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Document summary
This paper provides a discussion of the Commission's July 2008 proposal for a Directive on the application of patients' rights in cross-border healthcare (the proposed patient mobility Directive). It does so against the background of an overview of the preceding patient mobility case law of the European Court of Justice that is based on the freedom to provide services of Article 49 EC, from *Kohll* and *Decker* in 1998 to *Watts* in 2006. The findings are that the proposed patient mobility Directive is not a full codification of the case law as it leaves out certain guarantees developed by the Court, while it adds some new elements of harmonisation. The Court had in principle accepted public interest justifications for prior authorisation requirements with respect to hospital treatment and focused on developing substantive and procedural guarantees of patients' rights such as the criteria for "undue delay", in which case authorization for treatment abroad must be granted.

The Commission takes a different approach, by both requiring Member States to actually demonstrate the need for a prior authorization regime and at the same time itself providing evidence that this is in most cases unlikely to be warranted. Because the criteria for "undue delay" would no longer be used to determine when authorizations must be granted there will be no clear EU standard to apply if any authorisation requirements survive. The main innovation of the proposal are new patients' rights to accountability and transparency which apply not just to mobile patients but to all patients in each Member State. This represents a first step from negative integration (liberalisation) to positive integration (harmonisation). Moreover transparency and accountability will generate pressure for further change, not just in relation to the cross-border provision of services, but more broadly across the healthcare sector.

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1. Introduction

Across the EU, the national healthcare systems of its Member States vary widely in terms of key variables such as accessibility, quality and affordability.[1] They also vary considerably in the role played by the public respectively the private sector. Nevertheless a few basic types are traditionally identified. Broadly, healthcare systems in the EU can be categorized in three groups as either based on restitution, based on benefits in kind, or on a national health service (NHS). These are the classifications that play a key role in the patient mobility case law. The healthcare systems in the EU can also be divided more systematically into just two basic categories as either Bismarckian systems historically based on occupational health insurance (subdivided in restitution and/or benefits in kind systems) or universalistic (tax-funded) Beveridge systems of national health coverage (NHS, which can be subdivided into centralized and decentralized systems). These latter categories are more familiar from the social science literature.[2]

All these healthcare systems alike are based upon notions of national solidarity.[3] This solidarity however is under pressure as rising healthcare expenditure due to aging populations, ongoing medical innovation and rising expectations is almost universally leading to cost controls involving various forms of rationing of treatment, such as waiting lists. Vested interests resisting change in the healthcare sector – such as the promotion of efficiency by means of market-based incentives or new entry – are strong and (access to) healthcare is an emotive issue. Consequently healthcare reform is generally seen as one of the most intractable political problems at national level. The resulting inability to reform the status quo can lead to the emergence of parallel systems that are outside the scope of social security and based less on solidarity than on ability to pay. Thus rejecting change in fact erodes solidarity (not to mention quality). Meanwhile, in an attempt to maintain national control over healthcare provision, the Member States have limited the competence of the EU to take the initiative on healthcare issues by means of an explicit Treaty provision to this effect, Article 152 EC.

It is against this background that from *Kohll* to *Watts*[4] the European Court of Justice has developed a remarkable strand of case law over the past decade in which it applied the freedom to provide services to healthcare. In these cases the hand of the national authorities was forced by patients seeking what they considered to be better (including earlier) medical treatment in other Member States ("Member State of treatment") while claiming reimbursement of such treatment in accordance with the social security rules applicable in their home Member State ("Member State of affiliation").[5] Adopting what has been called a patient centred, needs-based

[1] However differences in efficiency appear to be as great within Member States as they are between Member States. Commission staff working document of 2 July 2008, accompanying document to the Proposal for a directive of the European parliament and of the Council on the application of patients' rights in cross-border healthcare: Impact Assessment, SEC(2008) 2163, pp. 42-44.

[2] Cf. M. Ferrara, *The Boundaries of welfare: European integration and the new spatial politics of social protection* (Oxford, OUP 2005) pp. 124ff and the references cited there.

[3] C. Newdick, "Citizenship, free movement and health care: cementing individual rights by corroding social solidarity", 43 *CMLRev* 2006, 1645-1668, at pp 1649ff; V.G. Hatzopolous, "Health law and policy: the impact of the EU", in G. de Búrca (ed), *EU Law and the welfare state. In search of solidarity* (Oxford, OUP 2005), pp. 111-168, at 118-119. M. Dougan and E. Spaventa, "Wish you weren't here… New Models of social solidarity in the European Union", in M. Dougan and E. Spaventa (eds), *Social welfare and EU law* (Oxford, Hart 2005), pp. 181-218; S. O'Leary, "Solidarity and citizenship rights in the charter of fundamental rights of the European Union", in de Búrca, ibid., pp. 39-87. More generally Ferrara, supra note 2, pp. 44-52.

[4] Case C-158/96 *Raymond Kohll v Union des caisses de maladie (Kohll)* ECR I-1931; Case C-372/04 *The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health (Watts)* [2006] ECR I-4325.

[5] This is the usage in the proposed patient mobility Directive, which will be employed throughout this text for reasons of consistency. The use of these terms runs parallel to that of the Member State of residence (also: competent Member State) versus Member State of stay in Regulation 1408/71, OJ 1971 L149/2 (see infra note 21), and to the more general usage of home Member State and host Member State.

approach,[6] the European Court of Justice has consistently supported such patient mobility. The Court's approach eventually inspired the Commission to propose legislation on this issue, first in 2004 in the context of the Services Directive – which failed – and, more recently, in July 2008 by means of a draft Directive on the application of patients' rights in cross-border healthcare ("proposed patient mobility Directive") in the context of the renewed social agenda of the EU. The latter proposal provided the reason for writing this paper.

The process summarised in the preceding paragraph appears to follow a familiar pattern in EU law where disparities between national markets lead to private litigation based on directly effective rights under the Treaty that triggers Court intervention striking down national barriers – resulting in deregulation or "negative integration" – which is then duly followed by legislative proposals to fill the remaining and/or resulting gaps by new rules at EU level – concluding by re-regulation of "positive integration".[7] This process of interaction between case law and legislation tends to involve both harmonisation and liberalisation of the applicable rules and a reassessment of the scope of legitimate public interests requirements. It will be seen to what extent the case law and the proposed Directive on patient mobility fit this mould. In addition the following three issues will be addressed:

- The interaction between the freedom to provide services in Article 49 EC and the applicable social security legislation at EU level (Regulation 1408/71)

- The shift in focus: whereas initially the proposals on patient mobility were bundled into the Services Directive (the last major internal market initiative), now they are presented as part of a raft of social policy proposals (the "renewed social agenda")

- Whether the proposed patient mobility Directive may act as a catalyst for change at national level that goes beyond its immediate requirements.

This discussion will be structured as follows. The first section of this paper will sketch the existing legal framework, starting from the relevant provisions of the Treaty and the Charter on fundamental rights, followed by the secondary law, i.e. Regulation 1408/71. The second section will discuss the patient mobility case law of the European Court of Justice in chronological order. The third section will cover the various steps leading up to the current proposal for a patient mobility Directive, i.e. the High Level process, the 2003 Review, the proposal to include patient mobility in the Services Directive and the 2006-2008 Consultation. The fourth section will discuss the proposed patient mobility Directive in detail. The fifth and final section will attempt to draw some conclusions from the foregoing.

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[6] G. Davies, "The effect of Mrs Watts trip to France on the National Health Service", 18 *King's Law Journal* 2007, pp. 158-167, at 160.

[7] Cf. G. Davies, "The Community's internal market-based competence to regulate healthcare: Scope strategies and consequences", 14 *Maastricht Journal of European and Comparative Law* 2007, pp. 215-238. The distinction between negative and positive integration was pioneered by J. Tinbergen, *International economic integration* (Elsevier, Amsterdam 1954), and developed for the EU by J. Pinder, "Positive and negative integration: Some problems of Economic Union in the EEC", 24 *The World Today* 1968, 88. Cf. F.W. Scharpf, "Negative and positive integration in the political economy of European welfare states", in G. Marks et al., *Governance in the European Union* (Sage, London 1996), pp. 15-39. Opinions generally differ on whether negative integration is as a rule more likely to trigger re-regulation at EU level, or whether due to decision-making difficulties (notably the high level of intergovernmental consensus required) at EU level it will simply lead to deregulation instead. In this respect F.W. Scharpf, "The European social model: Coping with the challenges of diversity", 40 *Journal of Common Market Studies* 2002, pp. 645-670, makes a plausible distinction between on the one hand policies promoting market efficiencies which often see successful EU regimes emerge based on mutual recognition and minimum harmonisation, and on the other hand policies promoting social protection, which tend to remain at the national level.

2. The legal framework

2.1. Primary law

As regards primary law, the legal framework for the discussion of patient mobility that is the topic of this paper consists of Article 49 EC on the freedom to provide services, and (to a lesser extent) Article 152 EC (Title XIII) on public health.[8] The Treaty also contains secondary references to public health and health in the context of proposals for harmonization in Article 46 and Article 95 paragraph 3 EC, as well as concerning complementary action to protect workers' health and safety in Article 137 paragraph 1 EC.[9] Finally, Article 3 paragraph 1 sub (p) EC includes among the activities of the Community "a contribution to the attainment of a high level of health protection".

Freedom to provide services

The text of Article 49 EC explicitly mentions only the freedom to provide services, and not that to receive them. However in cases such as *Luisi and Carbone* (1984), and *Bachmann* (1992), the European Court of Justice has clarified that this freedom does include the freedom for the recipient of services to travel to another Member State in order to receive the service there.[10] Traditionally, the freedom to provide services has been considered to be of secondary importance in relation to the other

[8] TITLE XIII: PUBLIC HEALTH

Article 152

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) By way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

[9] For a general overview of EU health law see T.K. Hervey and J.V. McHale, *Health law and the European Union*, (Cambridge, CUP, 2004). Also T.K. Hervey, "Mapping the contours of European Union health law and policy", 8 *European Public Law* 2002, pp. 69-104.

[10] See especially Joined Cases 286/82 and 26/83 *Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro (Luisi and Carbone)* [1984] ECR 377, para 16: "the freedom to provide services includes the freedom, for the recipients of services, to go to another Member State in order to receive a service there". (in this case, actually involving undefined healthcare services). Also generally quoted in this context is Case C-204/90 *Hanns-Martin Bachmann v Belgium* [1992] ECR I-249, para 31 which states the restrictions in the home Member State on the ability of consumers to purchase services in another Member State constitute a restriction on the ability of the providers in that other Member State to provide services to them. Combining these cases, such rules can therefore be seen as restricting both the freedom of the provider, and that of the recipient of the services in question, and therefore as a barrier to the freedom to provide services in both senses. Cf. Case C-158/96 *Kohll*, supra note 4, para 35.

market freedoms in the EU, in particular free movement of goods. Yet more recently the relevance of this freedom has increased, as testified by the (albeit delayed) adoption of the Services Directive[11]. As will be seen later, these various aspects of the freedom to provide services are relevant to patient mobility. Finally, it should be noted that Article 46 EC contains an explicit public policy exception to the freedom to provide services on grounds of public health.

Article 152 EC

The original EC Treaty did not contain a provision on public health except for the public policy exception to free movement on grounds of public health in Article 46 EC mentioned above. This is in line with the focus on free movement and negative integration – lifting barriers to trade to create a common market – of the original integration project. At the same time it was tacitly assumed that the Community would stay outside the social sphere (other than in relation to measures necessary to promote the freedom of movement of workers in Article 51 EEC (now Article 42 EC), on which more below) and lacked broader political ambitions.

Article 152 EC was introduced by the 1992 Maastricht Treaty (then as Article 129 EC) alongside comparable provisions on consumer protection and the environment that reflect the new political and social concerns that became relevant to European integration at the time. This provision was further reinforced by the 1997 Amsterdam Treaty. At the same time public health ("a contribution to the attainment of a high level of health protection") was added to the list of activities of the Treaty, where it is now found in Article 3 paragraph 1 sub (p) EC. This provision can be related inter alia to the core objective of raising of the standard of living and quality of life set out in Article 2 EC. Article 3 paragraph 1 sub (p) EC is echoed in Article 152 EC which sets out as its goal a high level of human health protection to be ensured in the definition and implementation of all Community policies and activities (technically known as "mainstreaming"[12]). It is also found in Article 95 paragraph 3 EC, which provides that the Commission in all its harmonization proposals on health matters will take as its base a high level of protection. Article 152 EC primarily provides for cooperation between the Member States and with third countries in relation to the improvement and promotion of health, and prevention. The Commission, in this context, is to play a subsidiary role – mainly, encouraging and promoting coordination and cooperation between the Member States – and Community action is complementary.[13]

Most importantly, Article 152 EC paragraph 5 explicitly states that Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. (Similarly, Article 152 paragraph 4 sub c states the Community may legislate on incentive measures designed to protect and improve human health, but "excluding any harmonisation of the laws and regulations of the Member States".) This sector-specific emphasis of the subsidiarity principle suggests there is little scope for harmonization on such matters, which is in line with the settled case-law of the Court of Justice according to which Community law does not detract from the power of the Member States to organise their social security systems.[14]

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[11] Cf. the Commission's analysis in An internal market strategy for services, COM(2000)888 of 29.12.2000, and the Report from the Commission to the Council and the European Parliament on the state of the internal market for services presented under the first stage of the Internal Market Strategy for Services, of COM/2002/0441 of 30.7.2002, culminating in Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ 2006 L376/36 (Services Directive).

[12] On mainstreaming of public health in EU policies cf. T.K. Hervey, supra note 9, at pp. 76-81.

[13] It should be noted that none of the abovementioned Treaty provisions mentions health*care*: instead they just refer to (public) health, which is usually associated with prevention and promotion (or improvement) of health. This could be read as excluding curative healthcare. Cf. Hatzopolous, supra note 3, at pp. 120-121.

[14] Case 238/82 *Duphar BV et al. v The Netherlands (Duphar)* [1984] ECR 523, para 16; Joined cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] I-637, para 6; Case C-70/95 *Sodemare SA, Anni Azzurri Holding SpA and*

Accordingly the individual Member States retain the power to determine the conditions concerning the right or duty to be insured with a national social security scheme,[15] and the conditions for entitlement to benefits under such schemes.[16] However the Member States must at the same time comply with Community law – including the freedom to provide services – when exercising that power. Over the past ten years the tension between on the one hand the free movement provisions and on the other hand the reservation of primary responsibility in the sphere of healthcare to the Member States has become manifest, as patients claimed their rights to mobility under the Treaty. It is the shifting balance between the two as developed in the case law that motivated the proposed patient mobility Directive, and this paper.

Article 35 Charter on fundamental rights

Finally among the sources of primary Community law on healthcare ranks Article 35 of the Charter on fundamental rights,[17] which provides a right to access to preventive healthcare (to the extent the Charter is capable of creating rights) but leaves the definition of other rights to medical treatment to the Member States. Like Article 152 paragraph 1 EC, it emphasizes a high standard of health protection as part of the policies and activities of the EU (mainstreaming).

2.1. Secondary law

Secondary EU law that is related to patient mobility has so far been restricted to social security legislation in the context of free movement for workers. Other EU legislation that is relevant to free movement and healthcare does exist but is mainly concerned with mutual recognition of professional qualifications,[18] with pharmaceuticals,[19] and more recently medical devices.[20]

Anni Azzurri Rezzato Srl v Regione Lombardia [1997] ECR I-3395, para 27 and Case C-158/96 *Kohll*, supra note 4, para 17.

[15] Case 110/79 *Una Coonan v Insurance Officer* [1980] ECR 1445, para 12, Case C-349/87 *Elissavet Paraschi v Landesversicherungsanstalt Württemberg* [1991] ECR I-4501, para 15, and Case C-158/96 *Kohll*, supra note 4, para 18.

[16] Joined Cases C-4/95 and C-5/95 *Fritz Stöber and José Manuel Piosa Pereira v Bundesanstalt für Arbeit* [1997] ECR I-511, paragraph 36, and Case C-158/96 *Kohll*, supra note 4, para 18.

[17] Charter of Fundamental Rights of the European Union (Title IV, Solidarity), OJ 2007 C303/9. "Article 35: Health care: Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities." The legal status of the Charter is subject to a rich debate, which appears to boil down to the fact that it is for the time being at best an interpretative guide to the meaning of other (legally binding) provisions and an expression of good intentions, not an independent source of enforceable rights and obligations. Cf. the discussion in O'Leary, supra note 3, pp. 47-54.

[18] The key text in this area is now Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications OJ 2005 L255/22 (last amended by Commission Regulation (EC) No 1430/2007, OJ 2007 L320/3) which covers inter alia specialised and general doctors as well as nurses, dental practitioners and pharmacists. Directive 2005/36/EC replaced a number of harmonization and mutual recognition directives for the individual health professions that dated back to the mid-1970s.

[19] E.g. Council Directive 89/105/EEC, of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems, OJ 1989 L40/8; Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ 2001 L121/34; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L311/67, last amended by Directive 2008/29/EC of the European Parliament and of the Council, OJ 2008 L81/51; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L136/1. Cf. L. Hancher, "The Pharmaceuticals market: Competition and free movement actively seeking compromises", in M. McKee, E. Mossialos and R. Baeten (eds), *The impact of EU law on health care systems* (PIE.-Peter Lang, Brussels 2002), pp. 235-275.

[20] E.g. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ 1990 L189/17; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ 1993 L169/1; Directive 98/79/EC of the European Parliament

In line with the requirement of Article 42 EC to adopt such measures in the field of social security as are necessary to provide freedom of movement to workers, Regulation 1408/71 provides for coordination on the applicable social security rules within the EU.[21] The objective of Regulation 1408/71 was not harmonisation of social security standards but mere coordination in relation to the aggregation of time periods relevant to acquiring rights to benefits, and the payment of such benefits, so the rights of workers under the different national schemes could be determined.[22] Consequently, Regulation 1408/71 strictly respects the right of the Member State to determine the extent and scope of its national social security benefits, provided these are applied in a non-discriminatory manner to workers from other Member States.[23]

However it is not necessary to make use of the right to free movement to invoke Regulation 1408/71.[24] Most importantly in the present context, with regard to the right to medical treatment, this is clearly shown by the fact that Regulation 1408/71 covers not only the right to emergency care, or the right to care when residing abroad but (remarkably) also the right to obtain treatment in another Member State, provided the conditions set in Article 22 of the Regulation are met. This right has been extended from time to time beyond those nationals of EU Member States who have at any time worked or resided in another Member State. Thus since 1995 it applies to all persons who are nationals of a Member State and who are ensured under the legislation of a Member State (and their family members residing with them),[25] and since May 2003 to legally resident nationals of third countries.[26]

Article 22 of Regulation 1408/71 provides an absolute right to emergency medical care in another Member State, as well as, subject to prior authorisation, a therefore qualified general right to medical care in another Member State (the Member State of treatment). It is this latter type of care, elective care, that is relevant here. According to Article 22 paragraph 2 (as it stood at the time of the *Kohll* judgment), this authorisation may not be refused:

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and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ 1998 L331/1; Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, OJ 2007 L247/21. Cf. C. Altenstetter, "Regulation of medical devices in the EU", in McKee, Mossialos and Baeten (eds), supra note 19, pp. 277-303.

[21] Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ 1971 L149/2), last amended by Regulation (EC) No 1992/2006 of the European Parliament and of the Council of 18 December 2006, OJ 2006 L392/1 (hereinafter Regulation 1408/71). Cf. R. Cornelissen, "The principle of territoriality and the Community Regulations on social security (Regulations 1408/71 and 574/72)", 34 *CMLRev* 1996, p. 439-471. It replaced Council Regulation No 3 on social security for migrant workers, OJ 1958, p. 597. Regulation 1408/71 will itself be replaced by Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ 2004 L166/1, once the implementing Regulation of Regulation 883/2004 takes effect (this is expected for the end of 2009).

