2006.

[58] Case C-70/95, *Sodemare*, above n.28, paras. 31–2.

more recent judgments.[59] The Court has always recognized Member States' sovereign powers to organize their social security systems in the absence of harmonization at EU level, as long as these powers are exercised in compliance with EU law, in particular the provision on the freedom to provide services.[60] Within these terms, the logic acknowledges the existence of differences between national regulatory regimes and accepts that public intervention may be necessary to correct for certain market failures or to guarantee certain principles and values of general interest, such as social justice.[61]

Despite the political importance of the *Sodemare* judgement, confirming the power of Member States to make strategic and value-based choices in the context of their social protection system by distinguishing between certain types of providers of social welfare services, it is clear that today this delicate balance between Member States' regulatory autonomy in the field of national health systems and the application of free movement rules will have to be implemented in the context of finding a justification for impediments. Thus, the key question focuses on whether the specific measure impeding free movement is necessary to fulfil a public interest objective and whether it is proportionate. The accepted grounds of justification and the manner in which the necessity and Proportionality Tests apply to health care will be analysed further in the following section.

3. Justified and unjustified restrictions to free movement in health care

A. From 'non-discrimination' to 'justification'

From the analysis above, it follows that the threshold for the application of EC Treaty free movement rules on health services is relatively low. Although rules on free movement of services were originally considered to target discrimination against service providers by another

[59] Hatzopoulos, 'Killing national health', above n.36, 721.
[60] Case C-372/04, *Watts*, above n.13, para. 92.
[61] T. K. Hervey and J. V. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004), p. 46; K. Lenaerts and T. Heremans, 'Contours of a European social union in the case-law of the European Court of Justice', *European Constitutional Law Review* 2 (2006), 101–15, at 109–10.

Member State, the European Court of Justice's scrutiny now extends to measures that apply without distinction to domestic providers and providers from abroad. Consequently, almost any regulatory or institutional aspect of health care provision can be challenged as a potential obstacle to free movement.[62]

Despite the fact there is a low threshold for the application of free movement, the EC Treaty does not intend to create a completely deregulated internal market nor does it give health care providers unconditional access to a particular domestic health care market. Regarding both the freedom to provide services and the freedom of establishment, Member States are allowed to maintain barriers to free movement provided that they are justified in the public interest. The justification consists of a Necessity Test and a Proportionality Test. Along with the condition that the measure is applied in a non-discriminatory manner, Member States have to prove that it is objectively necessary for ensuring the attainment of a public interest objective (Necessity Test), and that it does not exceed what is necessary to attain the objective, nor that the same result can be achieved by a less restrictive rule (Proportionality Test).[63]

For service providers established in a Member State wishing to provide their services temporarily abroad, we highlighted in the previous section that the Court introduced the principle of mutual recognition. However, this mutual recognition principle, according to which the rules of the Member State of origin (home state) prevail, is applied in a conditional manner. It allows the Member State of destination (host state) to justify a national measure that constitutes a barrier to the freedom to provide services.[64] Hence, the main question related to Article 49 EC seems to be to what extent the host Member State will be entitled

[62] G. Davies, 'The process and side-effects of harmonisation of European welfare states', Jean Monnet Working Paper 02/06 (2006), www.jeanmonnetprogram.org/papers/06/060201.pdf.

[63] See cases on patient mobility: e.g., Case C-385/99, *Müller-Fauré*, above n.12, para. 68; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.12, para. 75. See also Case C-76/90, *Säger*, above n.23, paras. 15–7; Case C-275/92, *Customs and Excise Commissioners* v. *Schindler and Schindler* [1994] ECR I-1039. Compare with Case C-405/98, *Gourmet International* [2001] ECR I-1795 (mutual recognition also amounts to an obligation in the home state to recognize the right of a provider established in its territory to provide services in another Member State).

[64] See also C. Barnard and S. Deakin, 'Market access and regulatory competition', in C. Barnard and J. Scott (eds.), *The legal foundations of the single European*

to impose additional requirements on health providers who are already subject to regulation in their home state.[65] Similarly, for service providers wishing to move more permanently to another Member State, the Court also gradually subjected to justification the 'national measures liable to hinder or make less attractive the exercise' of their freedom of establishment. In the *Gebhard* case, mentioned above, the Court agreed that the registration requirement was an obstacle to the freedom of establishment that needed justification: 'they must be applied in a non-discriminatory manner; they must be justified by imperative requirements in the general interest, they must be suitable for securing the attainment of the objective which they pursue; and they must not go beyond what is necessary in order to attain it'.[66] This *Gebhard* formula was later confirmed in two health care cases, *Mac Quen*[67] and *Gräbner*,[68] which dealt with national provisions reserving the exercise of certain medical activities to physicians. In both cases, the restrictions were considered justified and necessary to protect public health. We will now have a closer look at the way justification can be obtained.

B. The Necessity Test: is regulatory intervention in the field of health care imperative for the protection of a higher public interest goal?

Under the Necessity Test, Member States will have to show that it is 'not reasonably practical' to adjust their regulatory arrangements in the field of health care to allow free movement of services and that these arrangements are genuinely necessary.[69] As shown by recent case-law, the Court is well aware of the potentially devastating effects of applying free movement rules to the detriment of public health

market (Oxford: Hart, 2002), p. 213: once a market access test is adopted, there is a presumption in favour of market access, which can be rebutted by the Member State demonstrating an overriding national or public interest.

[65] Spaventa, 'From Gebhard to Carpenter', above n.25, 748.

[66] Case C-55/94, *Gebhard*, above n.28, para. 37.

[67] Case C-108/96, *Mac Quen*, above n.39: Belgian national rules reserve the task of carrying out certain optical examinations to a category of professionals holding specific qualifications, such as ophthalmologists, to the exclusion of opticians who are not qualified medical doctors.

[68] Case C-294/00, *Deutsche Paracelsus Schulen* v. *Gräbner*, above n.39, concerning prohibition of the exercise of the activity of 'healer' by people not qualified as doctors. See above.

[69] Davies, 'The process and side-effects', above n.62, p. 28.

or the sustainability of national health systems and related social protection.

At the heart of the Necessity Test lies the identification of a public interest objective. First of all, there is a specific Treaty-based exception in Article 46(1) EC for regulatory arrangements that protect public health.[70] Even if this exception could not permit the exclusion of the health care sector as a whole from the scope of free movement,[71] the Court accepted within this derogation that Member States could restrict the freedom to provide medical and hospital services in so far as this was deemed necessary for the objectives of maintaining a balanced medical and hospital service open to all and a treatment facility or medical competence within a national territory that is essential for the public health and even the survival of the population.[72]

Apart from the Treaty-based exception of the protection of public health, the Court has adopted the concept of the 'rule of reason' to justify non-discriminatory measures that serve the public interest. However, these rule of reason justifications can only be used for indirectly discriminatory measures, and thus not for measures that are directly discriminatory on grounds of nationality. In this respect, the Court accepts a long list of public interest objectives that need to be safeguarded in health care, such as the risk of seriously undermining the financial balance of the social security system[73] or to prevent overcapacity in the supply of medical care. In doing so, the Court's case-law recognizes the Member States' need for health care planning.[74] With regard to hospital planning, for instance,[75] the Court recognized that:

> For one thing, such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the State concerned. For another thing, it assists in meeting a desire to control

[70] Article 46 EC applies equally to free establishment as to free provision of services (see Article 55 EC).

[71] Case C-158/96, *Kohll*, above n.7, para. 46.

[72] *Ibid*., paras. 50–1.

[73] *Ibid*., para. 41. The Court, however, recalls that aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services.

