

Health Care Services and the Single European Market

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1. INTRODUCTION AND SUMMARY

On 2 July 2008 the European Commission published a proposal for a Directive on the application of patients' rights in cross-border health care¹. This draft Directive has been a long time in gestation. Its origin dates back to 1998 when two landmark rulings of the European Court of Justice (ECJ – hereafter "the Court") sent shock waves around EU health administrations². These rulings appeared to affirm the right of patients to obtain reimbursement from their health care systems for health care which they had purchased from another EU Member State, without prior authorisation. The rulings established unequivocally that health care goods and services, including the direct provision of health care to patients, were no different from any other types of goods and services to which the EU's internal market rules on freedom of movement apply. At the same time, it was not at all clear that the application of internal market trading conditions could and should be applied to health services.

Since these initial rulings, the Court has issued judgements on a succession of references to it by national courts seeking clarification on the applicability of internal market rules to cross-border health care. Requests for legal opinion have in the main focused on the circumstances, including conditions of price and access, under which patients may obtain reimbursement for health care which they obtain from another Member State³.

The reasons for the long delay between the initial rulings and the appearance of the proposal for a Directive seem quite straightforward. Until the Kohll and Decker rulings of 1998, no one thought that the

¹ COM (2008) 414 final, Brussels, 2 July 2008.

² C-158/96 Raymond Kohll v Union des Caisses de Maladie, 28 April 1998; C-120/95 Nicolas Decker v Caisse de Maladie des Employés Privés, 28 April 1998.

³ For a list and brief description of these cases, see Annex.

EU had any legal competence in the field of health care. Article 152 of the EC Treaty provided the legal basis for the EU to fund a series of health promotion and disease prevention research programmes in the field of non-communicable diseases, alongside the coordination of a cross-border monitoring facility in communicable diseases. However, Article 152 (5) explicitly postulates 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”. Consequently, without a clear legal mandate, and only in parallel with increasing scope for action provided by successive Court judgements, the Commission has moved cautiously. In the intervening ten years since the first rulings, several consultative initiatives have been launched, beginning with the “High Level Reflection on Patient Mobility”, which reported in 2003 and resulted in a Commission Communication in May of the following year. These continued with the High Level Group on Health Services and Medical Care, and a “Consultation regarding Community action on health services”⁴ which closed in January 2007, all of which suggested that the Commission was searching for a way forward in this sensitive and complex area.

At the same time, an attempt to include the health sector in the recent Services Directive⁵ met with failure in 2006 as the protests of Member States forced the exclusion of health from the scope of the Directive⁶. The Services Directive has been introduced in response to a perception at EU level that there is pent-up consumer demand for cross-border services, which is not being met due to legal and administrative barriers, including a lack of information on, and trust and confidence in, services from other Member States. Hence, one of the main objectives of the Services Directive is to make it easier for businesses to provide and use cross-border services in the EU by reducing legal, administrative and information barriers. The rationale for this is to increase cross-border competition in service markets, to bring down prices and to improve quality and choice for consumers. On the demand side, strengthening the rights of consumers as users of services is a key objective.

The Court judgements were a ready source of evidence of the existence of such legal and administrative barriers to cross-border supply of health services and, when initially including health in the draft Services Directive, the European Commission drew extensively on the ECJ judgements in this sector. The initial draft Services Directive would

have required Member States to introduce explicit systems for authorising and/or enabling patients to exercise their entitlements to cross-border health care according to the principles enunciated by the ECJ. In the event, and in the face of enormous concerns by Member States, health was withdrawn as one of the sectors to be covered. However, even when withdrawing health, the Commission noted the need to accommodate the Court rulings, and promised the separate proposal now published⁷.

A final explanation for the relative tardiness of the response is that for many Member States, particularly those which have operated more restrictive policies on patients’ access to health care abroad, there has been little incentive to obtain greater clarity by seeking the development of mechanisms which would further highlight for patients the possibilities open to them.

The issues which the ECJ rulings raised were partly questions of interpretation and applicability. For example, did the Court rulings apply to all the very different types of organisation of health care systems which can be found among Member States, including tax-financed and benefits-in-kind systems? The issues were also partly administrative: what procedures would have to be implemented, and would these imply radical changes in some Member States’ health systems? In its most recent consultation exercise, the Commission itself posed a number of questions as a precursor to developing a clearer legal framework for cross-border patient care, many of which sought to consider the practical implications of the Court judgements. For example: what is the impact of cross-border health care? How are safety, quality and efficiency of health services to be regulated? Where does responsibility and legal liability for iatrogenic injury lie? Interestingly, despite the origin of the Court judgements in internal market legislation, many questions appeared to take as their standpoint the rights of consumers within the context of instruments and initiatives such as the Charter of Fundamental Rights of the EU (Article 35) and the “Citizens Agenda”.

At the same time, in the initial reactions to the Court rulings were to be found deeply-held concerns about subsidiarity. Health care systems are usually carefully controlled and regulated, in a variety of different ways, in the interests of equity and financial stability, and it suddenly appeared that the rulings had the potential to seriously undermine Member States’ ability to control patients’ cross-border acquisition of services and thereby the ability to control important aspects of Member States’ health systems.

⁴ Communication from the Commission, Brussels, 26 September 2006.

⁵ Directive 2006/123/EC of the European Parliament and of the Council.

⁶ See, e.g. Statement by Charlie McCreevy, European Commissioner for Internal Market and Services on the Services Directive at the European Parliament Plenary session, Strasbourg, February 2006.

⁷ See, e.g. Statement by Charlie McCreevy, European Commissioner for Internal Market and Services on the Services Directive at the European Parliament Plenary session, Strasbourg, February 2006.

Above all, there has been anxiety that an area of such importance to national governments should be the subject of de facto policy making by a judicial body. The newly published proposal for a Directive on patients' rights in cross-border health care, therefore, reflects the need, however reluctantly perceived, for an explicit policy framework governing cross-border patient care to be developed by the EU's legislating institutions: the European Commission, Parliament and Council.

As the proposal for a Directive itself makes clear, the Court rulings have been concerned principally with the application of Treaty articles which underpin the development of the EU internal market in goods and services⁸. These rules were first formulated with the central objective of facilitating the emergence of an integrated European economy. The question remains whether it is appropriate to apply such rules to the health care market, on the grounds provided by the Court: namely that health care is to be defined as a service as it is provided for a consideration and has the essential characteristic of being offered in exchange for remuneration. Have the concerns of Member States which led to the exclusion of the health sector from the draft Services Directive yet been addressed as fully as they should be in the current draft Directive on patients' rights in cross-border health care?

The remainder of the paper explores these issues in more detail. It considers, first of all, the scope of Community Law vis-à-vis health care delivery, including Treaty provisions beyond the internal market rules. The glossary at the end of the paper sets out key elements of the Articles most often referred to in Court judgements. The paper explores the likely impact of ECJ judgements and how these have been translated into the draft Directive on patients' rights in cross-border health care. Will they require, or result in, an increased reliance on market mechanisms and competition in health care, and will they, as many Member States have claimed, weaken their ability to organise their national health care systems.