[22] Cf. Case 21/87 *Felix Borowitz v Bundesversicherungsanstalt für Angestellte* [1988] ECR 3715, para 23 (and the references provided there); Case 100/78 *Claudino Rossi v Caisse de compensation pour allocations familiales des régions de Charleroi et Namur* [1979] ECR 831, para 13.

[23] Remarkably enough, legally resident third country nationals (whose numbers are far higher than the number of EU migrant workers for whom Regulation 1408/71 was originally designed) have only been covered since the adoption of Council Regulation (EC) No 859/2003 of 14 May 2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to legally resident nationals of third countries who are not already covered by those provisions solely on the ground of their nationality, OJ 2003 L124/1. Note that according to Article 90 of Regulation 883/2004 its predecessor Regulation 1408/71 will remain in force – even when Regulation 883/2004 takes effect – for the purposes of Regulation 859/2003 until the latter is itself repealed or modified. This is because the scope of Regulation 883/2004 as set out in its Article 2 does not cover third country nationals, whereas Regulation 859/2003 was designed to extend social security coverage to them. Cf. F. Pennings, "Inclusion and exclusion of persons and benefits in the new co-ordination Regulation", in Dougan and Spaventa (eds), supra note 3, pp. 241-260.

[24] Case C-2/89 *Bestuur van de Sociale Verzekeringsbank v M.G.J. Kits van Heyningen* [1990] ECR I-1755.

[25] According to Article 22a, inserted by Council Regulation 3095/95, OJ 1995 L335/1.

[26] Council Regulation 859/2003, supra note 23.

> "(…) where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease."

However, as the beginning of this quotation shows, it depends on the scope of the social security legislation in the Member State of affiliation whether a treatment is covered by this provision in the first place. Article 22 provides for two alternative types of benefit: either benefits in kind (i.e. treatment) in the Member State of treatment, with compensation paid by the Member State of affiliation directly to the Member State of treatment based on Article 36 of Regulation 1408/71, or direct reimbursement at the level in force in the Member State of treatment by the Member State of affiliation of the patient in the event he or she had paid the relevant costs on their own account. It is primarily this latter situation that has given rise to litigation in the context of the patient mobility case law, along with the conditions of the prior authorisation requirement. Finally it is important to note that the levels of reimbursement applicable in the Member State of treatment under the Article 22 regime may be below the actual costs that patients have to meet, especially in Member States of treatment with significant co-payments (i.e. out-of-pocket expenses for patients).

In this manner Regulation 1408/71 provided for about 30 years not just the basic framework but the only framework for patient mobility in the EU. This changed over the course of the past decade as the result of the patient mobility case law that concerns both the applicability of Article 49 EC and the scope of Regulation 1408/71, establishing not just parallel but converging regimes between the two.

3. The patient mobility case law of the European Court of Justice

Originally, the case law on patient mobility was limited entirely to interpretations of Regulation 1408/71.[27] In this context the Court opted for sometimes extensive readings of the definition of worker, and of the related workers' rights under Regulation 1408/71, notably including the finding in the two *Pierik* (1978-79) judgments that there was an obligation to grant authorization for "necessary and effective" treatment in another Member State even where such treatment was not covered by national social security legislation in the Member State of affiliation.[28] Hereby the Court directly threatened national control over the scope of social security entitlements. This case law in turn triggered various amendments to Regulation 1408/71 that aimed to reassert Member State control.[29] Otherwise, its impact was again very limited.

Next came the initial rulings on the interpretation of the Treaty in relation to healthcare. In cases concerning the combination of a tourist visit with unspecified

[27] E.g. Case 117/77 *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland v G. Pierik (Pierik I)* [1978] ECR 825 and Case 182/78 *Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland v G. Pierik (Pierik II)* [1979] ECR 1977. Both *Pierik* cases concerned the rights to cross-border healthcare of pensioners. More recently on pensioners'rights to healthcare under Regulation 1408/71: Case C-326/00 *Idryma Koinonikon Asfaliseon (IKA) v Vasileios Ioannidis* [2003] ECR I-1703; Case C-156/01 R.P. *van der Duin v Onderlinge Waarborgmaatschappij ANOZ Zorgverzekeringen UA and Onderlinge Waarborgmaatschappij ANOZ Zorgverzekeringen UA v T.W. van Wegberg-van Brederode* [2003] ECR I-7045.

[28] Case 117/77 *Pierik I*, supra note 27, para 22; Case 182/78 *Pierik II*, supra note 27, para 13.

[29] Thus the original provision in Article 22 paragraph 2 that authorization may not be refused "where the treatment in question cannot be provided for the person concerned within the territory of the Member State in which he resides" was eventually replaced by "where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resided and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease". Similarly the concept of "worker" was replaced with "employed or self-employed person". Cf. Hatzopolous, supra note 3, at pp. 125-127.

medical treatment in *Luisi and Carbone* (1984),[30] and the medical termination of pregnancy (abortion) in *SPUC v Grogan* (1991),[31] the Court established the fundamental principles that healthcare falls within the scope of the freedom to provide services, and that, in this context, Article 49 EC concerns the freedom not only to provide but to receive services. Substantively however, the immediate impact of these cases was a limited one.

This changed quickly with the third generation of case law, which, starting with the landmark rulings in *Kohll* and *Decker* (1998),[32] and culminating in the *Watts* case (2006),[33] spelled out the implications of free movement for hospital services and outpatient services, and for the various types of Member States health systems (reimbursement, benefits in kind, and NHS). It is this latter case law that is primarily relevant to the development of patient mobility in Community law and the Commission's recent legislative proposals on this issue which concerns us, and that will now be dealt with in more detail.

3.1. Kohll and Decker

The *Kohll* and *Decker* Cases were decided in parallel on 28 April 1998.[34] *Kohll* concerned a claim for reimbursement of the costs of dental treatment received by his daughter in Germany by Mr Kohll, a Luxembourg national who had not obtained prior authorization based on Article 22 of Regulation 1408/71. *Decker* concerned the purchase by another Luxembourg national of spectacles in Belgium, likewise without prior authorization. In *Kohll* the applicability of the freedom to provide services of Article 49 EC was invoked, in *Decker* the free movement of goods under Articles 28 and 30 EC.

At issue were the questions whether the free movement provisions of the Treaty precluded such authorisation requirements, even if (in *Kohll*) their professed aim was to maintain a balanced medical and hospital service available to everyone in a given region.

Closely following the reasoning of the Advocate General, both in *Kohll* and in *Decker* the Court construed the applicability of the free movement provisions in three steps:

- The first step was for the Court to decide that although, in the absence of harmonization, the Member States remained in control of determining the scope of social security benefits and the conditions for entitlements, they must nevertheless comply with Community law and the national rules at issue were subject to the Treaty rules on free movement. In *Kohll*, Citing *Webb*, it held that "the special nature of certain services does not remove them from the ambit of the fundamental principle of freedom of movement."[35]

- Next the Court ruled that the free movement rules continued to apply in spite of the fact that the national measures concerned might be consistent with a provision of secondary legislation, in this case Article 22 of Regulation 1408/71.

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[30] Joined Cases 286/82 and 26/83 *Luisi and Carbone v Ministero del Tesoro* [1984] ECR 377, para 16.
[31] Case C-159/90 *Society for the protection of unborn children Ireland Ltd v Stephen Grogan* [1991] ECR I-4685, para 18.
[32] Case C-158/96 *Kohll*, supra note 4, and Case C-120/95 *Nicolas Decker v Caisse de maladie des employés privés (Decker)* [1998] ECR I-1831. Annotation by R. Giesen in 36 *CMLRev* 1999, pp. 841-850; P. Cabral, "Cross-border medical care in the European Union – bringing down a first wall", 24 *ELRev* 1999, pp 387-395.
[33] Case C-372/04 *Watts*, supra note 4.
[34] Case C-158/96 *Kohll* and Case C-120/95 *Decker* formed the subject of a joint Opinion by Advocate General Tesauro [1998] ECR I-1831, the Court's arguments in both cases run in parallel, and they were decided on the same day – but separately.
[35] Case C-158/96 *Kohll*, supra note 4, para 20, citing Case 279/80 *Criminal proceedings against Alfred John Webb* [1981] ECR 3305, para 10.

– Third, the Court observed that Article 22 of Regulation No 1408/71 is only intended to allow an insured person, following authorisation, to receive treatment in another Member State with a right to receiving reimbursement at the level established in the Member State of treatment. From this it concluded that Regulation 1408/71 does not regulate or prevent the reimbursement at the level established in the Member State of affiliation (where the person is insured), even without prior authorisation.

By taking this approach the Court in effect sidestepped the existing secondary legislation in this field – the scope of which is under the control of the Member States collectively in the Council, and individually as they determine the coverage of their respective social security regimes – and opened the alternative and parallel route of recourse to the directly effective Treaty provisions themselves, out of reach of the Member States.[36] Moreover, the two regimes were logically quite distinct: whereas the Council Regulation 1408/71 construed authorisation and hence patient mobility not as a right (apart from exceptional cases) but a as privilege, the reverse held for patient mobility based on Article 49 EC. As this was based on the Treaty freedom to provide services it would come to be seen as constituting a right that could only under exceptional circumstances be subjected to a prior authorization requirement.[37]

Next the Court held that although the prior authorisation requirement for reimbursement does not preclude patients from purchasing medical services or medical products in another Member State, they are denied reimbursement if they have not obtained that authorisation. Because no similar authorisation requirement existed for the reimbursement of medical services or medical products purchased in the Member State of affiliation this deterred patients from seeking cross-border services and products, as well as the provision to them of such services and products. It therefore constituted a barrier to free movement in both directions.[38]

In *Decker*, concerning the free movement of goods, the Court examined two defences to this finding:

– First, that a barrier might be justified by the risk of seriously undermining the financial balance of the social security system as an overriding reason in the general interest.[39] In line with the reasoning provided by the Advocate General,[40] the Court accepted that this did not form an aim of a purely economic nature and could therefore constitute an overriding reason of general interest. In particular in relation to protecting the national hospital infrastructure, the Advocate General held that prior authorisation might be legitimate to ensure forward-planning so an adequate number of medical

[36] Thus "the Court treats Regulation 1408/71 as a specific application of the general Treaty rules on free movement and not as the only occasion in which social security funds may be called upon to reimburse expenses incurred in other Member States," thereby greatly reducing the relevance of Regulation 1408/71 to the reimbursement of health expenditure. V.G. Hatzopoulos, "Killing national health and insurance systems but healing patients? The European market for health care services after the judgments of the ECJ in Vanbraekel and Peerbooms", 39 *CMLRev* 2002 pp. 683-730, at p. 696.

[37] Cf. A.P. Van der Mei, "Cross-border access to medical care: Non-hospital care and waiting lists", 31 *Legal Issues of Economic Integration* 2004, p. 57-67, at p 57-58; A, Kaczorowska, "A review of the creation by the European Court of Justice of the right to effective and speedy medical treatment and its outcomes", 12 *European Law Journal* 2006, p. 345-370.

[38] Case C-158/96 *Kohll*, supra note 4, para 35.

[39] It is noteworthy that the Court raised this possibility in view of the fact that overriding reasons in the general interest can in principle only be invoked with respect to non-discriminatory measures, whereas the authorization requirement was explicitly discriminatory. Meanwhile, the justification of maintaining the financial balance of the health insurance system had already been accepted in Case 238/82 *Duphar*, supra note 15, para 16. Cf. Giesen, supra note 32, pp. 845-846, who at p. 848 speculates that under this heading the Court might be condoning the limitation of "supply-induced demand".

[40] Opinion AG Tesauro, supra note 34, para 53, with reference to Case C-275/92 *Her Majesty' s Customs and Excise v Gerhart Schindler and Joerg Schindler* [1994] ECR I-1039, para 60, and Case C-415/93 *Union Royale Belge des Sociétés de Football Association ASBL v Jean-Marc Bosman* [1995] ECR I-4921, paras 106-107.

facilities would be available throughout the national territory.[41] However, in relation to the purchase of a pair of spectacles, for which the reimbursement rules in Luxembourg provided for a flat rate, the Luxembourg Government had to concede that there could not be any effect on the financing or balance of the social security system.

- Next, the Court rejected the argument that the quality of treatment could be invoked on the ground of protection of human health under Article 30 EC in this context. Given the existence of harmonisation and mutual recognition of professional education and training, and as the spectacles concerned were purchased on an ophthalmologist's prescription, the rules at issue could not be justified on this ground.[42]

In *Kohll* the Court similarly held that the requirement of prior authorization infringed the freedom to provide services of Article 49 EC unless it was justified either by an overriding reason in the general interest, such as the possible risk of seriously undermining the financial balance of a social security system, or by the public health exception contained in Article 46 EC.

As far as the quality of public health was concerned the Court held, as in *Decker*, that given the existence of coordination and harmonisation Directives on the conditions for pursuing the medical professions, and on the mutual recognition of diploma's, the restrictions at issue could not be justified by the need to protect the quality of medical services. It thus linked the freedom to provide services to mutual recognition guarantees established in the context of the freedom of establishment.

Hence, the Court held that the public health exception could be invoked only if the restriction involved served the objective of maintaining a balanced medical and hospital service open to all, or in so far as the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival of, the population. However in *Kohll* it had not been shown that the authorisation requirement was necessary or indispensable to these ends, e.g. for the maintenance of an essential treatment facility or medical service on national territory.[43]

As consequently all defences were rejected the authorisation requirements were held to be illegal in both cases, and reimbursement at the level of the Member State of residence was therefore mandatory.[44] A number of Member States intervened in *Kohll* and *Decker* and the rulings in these cases were widely regarded as important straight from the outset. However, widespread doubts remained whether they applied to Member States that operated systems other than reimbursement (i.e. benefits in kind and NHS systems) as well as concerning their relevance to hospital care.

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[41] At para 60 of his Opinion, the Advocate General suggested that a prior authorization requirement would be justified in relation to hospital treatment (without further qualification) as opposed to outpatient treatment. Critical, Cabral, supra note 32, p. 394. At the same point in his Opinion the Advocate General made a similar distinction between reimbursement in full and flat-rate reimbursement, which (unlike the distinction between hospital and outpatient services) however has not played a significant role in the subsequent case law.

[42] Case C-120/95 *Decker*, supra note 32, paras 41ff with reference to Council Directive 92/51/EEC on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC, OJ 1992 L209/25 and Commission Directive 95/43/EC of 20 July 1995 to Council Directive 92/51/EEC on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC, OJ L184/21.

[43] Case C-158/96 *Kohll*, supra note 4, paras 51-52, with reference to Case 72/83 *Campus Oil Ltd v Ministry for Industry and Energy* [1984] ECR 2727. It has been suggested that this should be read as a reference to nationwide availability of medical and hospital services. Giesen, supra note 32, p. 847.

[44] In the context of this finding it is notable that the Court did not address the legality of the authorization requirement of Article 22 of Regulation 1408/71. This issue was raised by Advocate General Tesauro but not concluded on. Cabral, supra note 32, pp. 392-393.

3.2. Vanbraekel

Three years later this case law was extended to hospital care in *Vanbraekel*[45] and especially in *Smits and Peerbooms*[46], two cases that were decided on the same day in July 2001. *Vanbraekel*, which is the less complex of the two, is dealt with first here.

In *Vanbraekel* the Court further examined the relationship between the freedom to provide services and Regulation 1408/71. This case was brought by the heirs of Ms Descamps, a Belgian national, concerning reimbursement of expenses made for orthopaedic surgery she received in France, for which a prior authorization request based on Article 22 of Regulation 1408/71 had been turned down (inappropriately as it turned out, based on national procedures that preceded the case at EU level). Here the Court addressed the question whether in this context reimbursement at the level of the Member State of treatment (France) or the Member State of affiliation (Belgium) was in order. The much more important underlying issue, whether hospital care was subject to Articles 49 and 50 EC, or was somehow excepted, was settled almost in passing.

The Court held that Article 22 of Regulation 1408/91 helps to facilitate free movement by providing access to treatment on conditions as favourable as those enjoyed by persons covered by the legislation of the Member State of treatment.[47] Under normal circumstances, following an authorization, the costs of treatment are reimbursed by the Member State of affiliation directly to the Member State of treatment as provided by Article 36 of Regulation 1408/71. In *Vanbraekel* the Court ruled that if authorization was initially refused and subsequently this refusal was established to be unfounded on the other hand, the reimbursement should be made directly to the person concerned.

Parallel application of Regulation 1408/71 and Article 49 EC

The next issue was the level of the reimbursement to be provided. The principle of Article 22 of Regulation 1408/71 is that medical expenses paid by the patient are reimbursed at the rate applicable in the Member State of treatment. In *Vanbraekel* however the refunds provided for by the applicable French legislation were lower than those that applied to comparable treatment in Belgium (the Member State of affiliation). The Court set the scene by repeating the argument first introduced in *Kohll* and *Decker*: it stated that Regulation 1408/71 did not intend to regulate and therefore does not prevent the reimbursement by the Member State of affiliation at its domestic level of costs for treatment in another Member State. Hence, the applicability of Article 22 of Regulation 1408/71 does not exclude that a patient also has the rights based on Article 49 EC to the assumption of costs on a different basis: the two regimes do not just apply in parallel, but simultaneously. This line of reasoning clearly ignored the intention of the Member States when adopting Regulation 1408/71 which was precisely to provide for a reimbursement regime which is exclusively that of the Member State of treatment. However, taking the opposite view enabled the Court to assess what the freedom to provide services required in this case.

Hospital services

Advocate General Saggio (as well as a number of intervening governments) had argued that in particular hospital services fell outside the scope of Article 49 EC as

[45] Case C-368/98 *Abdon Vanbraekel et al. v Alliance nationale des mutualités chrétiennes (Vanbraekel)* [2001] ECR I-5363. Annotation Hatzopoulos, supra note 36.

[46] Case C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen (Smits and Peerbooms)* [2001] ECR I-5473.

[47] Case C-368/98 *Vanbraekel*, supra note 45, para 32. This reasoning returns and is elaborated in Case C-56/01 *Patricia Inizan v Caisse primaire d'assurance maladie des Hauts-de-Seine (Inizan)* [2003] ECR I-12403, para 32.

they did not constitute economic activities.[48] As in *Kohll*, the Court found that the freedom to provide services applied as it was settled case law that medical services fell within its scope, adding without further reasoning "there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment".[49] Likewise as in *Kohll*, it added that the special nature of certain services did not remove them from the scope op free movement, and hence the fact that the rules at issue were social security rules could not exclude application of Articles 49 and 50 EC. With this the Court left few arguments at the disposal of those who believed particular medical services fell outside the scope of the freedom to provide services, apart from the question whether remuneration was involved, which was to come up in subsequent cases, notably *Smits and Peerbooms*.

Exceptions
Again, the Court found that Article 49 EC precluded national rules that had the effect of making the provision of services between Member States more difficult than the provision of services within a single Member State.[50] A restriction on reimbursement at the level of the Member State of affiliation was therefore construed by the Court as deterring or preventing the use of medical services in another Member State, and consequently a barrier to the freedom to provide services. It tested the objective justifications of seriously undermining the financial balance of a social security system as a possible overriding reason in the general interest, and the public health exceptions of maintaining a balanced medical and hospital service open to all, and the maintenance of treatment capacity or medical competence on national territory, but found none of them could justify the barrier in question. Given that an authorisation under Regulation 1408/71 existed the only substantive question at issue was the difference between the two levels of reimbursement which it held could not trigger any of the justifications.