[74] Lenaerts and Heremans, 'Contours of a European social union', above n.61, 110. See also Davies, 'The process and side-effects', above n.62, p. 111.

[75] Hospital planning is said to cover 'the number of hospitals, their geographical distribution, the way in which they are organised and the

costs and to prevent, as far as possible, any wastage of financial, technical and human resources. Such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied.[76]

While it is established case-law that 'purely economic' reasons cannot justify restrictions,[77] it is clear that, nevertheless, the Court considers the financial impact of the exercise of the free movement right on a case-by-case basis, through the justification of any threat of financial imbalance to the social security system (mentioned above).[78] The concern over financial balance not only relates to the national systems that are funded through the collection of social security contributions. In certain Member States, the health care budget is not (or not entirely) financed by social security contributions, but partly (or even entirely) financed by tax income. Thus, it is useful to qualify the assessment of the threat of financial imbalance as an assessment of the impact on so-called 'macro-affordability', which means the affordability of the whole welfare system.[79]

Apart from identifying public interest objectives motivating any regulatory intervention that might obstruct free movement, Member States will also have to adopt strict reasoning as to why these measures

facilities with which they are provided, and even the nature of the medical services which they are able to offer'. See, *inter alia*, Case C-372/04, *Watts*, above n.13, para. 108; Case C-385/99, *Müller-Fauré*, above n.12, para. 77; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.12, para. 76.

[76] Case C-372/04, *Watts*, above n.13, para. 109; Case C-385/99, *Müller-Fauré*, above n.12, paras. 79–80; Case C-157/99, *Geraets-Smits and Peerbooms*, above n.12, paras. 78–9.

[77] Case C-398/95, *SETTG* [1997] ECR I-3091, para. 23; Case C-158/96, *Kohll*, above n.7, para. 41; Case C-385/99, *Müller-Fauré*, above n.12, para. 72.

[78] This overriding reason is directly linked to the justification of 'the need to preserve the cohesion of the tax system' as introduced by the European Court of Justice in the *Bachmann* case. Case C-204/90, *Bachmann* [1992] ECR I-249. See also Case C-300/90, *Commission* v. *Belgium* [1992] ECR I-305; V. G. Hatzopoulos, 'Do the rules on internal market affect national health care systems?', in M. McKee, E. Mossialos and R. Baeten (eds.), *The impact of EU laws on health care systems* (Brussels: PIE-Peter Lang, 2002), pp. 138–9.

[79] Lenaerts and Heremans, 'Contours of a European social union', above n.61, 110–1. See also Davies, 'The process and side-effects', above n.62, p. 30. Davies argues that the Court will only consider the financial impact if it is such that the stability of the entire domestic system is threatened.

are the only ones possible to ensure the public interest objective, with less restrictive measures being insufficient to attain the objective. This will be assessed through the Proportionality Test.

C. The Proportionality Test: does the obstruction of free movement go beyond what is necessary?

The core of the justification procedure lies not so much in the identification of a public interest objective as in the proof of the targeted measure's proportionality towards achieving it. Member States' ability to regulate health service providers from abroad operating in their territory – either temporarily or more permanently through an establishment – seems to become subject to a general proportionality requirement,[80] even if rules are also applicable without distinction to domestic care providers. Member States wishing to maintain obstacles to free movement as proportionate measures face a relatively high burden of proof. In addition, the Court requires that all the particular circumstances of an individual case be examined. Even if a rule, in general, is justified, this does not automatically mean that it is justified in each specific situation. This flexibility requirement is very demanding for regulation.[81] Even though the Court tends to leave a wide margin of discretion to the Member States to substantiate that national measures are not disproportionate to the 'public interest' objectives concerned, such as the protection of public health or the safeguarding of the balance of the social security system,[82] it will often be difficult for health regulators to provide evidence on the proportionality of the regulation in question.

[80] Jorens and Coucheir, 'European legal framework', above n.41, p. 5; Davies, 'The process and side-effects', above n.62, p. 33.

[81] Davies, 'The process and side-effects', above n.62, p. 29.

[82] See, for example, Spaventa, 'From Gebhard to Carpenter', above n.25, 764; and Y. Jorens, M. Coucheir and F. Van Overmeiren, 'Access to health care in an internal market: impact for statutory and complementary systems', *Bulletin Luxembourgeois des questions sociales* 18 (2005), 1–136, at 27. This conclusion is somewhat different in the case of harmonizing measures at EU level. See, for example, W. Sauter, 'Services of general economic interest (SGEI) and universal service obligations (USO) as an EU law framework for curative health care', TILEC Discussion Paper, DP 2007–029, Tilburg University, September 2007.

The Proportionality Test in the case of temporary provision of health care services

In cases where Member State rules target health care providers offering services temporarily in their territory, they have to take into account measures to which these providers are already subject in their home states. In order to lawfully maintain rules imposed on health care providers established in another Member State, the host state will have to provide – on a case-by-case basis – very good reasons to maintain a double regulatory burden. This means that the host Member State will have to demonstrate that the legislation of the Member State of establishment does not adequately protect the particular public interest objective.[83] The host Member State, for instance, will have to accept the quality standards and the quality checks performed in the Member State of establishment, provided that they guarantee equivalent protection. In the above-mentioned case where France required a business seat in France for biomedical analysis laboratories to obtain the necessary operating license and to be authorized to work under the French statutory health insurance, the Court concluded that it went beyond what is objectively necessary for the purpose of ensuring a high level of public health protection as required under Article 46 EC.[84] In response to the French Government's argument that the requirement allowed effective quality controls, the Court stated that the French authorities could instead require laboratories established in another Member State to prove that the controls carried out by the Member State in which they already have their place of business 'are no less strict than those applicable in France and monitor compliance with provisions which safeguard at least the same level of health protection as the French rules'.[85]

The argument that, in the absence of EU-level harmonization or bilateral agreements, it is impossible for inspectors from one Member State to carry out on-the-spot checks with health care providers in other Member States was also raised in cases dealing with patients who sought reimbursement for treatment abroad. In the *Stamatelaki* case, the Greek national social security system

[83] Jorens and Coucheir, 'European legal framework', above n.41, p. 56; Davies, 'The process and side-effects', above n.62, p. 28. See Case C-272/94, *Guiot* [1996] ECR I-1905.

[84] Case C-496/01, *Commission* v. *France*, above n.24, para. 92.

[85] Case C-496/01, *Commission* v. *France*, above n.24, para. 74.

excluded all reimbursement of hospital treatment to Greek citizens provided by a private hospital in another Member State (in this case, the United Kingdom), with the exception of children under fourteen. The Greek Government argued that the exclusion was justified, *inter alia*, by the fact that:

> Greek social security institutions do not check the quality of treatment provided in private hospitals in another Member State and verification as to whether hospitals with which an agreement has been entered into are able to provide appropriate – identical or equivalent – medical treatment [is lacking].[86]

The Court dismissed the argument by saying that private hospitals in other Member States are also subject to quality controls and that doctors established in those states who operate in those establishments provide professional guarantees equivalent to those of doctors established in Greece, by reference to EU-level legislation on mutual recognition of professional qualifications.[87]

The argument that restrictions are justified on the basis of the need to guarantee quality of health services as part of the protection of public health was already dismissed by the Court in the *Kohll* judgement, also referring to the EU-level framework concerning the mutual recognition of professional qualifications.[88] However, such an EU-level framework does not exist for quality standards and quality controls in hospitals. Nonetheless, the Court also applied the mutual recognition principle in the *Stamatelaki* case.[89] For the attainment of the 'protection of public health' objective, the Greek Government needed to rely upon checks by the Member State of the treating hospital. However, the imposition of mutual trust in the absence of minimum rules at EU level or bilateral agreements is not a self-evident solution. As a recent European study shows, there is a wide variation between and within Member States in the way and the extent to which they have implemented programmes to ensure quality of care. In particular, there is great diversity in the quality