The paper goes on to explore what evidence exists for basing health care delivery on the competitive paradigm underlying the European Project. It considers whether the economic growth objectives of the internal market and the solidarity objectives of Member States' health systems are compatible, concluding that there are real tensions between the two. It scrutinises the available evidence concerning the impact of increased competition in its various aspects on efficiency, quality and access to health services, including the efficacy of relying on patient choice as a means of promoting competition. The

central point here is that where there is extensive market failure, as in health services, competition is not unambiguously good and the application of Treaty articles to health systems may therefore simply be unhelpful and counter-productive. What does the evidence have to say about the success or otherwise of attempts to introduce competition into health services, under what conditions, and how does this compare with other, non-market, policy instruments on which Member States may also rely when organising their health care systems?

Finally, we take the opportunity to comment on the implications of current English Department of Health (DH) policies for the scope of the application of EU law, Competition Law in particular, and for the risk of legal challenge.

2. THE SCOPE OF COMMUNITY LAW WITH REGARD TO THE HEALTH CARE SECTOR

2.1 The Internal Market rules

A central objective of the Single European Market is to facilitate the emergence of an integrated European economy with higher economic growth. To this end EU Treaty "internal market" rules governing trade between Member States, and thereby cross-border competition and market integration, are enshrined in EU Treaty articles which require Member States to observe and deliver the so-called "four freedoms" (Article 14): free movement of goods (Articles 28 and 30), services (Article 49), labour (Articles 39-42) and capital (Article 56) across their mutual borders.

As an economic sector, health has not escaped the extensive application of EU internal market rules. These already apply to trade in medical devices, pharmaceuticals and medical manpower. Treaty articles (for example on the mutual recognition of diplomas) as well as secondary regulation (for example governing the establishment of a unified means of licensing new pharmaceuticals throughout the EU) are directed at facilitating trade in health products and the movement of medical professionals between Member States⁹. Since 1992 there has also been a series of Directives on Public Procurement designed to eliminate discriminatory and preferential purchasing by public sector bodies. The scope of these is extensive and affects significant amounts of public expenditure across a range of procurement

⁸ COM (2008) 414 final, Brussels, 2 July 2008.

⁹ See e.g. Eds. McKee M, Mossialos E, Baeten R (2002) *The Impact of EU Law on Health Care Systems* P.I.E.- Peter Lang; Eds. Busse R, Wismar M, Berman PC (2002) *The European Union and Health Services The Impact of the Single European Market on Member States* Volume 50 Biomedical and Health Research.

activities from military equipment to building hospitals. The objective is to prevent national governments giving preferential treatment to domestic suppliers, thereby impeding the emergence of a competitive EU-wide market in goods and services purchased by the public sector. A succinct summary of the common principles is: “Community-wide advertising of public contracts above certain thresholds; prohibition of technical specifications capable of discriminating against potential bidders; and application of objective criteria of participation in tendering and award procedures.”¹⁰

2.2 Regulation 1408/71

Until judgements of the European Court of Justice (ECJ) in 1998, the internal market rules were understood not to apply to the direct provision of publicly funded health services to patients (although it is of course open to anyone to buy private health care abroad). Prior to these judgements, the only legal right for patients to obtain socially-funded health care in another EU country was thought to be that established by Regulation 1408/71. This Regulation was introduced in 1971 to facilitate cross-border movement of labour by establishing the portability of social security rights. It made provision for reimbursement of health care costs associated with the exercise of employment in another Member State (through the E106 form) and for reimbursement of the costs of emergency care incurred whilst temporarily in another EU Member State (for example by tourists), by means of the E111 procedure (now the European Health Card). In addition, Article 22 (2) of the Regulation includes two conditions according to which, when both are met, prior authorisation for a patient to receive non-emergency, i.e. elective, health care (through the E112 procedure) may not be refused by a Member State:

(i) where the treatment in question is among the benefits provided for by the legislation of the Member State in whose territory the person concerned resides; and

(ii) where s/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 her/his current state of health and the probable course of the disease.

So as to ensure that patients are not out of pocket as a result of obtaining health care abroad, Regulation 1408/71 also establishes the right to reimbursement of expenses in line with tariffs of the state where treatment is received.

2.3 Competition Law (Articles 81 and 82)

Separate Treaty articles on Competition Law, particularly Articles 81 and 82, govern trading market structure and behaviour and, with very few derogations, discriminatory provisions which might distort intra-community trade. Here, the central concept is that of “undertakings”, defined by the European Court of Justice (ECJ) as encompassing “every entity engaged in economic activity, regardless of the legal status of the entity and the way in which it is financed”. The extent to which EU Competition Law applies to Member States’ health systems depends entirely on how they are structured and organised. Hospitals may fall within the definition of “undertakings”, there being no distinction between public and private, as may health insurance funds and doctors. The crucial tests relate not to legal status, but to the type of activity in which such entities engage and the manner in which they conduct business¹¹. The more a Member State decides to model health care on a competitive paradigm (e.g. by making hospitals compete with one another for patients) the more likely it becomes that Competition Law will apply. This contrasts strongly with the requirement to open public procurement to EU-wide competition, which applies irrespective of whether delivery of the relevant public service is organized along competitive or non-competitive lines. For example, the National Health Service (NHS) in Scotland, with its integrated non-competitive health delivery system, is as subject to public procurement rules as is the NHS in England, with its pro-market, competitive organization.

2.4 Articles 5 and 152 of the Treaty: subsidiarity in health

A different European legal issue is that of *subsidiarity* in health, under whose provisions Member States are allowed to exercise responsibility for the organisation of their own health services. Here the concept of national competence and control has been assiduously guarded, although in principle and in practice it has also lacked clarity. EU internal market, competition and procurement rules clearly do apply to intermediate goods in health care delivery (pharmaceuticals, medical professionals and plant and equipment) and national control in these areas is therefore already affected by Community Law. There is also well established research evidence regarding the extent to which generic Community legislation, not directly related to the health sector, may have significant and sometimes unintended effects on Member States’ health systems. An obvious and far

¹⁰ Bovis C. (1997) *EC Public Procurement Law*. Longman, London.

¹¹ In particular cases: C-41/90 *Hofner and Elser* [1991] ECR I –1979, para 21; *Poucet and Pistre* [1993] ECR I – 637, para 17; FFSA C-244/94 [1995] ECR I-4013 para 14.

reaching example of the latter is the Working Time Directive¹² with its implications for medical working practices and the organisation of health care infrastructure. Other issues have also required changes in Member States such as the effect of the mutual recognition of diplomas on the pattern of training and accreditation of clinicians¹³.

Notwithstanding the extensive impact of EU Law on markets for health products and professionals, key aspects of the organisation of national health care systems, including the terms of patients' participation in them, have been understood to be within the exclusive control of national authorities under the terms of the EC Treaty, notably Articles 5 and 152. In some of its recent case law the ECJ has defined Member States' competence in health policy as the right to determine "the conditions concerning the right or duty to be insured with a social security scheme and..... the conditions for entitlement to benefits". The Court has also defended the right of Member States to take measures designed to safeguard access to health care by patients and to control costs and prevent wastage of financial, technical and human resources.