Consequently the Court held that the difference between the two levels of reimbursement should be compensated. This means that where an authorization under Article 1408/71 exists, the higher level of reimbursement prevails.

3.3. Smits and Peerbooms

In the *Smits and Peerbooms*[51] Case of July 2001, three key problems were addressed: the applicability of free movement to hospital services in general and to benefit in kind systems in particular, and the legality of prior authorization systems as such. At issue was the prior authorization system for treatment abroad that formed part of the (since then reformed) "benefits in kind" scheme in The Netherlands, where those persons who were subject to the social insurance scheme paid a nominal fee to a public health insurance provider (also funded by employers' contributions, and by State funds) who arranged for healthcare to be provided to them free of charge by contracted providers (which were almost exclusively located in The Netherlands). The authorization scheme for treatment abroad required first, that the treatment in question was considered "normal" treatment in national professional circles, and second that it was held "necessary" in the sense that adequate treatment would not be available without undue delay nationally. Ms Geraets-Smits had sought clinical treatment for Parkinson's disease in Germany, Mr Peerbooms had undergone clinical neurological (coma) treatment in Austria. In both

[48] Applying the logic of Case 263/86 *Belgium v René Humbel and Marie-Thérèse Edel (Humbel)* [1988] ECR 5365, the AG in his Opinion at para 21 stated that in the present case there was no service provided, as there was no consideration. Hence "services which, on the one hand, are an integral part of the public health-care system, in the sense that they are established and organised by the State, and, on the other hand, are financed by public funds, must be excluded from the provisions on freedom of movement." Consequently only Regulation 1408/71 (based on free movement of workers) would apply.
[49] Case C-368/98 *Vanbraekel*, supra note 45, para 41.
[50] Case C-368/98 *Vanbraekel*, supra note 45, para 45, citing Case C-381/93 *Commission v France* [1994] ECR I-5145, para 17, and Case C-158/96 *Kohll*, supra note 4, para 33.
[51] Case C-157/99 *Smits and Peerbooms*, supra note 46. Annotation Hatzopoulos, supra note 36.

cases prior authorization had been refused. The questions addressed to the Court in this context were whether having an authorization system in general, and more specifically whether the criteria on which this system relied constituted barriers to free movement, and if so, whether overriding reasons in the general interest might apply to justify such a scheme.

Remuneration

Repeating its position in *Kohll*, the Court started out by stating that notwithstanding the power of the Member States to arrange their own social security schemes they must abide by Community law when doing so. Next, it addressed the argument raised (as in *Vanbraekel*) by a number of intervening Member States that hospital services did not constitute an economic activity in the sense of Article 50 EC "particularly when they are provided in kind and free of charge under the relevant sickness insurance scheme" (i.e. the benefits in kind scheme prevailing in The Netherlands).[52] The arguments raised in this context focused on the absence of remuneration and/or of a profit motive in a benefit in kind system, and on the fact that the parties concerned do not determine the nature of the service provided nor the price paid, as these are set in the context of a social security system.

The Court rejected all these arguments. First it repeated the position taken in *Kohll* that medical activities fall within the scope of Article 50 EC and then extended it by stating "there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment".[53] After repeating that the fact the rules at issue were social security rules did not exclude application of Articles 49 and 50 EC it tackled the benefit in kind issues. It immediately cut short the argument by pointing not to the nature of the underlying system in the Member State of affiliation, but to those transactions that had actually taken place between the patients in the case at hand, and the medical establishments in the Member States where the treatment was provided, in exchange for direct payment: clearly remuneration had been involved at this level. The benefits in kind nature of the system of the Member State of affiliation could not change this.

In addition, the Court rejected the argument that Article 50 EC did not apply to benefit in kind systems as such, based on the fact that direct payments are in any event not required for Article 50 to apply, and given that the payments in fact made for hospital services by sickness insurance funds in The Netherlands (albeit at a flat rate) did indeed ("unquestionably") constitute consideration for these services and remuneration of the receiving hospitals which were consequently engaged in economic activities. In sum, the Court engaged in a comprehensive refutation.[54]

Restrictions and justifications

Next the Court considered the question whether a restriction of the freedom to provide services was involved. It quickly established that both the requirement of "normal" treatment and "medical necessity" were likely to limit the granting of authorization, which constituted a restriction when compared to national treatment

[52] Advocate General Ruiz Jarabo-Colomer took the same position, in relation to benefit in kind systems in general. Because as a result he did not distinguish between hospital services and outpatient services his Opinion had no bearing on one of the key outcomes of this case: the justification for prior authorization requirements for hospital services. He based his argument on Case 263/86 *Humbel*, supra note 48, following a complicated analysis (in paras 26-33 of his Opinion) distinguishing the Dutch system from the rule on third party payment qualifying as consideration in Case 352/85 *Bond van Adverteerders and others v The Netherlands* [1988] ECR 2085, finding that the payments involved were only indirectly based on the services performed and resembled those in National Health Services.

[53] Case C-157/99 *Smits and Peerbooms*, supra note 46, para 53. It had done the same in *Vanbraekel* without providing further reasoning on this point (and in the context of Regulation 1408/71). Case C-368/98 *Vanbraekel*, supra note 45, para 41.

[54] Critical, Hatzopoulos, supra note 36, p. 693, who sees "an affirmation more than an actual finding" and a "lack of actual reasoning" here.

for which no authorization was required at all.[55] Hence a barrier to the freedom to provide services was involved which could only be justified by overriding public interest considerations. This meant meaning first the overriding reasons should be shown, and then the safeguard measures invoked should be justified as necessary and proportionate in that light.

Citing *Kohll* (and like in *Vanbraekel*) the Court again raised the three possible defences:

- The possible risk of seriously undermining a social security system's financial balance as an overriding reason in the general interest

- The objective of maintaining a balanced medical and hospital service open to all in the context of the public health derogation under Article 46 EC

- Likewise under Article 46 EC restrictions where the maintenance of treatment capacity or medical competence on national territory is essential for the public health, and even the survival of, the population.

In each case, the defence concerned of course remained subject to the rules at issue actually being justifiable in the light of such overriding reasons and proportional to these ends.

In its assessment of the first question the Court focused on the need for planning as the key distinguishing characteristic for hospital services (compared against medical services provided in the surgeries of medical practitioners or at the patients' home). In this context it identified first, the need to ensure permanent access to quality hospital services, and, second, the need to control costs and prevent wastage as a result of overcapacity. Importantly, the Court recognized:

> "(…) that the hospital sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be available for healthcare are not unlimited, whatever the mode of funding applied."[56]

And it held:

> "(…) if insured persons were at liberty, regardless of the circumstances, to use the services of hospitals with which their sickness insurance fund had no contractual arrangements, whether they were situated in the Netherlands or in another Member State, all the planning which goes into the contractual system in an effort to guarantee a rationalised, stable, balanced and accessible supply of hospital services would be jeopardised at a stroke."[57]

The Court thus showed itself sensitive to the concerns of the Member State in terms of cost control and planning.

Hospital treatment versus non-hospital (outpatient) treatment
Based on this reasoning, which for the first time put flesh on the bones of the exceptions, the Court found a prior authorization requirement for the assumption of costs of hospital treatment provided in another Member State both necessary and

[55] The Netherlands government claimed that authorisation was not required where the sickness insurance funds had concluded prior agreements with hospitals in other Member States – just as they had with Dutch hospitals. The Court noted that it had received no information to this effect from the referring court, but noted this was not likely to have much impact outside some border areas and therefore had little bearing on the case. I.e. even if the claims of The Netherlands' government were true there was discrimination in effect if not formal sense. Case C-157/99 *Smits and Peerbooms*, supra note 46, paras 65-66.
[56] Case C-157/99 *Smits and Peerbooms*, supra note 46, at para 79.
[57] Case C-157/99 *Smits and Peerbooms*, supra note 46, at para 81.

reasonable.[58] Although the remainder of the judgment did not explicitly deal with non-hospital services, hereby a fundamental distinction was made between hospital services and non-hospital services that had first been proposed by Advocate General Tesauro in his Opinion on the *Kohll* and *Decker* cases,[59] and has remained key in all subsequent developments.

Concerning the proportionality of the authorization scheme and its key conditions the Court held (in line with standing case law on prior authorization schemes in relation to the effectiveness of Community law)[60] that procedural guarantees are required which provide for requests to be dealt with objectively and impartially within reasonable time and subject to judicial control.

The condition that the treatment be "normal" must be based on standards of international medical science. As regards the condition that the treatment must be "necessary", authorization may be refused "only if the same or equally effective treatment can be obtained without undue delay", which "undue delay" is to be determined "with regard to all the circumstances of the specific case and take due account not only of the patient's medical condition at the time when the authorization is sought but also of his past record".[61]

Concerning the condition of the necessity of treatment the Court noted:

> "Such a condition can allow an adequate, balanced and permanent supply of high-quality hospital treatment to be maintained on the national territory and the financial stability of the sickness insurance system to be assured."[62]

and

> "Were large numbers of insured persons to decide to be treated in other Member States even when the hospitals having agreements with their sickness insurance funds offer adequate identical or equivalent treatment, the consequent outflow of patients would be liable to put at risk the very principle of having agreements with hospitals and, consequently, undermine all the planning and rationalisation carried out in this vital sector in an effort to avoid the phenomena of hospital overcapacity, imbalance in the supply of hospital medical care and logistical and financial wastage."[63]

In this manner the Court demonstrated that, far from focusing solely on the market freedoms, it had an open eye for the needs of the Member States in the management of their social security systems.

In *Smits and Peerbooms* therefore the Court clarified the earlier case law on several key points. On the one hand it confirmed the applicability of the freedom to provide

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[58] Only after making a general statement to this effect did the Court relate this finding to the specifics of the sickness insurance system in The Netherlands with its system of contractual arrangements between hospitals and sickness insurance funds and all the planning effort required "to guarantee a rationalized, stable, balanced and accessible supply of hospital services". Case C-157/99 *Smits and Peerbooms*, supra note 46, paras 80-81.

[59] Opinion Advocate General Tesauro in Case C-158/96 *Kohll and Case* C-120/95 *Decker*, supra note 34, paras 59-60.

[60] Case C-157/99 *Smits and Peerbooms*, supra note 46, para 90, with reference inter alia to Case C-205/99 *Asociación Profesional de Empresas Navieras de Líneas Regulares (Analir) et al. v Administración General del Estado* [2001] ECR I-1271.

[61] Case C-157/99 *Smits and Peerbooms*, supra note 46, paras 103-104. This is reminiscent of Article 22 paragraph 2 of Regulation 1408/71 which provides authorization may not be refused "where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease". In subsequent case law the same undue delay criterion was applied under Regulation 1408/71 as under Article 49 EC. Cf. Case C-56/01 *Inizan*, supra note 47, para 46.

[62] *Case C-157/99 Smits and Peerbooms*, supra note 46, para 105.

[63] *Case C-157/99 Smits and Peerbooms*, supra note 46, para 106.

services in the context of benefit in kind systems and to hospital services generally. On the other hand it found that, subject to the abovementioned conditions, a prior authorization requirement for hospital treatment could be justified. Moreover it was willing to accept the principle invoked by the Member States as sufficient justification, without requiring actual proof of the impact of patient mobility.

3.4. Müller-Fauré

The *Müller-Fauré* and *Van Riet* case of May 2003[64] both confirmed and extended this case law in relation to benefits in kind systems and hospital care, and distinguished it in relation to non-hospital care. At issue were dental treatment received in Germany by Ms Müller-Fauré, and hospital and non-hospital treatment received in Belgium by Ms van Riet, both Dutch nationals. In the case of Ms van Riet, who was suffering from wrist pain that required a surgical examination and then corrective surgery, authorization for treatment had been refused because the treatment concerned was available in The Netherlands, albeit following much longer waiting times.

As in *Smits and Peerbooms* the question of prior authorization for non-contracted treatment was raised. This time the main questions addressed to the Court were, first, whether the essential characteristics of the benefits in kind system for sickness insurance in The Netherlands amounted to an overriding reason that might justify a derogation from Article 49 EC, and second, what in the authorisation context is meant by "without undue delay", especially whether that condition must be assessed on a strictly medical basis, regardless of the waiting time for the treatment sought. An issue not raised by the referring court but in the arguments submitted to the Court was that of the existence of waiting lists as such, due to the availability of limited resources which were cited as requiring limits on the benefits provided and strict prioritisation of their provision.

The Court quickly confirmed its findings in *Smits and Peerbooms* that medical activities are services and that the fact that the applicable rules are social security rules does not place them outside the scope for the freedom to provide services. Likewise an authorisation requirement that would deter or even prevent the use of services provided in other Member States constituted a barrier prohibited by Article 49 EC. The Court then examined whether this restriction might be justified by:

- The protection of public health inasmuch as the system of agreements is intended to ensure that there is a high-quality, balanced medical and hospital services open to all
- The financial balance of the social security system
- Essential characteristics of the sickness insurance system in The Netherlands, which provides benefits in kind.

In other words it departed from its practice so far by now examining only one exception based on Article 50 EC, and two (possible) overriding reasons of public interest.

On the first of these justifications, it concluded no relevant evidence had been adduced, and that in any event it was closely linked to the second justification concerning the financial balance of the social security system. When examining this second ground it started out by stating, for the first time, that as it is self-evident that the cost of an individual treatment can never have a significant impact on the financing of a social security system, a comprehensive approach must instead be adopted.[65] In previous cases the Court had applied an opposite logic: i.e. that individual cases did not have a (significant) impact as they would anyway have had

[64] Case C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen (Müller-Fauré)* [2003] ECR I-4509. Annotation M. Flear, in 41 *CMLRev* 2004 p. 209-233 and Van der Mei, supra note 37.
[65] Case C-385/99 *Müller-Fauré,* supra note 64, para 74.

to be reimbursed if the treatment had been provided in the Member State of affiliation, and that their effects could therefore be ignored.[66]

Therefore its willingness to look at overall effects formed a significant shift toward recognising the concerns of the Member States. In this context the Court made an explicit and fundamental distinction between hospital services and non-hospital services (although acknowledging this might sometimes prove difficult to do).[67]

Hospital services
Reaching back to *Smits and Peerbooms* the Court found that to enable the planning required to ensure accessibility, as well as to control costs and prevent wastage, a prior authorisation requirement appeared both necessary and reasonable.

Next it examined the requirements of necessity and proportionality of the conditions attached to the grant of an authorization, after restating the general requirements for a general authorisation scheme as also stated in *Smits and Peerbooms*. The focus here was on the necessity of the treatment, understood under the Dutch legislation as a function of the question whether the appropriate medical treatment was available nationally "without undue delay". The Court extended the rule established in *Smits and Peerbooms* that in making this assessment the national authorities must

> "(…) have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought but also of his past record"

by adding (instead of "but also of his past record")

> "(…) and where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history".[68]

By including these criteria it became clear that the Court was moving beyond a simple statement on the right to reimbursement for cross-border services to a more substantive evaluation designed to balance, on the one hand, the collective interest represented by the Member State to planning and financial control over social security services, and on the other the need for the health condition of the individual patient, including the impact on their job prospects, and the degree of pain involved. In other words at the same time as the Court accepted, in principle, public interest justifications it defined under which conditions a patient's right to cross-border treatment based on the freedom to provide services overrides even legitimate public interest justifications based on a substantive understanding of the individual health issues involved.

After recalling its reasoning in *Smits and Peerbooms* on the link between the condition between the necessity of treatment and the supply of hospital treatment and financial stability of the sickness insurance system, which might be threatened if an outflow of patients would lead to overcapacity, imbalance in supply and wastage, it then added:

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[66] This line of reasoning was applied concerning hospital services in Case C-368/98 *Vanbraekel*, supra note 45, para 52; non-hospital services in Case C-158/96 *Kohll*, supra note 4, para 42, and medical aids in Case C-120/95 *Decker*, supra note 32, para 40.
[67] Case C-385/99 *Müller-Fauré*, supra note 64, para 75. "In particular, certain services provided in a hospital environment but also capable of being provided by a practitioner in his surgery or in a health centre could for that reason be placed on the same footing as non-hospital services." Ibid. For an extensive discussion of this issue see Flear, supra note 64, pp. 223-226.
[68] Case C-157/99 *Smits and Peerbooms*, supra note 46, para 104; Case C-385/99 *Müller-Fauré*, supra note 64, para 90.

> "However, a refusal to grant prior authorisation which is based not on fear of wastage resulting from hospital overcapacity but solely on the ground that there are waiting lists on national territory for the hospital treatment concerned, without account being taken of the specific circumstances attaching to the patient's medical condition, cannot amount to a properly justified restriction on freedom to provide services. It is not clear from the arguments submitted to the Court that such waiting times are necessary, apart from considerations of a purely economic nature which cannot as such justify a restriction on the fundamental principle of freedom to provide services, for the purpose of safeguarding the protection of public health. On the contrary, a waiting time which is too long or abnormal would be more likely to restrict access to balanced, high-quality hospital care."[69]

In other words rationing, in particular by means of waiting times, that went beyond rationalizing the usage of the system to avoid overcapacity and led to denial of treatment (a fine line to draw in many cases) was not accepted. Although the individual Member States still decide on the scope of the national social security coverage, waiting lists caused by under-capacity jeopardize public health and are not tolerated. The Court thus lost no time qualifying the broad understanding of the systemic needs of the Member States that it had first offered in *Smits and Peerbooms*, indicating it would "tip the scale" in a greater number of cases to the patents interest.[70]

Non-hospital services
As regards non-hospital medical services the Court confirmed *Kohll* in finding there was no evidence that the absence of a prior authorisation requirement would have a significant impact on the social security system in The Netherlands, adding that:

> "(…) care is generally provided near to the place where the patient resides, in a cultural environment which is familiar to him and which allows him to build up a relationship of trust with the doctor treating him. If emergencies are disregarded, the most obvious cases of patients travelling abroad are in border areas or where specific conditions are to be treated."[71]

In the latter cases agreements would tend to exist. Finally because the reimbursement would in any event be limited to that which would apply for the same treatment in the Member State of affiliation the expenses involved would be the same and could not threaten the financial balance of the national social security system. Prior authorization could thus not be required for outpatient services.

Benefits in kind as overriding interest
Finally the Court addressed the question whether the essential characteristics of the Netherlands sickness insurance scheme merited being considered as an overriding reason of public interest. As a preliminary observation it noted first that the power of the Member States to organise their social security systems is not undermined by the fact that achieving the freedoms guaranteed by the Treaty would require making some adjustments to these systems – such as had been required by Regulation 1408/71.[72] Next it spelled out that "a medical service does not cease to be a provision of services because it is paid for by a national health service or by a system providing benefits in kind", and that it is the prior authorisation requirement which constitutes the barrier to the freedom to provide services, irrespective of the payment system in the Member State of affiliation.[73]

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[69] Case C-385/99 *Müller-Fauré*, supra note 64, para 92.
[70] Van der Mei, supra note 37, p. 66.
[71] Case C-385/99 *Müller-Fauré*, supra note 64, para 96.
[72] Case C-385/99 *Müller-Fauré*, supra note 64, para 102.
[73] Case C-385/99 *Müller-Fauré*, supra note 64, para 103. This paragraph concludes: "There is thus no need, from the perspective of freedom to provide services, to draw a distinction by reference to whether

Based on this it raised three arguments:

- That Member States with a benefits in kind system (or an NHS) already had to establish reimbursement mechanisms for treatment based on Article 22 of Regulation 1408/71
- That in any event the level of reimbursement was limited to that provided by the sickness insurance scheme of the Member State of affiliation
- That nothing prevented a Member State with a benefits in kind system to fix the reimbursement level for treatment in another Member State (i.e. where none existed in their own) provided these were based on objective, non-discriminatory and transparent criteria.