[86] Case C-444/05, *Stamatelaki* [2007] ECR I-3185, para. 36.
[87] Such as European Parliament and Council Directive 2005/36/EC on the recognition of professional qualifications, OJ 2005 No. L255/22.
[88] Case C-158/96, *Kohll*, above n.7, para. 49.
[89] Case C-444/05, *Stamatelaki*, above n.86, paras. 36–7.

of clinical care.[90] In its proposal for a health services directive, the European Commission included a provision imposing on Member States the responsibility to ensure quality and safety standards of health care, to redress this gap in EU law and to ensure quality standards to patients seeking care abroad.[91]

Another important aspect of the Proportionality Test is to assess whether there are no other measures available to the host Member State that are less restrictive to the freedom to provide services. In the French case of biomedical analysis laboratories, the Court suggested a less restrictive alternative in proposing that France might impose its level of public health protection on laboratories established in another Member State but wishing to offer services to members of the national sickness insurance scheme through an authorization scheme rather than requiring an establishment in France.[92] Similarly, in the *Stamatelaki* case, the Court concluded that excluding reimbursement of any treatment in a foreign private hospital was a disproportionate measure, because less restrictive alternative measures were available, such as the implementation of a prior authorization scheme and, if appropriate, the determination of reimbursement scales for the cost of treatment.[93] Nevertheless, the Court seems to provide Member States with 'a clear means of restricting, or at least rationalizing, "exodus" from the national welfare system towards other Member States' facilities, through the use of a prior authorization procedure'.[94] In line with the Court's rulings in the cases on reimbursements of costs for medical treatment abroad, authorization procedures must, however, 'be based on objective, non-discriminatory criteria which are known in advance'.[95]

In assessing whether the host Member State should have relied upon a less restrictive measure in a particular case, the European Court of Justice often directly refers to the presence (or the absence) of a

[90] H. Legido-Quigley *et al.*, *Assuring the quality of health care in the European Union* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2008).

[91] 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, 2 July 2008.

[92] Case C-496/01, *Commission* v. *France*, above n.24, para. 93.

[93] Case C-444/05, *Stamatelaki*, above n.86, para. 35.

[94] V. Hatzopoulos and T. U. Do, 'The case law of the ECJ concerning the free provision of services: 2000–2005', *Common Market Law Review* 43 (2006), 923–991, at 941.

[95] See, for example, Case C-372/04, *Watts*, above n.13, para. 116.

particular EU-level framework. In the *Gräbner* case, which dealt with the exercise of a particular medical profession in a Member State's territory, the Court recognized that:

> [T]he decision of a Member State to restrict to a group of professionals with specific qualifications, such as qualified doctors, the right to carry out medical diagnoses and prescribe treatments for illness or to alleviate physical or mental disorders may be considered to be a suitable means of achieving the objective of safeguarding public health.[96]

Faced with the question of whether a Member State could then lawfully prohibit the exercise of a medical activity by those not qualified as doctors – *in casu*, 'healers' – the Court concluded that this did 'not go beyond what is necessary to achieve the aim of safeguarding public health',[97] despite the fact that it could be argued that a less restrictive measure existed to safeguard public health. Deutsche Paracelsus Schulen submitted that the Austrian authorities could have made the exercise of the profession of '*Heilpraktiker*' subject to a certain period of practice or to an examination (of the knowledge and aptitude of the applicant) similar to that provided for by the German legislation.[98] The Court particularly referred to the fact that there was no definition at the EU level of activities that are restricted to persons with a doctor's qualification. Even though it respected the host Member State's assessment of the public health risk linked to the performance of medical acts by people without a doctor's qualification, it stressed nonetheless that this assessment was liable to change over time due to progress made on knowledge of methods and their effects on health.[99]

The analysis of the Proportionality Test in the Court's case-law clearly shows that the mutual recognition principle is applied in a conditional manner. However, under its initial proposal for a services directive, the European Commission opted for automatic mutual recognition.[100] Service providers, including health care providers, would only be subject to the national provisions of their Member State of origin and this principle would apply to all requirements applicable to access to service activities as well to the exercise thereof, regardless

[96] Case C-294/00, *Deutsche Paracelsus Schulen*, above n.39, para. 43.
[97] *Ibid*., para. 50. [98] *Ibid*., para. 45. [99] *Ibid*., paras. 48–9.
[100] European Commission, 'Proposal for a Directive' above n.53, Article 16.

of whether they fall within an area harmonized at the EU level and regardless of the legal field to which they belong under national law.[101] At the same time, the European Commission included a detailed (limited) list of derogations to the country of origin principle for certain service activities and certain EU-level rules, including the ones on the recognition of professional qualifications.[102]

Even though mutual recognition, as proposed by the European Commission, certainly drew inspiration from the Court's case-law, it clearly went significantly further. Whereas, under the Court's case-law, host Member State rules are only side-stepped in so far as their application would give rise to unjustified restrictions to free movement, the Commission's proposal declared the mutual recognition principle to be unconditional, since it prevented the host Member State from continuing to rely upon restrictions to free movement that were not necessarily prohibited under EC Treaty rules. The European Commission introduced a specific procedure for Member States wishing to apply for an individual derogation to the country of origin principle on the basis of public order, public health and public safety. However, the Commission's list of grounds – referred to earlier – was more limited compared to the justification grounds recognized by the Court.[103]

The introduction of the country of origin principle not only caused a legal debate, it prompted many health policy stakeholders to declare that the general application of the country of origin principle was incompatible with the provision of health care, which, by its nature, required a high level of regulatory intervention from the Member State in which the health care is provided.[104] The controversy surrounding the impact of

[101] *Ibid*., Articles 16 and 4(9), Juncto Recital 21.
[102] *Ibid*., Articles 17 and 18.
[103] The fact that the Commission's proposal only provided very specific harmonized rules to ensure protection of the general interest – namely, in the field of information duties for service providers, professional insurance and guarantees, information on the existence of after-sale guarantees and settlement of disputes (*ibid*., Articles 26–8 and Article 32) – also created a certain legal tension between the Commission's proposal and the EC Treaty. As indicated above, a certain 'harmonizing' Community measure only replaces the relevant EC Treaty provisions as the only framework of judicial review provided that the Community rules deal with these aspects exhaustively.
[104] European Health Policy Forum, 'Recommendations on health services and the internal market', 26 May 2005, p. 15, http://ec.europa.eu/health/ph_overview/health_forum/docs/Recom_health_services.pdf.

the country of origin principle came to an end after health care services were excluded from the scope of the Services Directive in 2006.[105]

The Proportionality Test in cases of permanent establishment of health service providers

Instead of focusing on whether the host state has very good reasons to maintain a double regulatory burden, in cases of restrictions that are directed at health care providers operating in their territory through an establishment, the Proportionality Test focuses on whether the rule securing the attainment of the public interest objective is indeed a suitable measure for securing the attainment of a public interest objective or the least restrictive measure for free movement.