Member States' legal competence in the organisation and delivery of health services can be taken, therefore, to include some basic aspects of health care policy including control of the total health budget, entitlement to services and conditions of access by patients, namely:

- basic package of services reimbursable from public funds (including access to medical devices and pharmaceuticals);
- permitted volumes of consumption;
- prices and co-payments;
- speed of access;
- location/provider of care.

Community regulators (the ECJ and Directives) have not so far attempted to impose on Member States either what these parameters should be, nor particular means of determining them although, as this paper goes on to describe, the Court has established that the organisation of health care systems must be compatible with the basic principles and tenets of Community Law.

2.5 Articles 28-30 and 49-50: the free movement of goods and services

The *Kohll* and *Decker* judgements of 1998 marked a highly controversial shift in the interpretation of the

application of Community Law to Member States' health systems¹⁴. In asserting that the internal market rules governing free movement of goods (Articles 28 and 30) and services (Article 49) do apply to health care goods and services respectively, the Court affirmed that EU citizens have a right to obtain automatic reimbursement of the cost of certain types of health care obtained abroad, without first obtaining prior authorisation from their own health care authorities. The basic rationale for the Court's judgements is that a requirement for prior authorisation constitutes an impediment to trade under Articles 30 and 49. By implication, the judgements appear to promote patient choice of cross-border provider.

These judgements concerned claims for reimbursement by two Luxembourgers for the cost of spectacles purchased in Belgium (*Decker*)¹⁵, and for the cost of orthodontic treatment obtained in Germany (*Kohll*)¹⁶, claims which had been refused by the Luxembourg authorities on the grounds that prior authorisation for the purchases had not been obtained as would normally be required under Regulation 1408/71, which Luxembourg domestic law followed closely. The question which the Court considered was whether the requirement for prior authorisation embedded in Luxembourg law, was an impediment to trade under Articles 28, 30 and 49 of the Treaty governing the free movement of goods and services. The ECJ determined that, *at the tariffs prevailing in the Member State in which the patient was insured* (in this case Luxembourg) the prior authorisation procedure did amount to such an impediment in the cases concerned. These two judgements indicated, therefore, the availability to patients of two separate procedures for obtaining publicly funded health care abroad: the E112 procedure, set up under Regulation 1408/71 to ensure that patients could access health care abroad in a timely way on conditions prevailing in the Member State of treatment and subject to prior authorisation; and a right under Article 49 of the Treaty to obtain health care abroad at tariffs prevailing in the Member State of insurance.

Both the *Kohll* and the *Decker* cases involved relatively low cost, ambulatory care, for which there are frequently high levels of patient co-payments in many EU countries. The ECJ subsequently ruled in *Smits Peerbooms*¹⁷ that a requirement for prior authorisation for cross-border hospital based care may be a

¹² Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organization of working time.

¹³ Working Group on Specialist Medical Training. *Hospital doctors: training for the future* Department of Health, London, 1993.

¹⁴ C-158/96 *Raymond Kohll v Union des Caisses de Maladie*, 28 April 1998; C-120/95 *Nicolas Decker v Caisse de Maladie des Employés Privés*, 28 April 1998.

¹⁵ C-120/95 *Nicolas Decker v Caisse de Maladie des Employés Privés*, 28 April 1998.

¹⁶ C-158/96 *Kohll v Union des Caisses de Maladie*, 28 April 1998.

¹⁷ C-157/99 *B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen*, 12 July 2001.

justifiable impediment to free movement of patients under Article 49 if the financial balance and security of a Member State's health care provision would otherwise be jeopardised and its health care provision fundamentally compromised as a consequence.

The interpretation of the applicability of, and the relationship between, these two routes to cross-border care has not been without difficulty and Member States have sought clarification on a number of points in the context of several subsequent referrals to the ECJ. Since the *Inizan* case¹⁸, however, that of a French woman insured in France who sought authorisation under Regulation 1408/71 to obtain pain treatment in Germany, and as subsequently reaffirmed in the ECJ's judgement on *Watts* (see below)¹⁹, it has been confirmed that the applicability of 1408/71 to a case does not preclude it from falling within the scope of Article 49 (a point now clarified in the draft Directive on patients' rights in cross-border health care – see below). The Court has also maintained that, as Regulation 1408/71 confers an additional right on patients, over and above Article 49, namely to reimbursement of costs at tariffs prevailing in the country in which health care is obtained, this additional right may legitimately be the subject of the prior authorisation procedure set up by the Regulation itself. However, the Court has also consistently judged that any attempt to require a patient to seek prior authorisation for reimbursement of the costs of health care obtained abroad under Article 49 is an infringement of trade unless there is an objective justification for doing so.

Three main grounds justifying a requirement for prior authorisation under Article 49 have been recognised by the Court:

- the need to guarantee the financial balance of a social security system;
- the need to maintain a balanced medical and hospital service open to all; and
- the need to ensure the maintenance of treatment capacity or medical competence on national territory.

The Court has also endorsed the view that a hospital infrastructure planning system may be necessary to prevent waste of financial, technical and human resources.

The Court has not, however, endorsed arguments based exclusively on cost considerations, and it has required that any authorisation procedure cannot "legitimise discretionary decisions taken by national

authorities which are liable to negate the effectiveness of Community Law". This includes the prior authorisation schemes which Member States are called upon to implement pursuant to Article 22 of Regulation 1408/71 (see *Müller-Fauré/van Riet* para 46)²⁰. According to the Court, a system of prior authorisation must be based on "objective, non-discriminatory criteria, which are known in advance and based on a procedural system which is easily accessible, and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time, with refusals to grant authorisation capable of being challenged in judicial or quasi-judicial proceedings"²¹.

EU regulations are *directly applicable*²² and in the UK, for example, there is no domestic legislation corresponding to Regulation 1408/71. The ECJ case law has revealed that some Member States, in contrast to the UK, embed explicit authorisation procedures for cross-border care in domestic legislation. Some national prior authorisation procedures offer rather different, and in some cases more liberal, terms than the Regulation itself. Some countries, for example, offer patients the opportunity to seek care abroad where it is not available at all in the country of insurance. Of itself this is not a legal issue. The Court has repeatedly confirmed that Regulation 1408/71 does not constrain Member States from offering more generous terms to patients for cross-border health care under the E112 rules. However, these prior authorisation procedures have not been drawn up with the provisions of Article 49 in mind. Consequently, the Court's scrutiny of, and commentaries on, the authorisation procedures it has encountered have turned out to have consequences for Member States which were certainly not foreseen when these procedures were initially drawn up and incorporated into domestic legislation – a point to which we revert below.

2.6 The impact of recent ECJ judgements: on competition between European health care systems

It is worth noting in passing that the principle at stake in the *Kohll* and *Decker* judgements was not, as some Member States tried to argue at the time, about whether the prior authorisation procedure administered by Luxembourg amounted to discrimination in trade in medical devices. In *Nicolas Decker v Caisse de Maladie des Employés Privés* of

¹⁸ C-56/01 *Patricia Inizan and Caisse Primaire d'Assurance Maladie des Hauts-de-Seine*, 23 October 2003.