The Court therefore confirmed *Smits and Peerbooms* in stating that a benefits in kind system was not exempt from Article 49 EC, explicitly overriding the claim that an "overriding reason" might exist in this case.

3.5. Inizan

The *Inizan*[74] Case of October 2003 concerned the reimbursement (under French law: at a flat rate) of multidisciplinary pain treatment that a French patient, Ms Inizan, had undergone in a German hospital. Addressing an issue first raised by Advocate General Tesauro in his Opinion on the *Kohll* and *Decker* cases, the referring court asked whether Article 22 of Regulation 1408/71, which deals with prior authorization, was compatible with Articles 49 and 50 EC. It also asked whether, in the light of this, the refusal of an authorisation to Ms Inizan was justified.

The legality of Article 22 of Regulation 1408/71

Before addressing the legality of Article 22 of Regulation 1408/71 the Court stated that this provision did not concern cases regarding reimbursement at the rates in force in the Member State of affiliation, but only at the rates in the Member States of treatment. Because the French authorisation system that was at issue in fact provided reimbursement for treatment abroad at a flat rate (and hence not at the level of the Member State of treatment) it could be argued that the legality of Article 22 of Regulation 1408/71 was not relevant to the case. The Court nevertheless decided to tackle this issue, and in the process substantively aligned the norms applicable to authorisation procedures under Regulation 1408/71 and Article 49 EC.

Remarkably the Court did not rule by analogy to its Article 49 EC case law in the earlier healthcare cases that prior authorization requirements under Regulation 1408/71 constituted a barrier to the freedom to provide services, that could be justified for hospital services, as might have been expected.[75] Instead it held that Article 22 confers an entitlement to reimbursement at the level of the Member State of treatment where none existed before, and as such "helps to facilitate the free movement of insured persons (…) and, to the same extent, the cross-border provision of medical services between Member States."[76] Hence there was no question of an a priori restriction of the freedom to provide services.

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the patient pays the costs incurred and subsequently applies for reimbursement thereof or whether the sickness fund or the national budget pays the provider directly." Flear, supra note 64, pp. 221-222 interprets these references to NHS and funding from the national budget as shots across the bow of the British National Health Service.

[74] Case C-56/01 *Inizan*, supra note 47. Discussed in P. Cabral, "The internal market and the right to cross-border medical care", 29 ELRev 2004, pp. 673-686.

[75] Critical, Cabral, supra note 74, p. 679. Contrast this approach to that in Case C-372/04 *Watts*, supra note 4, paras 70-71, where the exception developed in earlier Article 49 EC cases is applied in the context of Article 22 of Regulation 1408/71.

[76] Case C-56/01 *Inizan*, supra note 47, para 21, repeated in para 25. Also: "Insured persons are thus granted rights which they would not otherwise have since, as they involve reimbursement by the institution of the place of stay in accordance with the legislation administered by it, those rights cannot by definition be guaranteed to those persons under the legislation of the competent Member State alone". Ibid., para 22. Cf. Case C-368/98 *Vanbraekel*, supra note 45, para 32.

Authorization procedure under Article 22 of regulation 1408/71
Next, the Court examined whether the refusal of authorisation was justified. It started out by restating the criteria set out in Article 22 for cases where authorisation cannot be refused, i.e. the treatment concerned must be covered by the social security scheme of the Member State of affiliation, and the same or equally effective treatment cannot be provided there without undue delay. It then proceeded to extend its earlier Article 49 EC case law in *Smits and Peerbooms* and *Müller-Fauré* to the Article 22 context:

- Determining undue delay was found to require "to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history"[77]

- The procedural requirements of accessibility, objectivity and impartiality, concluding within a reasonable timeframe and the availability of judicial or quasi-judicial appeals were found to apply here as well.[78]

Articles 49 and 50 EC
Finally, the Court examined the question whether the national rules requiring authorization in order to receive reimbursement under the social security scheme in place in the Member State of affiliation were at odds with Article 49 EC. Following the line set out in *Smits and Peerbooms* and *Müller-Fauré*, it quickly established that a restriction was involved, but because prior authorisation in the case of hospital services appears both necessary and reasonable, a derogation may apply. Next, it recalled the by now familiar procedural requirements and the condition that equally effective treatment should be available without undue delay.

Apart from settling the question concerning the legality of Article 22 of regulation 1408/71 that was first raised in the context of *Kohll* and *Decker*, the Court therefore aligned the parallel approaches applicable under Regulation 1408/71 and under Article 49 EC.

3.6. Leichtle
The *Leichtle*[79] case of March 2004 concerned reimbursement of a health cure taken at an Italian spa by Mr Leichtle, a German national, after prior authorisation to do so had been refused. No major issues were settled in this case. The Court held the condition for reimbursement of a health cure taken outside Germany that it should be absolutely necessary due to greatly increased prospects of success to be a barrier to the freedom to provide services of Article 49 and 50 EC. A justification was not found to exist, with reference to the fact that in any event it was up to the Member State to limit the reimbursements for spa treatments generally, if the objective was to limit the expenses incurred in other Member States.

Remarkably in this context the Court did not made clear whether spa treatment should be considered equivalent to hospital treatment, or to outpatient treatment (where, following *Smits and Peerbooms* and *Müller-Fauré* different standards apply). Whether a registration requirement for health spas – as a precondition for reimbursement of treatment there – constituted a barrier was treated as factual

[77] Case C-56/01 *Inizan*, supra note 47, para 46 with reference to Case C-157/99 *Smits and Peerbooms*, supra note 46, para 104, and Case C-385/99 *Müller-Fauré*, supra note 64, para 90.
[78] Case C-56/01 Inizan, para 48, with reference to Case C-157/99 *Smits and Peerbooms*, supra note 46, para 90 and Case C-385/99 Müller-Fauré, supra note 64, para 85. The Court extended this previous case law by adding that the relevant courts or tribunals should have recourse to "fully objective and impartial independent experts." Case C-56/01 *Inizan*, supra note 47, para 49.
[79] Case C-8/02 *Ludwig Leichtle v Bundesanstalt für Arbeit (Leichtle)* [2004] ECR I-2641.

question for the national court. Finally the Court held that it constitutes a barrier to the freedom to provide services of Articles 49 and 50 EC if all reimbursement of contested healthcare expenditure is halted until judicial proceedings on the matter are concluded.

3.7. Bosch

The *Bosch*[80] case of October 2004 concerned the practice of the company sickness insurance fund of the Robert Bosch company in Germany to reimburse medical costs incurred in other Member States in full up to 200 Deutschmarks, irrespective of the applicable rate in the Member State of treatment. This was prohibited by the German federal insurance regulator (*Bundesversicherungsamt*), giving rise to further legal procedures. The question referred to the Court was whether the practice of the Bosch company sickness insurance fund was in line with the regime provided by Article 22 of Regulation 1408/71 and especially with Article 34 of its implementing Regulation 574/72[81], which provided an alternative regime for reimbursement in cases where certain formalities relating to the normal execution of obligations arising under Article 22 of Regulation 1408/71 could not be completed.

The answer of the Court was that (just as it had ruled in *Vanbraekel* concerning Article 22 of Regulation 1408/71 itself) Article 34 of Regulation 574/72 was not intended to (or: could not) regulate more favourable reimbursement at the rates in force in the Member State of affiliation. Because the disputed practice in *Bosch* ensured full reimbursement of medical costs and was therefore at least equivalent to what would be provided based on Article 34 it was not precluded by the regime provided in Regulation 574/72.

3.8. Keller

The *Keller*[82] case of April 2005 concerned the scope of treatment based on Article 22 of Regulation 1408/71. Ms Keller, a German national who was affiliated to the social security scheme in Spain had received an authorisation based on Article 22 of Regulation 1408/71 to obtain treatment of acutely life-threatening cancer during a stay in Germany. Her German doctors then referred Ms Keller for surgery to a clinic in Switzerland which was deemed leading in its field in Europe for this condition. The Court was asked whether once an authorisation based on Article 22 of Regulation 1408/71 had been given, the doctors in the Member State of treatment (or "of stay", a more accurate description in this case) had the authority to refer the patient for treatment in a third country, or whether the Member State of affiliation could require a further prior authorisation. It was also asked whether it was the coverage provided in the Member State of treatment that determined whether treatment in a third country would have to be reimbursed.

On the first question the Court held that in the context of the application of Article 22 there was a sharing of responsibilities between the Member State of affiliation and that of treatment, that the doctors in the Member State of treatment are the best place to make the assessments involved and that while the authorisation is valid, the Member State of affiliation is bound by their findings related to "urgent vital treatment".[83] Moreover, mutual recognition ensured that doctors' skills in making such assessments were equivalent between Member States. As regards the argument raised that the objective of planning and organising the provision of hospital care

[80] Case C-193/03 *Betriebskrankenkasse der Robert Bosch GmbH v Germany* [2004] ECR I-9911.
[81] Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community (OJ 1972 L74/1), as amended by Council Regulation (EEC) No 2001/83 (OJ 1983 L230/6), and Council Regulation (EC) No 1399/1999 (OJ 1999 L164/1).
[82] Case C-145/03 *Heirs of Annette Keller v Instituto Nacional de la Seguridad Social (INSS) and Instituto Nacional de Gestión Sanitaria (Ingesa)* [2005] ECR I-2529.
[83] Case C-145/03 *Keller*, supra note 82, para 53, with reference to Case 22/86 *Giuseppe Rindone v Allgemeine Ortskrankenkasse Bad Urach-Münsingen* [1987] ECR 1339 and Case C-45/90 *Brennet AG v Vittorio Paletta* [1992] ECR I-3423.

might be endangered as a consequence, the Court held that although this objective could provide the justification for having a prior authorisation requirement in the first place, it could no longer be invoked once a prior authorisation had in fact been given.

A right to treatment in a third country however was only found to exist if the Member State of treatment provided such an entitlement under the terms of its own social security scheme. Significantly therefore in this instance not the Member State of affiliation but the Member State of treatment determines the scope of the coverage. Adding to the complexity is the issue of costs, which must be assumed by the Member State of treatment, which is itself reimbursed by the Member State of affiliation but only if the treatment concerned is covered by the social security scheme of the latter. The same applies if the patient has directly assumed the costs, i.e. reimbursement by the Member State of affiliation depends on whether the treatment received is covered by the social security scheme of the latter. The incongruous result therefore is that the scope for treatment in a third country is determined by the coverage provided in the Member State of treatment and for reimbursement the scope of coverage in the Member State of affiliation is decisive.

3.9. Watts

In the celebrated *Watts*[84] case of May 2006, the Court for the first time extended its case law to a national health service (NHS) system. Ms Watts, a UK national, had undergone hip replacement surgery in France after repeatedly being denied authorisation for treatment abroad based on Article 22 of Regulation 1408/71 on the ground that the waiting time involved for treatment by the NHS involved no "undue delay" (although the UK consultant responsible for her referral had acknowledged both that Ms Watts was in constant pain from the outset and a subsequent deterioration in her condition). The referring court submitted a large number of questions which revolved around the possibility to distinguish the NHS system and its various features from the earlier case law of the Court on the applicability of free provision of services and Article 22 of Regulation 1408/71, and the relevance in this context of budgetary constraints.

Undue delay and Article 22 of Regulation 1408/71

Citing *Vanbraekel*, the Court held that rights to reimbursement based on Article 22 of Regulation 1408/71 and under Article 49 EC could coexist. It then explicitly aligned the two parallel systems by confirming that the criterion "within the time normally necessary for obtaining the treatment in question" in Article 22 was the same as that used to define the term "undue delay" in the context of Article 49 EC.[85]

The Court then set out to discuss the conditions under which this criterion was satisfied. In this context it first recalled its ruling in *Müller-Fauré* that the existence of waiting lists could not be decisive.[86] However in contrast to the more critical approach to rationing in *Müller-Fauré* which had appeared to suggest that only measures to avoid overcapacity and "wastage" were relevant, the Court also held that given constantly rising demand for hospital treatment (as a function of technical developments and rising life expectancy) and "necessarily" limited supply due to budget constraints, it could not be denied that waiting lists might be needed to manage supply and set priorities "on the basis of the available resources and capacities".[87] As funding was by definition finite, the principle of rationing was

[84] Case C-372/04 *Watts*, supra note 4. Annotation M. Cousins, "Patient Mobility and National Health Systems", 34 *Legal Issues of Economic Integration* 2007, pp. 183-193; Davies, supra note 6.
[85] Case C-372/04 *Watts*, supra note 4, para 60ff. Substantively it thus confirmed Case C-56/01 Inizan, supra note 47, at paras 45 and 46. Critical of the Court's creation of two parallel regimes Cousins, supra note 84, at p. 192 who notes that *Watts* could have been solved by "a broad interpretation of article 22 of Regulation 1408 as the implementation of the right to free movement under the Treaty." Arguably this bridge had already been burned in *Kohll*, however, when the Court first embraced the notion of two parallel regimes.
[86] Case C-385/99 *Müller-Fauré*, supra note 64, para 92.
[87] Case C-372/04 *Watts*, supra note 4, para 67.

therefore accepted. Next, the existence of waiting lists, and their legitimate use, was balanced with the rights of patients as follows.

According to the Court:

> "(…) in order to be entitled to refuse the authorisation referred to in Article 22(1)(c) of that regulation on the ground of waiting time, the competent institution must however establish that the waiting time, arising from objectives relating to the planning and management of the supply of hospital care pursued by the national authorities on the basis of generally predetermined clinical priorities, within which the hospital treatment required by the patient's state of health may be obtained in an establishment forming part of the national system in question, does not exceed the period which is acceptable in the light of an objective medical assessment of the clinical needs of the person concerned in the light of his medical condition and the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the authorisation is sought." [88]

If the resulting waiting time is a medically acceptable one set in a manner that takes account of developments in the health of the patient this would mean an authorisation under Article 22 of Regulation 1408/71 could legitimately be refused to avoid such patient migration as might put at risk planning and rationalisation in the hospital sector. Remarkably therefore – and unlike its earlier approach in *Inizan* – the Court thus made application of the authorisation system under Regulation 1408/71 conditional on an overriding reason of general interest.[89] By adopting this standard of medically accepted waiting time the Court thus balanced the interest of national authorities in containing the outflow of patients with the individual patients' interests in speedier treatment. Adopting the medical acceptability standard also made the position of those who opposed patient mobility at all costs untenable.

Patients' rights under Article 49 EC

Confirming the earlier finding in *Müller-Fauré* the Court held that Article 49 EC applied in the case of hospital treatment in another Member State, regardless of the way in which the national system in the Member State of affiliation operates. It therefore found it unnecessary to determine whether the NHS itself provided a service in the sense of Article 49 EC. Because prior authorisation was not required for NHS treatment, imposing it as a precondition for treatment in other Member States constituted an obstacle to the freedom to provide services.

Next it examined possible justifications for such a restriction, focusing on the planning needs for hospital care in order to guarantee accessibility and to control costs, from which point of view (as found earlier in *Smits and Peerbooms* and *Müller-Fauré*) a prior authorisation system appeared necessary and reasonable.

However the conditions for said authorisation would have to be justified in the light of the overriding considerations involved and be proportionate. In the first place the Court repeated the procedural requirements of decisions based on transparent objective and non-discriminatory criteria and open to judicial review that could be based inter alia on independent expert advice. The UK manifestly failed to meet this condition as no criteria for refusing or granting authorisation had been spelled out at all. Second, the Court recalled in slightly different wording the abovementioned criteria with regard to the use of waiting lists that it had previously set out in relation to authorisations based on Article 22 of Regulation 1408/71 in the same case:

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[88] Case C-372/04 Watts, supra note 4, para 68. In this context the Court also referred to the change made by Article 20 of Regulation 883/2004 replacing the relevant text of Article 22 of Regulation 1408/71 "within the time normally necessary for obtaining the treatment in question in the Member State of residence" with "within a time-limit which is medically justifiable".

[89] Case C-372/04 *Watts*, supra note 4, paras 70-71. Cf. Case C-56/01 *Inizan*, supra note 47, para 21ff.

> "A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.
>
> Where the delay arising from such waiting lists appears to exceed an acceptable time having regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated, the fact that the hospital treatment provided under the national system in question is free of charge, the obligation to make available specific funds to reimburse the cost of treatment to be provided in another Member State and/or a comparison between the cost of that treatment and that of equivalent treatment in the competent Member State."[90]

With this it addressed explicitly as unacceptable the various reasons brought forward to elevate planning above the needs of individual patients, even in the light of an objective medical assessment.

Calculation of costs

The first difficulty concerning the calculation of costs, as regards Article 49 EC, was that there was no natural comparing point for reimbursement at the level in the Member State of affiliation, because in a (tax-funded) NHS system hospital treatment is free of charge. The second difficulty, as regards Article 22 of Regulation 1408/71 EC, was that Member States of treatment might provide for reimbursement in full, or in part. This made the rule on the relationship between Article 49 EC and the Regulation 1408/71 regimes that was set out in *Vanbraekel* – which provided for reimbursement of the difference between the levels between the Member State of affiliation and the Member State of treatment – difficult to apply.

In a densely worded paragraph the Court ruled that in an NHS setting Article 49 EC required that treatment that was (or should have been) authorised must be reimbursed based on the objectively quantified costs of equivalent treatment[91] in that NHS system, but only up to the amount of the costs actually charged to the patient in the Member State of treatment. In other words where equivalent treatment by an NHS costs less (unless Regulation 1408/71 applies and the Member State of treatment provides for full reimbursement), this can lead to out-of-pocket expenses for patients, and it can never lead to reimbursements that are higher than the actual costs incurred.[92] Covering ancillary costs such as travel and accommodation was considered required (by Article 49 EC, but not by Article 22 of Regulation 1408/71) only in those cases where they would be covered as part of treatment in the Member State of affiliation, and not otherwise.[93]

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[90] Case C-372/04 *Watts*, supra note 4, para 123.

[91] Case C-372/04 *Watts*, supra note 4, para 143. The notion of the need to establish a basis for reimbursement using objective, non-discriminatory and transparent criteria was first raised in Case C-385/99 *Müller-Fauré,* supra note 64, para 107. The requirement set in *Watts* however goes further as it is cost-based. As observed by Davies, supra note 6, at pp. 164-165 this means that NHS systems that are based upon different funding principles will now have to establish the costs of individual (types of) procedure, which may have important side-effects in highlighting choices that had so far remained implicit, as well as (presumably) differences in efficiency.

[92] Critical Cousins, supra note 84, at p. 189.

[93] Case C-372/04 *Watts*, supra note 4, para 142 citing Case C-8/02 *Leichtle*, supra note 79, para 41ff.

Budgetary constraints
Finally, the Court addressed the provocative question whether, in the light of Article 152 paragraph 5 EC,[94] Article 49 EC or Article 22 of Regulation 1408/71 could force Member States to fund hospital treatment without reference to budgetary constraints. According to the Court

> "(…) the requirements arising from Article 49 EC and Article 22 of Regulation No 1408/71 are not to be interpreted as imposing on the Member States an obligation to reimburse the cost of hospital treatment in other Member States without reference to any budgetary consideration but, on the contrary, are based on the need to balance the objective of the free movement of patients against overriding national objectives relating to management of the available hospital capacity, control of health expenditure and financial balance of social security systems."[95]

With reference to its earlier findings in *Müller-Fauré*, it briefly recalled that the Member States' responsibilities regarding healthcare did not exclude the need to make adjustments to social security systems where required by other Treaty provisions such as Article 49 EC. Hence it concluded there was no conflict with Article 152 paragraph 5 EC.