As explained above, the Proportionality Test came into play only gradually, starting with Court cases on the national single practice rules. These rules prevented health professionals from maintaining their registration or practice in a Member State when wanting to establish themselves in another Member State. Even though the Court considered that these measures were indirectly discriminatory, it also applied a modest Proportionality Test by concluding that these rules could also raise obstacles to access to the profession that go beyond what is necessary for achieving the intended objectives,[106] that they applied more severely to foreign health professionals and that, hence, they were unduly restrictive.[107] It was only after the adoption of the *Gebhard* ruling[108] and the requirement to also scrutinize measures that applied without distinction to providers from abroad that a full Proportionality Test became common ground in the scrutiny of regulatory measures under Article 43 EC. Given the fact that health service providers moving to another state and setting up an establishment there could now challenge rules for which a specific cross-border element is lacking, the burden of proof that Member States face in showing that measures are not disproportionate is increasing.

[105] Article 2(2)(f), European Parliament and Council Directive 2006/123/EC on services in the internal market, OJ 2007 No. L376/36–68.

[106] Case C-96/85, *Commission* v. *France*, above n.36; Case 351/90, *Commission* v. *Luxembourg*, above n.36. See also Case C-107/83, *Klopp*, above n.21; V. G. Hatzopoulos, 'Killing national health', above n.36, 703.

[107] Case C-96/85, *Commission* v. *France*, above n.36, paras. 12–3; Case C-351/90, *Commission* v. *Luxembourg*, above n.36, paras. 15 and 19.

[108] Case C-55/94, *Gebhard*, above n.28.

The justification process for national regulatory measures under Article 43 EC, even in the absence of a specific cross-border situation, bears a particular resemblance to the screening and mutual evaluation process in the much-discussed Services Directive. According to Article 15 of the Services Directive in particular, Member States have to screen their national legislation for the very existence of specific requirements that are deemed particularly restrictive for access to, and the exercise of, service activity and to verify whether these requirements are non-discriminatory, necessary and proportional. The list of these requirements includes quantitative and territorial restrictions, the obligation on a provider to take a specific legal form, price fixing mechanisms, requirements fixing a minimum amount of employees, requirements stipulating that an intermediary provider must allow access to certain specific services provided by other service-providers and an obligation on the provider to supply other specific services jointly with its service. Clearly, all these types of requirements play an important role in national and regional health policies, for example in planning facilities, setting tariffs, establishing care pathways, setting up referral systems and ensuring quality of care. Generally, Member States implement these requirements to safeguard accessibility, sustainability and quality of health care services and pharmacies in their territory. However, a systematic and pre-emptive screening of all regulation in health care was considered undesirable by many stakeholders, as it would lead to legal uncertainty; it could turn out to be difficult in some cases to sufficiently substantiate certain measures and therefore could disrupt the consistency of the health system as a whole.[109] This was one of the main reasons why the inclusion of health services in the original Commission proposal was contested and finally led to health care being excluded.

Despite the removal of health services from the scope of the Services Directive, national regulatory measures on health care nonetheless remain subject to scrutiny under Article 43 EC provided that they are brought before a court that applies Article 43 EC. This could be either a national court (which could refer to the European Court of Justice under the preliminary ruling procedure) or the European Court of Justice, in actions brought by the Commission against a Member State

[109] For instance, European Health Policy Forum, 'Recommendations', above n.104, pp. 14–5.

for failure to fulfil an obligation under the Treaty.[110] A clear example is *Commission* v. *Germany*,[111] where the implementation of a quota system based on the effective needs of care for psychotherapists wishing to practice under the German statutory sickness insurance scheme was declared to restrict the freedom of establishment. More particularly, the Court condemned the way transitional provisions in German law favoured psychotherapists who already had practised under the German statutory health insurance in a region of Germany in the past, as it failed to take into account comparable or similar professional experience in other Member States.[112] Even though in his Opinion the Advocate General considered the restriction to be justified and proportionate to objectives of public interest – namely, on the one hand, the protection of established rights and the legitimate expectations of the practitioners already working under the German statutory health insurance and, on the other, the prevention of overcapacity and safeguarding a uniform supply of psychotherapeutic care to statutorily insured persons in Germany[113] – the Court found that the German Government failed to prove that extending the transitional provisions to psychotherapists with comparable activity under the statutory system of other Member States during the reference period would have jeopardized these objectives.[114]

Regulatory intervention in the field of health care can also be found to be an unjustified obstacle to the freedom of establishment because the measures that it involves are not appropriate for ensuring the attainment of a particular public interest objective. In the *Hartlauer* judgement, which concerned the refusal of the *Wiener Landesregierung* and *Oberösterreichische Landesregierung* to authorize a company (Hartlauer) to set up and operate independent outpatient dental clinics, the Court clarified that this implies that the measure genuinely reflects a concern to attain that objective in a consistent and systematic manner.[115] According to the Austrian legislation, a prior authorization scheme based on an assessment of the needs of the market was required for setting up and operating independent outpatient dental

[110] Article 226 EC.
[111] C-456/05, *Commission* v. *Germany*, above n.42.
[112] *Ibid*., para. 54.
[113] *Ibid*., Opinion of Advocate General Mengozzi, para. 95–7.
[114] *Ibid*., para. 72.
[115] Case C-169/07, *Hartlauer Handelsgesellschaft*, above n.51, para. 55.

clinics, but not for setting up new group practices. Having clarified that group practices may have comparable features, generally offer the same medical services and are subject to the same market conditions, the Court concluded that the prior authorization scheme could not have consistently and systematically pursued the public interest objectives involved.[116] Moreover, the fact that each of the involved Austrian provinces applied different criteria for the assessment of the existence of a need for the services of the new outpatient dental clinic led the Court to believe that the authorization scheme was not based on a condition adequately circumscribing the exercise of the national authorities' discretion and therefore was not a suitable means for attaining these objectives. These judgments indicate that Member States may not have that much margin to justify territorial and quantitative restrictions relating to health care activities (hospitals, clinic laboratories, pharmacies, etc.) under Article 43 EC. Moreover, qualitative restrictions imposed on health care providers, especially clinical biology laboratories, pharmacies and opticians, have increasingly come to the attention of the European Commission and the Court. In an earlier Greek case, the Court held that the prohibition on qualified opticians from operating more than one optician's shop could be not be justified, since less restrictive measures such as 'requiring the presence of qualified, salaried opticians or associates in each optician's shop, rules concerning civil liability and rules requiring professional indemnity insurance' could equally achieve the objective of protecting public health.[117] The Court could apply the same reasoning in similar situations, such as the case of *DocMorris*, a joint-stock company based in the Netherlands, which was authorized by the German *Landesregierung* of Saarland to take over and operate an existing pharmacy in Saarbrücken, even though it contradicted the Federal Law on Pharmacies, which contains a limitation in terms of the legal form a pharmacy should take.[118] While the Advocate General – in his Opinion on the *DocMorris* case – developed the

[116] *Ibid*., paras. 58–63.

[117] C-140/03, *Commission* v. *Greece* [2005] ECR I-3177, para. 35.

[118] C. Lafontaine, 'National law on pharmacies and its non-application by a Member State's public authorities – *DocMorris* again leading the way to accomplish freedom of establishment', *Zeitschrift für Europarechtliche Studien* 9 (2006), 301–40, http://archiv.jura.uni-saarland.de/projekte/Bibliothek/text.php?id=432.

argument that there would not be fundamental differences between the sale of optical products in the Greek case, on the one hand, and the sale of medicines, on the other hand,[119] the Court did not share this reasoning and concluded that Germany had not exceeded the limits of its discretionary powers in the field of health care by prescribing that only a qualified pharmacist can possess and run a pharmacy.[120] The Court adopted the same reasoning in *Commission v Italy* concerning Italian legislation reserving the operation of pharmacies to qualified pharmacists.[121] The European Commission also launched a series of infringement procedures against various other Member States – Austria, Germany and Spain – regarding their national legislation governing pharmacies.[122] In particular, these cases question the lawful character of national restrictions relating to the opening and running of pharmacies, such as discriminatory provisions for the purposes of obtaining a licence to operate a pharmacy, rules on the ownership of pharmacies, territorial planning, rules limiting the choice of legal form for a pharmacy and limitations on the number of pharmacies in a location based on the number of inhabitants and the minimum distance between them.[123] This list of requirements bears a particular resemblance to the requirements included in a European Commission report in 2004, which identified a series of regulatory restrictions in the professional services, including pharmacies, which have the biggest potential to harm competition without being objectively justified.[124] Apart from price fixing and advertising regulations, the Commission also refers to entry requirements and reserved rights, regulations governing the business structure and multidisciplinary practices. Even though the report focused on the impact of EU

[119] See Opinion of Advocate-General Bot in Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes and others*, above n.43, paras. 61–9.