¹⁹ C-372/04 *The Queen on the Application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 16 May 2006.

²⁰ C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen*, 13 May 2003.

²¹ C-56/01 *Patricia Inizan and Caisse Primaire d'Assurance Maladie des Hauts-de-Seine*, 23 October 2003.

²² The import of this is that regulations are taken to be part of Member States' national legal systems automatically without the need for separate national legal measures.

April 1998²³, the Court noted the observations of some Member States in support of prior authorisation that “the [Luxembourg] rules [requiring prior authorisation for treatment abroad]do not have the effect of prohibiting the import of spectacles, nor do they have any direct influence on the possibility of purchasing them outside the national territory. They do not prohibit Luxembourg opticians from importing spectacles and corrective lenses from other Member States, processing them and selling them [to patients in Luxembourg]”. Rebuffing these points, the Court made clear that what was at issue was rather the extent to which the value-added attributable to publicly financed health care provided by registered domestic health care providers could be protected from competition by foreign health care providers.

The impact of the Court judgements on trade and competition in socially funded health care services will depend in part on the resulting switch of patients from domestic to foreign providers. The Court has itself offered commentaries on the implications of its judgements for cross-border patient care, arguing at length, for example, in *Müller-Fauré/van Riet*²⁴ that there are many obstacles to wholesale increases in the movement of patients across borders, even for ambulatory care, which include linguistic, medical and organisational barriers, but which mainly derive from the overwhelming desire of most patients to be treated near to where they live.

Accurate and up to date data with which to monitor or predict cross-border patient movements in the EU are not available. Such historical estimates as exist, using data on the volumes and total costs of health services (including emergency and inpatient elective care) traded in the EU by means of the E111 and E112 mechanisms, have consistently put these at well below 1% of total EU expenditure on health care. The distribution of cross-border patient flows has also historically been highly variable between Member States, with France, Italy and Luxembourg traditionally accounting for the lion’s share of trade (although this is a situation that may now change following EU enlargement).

In England, the London Patient Choice Project (LPCP) was established in 2002 to reduce waiting times for patients who had been waiting for treatment at an NHS London hospital beyond a target waiting time. A high proportion of patients offered the choice of another hospital accepted (66%)²⁵. However, this was

a scheme that offered the patient choice of another hospital within the city of residence, arranged for and paid for all transport costs. As part of LPCP a large-scale study was undertaken of patient attitudes toward exercising choice of hospital. Results clearly indicate that as travel becomes more onerous patients become less willing to take up the offer of treatment at an alternative hospital and have a very strong preference for not travelling abroad for care, particularly where they bear their own travel costs²⁶. Several of the ECJ cases concerning cross-border patient care have clarified that patients may not claim costs of travel to foreign care providers where travel costs would not be payable in their own country.

Schemes to actively facilitate the movement of patients across EU borders have also reported little success. Three experiments to facilitate cross-border patient movement in the border regions of the Netherlands reveal that, in spite of efforts to reduce switching costs, the response was low²⁷. Other evidence suggests that willingness to travel within the Netherlands to reduce waiting times is also low.

While the ECJ judgements seem to promote the principles of a more competitive model of cross-border health care, by confirming that patients have rights to acquisition of care abroad beyond those which have been recognised historically, patient choice is likely in practice to be only a relatively weak promoter of cross-border competition between providers.

2.7 The impact of the ECJ judgements: on subsidiarity

Although at first sight these judgements raised the spectre of a patient-led free-for-all which might be capable of seriously compromising national control of health care provision, in practice the Court has always taken as given the limiting characteristics and provisions of the relevant Member States’ health systems. By determining that patients may only trade at prices and quantities permitted in the Member State of insurance (or those consistent with the terms of access to care in NHS-type systems) the Court declared in its early judgements that Member States’ essential regulatory control of access to care and total cost could be maintained, even though choice of provider had been extended. In Luxembourg, for example, volumes of ambulatory care, as well as prices, are very tightly controlled, often to a very detailed degree. Sometimes prior authorisation is

²³ C-120/95 *Nicolas Decker v Caisse de Maladie des Employés Privés*, 28 April 1998.

²⁴ C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen*, 13 May 2003.

²⁵ Dawson D, Jacobs R, Martin S, Smith P (2004) *Evaluation of the London Patient Choice Project: System-Wide Impacts*. Report to the Department of Health. University of York: Centre for Health Economics.

²⁶ Burge P, Devlin N, Appleby J, Rohr C, Grant J (2005) *London Patient Choice Project Evaluation*. Report to the Department of Health, January 2005.

²⁷ Brouwer W, van Exel J, Hermans B, Stoop A (2003) “Should I stay or should I go? Waiting lists and cross-border care in the Netherlands”, *Health Policy*, 63(3), 289-98.

required by the Caisses de Maladie (equivalent to the gatekeeping function in other Member States) where care would be particularly expensive. Consequently the detailed conditions and authorisations which apply in the internal health system tightly constrain reimbursable health care services obtained by Luxembourg patients from other Member States under Article 49. The Court has also explicitly endorsed a gatekeeping function, arguing for example in *Müller-Fauré/van Riet* that “The conditions on which benefits are granted ... remain enforceable where treatment is provided in a Member State other than that of affiliation. That is particularly so in the case of the requirement that a general practitioner should be consulted prior to consulting a specialist²⁸.”

However, there have been sufficient Court cases to demonstrate that the precise effects on Member States of the application of these principles may vary from health system to health system. In the *Smits Peerbooms*²⁹ judgements of July 2001 the Court commented at length on the application of a prior authorisation system based on Dutch health law which stated that “The qualifying test of whether the treatment in question is regarded as a qualifying benefit ... is whether the proposed treatment is regarded as normal in the professional circles concerned”. The Court observed that, whilst Community law could not require a Member State to extend the list of medical services paid for by its social insurance system, to apply a prior authorisation system based on objectivity, proportionality and non-discrimination it could not interpret “professional circles concerned” as synonymous with “professional circles in the Netherlands”, but only by reference to international medical science. An important implication of this case is that health systems which have a more general and open-ended system of entitlement may be more greatly affected by the Court judgements.

In the most recent case to be considered by the Court, that of Mrs Yvonne Watts³⁰, an English woman who sought reimbursement of the costs of a hip replacement operation in France, the UK government argued that, since there is no explicit system of entitlements to health care in England, final decisions on provision being at the discretion of the Secretary of State for Health, Mrs Watts had no entitlement to health care abroad.

In his Opinion of December 2005, the Advocate General dealt specifically with this point, arguing that a system without explicit entitlements, in which

decisions about medical treatment are devolved to “system operators” (i.e. NHS bodies) is itself an obstacle to a patient’s right to claim reimbursement for health care services obtained in another Member State³¹. The subsequent Court judgement did not deal explicitly with this issue, the main question being not whether Mrs Watts should have received treatment for her condition, but when and where. Both the Advocate General (at para 88 of his Opinion) and the Court (at paras 118-122 of its Judgement) noted the duty of national authorities to provide a mechanism under which patients may submit Article 49 claims for reimbursement of medical care obtained abroad, as the Court had previously also argued in *Inizan*³².