3.10. Herrera

The *Herrera* case[96] was ruled upon in June 2006, shortly after the landmark judgment in *Watts*. Mr Herrera, a Spanish national who had undergone hospital treatment in France after obtaining an authorization to do so based on Article 22 of Regulation 1408/71, claimed reimbursement from the Spanish public health service of the related travel, accommodation and subsistence costs for himself and a family member who had accompanied him. This gave rise to the question whether authorization based on Article 22 of Regulation 1408/71 included an entitlement to reimbursement for such ancillary costs. The referring court also asked whether national rules that excluded national treatment outside the public schemes (such as the Spanish NHS) to which individuals were entitled are consistent with the EU rules prohibiting discrimination, on the freedom to provide services, and the competition rules.

In relation to such ancillary costs the Court recalled its finding in *Kohll* and *Vanbraekel* that Article 22 of Regulation 1408/71 was not intended to regulate the costs incurred in connection with treatment in another Member State (but rather to enable an insured person to receive medical treatment there). As in *Watts*, it therefore found no obligation to reimburse ancillary costs could be based on Article 22. On the other hand, referring to *Watts*, excluding the reimbursement of ancillary costs in relation to treatment in another Member State while they would be covered in the case of national treatment would be at odds with the freedom to provide services. The Court held that the questions on discrimination, the freedom to provide services and the competition rules with respect to the exclusion of private healthcare in Spain from reimbursement as part of the public social security scheme in that Member State bore no relation to the subject matter of the main proceedings (the right to reimbursement of Mr Herrera) and therefore required no reply.

Clearly the Court preferred to steer away from what appeared to be predominantly domestic issues. However as the establishment of healthcare providers from other Member States is bound to be concentrated in the private sector similar issues are likely to arise under EU law before long.

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[94] The relevant part of this sector-specific subsidiarity provision reads: "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care."
[95] Case C-372/04 *Watts*, supra note 4, para 145.
[96] Case C-466/04 Manuel Acereda Herrera v Servicio Cántabro de Salud (Herrera) [2006] ECR I-5341.

3.11. Stamatelaki

Finally, in the *Stamatelaki* case[97] of June 2007, the issue of reimbursement of the costs of treatment in private hospitals abroad was tackled. Mr Stamatelakis, a Greek national, had been treated in a private hospital in the United Kingdom for which his wife as heir sought reimbursement from his insurer. At issue was a Greek rule which precluded the reimbursement of private treatment abroad for persons over 14 years of age. The Court quickly established that this deterred the provision of treatment in other Member States and therefore constituted a restriction on the freedom to provide services. When examining the possibility of an objective justification the Court accepted that overriding reasons of general interest such as the financial balance of the national social security system could in principle be invoked. However it rejected the Greek scheme as disproportionate given that it constituted a blanket prohibition whereas a less restrictive prior authorization scheme (meeting criteria such as set out in *Smits and Peerbooms*, *Analir* and *Müller-Fauré*), and the determination of scales for reimbursement, could have been adopted.

4. From case law to (proposed) legislation

The above review of the recent patient mobility case law shows that over the past decade the Court of Justice has developed a parallel regime for patient mobility based on the freedom to provide services of Article 49 EC, alongside the pre-existing rules based on the free movement of workers provided by Regulation 1408/71. The results are set out in the table below.

	Free movement of workers: Article 42 EC/Regulation 1408/71[98]	Free movement of services: Article 49 EC
Prior authorisation for hospital care	Required	May be required if justified and proportional
Prior authorisation for non-hospital care	Required	Not required
Means of payment	According to the rules of the Member State of treatment (may involve payment or co-payment by patient) Reimbursement of the Member State of treatment by the Member State of affiliation	By patient with subsequent reimbursement in the Member State of affiliation
Level of reimbursement	According to the rules of the Member State of treatment If reimbursement in the Member State of affiliation would be higher the difference may be awarded based on Article 49 EC	According to the rules of the Member State of affiliation (but capped at the level of actual costs)

Table 1: comparison between Regulation 1408/71 and Article 49 EC regimes for patient mobility (based on their interpretation in the ECJ case law). Source/inspiration: Impact Assessment, infra note 133, p.27.

Greatly simplified, the case law may be summed up as follows.[99] The scope of social security coverage as such is determined by the Member State of affiliation alone and

[97] Case C-444/05 *Aikaterini Stamatelaki v NPDD Organismos Asfaliseos Eleftheron Epangelmation (Stamatelaki)* [2007] ECR I-3185.

[98] This table deals only with elective (planned) treatment and not with emergency treatment – which is covered exclusively by Regulation 1408/71 and for obvious reasons does not require prior authorization. Benefits and reimbursement in this case are governed by the rules of the Member State of treatment.

therefore not at issue. Instead the focus of both regimes is on the conditions for the reimbursement of treatment abroad, when a patient is in principle entitled to the treatment involved in his Member State of affiliation.

- The basis of reimbursement is easily stated: when Article 49 EC is relied on, reimbursement is at the level of domestic treatment in the Member State of affiliation, based on Regulation 1408/71 reimbursement is at the level of the Member State of treatment. Where the latter is lower than the former, the difference may be claimed based on Article 49 EC.

- More complicated is the question when patient mobility will be reimbursed. Based on Regulation 1408/71 prior authorization of treatment abroad is always required as a condition for reimbursement, i.e. both for hospital and non-hospital care. Based on Article 49 EC, prior authorization – which is in principle a barrier to the freedom to provide services – cannot be required for non-hospital care. However, it may be required for hospital services. This is considered justified to safeguard the financial balance of the national social security system of the Member States and planning in the hospital sector. So far the Court has never required evidence before allowing this justification. Instead it has focused on elaborating procedural guarantees concerning the objective and proportionate nature of the authorization process, notably fleshing out in detail the concept of "undue delay" by requiring due regard to the individual circumstances of each patient. In this manner the Court has balanced the public interest justifications invoked by the Member States with the rights of individual patients based on free movement. Although these requirements are similar if not identical for the Article 49 EC setting and that of Regulation 1408/71 there is a clearly different starting point: Regulation 1408/71 always requires a prior authorization system to be in place, whereas in the case of Article 49 EC Member States may, but need not, require prior authorization for hospital care, and never for non-hospital care.

Against this background, the next section will deal with the run-up to the proposed patient mobility Directive, and with this proposal itself. This means the focus will shift from the Court, answering to the practical questions referred to it by national judges who are seeking to apply existing Community law, to the Commission's various attempts at codification of this case law, and to have new law created, by the Community legislature consisting of European Parliament and Council.

4.1. Setting the stage: initial analysis and fact-finding

The High Level process

The first reaction to the Court's case law at EU level occurred in December 2001 when an informal body advising the Commission on its health strategy, the High Level Committee on Health,[100] reported on the internal market and health issues

[99] For a more detailed survey including a full graphic summary cf. T.K. Hervey, "The current legal framework on the right to seek healthcare abroad in the European Union", 9 *Cambridge Yearbook of European Legal Studies* 2007, pp. 261-286; graphs also in J. Nickless, "The internal market and the social nature of health care", in McKee, Mossialos and Baeten (eds), supra note 19, pp. 57-82.

[100] The High Level Committee on Health consists of high level officials from the Member States. It is an informal advisory body that provides strategic advice on public health policy issues – notably the health strategy of the EU – and a forum to exchange information on related topics. The origins of the health strategy of the EU can be found in the Communication from the Commission on the development of public health policy in the European Community, COM(1998) 230 final of 15 April 1998. This eventually led to the first coherent programme in Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ 2002 L271/1. The most recent instalments of the health strategy are the European Commission White paper, Together for health: A strategic approach for the EU 2008-2013, COM(2007) 630 final of 23 October 2007; and Decision No 1350/2007/EC of the European Parliament and of the Council of 23

raised by the *Kohll*, *Decker* and *Smits-Peerbooms* cases,[101] and on cross-border healthcare more generally.[102] This report contained the first data on the expenditure related to patient mobility, which was estimated at between 0.3% and 0.5% of total EU healthcare expenditure. It also confirmed the by then evident finding that patient mobility (including in relation to hospital care) was covered by the freedom to provide services, and that Member States would find it increasingly difficult to justify authorisation for treatment abroad. However, given the wide divergence between the national systems involved and concerns about quality, outside interference, and the sustainability of financing systems, it concluded that "at present (…) there are neither legal powers nor recognizable political will within the Community to harmonise the delivery of health care in the Member States".[103] Consistent with this assessment it proposed instead to integrate healthcare into general Community strategies such as the Lisbon process – that aims to launch the EU as the leading knowledge-based economy – by means of the (then newly developed) open method of coordination (OMC).[104] It also proposed that a review of Regulation 1408/71 in the context of the direct application of the internal market case law could promote access to cross-border healthcare.[105]

Following an informal Health Council in Malaga of February 2002 where these expert findings were discussed, the Conclusions of the Health Council of 26 June 2002 on patient mobility and healthcare developments in the EU called for strengthened cooperation and a "high level process of reflection". For this purpose the Commission convened a working group at ministerial level (but with participation of interest groups such as the International Mutual Association, the standing Committees of hospitals and of doctors, as well as representatives of the European organizations of health managers, patients, and social insurance partners) which produced a reflection document in December 2003.[106] The latter covered issues such as rights and duties of patients, European centres of reference and health technology assessment that would remain on the agenda and later emerge in the proposed patient mobility Directive. It also raised issues such as access, quality and affordability that were to become the focus of subsequent OMC efforts, and – given its sponsorship by the health Ministers involved in this informal setting – was seen by the Commission as a political milestone in the acceptance of EU cooperation on health matters.[107]

October 2007 establishing a second programme of Community action in the field of health (2008-13), OJ 2007 L301/1. Cf. http://ec.europa.eu/health/ph_programme/keydo_programme_en.htm

[101] Case C-158/96 *Kohll*, supra note 4; Case C-120/95 *Decker*, supra note 32; Case C-157/99 *Smits and Peerbooms*, supra note 46.

[102] The internal market and health services: Report of the High Level Committee on Health, 17 November 2001. The working group that authored this report law was created in April 1999, i.e. in response to the *Kohll* and *Decker* cases. Cf. http://ec.europa.eu/health/ph_overview/keydocs_overview_en.htm

[103] The internal market and health services, supra note 102, p. 7.

[104] OMC involves agreeing to common objectives which set out high-level, shared goals; agreeing to a set of common indicators to measure progress; preparing national strategic reports, in which Member States set out how they intend to meet the common objectives over an agreed period; and collectively evaluating these strategies together with the European Commission. As such it is an alternative to harmonisation in policy areas where there is insufficient support for the latter. OMC is based on the precedents for a less structured form of policy coordination set by the Broad economic policy guidelines introduced by the Treaty of Maastricht in 1992 and the European employment strategy introduced by the Treaty of Amsterdam in 1997. OMC was introduced by the European Council of Lisbon in March 2000 in relation to combating social exclusion. Healthcare was only added in 2006. See infra note 111.

On OMC cf. N. Bernard, "Between a rock and a soft place: Internal market v open coordination in EU social welfare law", in Dougan and Spaventa (eds), supra note 3, pp. 261-286; J. Zeitlin, "Social Europe and experimentalist governance: towards a new constitutional compromise?", in de Búrca (ed), supra note 3, pp. 213-241. Critical of the usefulness of this approach which does not address the "constitutional asymmetry" between policies promoting market efficiencies and policies promoting social protection Scharpf, supra note 7 [2002].

[105] The report also raised issues such as legal liability, the importance of information for patients and contained such proposals as developing a system of European centres of excellence and arrangements for transferring patient data that were to re-emerge in subsequent documents.

[106] High level process of reflection on patient mobility and healthcare in the EU: Outcome of the reflection process, 9 December 2003, Cf. http://ec.europa.eu/health/ph_overview/keydocs_overview_en.htm

[107] "The report agreed by the reflection process at its final meeting on 8 December 2003 represented a political milestone by recognising the potential value of European cooperation in helping Member States to

This process in turn was followed by a December 2004 Communication from the Commission on patient mobility and healthcare developments in the EU that likewise covered the rights and duties of patients, sharing spare capacity across borders, the mobility of health professionals, European centres of reference, health technology assessment, health systems information strategy, cross-border care, data protection and e-health as well as suggestions for enhancing health policy cooperation.[108] The latter primarily involved setting up, by means of a Commission Decision of April 2004, a permanent High Level Group on health services and medical care to continue the coordination of work on these topics.[109] This High Level Group has produced work that is pertinent to the proposed patient mobility Directive such as concerning the purchasing of treatment abroad (at wholesale level) and common principles of care.[110] In parallel to its December 2004 Communication on patient mobility, the Commission proposed to extend the OMC process to healthcare (focusing on the shared values of access, quality and affordability).[111]

The Commission's 2003 Review

In parallel to its role in the developments involving the various groupings representing the Member States that were discussed in the preceding section the Commission also reacted directly to the innovative case law of the Court. In the first place it did so by fact-finding. On the basis of the data collected, the Commission services published a working paper in July 2003 (the "2003 Review")[112] reviewing the extent to which the Member States had taken on board the case law of the Court of Justice on patient mobility to date – essentially the 1998 *Kohll* and *Decker* and 2001 *Smits and Peerbooms* and *Vanbraekel* judgments (as *Müller-Fauré* had only been decided two months prior to the publication of the 2003 Review).[113]

In this Review the Commission found that the take-up of the implications of the case law by the Member States had been slow and piecemeal. This was at least in part due to the fact that the Member States had generally taken a conservative approach to the case law as it emerged, and new developments were not anticipated. For

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achieve their health objectives." Commentary on the background of patient mobility, DG Sanco website at http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm

[108] Communication from the Commission, Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, COM(2004) 301 final of 20 April 2004.

[109] Commission Decision C(2004)1501 of 20 April 2004. The High Level Group consists of high officials from the Member States, has a number of working groups, and reports annually to the Employment, Social Policy, Health and Consumer Affairs Council. In parallel, the High Level Committee on Health (supra note 100) continued its role as informal advisory body on public health and forum for information exchange.

[110] Guidelines for purchase of treatment abroad, 9 November 2005; Summary paper on common principles of care, from the mapping exercise of the High Level Group on health care services, 3 November 2006. On the former: T.K. Hervey, "New governance responses to healthcare migration in the EU: the EU guidelines on block purchasing", 14 *Maastricht Journal of European and Comparative Law* 2007, pp. 303-333. http://ec.europa.eu/health/ph_overview/co_operation/healthcare/high_level_hsmc_en.htm

[111] Commission Communication, Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the "open method of coordination", COM(2004) 304 final of 20 April 2004. It was again proposed in the Commission Communication, Working together, working better – a new framework for the open coordination of social protection and inclusion policies in the European Union, COM(2005) 706 of 22 December 2005. This resulted in a new Framework for the social protection and social inclusion process that was adopted by the European Council in March 2006 and added cooperation in the field of health and long-term care to the OMC process. The OMC process in healthcare and long term care primarily aims to ensure access, quality and affordability. It is managed by the Social Protection Committee (Council Decision 2004/689/EC of 4 October 2004 establishing a Social Protection Committee and repealing Decision 2000/436/EC, OJ 2004 L314/8). On the Social Protection Committee see Bernard, supra note 104 pp. 283-284. Both the OMC process and the High Level Group on health services and medical care (supra note 109) are presented as key to cooperation between the Member States in this area in the Council Conclusions on common values and principles in European Union health systems, OJ 2006 C146/1 (Statement in Annex). In parallel, there is the High Level Committee on Health (supra note 109).

[112] Commission staff Working Paper, Report on the application of internal market rules to health services: Implementation by the Member States of the Court's jurisprudence, SEC(2003) 900 of 28 July 2003.

[113] Case C-158/96 *Kohll*, supra note 4; Case C-120/95 *Decker*, supra note 32; Case C-157/99 *Smits and Peerbooms*, supra note 46; Case C-368/98 *Vanbraekel*, supra note 45; Case C-385/99 *Müller-Fauré*, supra note 64.

example, following *Kohll* and *Decker* the Member States had generally assumed these rulings would neither apply to hospital services, nor to any type of healthcare in the context of benefits in kind and NHS systems. Moreover, the distinction between hospital services (for which an authorization could be required) and non-hospital services (for which it could not) made in *Smits and Peerbooms* and repeated in *Müller-Fauré* was almost generally not acted upon.

As far as implementation of the Court's jurisprudence by the Member States was concerned, the Commission found that by and large prior authorization was still being required even for non-hospital services, and that the authorization systems in place were often inadequate and, due to procedural problems and the time required, likely to frustrate patient mobility. In a number of Member States authorization for treatment abroad was only provided based on Article 22 of Regulation 1408/71 (and therefore not based on Article 49 EC). Criteria for deciding whether treatment was normal and the existence of medical necessity often did not reflect the case law, i.e. treatment tried and tested by international medical science, and necessity assessed in the light of the concrete circumstances of the patient concerned (such as the degree of pain or nature of the patient's disability, the ability to carry out a professional activity and his medical history).

At a quantitative level the data provided by the Member States were difficult to compare and figures varied widely.[114] Nevertheless, even on this uneven basis the Commission found that so far the impact of patient mobility was negligible. In only two Member States (Italy and Luxembourg) did more than 10.000 requests for prior authorization occur annually. Only two Member States had attempted to measure the effects of the possibility to apply for reimbursement without prior authorization, leading to inconclusive data. In the Member State most affected (Austria) slightly over 1% of the persons insured were treated abroad annually (mainly for dental services in Hungary, apparently), spending 0.03% of the social security budget.

In conclusion the Commission found that the internal market in health services was not functioning satisfactorily: applications for reimbursement of non-hospital costs and for authorization of hospital treatment in other Member States were frustrated and, unsurprisingly, patients were not availing themselves of their rights. Among the solutions mooted was creating a Community legal framework. The Commission would soon take this up in practice – in spite of the lack of enthusiasm at Member State level shown both in the context of the High Level process and in that of its own 2003 Review.

4.2. Failing to complete the internal market: the Services Directive[115]

The initial strategy of the Commission concerning legislation on patient mobility following the 2003 Review was to include health services in the Services Directive that was presented as a key step in completing the internal market. And although this view was possibly out of step with the mood of the times, the internal market was then still seen by many as a platform popular enough to carry the added weight of this particular liberalisation proposal. Thus Article 23 of the original proposal for the Services Directive in March 2004 codified the case law on free movement in healthcare.[116] However while the Commission's elaboration in several supporting

[114] For instance figures for E-111 forms (for permanent residents) and E-112 forms (for patients relying on Article 22 of Regulation 1408/71) were often aggregated, confusing the issue, and figures for patients relying on Article 49 EC were only collected by two Member States.

[115] Directive 2006/123/EC, supra note 11.