[120] Joined Cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes and others*, above n.43, para 60.

[121] C-531/06, *Commission v. Italy*, above n.43, para 90.

[122] Eubusiness, 'European Commission targets Germany over pharmacy rules', 2 February 2008, www.eubusiness.com/news-eu/1201871822.86/; and European Commission, 'Internal market: infringement proceedings concerning Italy, Austria and Spain with regard to pharmacies', Press Release No. IP/06/858, 28 June 2006.

[123] European Commission, 'Internal market', above n.122.

[124] European Commission, 'Report on competition in professional services', COM (2004) 83 final, 9 February 2004. Medical professions are not covered by this report.

competition rules on professional regulations, it is clear that these requirements also can be considered to be obstacles to the freedom of establishment and that national governments are increasingly likely to be invited to provide sufficient justification for maintaining these requirements in the public interest.

4. Health care and free movement: the policy challenge

A. National actors and the call for more legal certainty

Member States, health care regulators, public authorities and concerned stakeholder groups only became aware of what is at stake in a piecemeal way.[125] Indeed, to date, most of the Court's jurisprudence has addressed the issue of statutory reimbursement of health care provided in another Member State, which in itself is only a limited phenomenon with low financial impact. Although extensive case-law has clarified the scope of Member States regulatory capacity in the case of patient mobility,[126] recent infringement procedures and pending cases address other regulatory aspects, triggered by health service providers wishing to move to other Member States to offer their services there. In fact, sometimes these complaints filed with the European Commission are instigated by domestic competitors challenging measures that limit their freedom in the market. Increasingly, internal market rules have been discovered as a useful political argument to criticize the rigidity of health care systems and to argue in favour of market-oriented reforms, enhancing free choice and opening new markets. Commercial interest groups, including international hospital chains and pharmaceutical manufacturers and wholesalers supported by free market think tanks, are using free movement as an effective tool to foster for-profit activities in the health sector. Health care systems and their governing bodies thus will increasingly

[125] As expressed by Davies: 'precisely because obedience to the law is relatively low or at least often delayed, it becomes possible to sneak surprisingly radical principles into the case-law. By the time Member States realize their implications – because national authorities are at last beginning to apply them, or the ECJ is using them more often and widely – they have been around long enough to seem established.' Davies, 'The process and side-effects', above n.62, p. 13.

[126] See Chapter 12 in this volume.

be challenged by external actors.[127] Member States' policies allowing more room for commercial providers can inadvertently spill over into other systems.

Member States have come a long way in acknowledging the applicability of related case-law to their respective health systems and to grasp its wider potential impact. The diversity of national health systems also means that free movement provisions affect Member States in very different ways. In addition, differences in the political composition of governments and in national approaches to the role of commercial actors in health care systems also lead to different positions. While some Member States have openly and proactively addressed the question of the EU-compatibility of their health systems and reforms, others have tended to disregard potential incompatibilities between their regulation and internal market rules, trying to 'hide' their legislation from EU institutions.[128] Within governments, the concerns of health ministers are not always shared either by their colleagues of other departments (such as economic affairs). Some policy departments, striving for increased economic growth, are in favour of supporting the export of health services. Such policies can be pushed by actors in the domestic health system hoping to benefit from increased mobility. As a result, Member States, even if they all seem to voice a similar concern, do not necessary have the same motives when dealing with patient mobility and health care issues at the EU level.

There seems to be at least a shared concern among Member States' health sector authorities and policy-makers that the internal market rules may have adverse effects on the basic objectives of their systems. This is also why, in June 2006, the EU health ministers issued a common statement to emphasize the need to protect the values and principles that underpin the health systems of the EU and to ensure that EU integration supports these values and contributes to the important challenges that lie ahead in reconciling individual needs with available finances.[129] These concerns, which have also been voiced by social and professional organizations involved in health care, centre around

[127] M. Ferrera, *The boundaries of welfare: European integration and the new spatial politics of social protection* (Oxford: Oxford University Press, 2005), p. 49.

[128] *Ibid*., p. 157.

[129] Conclusions of the Health Council, 26 June 2002, http://ec.europa.eu/health/ph_overview/Documents/mobility_council_ccl_En.pdf; Council of

the impact of free movement provisions on the social character of national health care systems, their internal cohesion and the steering capacity of public authorities. However, Member States seem less able to substantiate the concrete impact of internal market rules. To illustrate this, in their replies to the 2006 Commission consultation on cross-border care,[130] only a few Member States went beyond the issue of patient mobility to point to the deregulating effect of provisions on free movement of services.[131]

Although the Court's case-law allows for striking a balance between free movement, on the one hand, and the protection of public interest objectives, on the other, it does not provide legal certainty. It ultimately depends on the particular circumstances of each case whether a restrictive measure is actually considered necessary and reasonable under EC Treaty rules on free movement. Although political reactions after the first Court rulings focused on the conditions for reimbursing care abroad and on the necessary preconditions to allow more flexible patient mobility, the concern about the potential loss of steering capacity for health sector authorities and the call for legal certainty, not only for patients, but also for public authorities, was present from the outset.[132]

However, when it comes to determining action to address these concerns, Member States are less clear as to the kind of policy instruments to be applied. Traditionally, they are extremely reluctant to allow any intrusion on their national autonomy and try to shelter their systems from EU interference. Even if the creeping pressure from EU law made them hesitantly engage in a debate at the EU level on finding a common policy response, the Member States seem to be caught in the paradox that, in order to safeguard their steering capacity and autonomy in this domain, they would have to accept some EU interference in their

the European Union, 'Council Conclusions on common values and principles in EU health systems', 2733rd Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 1–2 June 2006, www.eu2006.at/en/News/Council_Conclusions/0106HealthSystems.pdf.

[130] http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm#2.

[131] These include Portugal, Luxemburg, Germany and Belgium, as well as, to some extent, France and Norway.

[132] See, for example, W. Palm *et al.*, 'Implications of recent jurisprudence on the coordination of healthcare protection systems', General report produced for the Directorate-General for Employment and Social Affairs of the European Commission (2000).

health care systems. Any EU legislative proposal will indeed entail the sharing of some powers over health care systems between the national and the EU levels. This explains why Member States, which are in principle in favour of an EU-level legislative initiative, tend to become reluctant once concrete proposals have to be discussed.