A second key area of health care management is timeliness of access to care. Some Member States use waiting lists as a means of setting priorities, controlling demand and hence retaining overall financial control. However, inability to access care in a timely way is an explicit condition for entitlement to cross-border care under Regulation 1408/71.

The Court’s judgement in the *Smits Peerbooms*³³ cases considered the question of timeliness of access – translated from Dutch legislation as “without undue delay”. Since then much legal effort and debate has gone into discussing the precise interpretation of “without undue delay” as applicable to Article 49 claims, and whether the phrase “without undue delay” is interchangeable with the phraseology of Article 22 of Regulation 1408/71: “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 *Müller-Fauré/van Rie*³⁴, the Court was asked for an elaboration of the phrase, to which it responded that national authorities should 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”. In *Inizan*³⁵, the Court confirmed that “without due delay” could be regarded as equivalent to the timeliness provisions set out in Article 22 of 1408/71.

²⁸ C-385/99 V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen, 13 May 2003.

²⁹ C-157/99 B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen, 12 July 2001.

³⁰ C-372/04 *The Queen on the Application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 16 May 2006.

³¹ C-372-/04 Opinion of Advocate General Geelhoed of 15 December 2005 paras 66-67.

³² C-56/01 *Patricia Inizan and Caisse Primaire d’Assurance Maladie des Hauts-de-Seine*, 23 October 2003.

³³ C-157/99 B.S.M. Geraets-Smits v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen, 12 July 2001.

³⁴ C-385/99 V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen, 13 May 2003.

³⁵ C-56/01 *Patricia Inizan and Caisse Primaire d’Assurance Maladie des Hauts-de-Seine*, 23 October 2003.

The significance to Member States of these legal debates concerning the precise interpretation of the criterion of timeliness of access to care has become particularly evident in the *Watts*³⁶ case. Mrs Watts went to France for her hip replacement because of the prevailing delay in NHS treatment (then of about 12 months). The UK government argued that as Mrs Watts was initially offered treatment in line with current Department of Health waiting time targets, there was not “undue delay”. The government also argued that given the limited capacity of the NHS, it was necessary to manage waiting lists so that patients in greater need were treated first.

Whilst the Advocate General, in his Opinion on the case, recognised the inherent tension between the existence of waiting lists as an instrument for management and allocation of limited resources, and the interests of the patient in receiving adequate and timely treatment, he considered that “these two conflicting interests can only be reconciled in a manner compatible with the Court’s case-law if a number of conditions are imposed on the way in which waiting lists are managed...Waiting lists should not be confined to registering that a given patient is eligible for a given type of treatment with a given degree of urgency. They should be managed actively as dynamic and flexible instruments which take into account the needs of patients as their medical condition develops... Moreover, ...decisions regarding the treatment to be provided and when that is likely to be, should be taken on the basis of clear criteria restricting the discretionary power of the decision-making body”³⁷. The Court agreed with this view, arguing that the use of waiting lists to manage hospital capacity was not of itself contrary to EU law governing cross-border health care, as long as the medical circumstances and individual clinical needs of patients were taken into account in determining an appropriate waiting time. This central finding of the Court has the effect of ruling out the use of institutionalised waiting time targets such as those currently adopted by the English NHS, in arguments relating to access to cross-border health care.

Although not subsequently taken up by the Court, the Advocate General also argued in this case that any additional short term increase in expenditure incurred by granting authorisation to receive care abroad as necessitated by a patient’s condition, should be balanced against future savings in the longer term, i.e. that “financial balance” should not necessarily be determined by reference to a need to balance budgets on an annual basis.

In the *Watts* judgement, therefore, the Court, with growing confidence, went well beyond its initial caution – where it acknowledged and gave some emphasis to the importance of the financial balance of the health care system – in favour of a ruling which emphasised the primacy of the patient’s condition as a criterion for a decision.

The questions left essentially unanswered were those raised by the Advocate General in his Opinion in the *Watts* case, namely at what point could an increasing number of patients moving across borders become difficult for Member States to manage, in terms of the likelihood of their undermining the efficiency, as well as the financial stability, of individual, national health care systems? These are issues where Member States’ sensitivities run high, particularly in those Member States, including the UK, where waiting times have been among the highest in Europe. However, as long as patients are not prepared to move across borders for health care in large numbers, and as long as the organisation of Member States’ health care systems carefully defines patient entitlements, the direct impact of the Court judgements on competition and budgets will be confined.

2.8 The draft Directive

The European Commission’s proposals are now somewhat clearer, and the recently-published draft Directive on patients’ rights in cross-border health care will now be the subject of a formal co-decision procedure. It is likely to go through many transformations as its implications are scrutinised closely by Member States’ representatives in Parliament and ministers in Council, and it will be extremely interesting to see the nature of the discussion which it prompts. This will indicate the extent to which Member States’ initially alarmist responses have been modified over the years.

A central requirement of the draft Directive, as expected, is that Member States should establish an objective, transparent, proportional and non-discriminatory procedure, with the associated provision of information to the public, for enabling its citizens to obtain health care from another Member State. Applications for cross-border health care which are made under Article 1408/71 and which may not be refused under the terms of that Regulation, are to be reimbursed under the terms of that Regulation. In that case, provisions in the draft Directive (Articles 6-9) relating to the terms of access to and reimbursement for cross-border health care do not apply. Otherwise, applications may be made under the Directive provisions, which allow for the reimbursement of hospital and ambulatory care up to

³⁶ C-372/04 *The Queen on the Application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 16 May 2006.

³⁷ C-372-/04 Opinion of Advocate General Geelhoed of 15 December 2005 paras 66-67.

the level of costs prevailing in the Member State of insurance (affiliation). Where no explicit tariff exists, it is the responsibility of each Member State to ensure that there is a mechanism for the calculation of costs which should be not less than the cost of health care provided in that Member State.

Also as established in ECJ judgements, access to cross-border hospital care under freedom of movement of services (Article 49) may be subject to a prior authorisation procedure where the expected outflow of patients is likely to undermine the financial balance of the social security system, or the planning of the hospital system. As the preamble notes, the ex ante assessment of the precise impact of an expected outflow of patients “requires complex assumptions and calculations”, and so the allowance of a system of prior authorisation under Article 49 of the Treaty is made following “sufficient reason” of expectation. Hospital and specialised care is defined as:

- health care which requires overnight accommodation of the patient in question for at least one night;
- health care included in a specific list, to be drawn up and regularly updated by the Commission, that does not require overnight accommodation; the list to be limited to:
 - health care that requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
 - health care involving treatments presenting a particular risk for the patient or the population.

In all cases, a prerequisite of obtaining cross-border health care is that it is for the Member State of insurance (affiliation) to establish what health care is to be provided. Furthermore, as is worth quoting in full, the draft Directive establishes that:

“The Member State of affiliation may impose on a patient seeking health care provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving health care and reimbursement of health care costs as it would impose if the same or similar health care was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons.”