[116] European Commission, Proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD) [SEC(2004) 21] COM(2004) 2 final/3, 5 March 2004. "Article 23 Assumption of health care cost:

1. Member States may not make assumption of the costs of non-hospital care in another Member State subject to the granting of an authorisation, where the cost of that care, if it had been provided in their territory, would have been assumed by their social security system. The conditions and formalities to which the receipt of non-hospital care in their territory is made subject by Member States, such as the requirement that a general practitioner be consulted prior to consultation of a specialist, or the terms and

documents on Article 23 was exhaustive on the need for a codification on patients' rights, it failed to explain – at least to the satisfaction of the Community legislature – why this should be done in the context of the Services Directive.[117] The inclusion of health services was in fact strongly resisted both by the European Parliament and the Council from the outset and became one of the reasons why the Services Directive eventually seemed in danger of foundering completely. According to the Commission's own subsequent analysis the approach of including patient mobility in the Services Directive was unacceptable to the Commission legislature because it failed to take into account the technical complexity, sensitivity to public opinion and major support from public funds involved in healthcare.[118]

Thus the European Council of March 2005 already indicated that the proposed Services Directive was not acceptable as it stood.[119] In its April 2005 Report on patient mobility and healthcare developments, the European Parliament objected strongly against inclusion of healthcare in the proposed Services Directive, although it called for the Commission to act on a wide range of issues related to patient mobility and wider cooperation between health systems.[120] The amendments to the Services Directive that were proposed in the November 2005 Report by the internal market and consumer protection committee of the European Parliament also included deletion of Article 23.[121] Alongside a number of other significant changes the Commission subsequently removed this article from its amended proposal of April 2006 in order to forestall failure of the Services Directive as a whole.[122] As a result, health services are now completely excluded from the scope of the Services Directive as it was finally adopted in December 2006, as made explicit by its Article 2 paragraph 2 sub f.[123]

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conditions relating to the assumption of the costs of certain types of dental care, may be imposed on a patient who has received non-hospital care in another Member State.

2. Member States shall ensure that authorisation for assumption by their social security system of the cost of hospital care provided in another Member State is not refused where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation and where such treatment cannot be given to the patient within a time frame which is medically acceptable in the light of the patient's current state of health and the probable course of the illness.

3. Member States shall ensure that the level of assumption by their social security system of the costs of health care provided in another Member State is not lower than that provided for by their social security system in respect of similar health care provided in their territory.

4. Member States shall ensure that their authorisation systems for the assumption of the costs of health care provided in another Member State are in conformity with Articles 9, 10, 11 and 13."

[117] Proposal for a Directive on services in the Internal Market - Explanatory note on the activities covered by the proposal, 25.06.2004 and Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs, 16.07.2004, both found on the DG Markt site dedicated to the Services Directive and its background http://ec.europa.eu/internal_market/services/services-dir/proposal_en.htm. The main argument was that patient mobility was a key citizens' right and therefore required inclusion in the section of the Services Directive that was dedicated to strengthening the rights of European citizens as recipients of services.

[118] Commission Communication of 2 July 2008, Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare presented by the Commission, COM(2008) 414 final, Explanatory Memorandum, para 1.

[119] Council of the European Union, European Council Brussels 22 and 23 March 2005, Presidency conclusions, at para 22.

[120] European Parliament Committee on the Environment, Public Health and Food Safety, Report on patient mobility and healthcare developments in the European Union (Rapporteur: John Bowis) A6-0129/2005 final (dated 19 April 2005). At this stage the EP did not call for new legislation however but for Commission guidelines and a "Charter" on patients' rights.

[121] European Parliament Committee on the Internal Market and Consumer Protection, Report on the proposal for a directive of the European Parliament and of the Council on services in the internal market (COM(2004)0002 – C5-0069/2004 – 2004/0001(COD)) (Rapporteur: Evelyne Gebhardt) A6-0409/2005 final (dated 15 December 2005).

[122] European Commission, Amended proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD), COM(2006) 160, of 4 April 2006.

[123] Which excludes: "healthcare services whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organized and financed at national level or whether they are public or private". Recital 22 of the Preamble states: "The exclusion of health services from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided"; and recital 23 of the

After all references to healthcare had been expunged from the Services Directive institutional support did begin to emerge for specific Community legislation concerning patient mobility. At the Health Council of 1 June 2006, Ministers adopted Conclusions and a Statement of common values and principles in EU health systems[124] which noted that the Commission had not just withdrawn Article 23 on healthcare from the proposed Services Directive but also intended to develop a Community framework providing legal certainty in this area. The Council recognised the need to clarify the implications of the Court's case law on free movement and while underlining the importance of "protecting the values and principles that underpin health systems in the EU" called for the Commission to take these into account when drafting specific proposals concerning health services.

This appears to have tied in with parallel developments in the European Parliament. In spite of its earlier resistance to legislation on healthcare and the freedom to provide services in this context (it had instead called for guidelines and various other softer forms of intervention in its April 2005 Report referred to above), the European Parliament soon came round to the need for a binding instrument. Thus in a Resolution on cross-border healthcare of March 2007, it called inter alia for codification, by introduction of a legislative framework, of the case law of the Court of Justice.[125] The European Parliament did so again in a subsequent Resolution evaluating the exclusion of healthcare from the Services Directive in May 2007, calling for an appropriate legal instrument.[126]

4.3. Testing the waters: the 2006-2008 Consultation

Parallel to these political developments the Commission carried out a consultation on Community action concerning health services that was launched in September 2006 and lasted until early 2008.[127] Given the background of failure of the Services Directive and because the abovementioned support from the European Parliament and the Council had not (fully) emerged yet, the Commission took a careful approach. In this consultation it aimed to collect information not just on patient mobility,[128] which it estimated to affect less than 1% of healthcare expenditure within the EU, but more broadly on healthcare issues where the Member States might welcome Community action. As such it focused on the need for legal certainty and on identifying areas where EU action might be complementary to that at national level.

Regarding legal certainty the Commission started from the premise that the Court's rulings were clear in and of themselves and that no preconditions could be attached to the exercise of patients' rights as recognized by the Court. Consequently, the main issues it raised for consultation concerned the need for clarifying procedures, for the

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Preamble reads: "This Directive does not affect the reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident. This issue has been addressed by the Court of Justice on numerous occasions, and the Court has recognised patients' rights. It is important to address this issue in another Community legal instrument in order to achieve greater legal certainty and clarity to the extent that this issue is not already addressed in Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community".

[124] Council Conclusions on common values and principles in European Union health systems, OJ 2006 C146/1 (Statement in Annex).

[125] European Parliament Resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (2006/2275(INI)) P6_TA(2007)0201.

[126] European Parliament Resolution of 15 March 2007 on Community action on the provision of cross-border healthcare. P6_TA(2007)0073.

[127] Commission Communication of 26 September 2006 on the Consultation regarding Community action on health services, SEC(2006)1195/4. The results were summarised in the Commission document, Summary report of the responses to the consultation regarding "Community action on health services" (not dated, 2007). Cf. http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm

[128] As is recognised by the Communication on the Consultation SEC (2006) 1195/4, p. 5, patient mobility is only one of four possible types of cross-border healthcare. These are: cross-border provision of services, the use of services abroad (patient mobility) permanent establishment of healthcare providers in other Member States, and temporary mobility of health professionals. The Consultation aimed to cover all four of these aspects.

identification of competent authorities and their responsibilities, a liability and compensation regime, and for a safeguard regime for the Member State of treatment. In addition the Commission wanted to know whether a binding legal instrument (Regulation or Directive) or instead a soft law form of guidance was preferred. As regards complementary action it identified mainly European networks of centres of reference (for specialization in e.g. rare diseases or complex treatment), management of innovation and sharing data and evidence for policy making.[129]

As regards the impact of patient mobility, the responses to the consultation again revealed a general lack of data but were not inconsistent with the Commission's prior estimate of 1% of healthcare expenditure,[130] and an upwards trend. Legal clarification was suggested in relation to the right to treatment abroad, on the conditions for prior authorization, the definition of health services and hospital care,[131] and of pricing for cross-border care. As might have been expected, it was widely held that responsibility for clinical supervision should rest with the Member State of treatment, and liability for harm and redress thereof with the provider of the treatment. More remarkably, the Commission reported no coherent requests for a safeguard procedure in the Member State of treatment – i.e. to avoid them being flooded with patients (although the fact this was not signalled may simply be consistent with the very low numbers so far involved). Equally remarkable was the apparent lack of responses concerning provider establishment.

Finally, concerning the legal instrument to be chosen with regard to patient mobility, the Commission reported an even mix between those who preferred extending the existing Regulations on the coordination of social security systems, and those preferring a new Directive on patient mobility. In fact the Commission was already engaged in preparing a proposal for such a Directive during the course of the consultation, which the Commission (having originally planned to adopt it in December 2007) eventually adopted on 2 July 2008.

5. Renewing the social agenda: the proposed patient mobility Directive

5.1. Context, background and structure

Context

The Commission's legislative proposal for a Directive on patient mobility (or, as it is called literally: "on the application of patients' rights in cross-border healthcare") as presented on 2 July 2008 formed part of a raft of 19 documents and proposals of the same date jointly billed as a renewed social agenda for 21st century Europe.[132] It thus featured among worthy proposals inter alia on combating Roma exclusion and discrimination beyond the workplace, on reviewing legislation on European works councils and on improving working conditions for maritime workers, as well as among reports on social services of general interest and on the European globalization adjustment fund, and a consultation on improved website access for the disabled. In stark contrast to the earlier embedding of patient mobility in the undiluted economic logic of the Services Directive, the connecting theme behind the July 2008 package

[129] As identified in the Commission Communication on the Consultation, supra note 127, at p. 9, these included, broadly, the topics that were also under the scope of the High Level Group of high level officials of the Member States and that had been flagged by the earlier High level process of reflection (at ministerial level). Supra note 106. They were thus well-established.

[130] Although the impact could obviously be higher in border regions, smaller Member States, and in areas attracting large numbers of tourists. Summary Report, supra note 127, p. 9.

[131] Including a query from the UK Government on whether the Court had in fact ruled there could be no justification for a prior authorization regime for non-hospital care, or whether it had just ruled that it had not so far seen a justification for such a regime. Summary Report, supra note 127, p 15.

[132] Cf. Commission Communication of 2 July 2008 on the Renewed social agenda: Opportunities, access and solidarity in 21st century Europe, COM(2008) 412 final; Commission press release IP/08/1070, Commission proposes renewed social agenda to empower and help people in 21st century Europe, Brussels, 2 July 2008; Commission memo MEMO/08/471, Renewed Social Agenda: The elements of the package, Brussels 2 July 2008.

was to constitute a counterpoint to the Lisbon growth strategy of the EU, i.e. to develop further the social conscience of EU capitalism.

It is of course well beyond the remit of this paper to comment on these broader ambitions and it remains to be seen whether patient mobility will in fact fare better in the renewed social agenda context. At first sight the logic involved is, if anything, limited. Member States that are afraid their social security systems will come under threat or may unravel as a result of this proposal are unlikely to spot any obvious social dimension in it. However, there is another aspect that clearly distinguishes the proposed patient mobility Directive from the earlier attempt to include a single article on healthcare in the context of the Services Directive: it is now a phenomenon of a different order as it is in fact a full-fledged dedicated legal instrument purporting to provide a complete and coherent legal regime for all the issues involved. It is as such that the proposed patient mobility Directive will be examined in greater detail here.

Impact assessment

The proposal for the patient mobility Directive was published jointly with an accompanying Communication and an Impact Assessment as well as a summary of the latter.[133] The aim of the Impact Assessment was to assist the Commission in its choice between different policy options – as well as, implicitly, to back up the policy option that was actually selected. The Impact Assessment cites Eurobarometer survey data to show that over the past 12 months 4% of the EU population has received medical treatment in another Member State, that 70% of the EU population believes such treatment would be reimbursed, and that just over half the EU population is open to travelling to another EU Member State to receive treatment.[134] However the Impact Assessment also states that generally patients will prefer to receive care in their local environment and that it is generally considered to be safer and more efficient to be treated within a single (national) healthcare system with the exception of three cases:

- Highly specialized care
- Border regions (where the nearest provider may be across the border)
- Where there is lack of capacity locally and capacity is available in another Member State.

Although these assertions make obvious intuitive sense the Impact Assessment does not make clear to what extent they are backed up by the survey data or in some other way. In any event, they do not square with the scope of the proposed patient mobility Directive which, as will be seen below, is considerably broader than these three categories (while Regulations 1408/71 and 883/2004 already provide a more liberal regime for frontier workers, and in the latter case, their families). The Impact Assessment further confirms the Commission's earlier claims in its 2006-2008 Consultation exercise that cross-border healthcare accounts for 1% of public expenditure on healthcare, equalling approximately €9.7 billion.[135] The overall impact of patient mobility in the EU is thus small. At the same time the Impact Assessment states its actual impact may be much greater locally e.g. in border regions, smaller

[133] Commission Communication of 2 July 2008, Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare presented by the Commission, COM(2008) 414 final (including an Explanatory Memorandum); Commission Communication of 2 July 2008, A Community framework on the application of patients' rights in cross-border healthcare, COM(2008) 415 final; Commission staff working document of 2 July 2008, accompanying document to the Proposal for a directive of the European parliament and of the Council on the application of patients' rights in cross-border healthcare: Impact Assessment, SEC(2008) 2163; Commission staff working document of 2 July 2008, accompanying document to the Proposal for a directive of the European parliament and of the Council on the application of patients' rights in cross-border healthcare: Summary of the impact assessment, SEC(2008) 2164.

[134] Impact Asessment, supra note 133, pp. 6-7 citing Flash Eurobarometer series #210, Cross-border health services in the EU, Analytical report for DG Sanco, 2007.

[135] EU GDP is €12,149 billion of which presently 7.6% (€967 billion) is spent on public healthcare. Impact Assessment, supra note 133, p. 9 (Eurostat figures 2006/2007).

Member States such as Cyprus, Luxembourg and Malta, in tourist areas, and in systems or for treatments involving high co-payments (i.e. out of pocket expenses for patients leading them to seek out less costly treatment abroad).

Overall, the Impact Assessment identifies "a rising trend for cross-border healthcare and significant potential demand from citizens to explore cross-border healthcare where it is quicker, better, cheaper or more convenient for them".[136] Such a trend would be consistent with prospects of demand-driven markets generating greater overall efficiency as consumer choice rewards providers who perform better, providing an incentive for providers more generally to improve their performance. In this context it is worth noting that the Impact Assessment estimates the average pent-up demand (or unmet healthcare need) in the EU as affecting 8.5% of its population, 10% of which 8.5% (i.e. 0.85% of the population) presently go abroad to receive care.[137] It is not very clear how these figures relate to the earlier data showing 4% of the EU population goes abroad to receive healthcare – which incongruously suggests that the majority of them do not suffer from needs unmet at home – but at least the overall pattern suggests potential for change exists.

The main message of the Impact Assessment is its quantified comparison of four policy options:

- No action at Community level
- Non-binding guidance on cross-border healthcare issues
- Providing a general legal framework through a Directive on health services in two alternative versions:
    - either covering both hospital services and non-hospital services
    - or covering only non-hospital services
- A detailed legal framework of harmonizing legal measures.

Assessing the validity of the quantification involved of the treatment costs, treatment benefits (measured in quality-adjusted life years, or QALYs), compliance and administrative costs, and social benefits (extra number of patients to receive treatment) is better left to health economists. In any event the Impact Assessment shows that only the option eventually chosen by the Commission – that of a dedicated Directive covering both hospital and non-hospital care – provides net benefits in relation to the costs involved, more specifically a positive balance of € 179,6 million, with 780,000 extra patients receiving treatment for the EU as a whole.

As the other options provide only provide negative benefits (albeit to greater and lesser degrees) they must obviously be discarded. However, do the gains claimed in relation to the preferred policy option not seem rather small – or perhaps more accurately: staggeringly low – as a basis for making the case for EU action? And the same time, as will be seen below, the Commission is using the minor impact that patient mobility is expected to have in order to argue that prior authorization requirements are unlikely to be justified. In other words, the Commission appears caught between the need to argue on the one hand, that something meaningful is at hand requiring EU legislation and, on the other hand, that its impact on national social security regimes will be so minor as to forestall safeguard measures that might frustrate the initiative.[138] There seem to be only two possible justifications for doing this: the principled one, based on the argument that this is all required in order to enable patients to enjoy the rights that were already conferred upon them by the Treaty itself, and a more practical or opportunistic one, which assumes that this is

[136] Impact Assessment, supra note 133, p 11.
[137] Impact Assessment, supra note 133, p 11-12.
[138] As expressed more provocatively by Bernard at an earlier stage, "Besides the argument about the probable limited economic impact of free movement rights on national social protection systems is a two-edged sword. If the right to be reimbursed for medical treatment in another Member State is going to make, at best, no difference to the overwhelming majority of people, why bother? Why stretch Treaty articles to breaking point if this will have negligible impact?", supra note 104, p. 275.

merely the first step on the road toward creating further incentives for greater efficiency in healthcare, setting in motion a process that will be difficult to stop. Most likely, as is often the case in practice, these motives have been mixed.

In any event, it is on the basis described above that the Commission submitted its proposal for a patient mobility Directive covering both hospital services and non-hospital services, which is discussed below.

Patients' rights
It should noted at the outset that the proposal as it finally emerged on 2 July 2008 is labelled the Directive on the application of *patients' rights* to cross-border healthcare. An earlier version of the Directive that was substantively largely identical to the current proposal was titled: "on safe, high-quality and *efficient* cross-border healthcare". Apart from neither being particularly snappy nor unambiguously identifying the consumer as the primary intended beneficiary of the Directive, this title appeared suggestive of a probably overly optimistic expectation that the objective of efficiency in healthcare is a widely shared one in the EU today (and apart from being provocative it had the added drawback of being needlessly provocative: see the remarks on the aim of the proposed Directive below).

"Patients' rights", the title eventually plumped for by the Commission, refers to a concept traditionally understood as being considerably broader in scope than merely the reimbursement of cross-border medical treatment.[139] It is true that in the context of the proposed patient mobility Directive this concept can also be linked to the common principles in its Article 5, framed as obligations of the Member State of treatment. These include quality and safety standards, information necessary for informed choice, the means to complain and obtain remedies, compensation for harm and privacy rights, and could in effect easily be rephrased as (a set of) patients' rights. However, given that at least so far the key issue is that of patient mobility (to which the prospective rights are secondary or auxiliary in nature) this is the term used here to indicate the proposed Directive and its purpose.

Structure
After setting out legal definitions and general provisions (including aim and scope), the structure of the proposed Directive is in three parts:

- Common principles in EU health systems
- Specific framework for cross-border healthcare
- EU cooperation on healthcare.

The discussion below will focus on the second of these three elements, which is the core of the Directive as codification of the case law of the European Court of Justice on patient mobility that was discussed above. The other elements however will also be addressed briefly.

5.2. Legal basis and general principles

Harmonization
The legal basis of the proposed patient mobility Directive is Article 95 EC, i.e. the harmonization provision aimed at securing the establishment and functioning of the

[139] Cf. the documentation and the links on this topic available on the website of the World Health Organisation (WHO) at http://www.who.int/genomics/public/patientrights/en/. According to the WHO although conceptions of patients' rights vary widely there are four basic models of the relationship between the patient and the physician that shape thinking about of patients' rights: the paternalistic model, the informative model, the interpretive model, and the deliberative model. At the same time the WHO notes "growing international consensus that all patients have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be informed about relevant risk to them of medical procedures".

internal market.[140] This is justified by the fact that although the Court judgments clarified patients' rights they have not proven sufficient in and of themselves to enable patients to avail themselves of these rights widely or in an effective manner. (A claim that is substantiated by the Impact Assessment, and further research funded by the Commission cited there.) The Commission's proposal therefore follows a familiar pattern in the process of European integration: i.e. negative integration – striking down barriers to the market freedoms – breeds the need for positive integration, or harmonization – elaborating rights and obligations in legislation that strikes a new balance between private freedoms and legitimate public interests. Also, in this manner private action by individuals invoking the primary rights set out in general terms in directly effective Treaty provisions eventually triggers secondary legislation endowed with democratic legitimacy by the intervention of the European Parliament and the Council and that is of horizontal application across the EU.