Spurred by the 'threat' of an all-encompassing screening exercise, as proposed by the Services Directive, Member States have shown some willingness to engage in the pragmatic approach of the High Level Group on Health Services and Medical Care (see below). After actively pushing for the exclusion of health services from the scope of the Services Directive, the Member States also accepted the alternative of a more adapted health services directive, which – as expressed under the German Presidency in 2007 – sought to provide a broad framework, not limited to patient mobility.[133] This position, to some extent, was inspired by an informal grouping of social democrat health ministers, involving influential Member States such as the United Kingdom, Germany and Spain.[134] This group suggested that a sector-specific directive could describe the common values and principles underpinning European health systems, outline their objectives, define the different types of instruments public authorities use to properly manage their systems (such as planning, tariff setting mechanisms, authorization schemes for providers, etc.) and identify the conditions under which the use of these instruments would be in conformity with Treaty provisions.[135] The ideas of the 'Aachen group' were presented at an informal Health Council meeting in 2006 and Belgium attached this position in a 'non-paper' to its reply on the Commission consultation.[136]

[133] Council of the European Union 'Health care across Europe – Community framework for health services, exchange of views / adoption of Council conclusions', Doc. No. 9540/07, 16 May 2007, http://register.consilium.europa.eu/pdf/en/07/st09/st09540.en07.pdf.

[134] The so-called 'Aachen group', named after the place they first met. The composition of this group varies over time, depending on the composition of the respective governments. Ministers that participated in the group during the elaboration of these proposals include: the United Kingdom, Germany, Luxemburg, Belgium, Portugal and, at some times during the process, Sweden, Italy and Spain.

[135] Non-paper presented at the Informal Council Meeting of the Employment, Social and Health Ministers, Helsinki, 6–8 July 2006.

[136] http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm#2.

B. Searching for policy responses at the EU level

Despite the growing awareness of the need to provide a more consistent and political solution to the problems created by the application of free movement rules to the health sector, and the pressure created by new judgments and infringement procedures, it has proven difficult to find an adequate policy response to the developments described in this chapter. Member States' differing opinions and hesitant positions, as well as the complexity of the issues at stake, the lack of a clear legal basis in the Treaty to deal with these issues and an inherent inertia towards any fundamental changes to the rules of the game, certainly play an important role. But it is also true that not all of the stakeholders involved have the same concerns and objectives.

Since 2002, several policy initiatives have been taken at the EU level in an attempt to clear the legal uncertainty and to alleviate the pressure on the regulatory powers of health authorities. Various processes have been led by different Directorates-General in the European Commission, reflecting different approaches and objectives. However, it seems that, so far, none of these policy processes has succeeded in providing adequate answers to the issues at stake.

The horizontal (internal market) approach

As the guardian of the EC Treaty and instigator of Community legislation, the European Commission is one of the most important drivers in ensuring that territorial, quantitative and qualitative requirements in the field of health care are not too restrictive in the context of free movement principles. Health services are explicitly mentioned in a Communication on the internal market as 'a new emerging sector where the benefits of the internal market have to be made tangible'.[137] More specifically, the Directorate-General for the Internal Market and Services (DG MARKT), whose central mission is to secure for the benefit of the EU's citizens and businesses ever greater European market integration, monitors Member States' compliance with EU rules on free movement. This DG is inclined to deal with health services in the

[137] European Commission, 'Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on a single market for citizens. Interim report to the 2007 Spring European Council', COM (2007) 60 final, 21 February 2007.

same way as other economic services. It is used to being confronted, in all economic sectors, by Member States and other actors trying to justify specific rules and approaches that are considered (by DG MARKT) to be protectionist and to hinder free movement. The DG is suspicious of any initiative that attempts to emphasize the specificities of health care services in their relation to free movement provisions or to define health care as a service of general interest. Moreover, it lacks structural links with the public authorities responsible for funding and organizing health care systems.

One way for DG MARKT to further a single market in services is the possibility of launching infringement procedures against Member States to force them to remove obstacles to the free movement of services and the freedom of establishment. The Commission could also take initiatives that go beyond infringement procedures in order to ensure the application of free movement rules in particular fields. This was suggested, for instance, in a recent study on regulatory restrictions on pharmacies.[138] This study suggests that reducing these barriers would not only enhance productivity in the EU but also lead to substantial social welfare increases, after which it concludes: '[t]here seems to be a need for further policy aimed at removing obstacles to the freedom of establishment in the field of pharmacy services'.[139] In addition, in its report of July 2003 on the application of internal market rules to health services, DG MARKT concluded that the internal market in health services was not functioning satisfactorily and that different tools were being considered to ensure Member States' compliance with the Court's rulings, including the SOLVIT network[140] and the creation of an EU-level legal framework.[141]

Although launching infringement procedures are indeed a powerful tool to remove obstacles to free movement, at the same time it has its weaknesses and limitations, as it operates very slowly and in a piecemeal

[138] Ecorys Nederland BV, 'Study of regulatory restrictions in the field of pharmacies', Report commissioned by the European Commission, DG Internal Market and Services, 22 June 2007, http://ec.europa.eu/internal_market/services/docs/pharmacy/report_En.pdf.

[139] *Ibid*., p. 83.

[140] SOLVIT is a network linking the national administrations of every Member State. Its task is to find rapid solutions to problems arising from the application by Member States of the rules governing the internal market.

[141] European Commission, 'Report on the application of internal market rules to health services. Implementation by the Member States of the Court's

fashion. This is also why, in January 2004, the Commission adopted a proposal for a directive on services in the internal market. This 'horizontal' directive, applying to all services falling under the scope of Articles 43 and 49 EC, was to implement free provision of services and free establishment in a more systematic manner. The inclusion of health services in its scope was mainly motivated by the fact that it would be a means of codifying the Court's jurisprudence on statutory reimbursement of cross-border health care. However, the Commission's proposal also illustrated in a very clear way how the impact of the free movement provisions on health care systems went far beyond the issue of patient mobility. Even if, after two years of fierce policy debate, health care services were finally excluded from the eventual Directive 2006/123/EC,[142] this did not eliminate the applicability of the Treaty's free movement rules to health services. The European Commission, as guardian of the Treaty, thus keeps on targeting restrictions imposed by particular Member States that are deemed to be unjustified barriers.[143] It could even be claimed that since health services were excluded from the Services Directive, the Commission has stepped up its infringement activity.

The sectoral (health systems) approach

While the purely internal market approach failed, another more pragmatic approach was simultaneously pursued. Already, in 2003, at the request of the Council,[144] a 'High Level Process of Reflection on Patient Mobility and Health Care Developments in the European Union' was set up by the European Commission. This informal process was composed of health ministers from most EU15[145] Member States (later extended to the new candidate Member States), some European stakeholder organizations and a representative from the European Parliament, and was chaired by the three EU Commissioners responsible for the internal market, health and social affairs. Its goal was to step up cooperation among Member States in the field of health care with a view to making better use of resources, improve sharing of

jurisprudence', Commission Staff Working Paper, SEC (2003) 900, 28 July 2003.

142 Directive 2006/123/EC, above n.2.

143 See section 3 above.

144 Conclusions of the Health Council, 26 June 2002, http://ec.europa.eu/health/ph_overview/Documents/mobility_council_ccl_En.pdf.

145 States belonging to the EU before May 2004.

information, accessibility and quality, as well as to enhance legal certainty over the application of internal market rules to health care.

This broad and consensual approach was much promoted by the Directorate-General for Health and Consumer Protection (DG SANCO), whose powers are intrinsically linked with Article 152 EC, allowing EU action to complement national policies and to encourage cooperation among Member States, provided that the responsibility of Member States to organize and deliver health services and medical care is respected. DG SANCO can be considered to be the EU counterpart of national health ministries and is thus more aware of their concerns about the impact of free movement rules. Given its responsibility with regard to consumer protection, it is also more inclined to look after the interests of the health care 'consumer' than the health care provider. Therefore, its approach is broader than just removing obstacles to free movement, and extends to ensuring that free movement can take place under conditions that are optimal for patients.