In principle, therefore, it would seem that the gatekeeping function for referral to secondary care is preserved. Furthermore, where waiting time limits are set, these must, as the Court judgements established, take into account “the specific medical condition, the patient’s degree of pain, the nature of the patient’s disability and the patient’s ability to carry out a professional activity”.

Other noteworthy provisions in the draft Directive, which may actually prove to have an even greater impact on Member States than the Court judgements in themselves, relate to: the mutual recognition of prescriptions issued in another Member State (Article 14); the establishment of European reference networks for highly specialised areas of medical care (Article 15); mechanisms to establish inter-operability of information and communication technology systems (Article 16); and cooperation between Member States in the field of Health Technology Assessment (HTA). Above all, the draft Directive seeks to influence Member States’ oversight of quality of health care provided, as well as to locate liability for redress with provider institutions, requirements which could have far reaching implications for clinical and organisational regulation. We return to consideration of these issues in the concluding sections of this paper.

3. ISSUES AND EVIDENCE ON COMPETITION IN HEALTH CARE MARKETS

Some commentators on the series of ECJ judgements reviewed above are concerned that the Court is driving Member States to adopt more pro-market and competitive models for delivering health care. To date, this has not been the case. However, the concern remains that, given the economic objectives of the single market, future judgements could embrace a more competitive structure for health care. It is therefore useful to review the issues and available evidence on competition in delivery of health care services.

3.1 The cross-border market

Normally, competition is expected to affect economic performance by putting pressure on unit costs of producers and, through price and quality competition, to increase the size of the market domestically and internationally. This is the role of competition embraced by the Single Market and its objective of achieving higher rates of economic growth through integration. However, the effectiveness of competition in promoting more efficient production varies with the nature of the market and the scope for securing global market share. The market for delivering health care to patients accounts for a significant share of GDP in EU Member States (7-11%). Appreciation of the potential role of competition in this sector is therefore important.

As in other economic sectors, cross-border competition in producing and delivering health care

services can take different forms. Countries may import or export patients. Production takes place within national borders and patients (“consumers”) move from the country of residence to the country of production in order to obtain health care services. Alternatively, overseas direct investment means that producers from one country invest in facilities to provide services in another country. In this case, services move to the patient rather than the patient moving to the services. Given the reluctance of most patients to travel for health care, growth of international competition in delivering health care services is more likely to occur as a result of growth of direct investment and movement of professionals. For example, annually around one thousand NHS patients apply for and are given prior authorisation for treatment abroad. This is an underestimate of the numbers willing to travel as we lack data on the numbers who choose to go abroad and pay for themselves. By contrast, in 2005 the Department of Health announced plans to encourage overseas companies to invest in hospital facilities in England and to compete for NHS patients. The Department expected that over the following five years 250,000 NHS patients annually would be treated as a result of this direct investment. Numbers actually treated were below expectation at around 150,000 but even at this rate, the competition provided via direct investment was considerably in excess of that associated with patients travelling abroad.

3.2 Competition in health care: role and limitations

One of the many problems of applying a competitive model of production and growth to health services in Europe is that, unlike most other services, the principle of solidarity dominates: all members of society must have access to health care regardless of their medical condition or ability to pay. Competitive behaviour that focuses on the most profitable patients and excludes others is socially unacceptable.

Primarily to implement solidarity, public finance covers the cost of most health care in the EU. This ranges from direct tax finance (UK, Denmark, Sweden) through earmarked social security and employment taxes (France) to coverage of the significant proportion of the population unable to afford private insurance in Bismarckian³⁸ systems (Germany, Netherlands). Given the fiscal problems of the new Member States, the public expenditure implications of providing services consistent with the solidarity principle are considerable. The significant

role of public finance in providing for equitable access to health care means that growth of the domestic market is not necessarily desirable as more and more services cannot all be funded. Cost containment and reduction in the rate of growth of health care expenditure is high on the agenda of most European countries.

There are no objective criteria for determining an efficient level of expenditure on health care and the appropriate level will vary by Member State. However, growth in demand that exceeds the ability of governments to finance expansion of health care delivery can undermine maintenance of solidarity. To balance the need to contain the growth of health care expenditure with other fiscal responsibilities it is common in European countries to adopt a fixed global budget within which total health care expenditure is to be contained. The effectiveness of this system varies. In England a fixed national budget allocated among local purchasers via a risk-adjusted capitation formula has, some would argue, been overly successful in containing costs. In France, the global budget is often exceeded³⁹. Despite this variable experience, European systems have been more effective overall in controlling total health care expenditure than the US, with its much greater reliance on market competition in health care.

The tension between encouraging competitive markets and the need to control health care costs can be seen in policies towards the pharmaceutical industry. At the EU level, the pharmaceutical industry is seen to be one where growth should be encouraged: it is profitable and globally competitive. However, each Member State faces considerable difficulty controlling expenditure on drugs for its patients. The financial incentives for pharmaceutical companies to develop effective new products and charge high prices for them are strong but some of these products may be of questionable cost-effectiveness at the prices sought⁴⁰. Within Europe there is a two-pronged approach to dealing with this problem. First, governments (or arm’s-length institutions) negotiate prices with pharmaceutical and medical equipment companies. Second, some European countries have created institutions to review research evidence on the clinical effectiveness and cost-effectiveness of pharmaceuticals and medical procedures and to recommend which should (or should not) be made available to insured patients. The National Institute for Health and Clinical Excellence (NICE) in England and Wales is perhaps the best known but the approach is being introduced

³⁸ EU health care systems are sometimes referred to either as Bismarckian, where they involve social insurance/third party payers providing reimbursement insurance or benefits in kind, or as Beveridge systems which are based predominantly on taxation.

³⁹ Rodwin VG, Le Pen C (2004) Health Care Reform in France – The Birth of State-Led Managed Care. *N Engl J Med* 351:2259-2262, Nov 25, 2004.

⁴⁰ There is a vast literature on this issue but, as an example, see Garattini and Bertele (2002) Efficacy, safety and cost of new anticancer drugs. *BMJ*, 325;269-271.

in other countries⁴¹. Regulation is central to efficient delivery of universal health care.

To keep the debate in perspective, it is worth recalling that in all markets regulators act to circumscribe the scope for competition: there is no such thing as a (legal) “free market”. Common law and statute seek to protect individuals from the consequences of competitive behaviour through myriad regulations on conduct ranging from misleading advertising, fraud and negligence to specific health, safety, environmental and labour market regulations. Most regulation reflects the need to correct for asymmetric information, externalities and abuse of market power. The degree of market failure is likely to be far greater in some markets than others. Production and delivery of health care is known to be subject to significantly greater risk of market failure than other economic activities to the extent that reducing the inefficiency of competitive health care markets requires instruments that usually go beyond traditional regulatory control of markets.

In the health economics literature most discussion of how to improve the efficiency of “competitive” health care markets refers to instruments for “managing” the market. The best known models are those of *managed care* and *managed competition*⁴². It is worth noting that most of the analysis of “managed” markets has been developed in the context of the US health care system, the country with the greatest experience of market-based delivery of health care.