Subsidiarity
At the same time the proposed patient mobility Directive is required to respect not just to the subsidiarity provision in Article 5 EC but also the provisions of Article 152 paragraph 5 EC, which provides a special subsidiarity clause with respect to the responsibility of the Member States for the organization and delivery of healthcare. As was already clarified by the Court in *Müller-Fauré* and *Watts*, this provision does not mean that adjusting national systems may not be required by other Treaty obligations, such as Article 49 EC.[141] In this context, the proposed patient mobility Directive claims to form a framework that, first, provides clarity about the rights to reimbursement for healthcare provided in other Member States as well as, second, ensuring that such cross-border healthcare is of high quality, safe and efficient, which could not be done effectively by individual Member States. At the same time, the basic assumption is that, in line with Article 152 EC, the Member States retain full responsibility for determining what medical services are covered by their national social security regimes and for the actual provision of healthcare.

Nevertheless it should be noted that a clear statement confirming the autonomy of the Member States of affiliation in relation to determining the scope of their respective national social security coverage is lacking in the body of the text of the proposed patient mobility Directive.[142] This is odd as it concerns one of the central tenets of the EU division of competencies in this area as well as in view of Article 152 paragraph 5 EC, and it appears likely that the Community legislature will wish to address this point when considering the proposal.

Proportionality
According to the Commission's Explanatory Memorandum, its proposal respects the proportionality requirement of Article 5 EC because the Member States (as under the subsidiarity argument) retain the right to choose which healthcare benefits they provide for their citizens. Moreover, Article 6 paragraph 4 of the proposed patient mobility Directive provides that in so far as they are the same for care provided in the Member State of affiliation or another Member State, are non-discriminatory and do not obstruct the free movement of persons, Member States may continue to impose conditions, criteria of eligibility and regulatory and administrative formalities on patients seeking healthcare. An example is the obligation to obtain a referral from a general practitioner before seeking specialized care. Recital 28 of the Preamble (but

[140] On the legal basis for Community legislation on healthcare cf. D. Wyatt, "Community competence to regulate medical services", in Dougan and Spaventa (eds), supra note 3, pp. 131-143.
[141] Case C-385/99 *Müller-Fauré*, supra note 64, para 102 (without specific reference to Article 152 paragraph 5 EC); Case C-372/04 *Watts*, supra note 4, para 147.
[142] Recitals 25 and 26 of the Preamble do mention that there shall be no entitlements to reimbursement of treatment that is not among the benefits defined in the Member State of affiliation, and that the Member States of affiliation alone will determine the scope of coverage of their social security schemes. These are presumably to be read as background to Article 6 paragraph 1 of the proposed patient mobility Directive which provides for reimbursement "where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled."

not the text of the proposed patient mobility Directive) suggests the – considerably more stringent – requirements of necessity and proportionality must be met before such conditions, criteria and formalities may be imposed.

5.3. Aim, scope and definitions

Efficiency?
The aim stated in Article 1 of the proposed patient mobility Directive is to provide a general framework for the provision of safe, high quality and efficient cross-border healthcare. Of these aims that of efficiency is noteworthy, not just because it seems unlikely to enjoy broad political support in the abstract at least for healthcare – generally values like solidarity or access and affordability are embraced instead – but also because in effect the proposed patient mobility Directive fails to live up to the expectations perhaps inadvertently raised by including this potentially provocative concept.

Thus the body of the text directly refers to efficiency only in Article 16 in relation to E-health, and via the Preamble, in relation to central contact points (Article 12), cooperation in border regions (presumably Article 13), cooperation in the evaluation of health technologies (Article 17), and the collection and exchange of data (Article 18).[143] Valuable as these processes of enhanced administrative coordination and exchange may be in their own right they reflect a notion of efficiency that is a far cry from the competitive process as an efficiency driver that is familiar from market-based environments.

(Cross-border) healthcare
The scope in Article 2 of the proposed patient mobility Directive extends to all healthcare without distinction to its organization, delivery or financing. This is significant first, because it thus explicitly includes healthcare within the terms of Article 158 paragraph 5 EC and second, also includes healthcare provided outside social security systems, in particular private healthcare. These points are made explicit in the definition of healthcare in Article 4 sub (a) of the proposed patient mobility Directive:

> "'healthcare' means a health service provided by or under the supervision of a health professional in the exercise of his profession, and regardless of the ways in which it is organized, delivered and financed at national level or whether it is public or private."

The definition of cross-border healthcare is also worth noting, not so much for what it says in Article 4 sub (b) of the proposed patient mobility Directive[144] but for what recital 10 of the Preamble claims this means:

> "For the purpose of this Directive, the concept of "cross-border healthcare" covers the following modes of supply of healthcare:
> - Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
> - Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;
> - Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,

[143] Respectively recitals 34, 37, 43 and 42 of the Preamble.
[144] I.e.: "cross-border healthcare" means healthcare provided in a Member State other than that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established.

– Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).”

Of these, really only the first is in fact dealt with in the proposed patient mobility Directive. In contrast to the other three aspects that are related to the provision of services, the third firmly concerns the freedom of establishment, which the proposed patient mobility Directive does not even begin to address.

Hospital services and specialized care
Hospital services, a contested topic because it determines the scope of the permissible prior authorization regime, and specialized care (in an innovation to the case law) are defined elsewhere in the text, i.e. in Article 8 in the core section on patient mobility. Hospital services and specialized care concern healthcare that requires an overnight stay (for one or more nights) or that is included on a limited list that is established according to comitology procedures and involves the use of highly specialized and costly medical infrastructure or equipment, or involves treatments that present a particular risk to the patient or the population at large.

5.4. Relationship with Regulation 1408/71

Parallel regimes
The EU will continue to have two parallel authorization regimes, one the existing one based on Regulation 1408/71, the other a new one of the proposed patient mobility Directive, replacing that of Article 49 EC (which in most Member States in fact never existed). As before, the relationship between the two is less than straightforward.

Article 3 paragraph 2 of the proposed patient mobility Directive states that it shall apply without prejudice to Regulation 1408/71 and its successor legislation (Regulation 883/04), specifying that where an authorization for treatment based on Article 22 of Regulation 1408/71 must be granted that Regulation shall apply, and not the proposed patient mobility Directive. In all other cases the reverse holds, i.e. the relevant provisions of the proposed patient mobility Directive apply, and not Article 22 of Regulation 1408/71. This rule which purports to frame the “coherence” of the two legal measures is in essence repeated in Article 9 paragraph 1 of the proposed patient mobility Directive.

There are three remarks to be made on this relationship. These concern respectively the use made of the undue delay criterion, the basis for reimbursement, and the possibility of amending Regulation 1408/71. These will each be addressed in turn.

Undue delay and division of labour
First, as is explained in recital 22 of the Preamble this means that where the treatment in question cannot be given within the time medically justifiable, taking into account the state of health of the patient and the probable cause of the disease, Regulation 1408/71 applies as patients should not be “deprived of the more beneficial rights” guaranteed by the Regulation. At first reading this appears distinctly odd because according to the case law the “undue delay” test applied in the context of Regulation 1408/71 is not significantly different from the test that applies in the context of Article 49 EC. In fact the Court has merged the two, first effectively in the *Inizan* case,[145] and then explicitly in *Watts*:[146]

[145] More precisely determining undue delay requires “to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history” Case C-56/01 *Inizan*, supra note 47, para 46 with reference to Case C-157/99 *Smits and Peerbooms*, supra note 46, para 104, and Case C-385/99 *Müller-Fauré*, supra note 64, para 90.
[146] Case C-372/04 *Watts*, supra note 4 , para 60.

> "(…) there is no reason which seriously justifies different interpretations depending on whether the context is Article 22 of Regulation No 1408/71 or Article 49 EC, since in both cases the question is (…) whether the hospital treatment required by the patient's medical condition can be provided on the territory of his Member State of residence within an acceptable time which ensures its usefulness and efficacy."

It seems strange, therefore, for the proposed patient mobility Directive to refer to the "undue delay" criteria in relation to superior rights under Regulation 1408/71, unless, of course, the Article 49 EC rights on this point will in fact be reduced by the proposal. And indeed they will be. The rule established by Article 3 paragraph 2 of the patient mobility Directive is that in cases of undue delay Article 22 of Regulation 1408/71 applies, and in all other cases the regime (which may in the case of hospital care and specialized care involve prior authorization) of the proposed Directive. In effect the undue delay case law of the Court in relation to Article 49 EC is dropped from the codification programme, and at the same time the scope of Regulation 1408/71 is reduced to cases of "undue delay". It is questionable how practical this criterion is because it will require, at least in non-obvious cases (the number of which will depend largely on the willingness of the authorities involved), making an application under Article 22 of Regulation 1408/71 to find out if in fact there is "undue delay", and therefore which regime is applicable. Perhaps this objection will be less relevant if in practice few if any authorizations are required based on the proposed patient mobility Directive, making this route more attractive to patients. But is anything gained hereby that is really worth taking a gamble with the principles hard-won in the case law? (See also the section on the framework for cross-border care further below.)

The basis for reimbursement

Second, the basis for reimbursement (at the level prevailing in the Member State of treatment for Regulation 1408/71 and at that of the Member State of affiliation for Article 49 EC, or now the proposed patient mobility Directive) will continue to differ under the two regimes. Another difference is that whereas under Regulation 1408/71 the general rule is that patients do not have to meet the costs of treatment directly, under the regime of the proposed patient mobility Directive payment by the patient subject to subsequent reimbursement is the rule. As far as the benefits themselves are concerned, recitals 22 and 23 of the Preamble to the proposed patient mobility Directive variously suggests that the regime of Article 22 of Regulation 1408/71 must be maintained as it is more favourable to the patient ("the more beneficial rights guaranteed by Regulation 1408/71 and 883/04") and that the patients may choose which mechanism they prefer.

There are at least two reasons to question this confusing approach:

- First, it is not obvious that much choice will be available: as Article 3 paragraph 2 and (to a lesser extent) Article 9 paragraph 1 of the proposed patient mobility Directive determine that patients who wish to rely on "undue delay" arguments must seek recourse to Article 22 of Regulation 1408/71, and in all other cases the proposed patient mobility Directive applies, there are few cases of parallel applicability. If there is no prior authorization regime in place based on the proposed patient mobility Directive, could a request under Article 22 of Regulation 1408/71 still be made? Probably it could and in this case the patient would have a choice. Moreover an application for authorization under Article 22 of Regulation 1408/71 may at least in some cases be needed to establish which regime applies, i.e. if "undue delay" is involved or not, but would this really involve choice in any meaningful way? As it is difficult to see which other instances of choice exist, it appears that the choice involved is largely illusory.

– Second, which regime is more favourable will actually differ with each particular combination of Member State of affiliation and Member State of treatment and clarity on this issue will not increase as a result of the proposed patient mobility Directive. It is therefore not clear either whether mobile patients will see a net improvement in the level of reimbursement, while it is fairly evident that the conditions involved will not improve – assuming that patients would normally prefer benefits in kind under Regulation 1408/71 over ex post reimbursement based on the proposed patient mobility Directive.

A final note on the two reimbursement regimes is that the proposed patient mobility Directive will for the first time lead to "Article 49 EC" authorization procedures which in many cases at present simply do not exist – with only authorization procedures for Article 22 of Regulation 1408/71 actually in place. The main difference between the parallel regimes appears to be whether prior authorization can be required in the first place: whereas it is always required in case of Regulation1408/71, the scope for prior authorisation in the proposed patient mobility Directive will be much more limited, as will be seen below.

Would an amendment of the social security rules suffice?
Finally, these observations again raise the question whether a separate Directive is in fact necessary and whether it would not have sufficed to amend Regulation 1408/71 (read: its successor Regulation 883/04) instead, for example by simply providing that the more favourable of the two funding regimes applies and by codification of key elements of the case law. It is of course the Court itself that opened up these parallel tracks in *Kohll* before making them converge again in cases such as *Inizan* and *Watts*. But would it be impossible to satisfy the Court that Article 49 EC could adequately be addressed based on incorporating the key elements of its own case law in the social security Regulations? And would this not have been logically consistent with the aim of strengthening the renewed social agenda?

The Commission appears reluctant to address this issue squarely. In the Impact Assessment that accompanied the proposed patient mobility Directive it did compare the option ("3A") of establishing a general legal framework through a Directive on health services for both hospital services and non-hospital services to an option ("3B") with a directive for non-hospital services only, with hospital services being covered exclusively by Regulation 1408/71 (without amending the latter). Given the nature of the Impact Assessment exercise, the choice between these two alternative approaches was settled on the basis that option 3A led to a positive balance between costs and treatment benefits, and option 3B did not. Yet extending and/or amending the existing social security Regulations, arguably the most straightforward alternative, was not explicitly considered.

5.5. Common principles for healthcare

Responsibilities of Member States of treatment
Significantly, Article 5 of the proposed patient mobility Directive sets out common principles for healthcare. These correspond with the responsibilities of the Member States of treatment and are not based on the free movement case law of the Court. Instead, these principles are based on Council Conclusions of 2006 to the same effect,[147] which drew on the existing systems (or at least ambitions) of the Member States and should therefore, according to the Explanatory Memorandum, not require major adaptations. However these principles are now made binding on the Member States, and will therefore presumably become justiciable in some form. Universal access to high-quality care based on equity and solidarity is asserted as the general overriding objective.[148] This is not new in relation to the abovementioned Council

[147] Council Conclusions on common values and principles, supra note 124.
[148] This corresponds with the overarching values identified in paragraph 6 of the Council Conclusions on Common values and principles, supra note 124. It is worth noting that the Council had resisted earlier

Conclusions, but it is noteworthy that it should be proposed to promote in particular equity and solidarity from a grand but non-committal setting to a measure of Community law, raising the question what these objectives and principles could mean if the power to define the scope of benefits and of access to them, as well as their funding, remain at national level. Likewise it will be interesting how these prerogatives of the Member States can be squared with EU legislation promoting universal access to high-quality care (assuming the latter is not merely defined as that which is actually provided at any given time).

Consistent with Article 152 paragraph 5 EC, Article 5 of the proposed patient mobility Directive starts by setting out the key principle that the Member State of treatment bears responsibility for the organization and delivery of healthcare. In substance Article 5 mainly requires the Member States of treatment to provide quality and safety standards for healthcare based on dynamic international best practice standards (the application of which is monitored and enforced), and to ensure the right to the information necessary for an informed choice, the right to make complaints and guarantees of redress and remedies, to privacy, equal treatment and non-discrimination. Finally the Member State of treatment is obliged to provide for adequate systems of liability insurance.

These topics are not elaborated or integrated further on in the proposed patient mobility Directive. Instead, paragraph 3 of Article 5 provides that the Commission shall develop Guidelines for its implementation in cooperation with the Member States – i.e. not based on the "comitology" procedures established in other provisions of the proposed Directive, but on a form of coordination that may either be based on the High Level Group on health services and medical care, a loose form of cooperation between the Commission and high officials representing the Member States[149] or (as the use of Guidelines appears to suggest) on more standardized OMC type procedures. On the one hand these are all mild forms of coordination that stop well short of harmonisation. On the other hand given the range of topics involves, this provision may eventually yet give rise to dynamics that lead to a significant further harmonization across the EU.

Finally, it is noteworthy that the scope of this provision is not defined clearly: the heading (Member State of treatment) suggests norms that apply for patients from other Member States, while the wording (referring to healthcare in general, and not to cross-border healthcare) of Article 5 itself implies a general application. The

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proposals to define patients rights at EU level in the context of the first programme on public health (Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ 2002 L271/1). Recital 24 of the Preamble of the Commission's proposal had stated: "The programme should in this context contribute to the definition of minimum quality standards applicable to health and minimum standards governing patients' rights." Amended proposal for a Decision of the European Parliament and of the Council adopting a programme of Community action in the field of public health (2001-2006), COM(2001) 302 final of 1 June 2001. On this issue the Council noted that "quality standards and guidelines and patients' rights are areas of Member State competence" and amended the proposal accordingly, in its Common Position (EC) No 34/2001 of 31 July 2001 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a Decision of the European Parliament and of the Council adopting a programme of Community action in the field of public health (2001 to 2006), OJ 2001 C307/27. Cf. T.K. Hervey, "The legal basis of European Community public health policy", in McKee, Mossialos and Baeten (eds), supra note 19, at pp. 46-47. The Council's position appears to have changed as the result of the High Level Reflection process (notably the resulting Report of December 2003) and the subsequent work of the High Level Group (supra note 109). After getting the Council to define common principles the Commission is therefore now proposing to elevate them to the status of EU law, and to create a basis for elaborating their application.

[149] Supra, note 109. Note that the High Level Group on health services and medical care is a specialized group based on a Commission Decision, the Social Protection Committee, the advisory committee which features in the OMC (supra note 104) a general grouping, based on a Council Decision, which operates as an Advisory Committee in accordance with standard "comitology" procedures, based on Council Decision 1999/468/EC of 28 June 1999 laying down procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L184/23), as last amended by Council Decision 2006/512/EC of 17 July 2006, OJ 2006 L200/11.

Preamble and explanatory memorandum focus on the justification that confidence building measures for mobile patients are at stake. Because it is difficult to see how these norms could possibly be implemented solely for the benefit of patients from other Member States they are likely to impact all patients, not just those moving across borders. This is also how they are phrased in Article 5 which therefore would involve a major step, in particular in terms of accountability to patients, and by healthcare providers.

No safeguard procedure for Member State of treatment

In this context of the rules applicable to Member States of treatment it should be noted that although the proposed patient mobility Directive contains provisions to allow a derogation to free movement to the Member State of affiliation (Article 8, see below) it foresees none for the Member State of treatment. Hence, there are just obligations for Member States of treatment, no rights. The only relevant text appears to be recital 12 of the Preamble, which states that:

> "(…) nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment."

This ambiguous wording is equally suggestive of a possibility to refuse patients from other Member States, because arguably their treatment will always lead to longer waiting times for at least some domestic patients, or an anodyne statement that patients from other Member States will not be required to receive priority. As such it is not helpful. The position taken in the body of the proposed patient mobility Directive is that of strict non-discrimination in its Article 5 paragraph 1, sub (g):

> "Patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including protection provided for according to Community law and national legislation in force in the Member State of treatment."[150]

This appears to be a categorical statement that no form of preference can be given to domestic patients except on medical grounds.[151]

It should be emphasized that even with regard to planning treatment and prioritizing patients in the abovementioned Recital 12, the perspective taken is exclusively that of the position of patients in the Member States of treatment, not e.g. the (financial) balance of the national social security systems of these Member States. Yet in the absence of tariff rebalancing it may clearly happen that charges for treatment of patients from other Member States are out of line with actual costs but attractive to the healthcare provider in question (e.g. to "fill empty beds"). In such cases payment is likely to be for marginal costs only rather than for a share of fixed costs – putting pressure on public funding. Meanwhile competition between healthcare providers to attract mobile patients would be likely to trigger new dynamics feeding through into the national market.[152] Such developments could well contribute to undermining the

[150] Recital 13 also states "Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds (…)."

[151] This is remarkable in the view of some commentators that "host states are entitled (…) to discriminate directly or indirectly on the basis of nationality as regards access to welfare benefits, (…) without exposing themselves to the possibility of a legal challenge by adversely affected temporary visitors relying upon Article 49 EC", Dougan and Spaventa, supra note 3, at p. 197 with reference to the patient mobility case law as pertinent only to treatment in the home Member State.