After the High Level Process – and as one of its outcomes – a High Level Group on Health Services and Medical Care (HLG) was created, with the aim of taking forward the recommendations to support European cooperation in the field of health care and to monitor the impact of the EU on health care systems. This Group, consisting of senior officials of EU Member States and chaired by the European Commission, looked for pragmatic solutions to a range of specific issues, such as defining common guidelines for cross-border contracting, establishing better information sharing on health professionals and patient safety issues, and defining the role and criteria for European reference centres. One of the subgroups developed a methodology and practical tool for systematically assessing the impact of EU policy and legislative initiatives in various fields on health systems.[146]

Although the objectives of the High Level Process also included finding ways to reconcile national health policy with European obligations, the final report did not introduce concrete proposals, but instead enumerated a full range of possible governance instruments, ranging from 'changing the Treaty' to 'initiatives by Member States

[146] http://ec.europa.eu/health/ph_overview/co_operation/high_level/index_En.htm.

and bilateral cooperation'.[147] It was suggested that these options could be considered in more depth once the final text of the then Constitutional Treaty was approved, in the context of which the option of a new legal basis to legislate on services of general interest, including health services, was discussed. Besides the creation of the High Level Group as a 'permanent monitoring mechanism', the only other concrete element was the integration of health care into the draft Services Directive, which was adopted only a few weeks after the High Level Process ended, and which was later presented by the Commission as one of the outcomes of this Process, although it was never presented there nor discussed.[148]

When the purely internal market approach of DG MARKT crash-landed with the removal of health care services from the Services Directive, DG SANCO took over to lead the process to develop a separate initiative in the area of health.[149] It started by organizing a broad consultation to find out what the sector's expectations were and what a 'more adapted' proposal should look like. However, from the start, it was clear that DG SANCO aimed for a broader 'Community framework for safe, high quality and efficient health services … reinforcing cooperation between Member States and providing certainty over the application of Community law to health services and healthcare'.[150]

While it is not the intention of the Commission to encourage citizens to look for care in another Member State, it seeks to ensure that, if they do, they can be confident about the care they receive and are sufficiently informed about their rights. Next to clarifying the entitlements of citizens to statutory cover for health services provided in another Member State, this proposal for a new directive on the application of patients' rights in cross-border health care also

[147] European Commission, 'High Level Process on Patient Mobility and Healthcare Developments in the European Union, outcome of the reflection process', HLPR/2003/16, 9 December 2003, http://europa.eu.int/comm/health/ph_overview/Documents/key01_mobility_En.pdf.

[148] European Commission, 'Follow-up to the High Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union', COM (2004) 301 final, 20 April 2004.

[149] European Commission, 'Amended Proposal for a Directive of the European Parliament and of the Council on services in the internal market', COM (2006) 160 final, 4 April 2006.

[150] European Commission, 'Consultation regarding Community action on health services', SEC (2006) 1195/4, 26 September 2006, p. 2.

addresses the question of what Member States should be responsible for in cross-border care – namely, to secure common principles, such as ensuring quality and safety standards, information, redress and liability, as well as privacy protection against unlawful processing of personal health data. Finally, the proposal sets a basis for cooperation between Member States on a range of aspects that would facilitate cross-border health care.[151]

While the consultation received a high level of response and was followed by a comprehensive impact and feasibility assessment,[152] the formal adoption of the proposal by the College of Commissioners was repeatedly postponed. This delay seems to reflect important disagreements within the Commission, also fuelled by the fear that any new dissonance might jeopardize the ratification process of the Lisbon Treaty or the reinstatement of the next EU Commission in 2009.

Despite the ambitious plans to develop an amended proposal that would include all dimensions of cross-border health care (patient mobility, provider mobility, service mobility) and that would 'also contribute to the wider challenges facing health systems, beyond the specific case of cross-border healthcare itself', the proposal mainly focuses on cross-border patient rights. The proposal does not provide any of the much needed legal certainty regarding how national health authorities can ensure the common values of their health systems, such as universality, equity and solidarity, without infringing free movement rules.

The generic (social services of general interest) approach

As it seems that neither the horizontal nor the sectoral approach can produce the required guidance on how to strike a balance between free movement principles and Member States' regulatory intervention in health care, final rescue perhaps may come from another DG, the Directorate-General for Employment, Social Affairs and Equal Opportunities (DG Social Affairs). This DG, whose mission it is to

[151] European Commission, 'Proposal for a Directive', above n.91. See also Chapter 12 in this volume.

[152] W. Palm, M. Wismar and K. Ernst, 'Assessing possible directions for the Community action on healthcare services: summary of the expert panels', in M. Wismar *et al.* (eds.), *Cross-border healthcare: mapping and analysing health systems diversity* (Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2009).

contribute to the development of a modern, innovative and sustainable European Social Model, has traditionally played a leading role in the debate on the social dimension of the internal market. While, for more than forty years, through the EU regulatory framework on the coordination of social security systems for persons moving within the Community,[153] it was the uncontested guardian of EU citizens' access to health care outside the state of affiliation, its role has been increasingly challenged by Court rulings on patient mobility. After it failed to integrate the ambit of the rulings fully within the scope of the modernization process of EC Regulation 1408/71/EEC, DG Social Affairs only played a secondary role in the political process of dealing with the concrete consequences of the Court's case-law. However, when it comes to addressing the wider implications of applying internal market rules to health care, it could claim back its central role through its work in developing a generic framework for social services of general interest.

Health services are indeed also part of a broader framework of services of general interest, particularly social services of general interest (SSGI).[154] The concept of services of general economic interest refers to Article 86(2) EC, according to which service providers entrusted with a mission of general interest and engaging in economic activities can be partly or even completely exempt from competition rules if these rules are liable to hinder or render the task assigned to these providers impossible. Since EU competition rules pose very similar challenges to the organization and financing of national health care systems to those challenges posed by free movement rules, the concept of services of general economic interest seems to be a valuable opportunity in the search for an appropriate EU legal framework.

In its 2004 White Paper on services of general interest, the European Commission stressed that the personal nature of many social and health services leads to requirements that are significantly different from those in networked industries.[155] It favoured a 'systematic approach

[153] Council Regulation 1408/71/EEC on the application of social security schemes to employed persons and their families moving within the Community OJ 1971 No. L149/2; Council Regulation 574/72/EEC fixing the procedure for implementing Regulation 1408/71/EEC on the coordination of social security schemes for persons moving within the Community OJ 1972 No. L74/1. See also Chapter 12 in this volume.

[154] See Chapter 7 in this volume.

[155] European Commission, 'Services of general interest', White Paper, COM (2004) 374 final, 12 May 2004.

in order to identify and recognise the specific characteristics of social and health services of general interest and to clarify the framework in which they operate and can be modernised' and announced a Communication on SSGI, including health services.[156] Even though the publication of this Communication, due in 2005, was postponed to await the outcome of the debate on the Services Directive, after the exclusion of health services from that Directive, the Commission also excluded them from the scope of this Communication, claiming that a specific initiative would be taken in this area, which would also cover this wider aspect.[157] Even if the European Parliament, in its first reading of the Services Directive, had advised separately that both health and social services should be excluded from the scope of the Directive, there was no real reason to lift health services out of the Communication. Although the Communication outlined the characteristics of SSGI and described specific problems they could encounter, these problems would definitely also apply to health, and in some instances, direct reference was made to health care.[158]

In spite of the fact that the issues at stake are nearly identical for both sectors, the distinction between these two policy processes is also confirmed in the Commission's most recent Communication on services of general interest, including SSGI, which was attached to its 2007 Communication on 'a single market for the 21st century'.[159] While this Communication does not really provide new elements, it mainly encourages Member States to endow services of general

[156] Member States contributed to the preparation of this Communication by reporting on the situation of social and health services in their countries through a questionnaire prepared in the Social Protection Committee (SPC), 'Social Services of General Interest', Questionnaire, http://ec.europa.eu/employment_social/social_protection/docs/questionnaire_En.pdf, and Member States that replied to the SSGI questionnaire, http://ec.europa.eu/employment_social/social_protection/answers_En.htm.