“Managed care” seeks to overcome several well known sources of market failure in health care. Given the problem of *moral hazard*, whereby the demand by insured patients for health care may be excessive, and *information asymmetry*, the dependence of patients on clinicians for information about necessary treatments, the problem is to deter clinicians from over-providing care by creating incentives for them to select cost-effective treatment programmes and prescribing. The policy instruments usually deployed are gate-keeping, selective contracting, utilisation review (employing best practice guidelines) and pharmaceutical formularies. Payment of providers on the basis of capitation or prospective prices rather than fee-for-service is often seen as the key to strengthening incentives for providers to offer cost-effective medical care⁴³. All of these techniques involve some limitations on patient choice.

To date EU regulators have raised no objections to these techniques for managing the market. All EU countries use some of these instruments or are in the process of introducing some of them. EU regulators simply require that the measures adopted be non-discriminatory (for example, selective contracting must not discriminate between domestic providers and those in other Member States) and transparent (as when the availability of treatments is to be limited or formularies restricted⁴⁴).

“Managed competition” refers to policies which seek to regulate the market in health care plans and is of particular relevance to those EU countries that rely on choice between competing statutory and private health insurance/sickness funds. Enthoven⁴⁵, the economist primarily responsible for developing the analysis of managed competition, stressed that the traditional economic model of a market – individual purchasers buying from suppliers – was rarely observed in health care and, where it was, had been demonstrated to be both inequitable and inefficient. “Efficient” insurance markets differentiate products in ways that undermine population risk pooling and hence solidarity. Product differentiation makes it difficult for individuals to compare the coverage of one plan with another. It is of particular significance that in a health care insurance market there is rarely evidence on quality of care to inform choice between plans. Managed competition aims to minimise risk selection. Attempts by providers to avoid cost-effective treatments are controlled through regular adjustments to the regulatory framework. There is an organiser/regulator which sets rules of equity, develops standardised plans that must be available to all citizens and ensures all relevant information is made available by providers to an independent quality monitoring organisation (such as the Healthcare Commission in England).

Managed competition was seen as a means of creating countervailing market power relative to health care providers that would permit greater reliance on market forces in the pursuit of efficiency. In the US, the country with most experience of managed competition, research evidence suggests it has failed to deliver on this objective⁴⁶.

3.3 Competition in health care: the evidence

Evidence on the effectiveness of competition in delivering improvements in cost-efficiency and quality is mixed. There is virtually no research evidence on

⁴¹ Jost TS (2005), *Technology Assessment for Coverage Policy: An International Comparative Study*. Maidenhead, UK: Open University Press.

⁴² Reinhardt U (1998) *Accountable Health Care: Is it Compatible with Social Solidarity?* The Office of Health Economics, London.

⁴³ For a concise review of the economics of managed care see Glied S (2000) “Managed Care” in *Handbook of Health Economics*, eds. Culyer AJ, Newhouse JP. A Department of Health commissioned review of the evidence on managed care is in Robinson R, Steiner A (eds.) (1998) *Managed Health Care*. Open University Press. London.

⁴⁴ *Regina v Secretary of State for Health ex parte Pfizer Ltd*. Case No:C/4934/98. 26 May 1999.

⁴⁵ Enthoven AC (1993) The History and Principles of Managed Competition. *Health Affairs* Vol.12, Suppl.1: 24-48.

⁴⁶ Nichols LM et al. (2004) Are Market Forces Strong Enough to Deliver Efficient Health Care Systems? Confidence is Waning. *Health Affairs* 23(2): 8-21.

competition in delivering primary care. Almost all robust evidence comes from the US where competition to provide both publicly and privately funded health care has been the norm for decades. There is a legitimate concern that this evidence may be of limited relevance to European health care systems that operate within a framework of publicly funded, universal access. The US has a hybrid health economy. Half of US health care is provided in a publicly funded system: Medicare for people over 65 years of age and Medicaid for the poor. In terms of coverage and funding these schemes are close to European systems. Coverage and funding for most of the US working age population (and their children) is radically different from the European model with access to health care dependent on whether employers offer health benefits and leaving about 15% of the population without health insurance. Fortunately, for the purpose of this review, most of the major US research on the impact of competition draws on data for patients treated under Medicare – the publicly funded system with universal access for individuals over the age of 65 – and other publicly funded care.

The key message from these studies is that the impact of competition between providers (hospitals) depends on the incentives available to third party payers (purchasers). It is necessary to distinguish between:

- Indemnity insurers with retrospective payment of hospitals;
- Managed Care Organisations (MCOs) engaged in selective contracting, limited patient choice and negotiated prices (payer driven competition);
- Medicare that pays fixed DRG⁴⁷ prices with patients exercising choice of hospital and doctor (yardstick competition).

In the remainder of this section, we set out the key results of the research. Space does not permit detailed summaries of all papers but full references are provided to relevant papers for those who wish to obtain further information and an extended discussion of the research evidence is available⁴⁸.

Before the 1990s, the most competitive US hospital markets were associated with higher costs than those observed in less competitive markets and with proliferation of treatments of marginal or

questionable value⁴⁹. With indemnity insurance and retrospective payment, market competition contributed to inefficiency. Following the introduction of selective contracting, there was evidence from the US that payer-driven price competition, identified by the increased market share of managed care companies, had reduced prices and hospital costs⁵⁰. A study of selective contracting in California from 1983-1997 suggests that for-profit plans may have been somewhat more effective drivers of this price competition than non-profit plans⁵¹.

Evidence of the effect of competition on quality of care is more limited and contradictory^{52,53}. One of the more rigorous econometric studies⁵⁴ found that after 1991 hospital competition improved quality of care as measured by one-year mortality rates and readmission rates following admission for acute myocardial infarction (AMI). However, these findings conflict with those of other US studies suggesting that competition has a negative or negligible effect on quality⁵⁵. A later study⁵⁶ using risk adjusted mortality rates for AMI and pneumonia as measures of quality, found that the impact of competition on quality differed by method of payment. Vigorous competition for (fixed price) Medicare patients was associated with higher mortality rates while increased competition for HMO patients (negotiated contracts) was associated with reduced mortality rates.

The NHS “internal market” in England from 1991-1997 was an attempt to introduce hospital competition into a publicly funded health care system. A number of studies investigating impact on efficiency

⁴⁷ Diagnosis related group (DRG): a system to classify hospital cases into one of several hundred groups, expected to have similar hospital resource use. DRGs are used as the basis of prospective payment systems: hospitals receive a pre-set price per case treated according to the DRG for that case.

⁴⁸ Cookson R, Dawson D (2006) Hospital competition and patient choice in publicly funded health care. In *The Elgar Companion to Health Economics*, Ed. Jones AM, Edward Elgar, Cheltenham, UK and Northampton, MA, USA.

⁴⁹ Robinson J, Luft H (1985) The Impact of Hospital Market Structure on Patient Volume, Average Length of Stay and the Cost of Care. *Journal of Health Economics*, 4(4): 333-356.