[152] This competition is not limited to the EU or even to "developed" countries as increasingly the best hospitals in Asia and Latin America are attracting Western patients. Cf. "Briefing on globalization and health care: operating profit", *The Economist*, August 16th-22nd 2008, pp. 66-68. Admittedly this trend seems to affect mainly patients paying directly for the healthcare received, not treatment for which reimbursement is claimed based on the social security regime of the Member State of affiliation as is the case in the context of patient mobility within the EU. However, to the extent that private health insurance

financial sustainability and coherence of the existing national social security systems – while at the same time contributing to pressure toward much needed rationalization and rebalancing. Clearly therefore the impetus toward change as a result of the proposed patient mobility Directive is likely to involve Member States in their manifestation as Member States of treatment, not just as Member States of affiliation.[153]

5.6. The framework for cross-border healthcare

The core of the proposed patient mobility Directive is formed by its codification of the Court's case law in its Articles 6, 7 and 8.

The provision of healthcare in another Member State

As a counterpoint to the obligations of the Member State of treatment set out in Article 5 of the proposed patient mobility Directive, its Article 6 sets out a number of obligations on the Member States of affiliation in relation to patients ("insured persons") travelling to other Member States for treatment that is covered by the benefits to which they are entitled in their Member State of affiliation.[154] (This also provides the only, albeit oblique, reference in the body of the text that the Member State of affiliation determines the scope of coverage.) The most important of these obligations is that the Member States of affiliation must reimburse the actual costs for such treatment up to the level applicable to the same or similar treatment in the Member State of affiliation.

Member States of affiliation are also required to have a mechanism for the calculation of such costs, which must be based on objective, non-discriminatory criteria that are known in advance.[155] This requirement is especially relevant to benefits in kind and NHS systems that in most cases are likely to lack useful pre-existing cost information on which reimbursement can be based. Given the immense difficulties associated with the introduction of sound cost accounting principles in industries where such practices were not already in place (e.g. in the context of the liberalization of the various utilities) the effort required is likely to be commensurate, may give rise to significant litigation, and may have unexpected side-effects in highlighting cross-subsidies and inefficiencies that had so far remained hidden. Although this suggestion is unlikely to be popular, it may well be that this is an area where a common Community understanding of the relevant principles will be required, a topic which is not addressed by the proposed patent mobility Directive.

As was already mentioned above under proportionality Article 6 paragraph 4 explicitly provides that those non-discriminatory conditions and formalities that do not obstruct the free movement of persons (such as the requirement to consult a general practitioner before seeing a specialist) are allowed. Given that this issue of secondary importance is spelled out explicitly it is all the more odd that the competence to determine coverage in the first place is not given more attention.

Non-hospital care

Article 7 of the proposed patient mobility Directive provides that patients are entitled to seek non-hospital care which is covered by their national social security regime in other Member States without prior authorization, and are entitled to reimbursement

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for treatment not covered by the social security system and co-payments by patients for all types of treatment increase, so will the relevance of treatment outside the EU.

[153] For a vision of such developments and EU law implications see Davies, supra note 7. According to the Impact Assessment, supra note 133, at p. 41 "the evidence available (…) suggests that a clear framework for cross-border care will improve efficiency in healthcare, both for the healthcare provided abroad and through transferring best practice into domestic care". (The actual figures provided however are not very impressive.)

[154] It should be noted that by linking the definitions of "patient", "insured person" and "Member State of affiliation" it is in fact Regulation 1408/71 (respectively from the date of its application Regulation 883/2004) that determines the scope of the proposed patient mobility Directive.

[155] Cf. Case C-358/99 *Müller-Fauré*, supra note 64, para 107; Case C-372/04 *Watts*, supra note 4, para 143. Cf. Davies, supra note 6, at 164-165.

at the level as if the care had been provided in the Member State of affiliation. It is assumed therefore that this will by definition not undermine the financial equilibrium of social security systems. This appears to extend the case law, albeit marginally. Although admittedly from *Kohll* and *Decker* onward the Court had so far never found a justification for an authorization in the case of non-hospital care it had not fully excluded this possibility in general terms either.

Hospital care and specialised care
As already discussed above under definitions, Article 8 of the proposed patient mobility Directive governs hospital care and, specialized care. In contrast to non-hospital care the Member State of affiliation may impose a prior authorization requirement under the following conditions:

> "The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:
>
> (a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and
>
> (b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:
>
> > (i) the financial balance of the Member State's social security system; and/or
> >
> > (ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State."

It is furthermore provided that such a prior authorization system shall be limited to what is necessary and proportionate, and not constitute a means of arbitrary discrimination.

At first sight, this may appear to represent merely a faithful transcription of the case law. It is not. By comparison the relevant provision in Article 23 of the Services Directive that raised such violent opposition looks positively designed to facilitate prior authorization.[156] Above all it should be recalled that the Court was so far content to assume that if the abovementioned grounds were invoked in the context of hospital care requiring prior authorization could be considered necessary and reasonable, and then to focus on the procedures and conditions for authorization (including criteria when authorization must be granted based on "undue delay" on which more below).[157]

What is intended here is something very different: the Member States will now have to provide actual evidence that the outflow of patients due to cross-border hospital

[156] "Member States shall ensure that authorisation for assumption by their social security system of the cost of hospital care provided in another Member State is not refused where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation and where such treatment cannot be given to the patient within a time frame which is medically acceptable in the light of the patient's current state of health and the probable course of the illness." Proposed Services Directive COM(2004) 2 final/3, supra note 116.
[157] E.g. Case C-372/04 *Watts*, supra note 4, para 110; Case C-385/99 *Müller-Fauré*, supra note 64, para 81; Case C-157/99 *Smits-Peerbooms*, supra note 46, para 80.

care seriously undermines their social security system or planning in the hospital sector. Presumably the data underpinning such an assessment will have to be made available pursuant to Article 8 paragraph 5 (which provides that all relevant information shall be made publicly available). However, the Commission clearly believes these data do not exist and is in fact proposing that the Directive should state so explicitly. Thus recital 31 of the Preamble now reads:

> "The evidence available indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems."[158]

Thus the burden of proof would be shifted fundamentally, and the Commission has increased it further by providing up-front its own evidence to the contrary (albeit in general terms). Few if any Member States may be expected to dispose of the data required to back up a prior authorization requirement at present, and, if the Commission is right, their chances of doing so in future are slim. On the other hand, as the proposed patient mobility Directive provides no procedure to settle whether the required standard is actually met,[159] this would have to be decided in the course of private litigation and infringement procedures that are likely to be costly and time-consuming. Surely it cannot be the purpose of new legislation on this issue to set the stage for years of conflict? In any event it appears likely that Article 8 of the proposal will lead to lively discussions if there are any Member States left who wish to maintain prior authorization requirements.

Procedural guarantees

Article 9 of the proposed patient mobility Directive codifies and somewhat extends the procedural guarantees that the Court has set out in its case law. These are the familiar categories of objective, transparent and non-discriminatory criteria, necessity and proportionality, access to judicial review etc.[160] The minor innovations involve the requirement that the criteria for refusal of prior authorization must be specified in advance and in a transparent way – yet there is no notion of what they might involve. At the same time therefore this summing up of general principles of administrative law adds up to a fairly shocking degree of imprecision in relation to what is and what is not acceptable in terms of prior authorization requirements.

In this context it is remarkable is that the substantive criteria from the "undue delay" case law (medical condition, degree of pain, nature of the disability involved and ability to carry out a professional activity) are now listed in paragraph 4 of Article 9 of the proposed patient mobility Directive only as factors that the Member States must take into account "when setting out time limits within which requests for the use of healthcare in another Member State must be dealt with".[161] This is no doubt

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[158] Likewise in its Explanatory Memorandum (supra note 133, at p. 16) the Commission clearly states that based on its Impact Assessment, "there is no evidence to suggest that such care [hospital care] will undermine the financial sustainability of health and social security systems overall or the organization, planning and delivery of health services." Ibid, at p 14: "The evidence available as set out in the impact assessment indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover or the sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems". I.e. not undermine at all, let alone seriously.

[159] In a preparatory version of the proposed patient mobility Directive the Commission had foreseen a notification requirement and powers for itself to approve, propose amendments to or reject the provisions for prior authorization systems submitted by the Member States.

[160] Article 9 paragraph 1, as noted earlier, states that where the conditions for the application of Article 22 of Regulation 1408/71 are met the authorisation pursuant to this Regulation shall be granted: presumably this is meant to reinforce the rule in Article 3 paragraph 2 that where the conditions where authorization under the Regulation must be granted are met, the provisions relative to patient mobility of the proposed patient mobility Directive do not apply.

[161] Recital 33 of the Preamble suggests that "patients should normally have a decision regarding the (sic) cross-border healthcare within fifteen calendar days" and "that period should be shorter where warranted

based on the assumption that the cases concerning undue delay will in any event be dealt with based on authorization provided in accordance with Article 22 of Regulation 1408/71. Also, as was seen above, one of the fundamental tenets of the proposed patient mobility Directive seems to be the expectation that prior authorization requirements will not become the norm, and they may be regarded as less significant for that reason as well.

However the point of the "undue delay" criteria as intended by the Court in its patient mobility case law on Article 49 EC and Regulation 1408/71 alike was to establish when authorization must be granted, not just to promote the superior design of waiting lists. The basic idea driving the Court's rulings on this matter was that under some circumstances the Treaty provides patients with a right to treatment abroad that can no longer be trumped by a public policy justification or by an overriding reason of general interest. How can the proposed patient mobility Directive possibly misconstrue this most crucial patients' right as it now does? The medical condition and the degree of pain involved, inter alia, should determine how a request is dealt with on substance, i.e. its outcome, and not merely how long one should be made to wait before a request is dealt with at all, based on criteria that remain unspecified. If the prior authorization process is to be taken seriously – and it clearly should be if the proposal includes the possibility of having it – then the criteria for granting or refusing authorization should be set out in the Directive itself. The undue delay criteria set out by the Court may not be perfect, but they would certainly be a good place to start from. If this requires a rethink on the delineation between the proposed Directive, and Regulation 1408/71 that seems a price well worth paying.

Other provisions relevant to Member States of affiliation
Various provisions impose further obligations on Member States of affiliation that are intended to aid patient mobility. These include the duty to provide easily accessible information on entitlements, on liability issues, on legal recourse, and to designate single national contact points, with a detailed list of their responsibilities in terms of providing information and facilitating dispute settlement. Somewhat oddly, a provision stating that in cases of patient mobility the law of the Member State of treatment applies is included. It is not clear if this is intended to be directly effective or whether this requires implementation and how it relates to general rules on applicable law.

5.7. EU cooperation on healthcare

The provisions concerning cooperation involve the duty of cooperation as such, the recognition of prescriptions issued in other Member States, the creation of European reference networks for cooperation on highly specialized healthcare, the promotion of interoperability of information and communication technology systems to benefit E-health, cooperation on the management of new health technologies – notably by the creation of a health technology assessment network – and on data collection for statistical and monitoring purposes. As was mentioned above, it is typically in these areas of enhanced administrative cooperation that the expectation of a potential for achieving efficiencies in cross-border healthcare is expressed (except in the case of E-health, this is set out by means of the Preamble). These are also the areas where preparatory work has generally already been carried out by the High Level Group on health services and health care.[162]

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by the urgency of the treatment in question". Presumably achieving this is what is intended by Article 9 paragraph 4 of the proposal. Perhaps simply setting a two week deadline with an exception for emergencies and retaining the familiar criteria for whether to award authorization or not would be more appropriate.

[162] Supra, note 109. These topics go back to the Ministerial group which drafted the "High level process of reflection on patient mobility and healthcare in the EU: Outcome of the reflection process" of 9 December 2003, that was considered a breakthrough in thinking on the usefulness of EU coordination on healthcare issues.

As is standard practice in EU Directives, several provisions in the proposal, predominantly in this section on cooperation, envisage delegated rulemaking by the Commission assisted by a committee of Member State representatives.[163] These do not include the Guidelines envisaged for elaboration of the responsibilities of Member States of treatment in Article 5 paragraph 3 of the proposed patient mobility Directive, which instead provides for an ad hoc procedure ("in cooperation with the Member States") that is likely to involve either the abovementioned High Level Group on health services and medical care or OMC procedures (or perhaps a form of cooperation yet to be established).[164]

6. Conclusions

On the one hand the development of the law on patient mobility appears to fit the mould of the standard interaction between positive and negative integration: first national measures obstructing the freedom to provide services (in this case) are struck down by the Court, and then the need arises for re-regulation to fill the gap left, providing sufficient consensus for a more liberal Community regime to emerge. On the other it is questionable to what degree positive integration is involved in the proposed patient mobility Directive, as it is primarily concerned with ensuring the effectiveness of the removal of barriers to patient mobility. Hence, it not so much sets out a new harmonised Community regime for patient mobility as fleshes out the prohibition of Article 49 EC. It does so inter alia by undermining ex ante the prospects of prior authorisation regimes not just by requiring evidence that they are necessary and proportionate (rather than accepting them as justified in principle provided the right grounds are invoked as the Court had done) but also by incorporating an initial assessment that there will be no serious effects on the social security systems of the Member States (based on supporting evidence, such as that on average only 1% of healthcare expenditure is affected).

The practical difficulties of actually demonstrating the need for a prior authorization system are in any event considerable. Justifying prior authorisation raises a number of questions:

- How in a sector where the cost of an individual treatment is not known can it be plausibly argued that transferring such treatments abroad would jeopardise the financial balance of the system? In such a case the balance would appear be threatened by the lack of information about the system itself.

- Moreover, how to demonstrate the financial balance of a social security system is threatened if other basic measures of sound administration and business practice (starting from cost accounting and tariff rebalancing) are not taken first or at least in tandem?

- And who could credibly argue in favour of preserving the status quo at the expense of patients who could be helped more efficiently abroad while ignoring systemic failure at home – especially if the latter were to be more fully exposed in the process?

- It may well be that raising such issues will be the primary benefit of any attempts to introduce prior authorization under the proposed patient mobility Directive. Or perhaps, more cynically, to avoid exposing themselves in this manner the Member States will prefer to forego the introduction of prior authorisation requirements?

[163] This concerns a standard format for providing information on patient mobility, measures relating to the network of national contact points, measures to ensure mutual recognition of prescriptions, criteria for European reference networks, interoperability of E-health data, and the health technology assessment network. These are subject to "comitology" decision making procedures according to the regulatory procedure, respectively the regulatory procedure with scrutiny, in accordance with Council Decision 1999/468/EC, supra note 149.

[164] Supra note 111.

At the same time the proposed patient mobility Directive does not form a strict codification of the case law in more worrying respects as well. By creating a division of labour whereby "undue delay" cases are dealt with exclusively under the social security Regulations (based on the free movement of workers), and everything else falls under the proposed patient mobility Directive, it guts the "undue delay" case law on Article 49 EC of the Court without providing an alternative standard for approving or denying authorisations – the relevant criteria are to be developed nationally. Unless authorisation regimes based on the proposed patient mobility Directive fail to arise at all – for example for the reasons given above – this seems a recipe for trouble. On a more principled note, it appears careless to sign away hard won patients' rights based upon the directly effective Treaty freedoms in this manner just in order to settle a boundary dispute with the social security Regulations.

The main innovation of the proposal in relation to the case law are the obligations of Member States of treatment, or patients' rights, which are likely to ensure the impact of patient mobility on Member States both when sending patients abroad, and when receiving them. These obligations have their origins in Council Conclusions of 2006,[165] but if the proposed patient mobility Directive is adopted will now be made legally binding and justiciable. Moreover, the ensuing rights – especially to accountability, and transparency on availability prices and outcomes of healthcare – will accrue not just to mobile patients, but to all patients in each Member State. Arguably, this is – or will presumably become – the key element of positive integration introduced by the proposed patient mobility Directive. The Guidelines that the Commission proposes to develop in cooperation with the Member States in this context could be a catalyst for further change. The other novel aspects of the proposed patient mobility Directive are related to cooperation between Member States and, although without doubt fascinating to specialists (and for this reason no doubt useful in co-opting them into a constituency supportive of further EU level cooperation), are of less relevance here.

By choosing the legislative route on patient mobility the Commission is taking a calculated risk. This risk is that in the process of law making the relatively clear-cut and far-reaching case law of the Court based on Article 49 EC itself – and therefore at present unassailable by reluctant Member States – will be diluted. As has been indicated above the Commission's proposal itself shows this dilution is taking pace already. Realistically however the stratagems that can be deployed at national level in order to frustrate patients actually availing themselves of their rights under EU law, no matter how well-grounded in the Treaty these might be, are almost endless. In this context it is worth recalling how a significant number of the cases concerning reimbursement of medical treatment discussed above (*Vanbraekel*, *Keller* and *Stamatelaki*) were conducted by heirs to patients who had already deceased in the course of lengthy administrative and judicial procedures. Hence, the Commission is probably right in its assessment that to give teeth to patient mobility based on Article 49 EC, secondary law is required, although it has not (fully) explained why this could not have been done by extending the existing social security Regulations.

A partial explanation to the latter question may be that the proposed patient mobility Directive incorporates a number of elements designed to set in motion further changes in healthcare systems at national level, which will in the longer term promote greater efficiency as well as accountability. For those who think these things are desirable, the proposed patient mobility Directive is therefore clearly a first step in the right Direction. At the same time the fact that the focus both of the recent case law and of the proposed Directive has been centred on the patient fits well with in a consumer (and/or citizen) oriented approach to European integration and is consistent with the social policy agenda that is being developed as a response to

[165] Council Conclusions on common values and principles, supra note 124.

public scepticism about the benefits of the EU, just as, incidentally, it would be in line with a demand based economic view. That does not make this proposal immune to criticism from those who fear any form of change may erode national solidarity (nor from those who simply represent vested interests), but it is consistent with most perspectives that accept the potential of a positive role for the EU.

Before concluding it is worth pointing out that patient mobility is strictly speaking only one of four possible types of cross-border healthcare that the proposed Directive purports to deal with. These are:

- the use of services abroad (patient mobility)
- cross-border provision of services (such as might be based on e-medicine)
- temporary mobility of health professionals and
- the permanent establishment of healthcare providers in other Member States.

As has been seen, in practice patient mobility, some ancillary rights, and mild forms of cross-border cooperation provide the substance of the proposed patient mobility Directive. Of the other three types of cross-border healthcare, it is arguably the freedom of establishment that could have the most significant impact by introducing a dose of competition that may be expected to have a salutary effect on healthcare systems throughout the EU. In many Member States, parallel systems of public and private provision of healthcare raise issues about discrimination in funding deterring entry (which for entrants from other Member States will almost invariably take place in the private sector), given that accurate costing and pricing is almost unknown in the public healthcare sector. Even in systems that are nominally wholly private the same will de facto hold for incumbents vis-à-vis prospective entrants. Likewise constraints e.g. on the distribution of dividends or requiring non-profit status form de facto entry barriers for newcomers who must by definition attract outside capital (and would use it to build more efficient facilities). However the proposed patient mobility Directive as it now stands contains nothing of substance on establishment.

In this context, elements missing from the proposed Directive that would fit in with patient mobility but are also significant in the context of establishment are defining services of general economic interest for healthcare, and standardisation of the diagnosis related groups (DRGs) that are the basis costing and accounting units in most modern healthcare systems. Defining services of general economic interest is a crucial step setting out public service objectives in terms of consumer rights and ensuring that any related ancillary restrictions are proportional thereto. It is therefore key both to rationalisation and promoting market entry in healthcare. DRGs that were either standardised or based on common principles would be immensely useful for transactions and reimbursements across borders, increase transparency (exposing differences in efficiency), and would likewise facilitate entry – not just of healthcare providers but also of health insurers.

For the time being however we await the fate of the first proposal for a liberalization Directive concerning healthcare services: that on patient mobility. Although unsurprisingly imperfect, it deserves a better fate than the corresponding section of the proposed Services Directive.

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