[157] See R. Baeten, 'Health and social services in the internal market', in C. Degryse and P. Pochet (eds.), *Social developments in the European Union 2006* (Brussels: ETUI-REHS, Observatoire social européen and Saltsa, 2007), pp. 161–85.

[158] European Commission, 'Communication from the Commission, implementing the Community Lisbon programme: social services of general interest in the European Union', COM (2006) 177 final, 26 April 2006.

[159] European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, accompanying the

interest with a clear mandate through official legislation and provides a further explanation on the applicable rules. The document leaves few hopes for securing the long-debated specific legislative framework for services of general interest (SGI), arguing that the Lisbon Treaty includes a protocol on services of general interest.[160] Instead, it opts for a pragmatic approach and intends to provide concrete solutions to concrete problems. One such solution was the launch of a web site providing information and answers to frequently asked questions on the application of EU law on SGI.[161] The first two working documents deal with the rules on state aid and on public procurement with regard to SSGI.[162] Strikingly, these documents do explicitly deal with health care services.[163]

In conclusion, even if it remains unclear as to whether the Commission intends to approach health services as services of general interest,[164] some may interpret the fact that the proposal for a new directive on health services is integrated into the new social agenda as an indication that the different processes in the future may at least become better aligned or even integrated.

5. Conclusions

This chapter focused on the impact of the fundamental principles of free provision of services and free establishment of service providers

Communication on "a single market for 21st century Europe", services of general interest, including social services of general interest: a new European commitment', COM (2007) 725 final, 20 November 2007.

[160] See Chapter 7 in this volume.

[161] http://ec.europa.eu/services_general_interest/index_en.htm.

[162] European Commssion, 'Frequently asked questions in relation with Commission Decision of 28 November 2005 on the application of Article 86(2) of the EC Treaty to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest, and of the Community Framework for State aid in the form of public service compensation', Commission Staff Working Document, SEC (2007) 1516, 20 November 2007; and European Commission, 'Frequently asked questions concerning the application of public procurement rules to social services of general interest', Commission Staff Working Document, SEC (2007) 1514, 20 November 2007. For discussion of these documents, see Chapter 9 in this volume.

[163] See Chapter 9 in this volume.

[164] The Commission's legislative proposal on patients' rights only contains a general statement that health systems are also part of the wider framework

on health systems, as enshrined in Articles 49–50 EC and Article 43 of the EC Treaty. Besides the fact that all health systems are based on a common set of values and objectives – as was explicitly confirmed by health ministers in their statement of June 2006[165] – they also share the common feature of requiring a high degree of regulation to implement these underpinning values and to organize health care that is safe, high quality and cost-effective for the whole population. However, public intervention in health care increasingly faces challenges from an EU perspective. While the European Court of Justice and the European Commission act as guardians over compliance with EC Treaty rules and are driven by the need to preserve non-discrimination, free movement and choice, Member States, as well as other actors involved in the health sector, are more concerned about the potential crippling effect on their steering capacity over publicly-run health systems.

In fact, the threshold for the application of rules on the free movement of services is relatively low. From the moment it is established that health care is an economic activity provided for remuneration, irrespective of whether it is funded publicly, any national measure that would deter or even prevent health care providers from offering their services, temporarily or more permanently, in another Member State – or, inversely, citizens from applying to these providers – would formally constitute an obstacle to free movement. In the case of providers temporarily providing services in another Member State, the fact that they would face a double regulatory burden is already likely to hinder free movement. Based on the principle of mutual recognition, Member States are invited to rely on each others' regulation and assessment to accept providers entering the market. But, even more so in the context of ensuring free establishment of providers, virtually any regulatory or institutional aspect that health care providers have to comply with to operate in the territory of a Member State or to work under its statutory health insurance could be challenged, even if at first sight it would not be linked to cross-border situations. This can range from measures restricting the quantity of providers according to population size or catchment area, rules establishing norms

of services of general interest. See European Commission, 'Proposal for a Directive', above n.91, Recital 4.

[165] Conclusions of the Health Council, above n.129.

on staff levels, pricing and quality, to more qualitative restrictions, such as rules on professional conduct and qualification, ownership, or legal form. All of these rules include both individual health professionals and health care facilities such as hospitals, pharmacies and clinical laboratories, even if for the latter no specific EU framework for mutual recognition of qualifications and quality standards exists.

However, the application of free movement rules in the field of health care is not unconditional. The EC Treaty provides the possibility to justify any measure hindering free movement if it proves to be necessary for protecting public health or another public interest objective, such as the health system's financial sustainability. In several instances, the European Court of Justice has recognized the need for Member States to regulate health services and providers in order to preserve the public interest. As demonstrated in this chapter, the core of the justification does not lie so much in the so-called 'necessity' test, identifying the public interest objective and proving that the targeted measure is necessary to preserve it, but rather in the 'proportionality' test, proving that the measure is an appropriate means for attaining the public interest objective, that it does not exceed what is necessary to attain this objective and that it cannot be achieved by a less restrictive measure. Member States face a relatively high burden of proof, as they need to provide sufficient evidence showing that the non-application of a restrictive measure in a particular case would jeopardize the public interest objective. Not only is it difficult to demonstrate what would happen without the measure, this leaves little room to consider the measure in its wider context and assess its coherence within the broader regulatory framework, taking into account the role of public payers and purchasers.

For this reason, the introduction of a mutual evaluation process, as proposed in Article 15 of the Services Directive, to systematically screen national regulation of health services for unjustified barriers to free movement of health services was deemed particularly risky and undermining for health systems' governance. Such a measure could lead to undesirable deregulation and force Member States to dramatically adjust the organization of their health care system, even partly retreating from it.

Being aware of this problem, policy-makers have been looking for ways to reconcile the individual right to free movement with the public objective of running an efficient health system, guaranteeing

citizens equal access to health care that is affordable, safe and of high quality, and that produces the best value for money. While Member States seem to be caught in the paradox that, in order to safeguard their steering capacity and autonomy, they would have to accept some EU interference in their health care systems, the European Commission seems neither willing nor able to provide guidance, as it is torn between different currents, reflecting the different objectives and responsibilities of the respective Directorates-General. After the backlash on the inclusion of health care in the Services Directive, the Commission announced a new, flexible proposal for health services. While the adoption of this proposal has been delayed because of internal division within the College of Commissioners and the fear that a renewed uprising would be detrimental at a critical time (the ratification of the Lisbon Treaty and the ending of terms for both the European Commission and Parliament), the new proposal seems to essentially focus on establishing a framework for patients using cross-border care[166] and tries to carefully sidestep the more delicate question of clarifying the impact of EU rules on free movement on health systems at large.

Despite the fact that the Court has indeed demonstrated its awareness of important market failures occurring in health care and has accepted the need to regulate health services, a more consistent and less piecemeal solution is still needed, providing more certainty to health policy-makers. This could be done by making explicit what measures can be upheld, establishing a broader justification test or even reversing the burden of proof. Given the similar problems related to the concept of services of general economic interest under Article 86(2) EC, a combined approach for health care should be considered.

[166] See also Chapters 9 and 12 in this volume.