⁵⁰ Zwanziger J, Melnick GA (1988) The Effects of Hospital Competition and the Medicare PPS Program on Hospital Cost Behaviour in California. *Journal of Health Economics*, 7(4): 301-20. Dranove D, White WD (1994) Recent Theory and Evidence on Competition in Hospital Markets. *Journal of Economics and Management Strategy*, 3: 169-209. Keeler EB, Melnick G, Zwanziger J (1999) The Changing Effects of Competition on Non-Profit and For-Profit Hospital Pricing Behaviour. *Journal of Health Economics*, 18(1): 69-86. Dranove D, Satterthwaite MA (2000) The Industrial Organization of Health Care Markets. Volume 1B, in Eds. Culyer AJ, Newhouse JP, *Handbook of Health Economics*, Amsterdam; New York and Oxford: Elsevier Science, pp. 1093-1139.

⁵¹ Zwanziger J, Melnick GA, Bamezai A (2000) The Effect of Selective Contracting on Hospital Costs and Revenues. *Health Services Research*, 35(4): 849-867.

⁵² Robinson R (2000) Managed Care in the United States: a Dilemma for Evidence-Based Policy? *Health Economics*, 9(1): 1-7. Romano PS, Mutter R (2004) The Evolving Science of Quality Measurement for Hospitals: Implications for Studies of Competition and Consolidation. *International Journal of Health Care Finance and Economics*, 4: 131-157.

⁵³ Gaynor M (2006) *What do we Know about Competition and Quality in Health Care Markets?* NBER Working Paper No 12301, June 2006

⁵⁴ Kessler DP, McClellan MB (2000) Is Hospital Competition Socially Wasteful? *Quarterly Journal of Economics*, 115(2): 577-615.

⁵⁵ Sari N (2002) Do Competition and Managed Care Improve Quality? *Health Economics*, 11(7): 571-584. Shortell SM, Hughes EF (1988) The Effects of Regulation, Competition, and Ownership on Mortality Rates among Hospital Inpatients. *New England Journal of Medicine*, 318(17): 1100-1107. Volpp KG, et al. (2003) Market Reform in New Jersey and the Effect on Mortality from Acute Myocardial Infarction. *Health Services Research*, 38(2): 515-533. Volpp KG, Buckley E (2004) The Effect of Increases in HMO Penetration and Changes in Payer Mix on In-Hospital Mortality and Treatment Patterns for Acute Myocardial Infarction. *American Journal of Managed Care*, 10(7): 505-512.

⁵⁶ Gowrisankaran G, Town R.J (2003) Competition, Payers, and Hospital Quality. *Health Services Research*, 38:6, Part 1.

and quality have attempted to control for selection and other biases⁵⁷.

Hospital competition was driven by two main public payers: District Health Authorities and General Practice Fundholders. The former were ineffective drivers of competition. This is usually attributed to poor information, weak incentives and political constraints on “destabilising” local hospitals⁵⁸. Effects of General Practice Fundholding included reduced hospital prices and waiting times for non-emergency treatment, and reduced referral rates. One study found that price competition slightly reduced hospital quality of care as measured by 30-day mortality rates following AMI admission⁵⁹.

Policies are currently being implemented in England which are expected to create stronger incentives for providers to compete – even though limited to non-price competition – than were found in the internal market of the 1990s. It will be several years before evidence is available to assess the impact of the new competition conditions on quality, cost and access.

Many low- and middle-income countries, including new EU Member States, have a high proportion of public funding in health care. However, competition within the publicly funded sector is not (yet) a live issue in such countries, since it would require expensive infrastructure investment in cost accounting and quality monitoring systems. Several high-income countries outside the US and UK have experimented with hospital competition but there is limited statistical evidence attempting to quantify the effects.

3.4 Patient choice as a promoter of competition

Payer driven market competition has a serious drawback. Effectiveness in reducing costs depends on restricting patient choice. This has led to a political backlash in the US and in recent years to a reduction in the market power of managed care. This is an important issue for European countries. In some Member States patient choice is seen as an historic right, in others patient choice is being introduced as an instrument to encourage competition on quality between hospitals. Some Member States are attempting to reduce patient choice in an effort to contain costs.

⁵⁷ Croxson B, Propper C, Perkins A (2001) Do Doctors Respond to Financial Incentives? UK Family Doctors and the GP Fundholder Scheme. *Journal of Public Economics*, 79(2): 375-398. Propper C, Wilson D, Soderlund N (1998) The Effects of Regulation and Competition in the NHS Internal Market: the Case of General Practice Fundholder Prices. *Journal of Health Economics*, 17(6): 645-73.

⁵⁸ Le Grand J, Mays N, Mulligan K (eds.) (1998) *Learning from the NHS Internal Market: a Review of the Evidence*, London: King's Fund Publishing.

⁵⁹ Propper C, Burgess S, Green K (2004) Does Competition between Hospitals Improve the Quality of Care? Hospital Death Rates and the NHS Internal Market. *Journal of Public Economics*, 88(7-8): 1247-1272.

Most of the “Bismarckian” health care systems in Europe with employer-based social insurance schemes (Austria, Belgium, France, Germany, Luxembourg), have long had unrestricted patient choice of provider but limited hospital competition. France and Germany – the two highest spending of the Bismarckian countries – are currently trying to reduce patient choice in order to contain costs⁶⁰. Denmark since the early 1990s and Norway and Sweden more recently have offered patients choice of any hospital in the country. Studies report little patient movement and no sign of competition⁶¹. Two comments are common. First, patients are reluctant to travel outside their local area due to search and travel costs⁶². Second, historic reimbursement regimes make it unattractive for hospitals to expand capacity and attract non-resident patients.

There are important differences between European countries in willingness to adopt payer driven competition, and patient choice per se appears a weak instrument for stimulating competition. However, there may be an emerging consensus on the use of yardstick competition⁶³. A number of European countries are adopting elements of prospective reimbursement, fixed DRG⁶⁴ prices, to exert downward pressure on the costs of relatively high unit cost providers as an alternative to reliance on market competition⁶⁵. In some countries there is the expectation that the administered price regime will encourage some competition for patients. However, there remain powerful political constraints on closing failing hospitals and this will blunt most initiatives to increase competition.

Some EU countries (England, the Netherlands, Germany) are moving toward creating a more contestable market for hospitals in which international, for-profit companies are being allowed to enter the market or take over existing public/private facilities. These experiments are too recent yet to have generated any evidence concerning their impact on economic performance in health care.

⁶⁰ Rodwin VG, Le Pen C (2004) Health Care Reform in France – The Birth of State-Led Managed Care. *N Engl J Med* 351:2259-2262, Nov 25, 2004.

⁶¹ Williams J, Rossiter A (2004) *Choice: the Evidence*, London: Social Market Foundation.

⁶² Goddard M, Hobden C (2003) *Patient Choice: a Review*. Report to the Department of Health, University of York: Centre for Health Economics.

⁶³ Shleifer A (1985) A Theory of Yardstick Competition. *Rand Journal of Economics*, 16(3): 319-327.

⁶⁴ Diagnosis related group (DRG): a system to classify hospital cases into one of several hundred groups, expected to have similar hospital resource use. DRGs are used as the basis of prospective payment systems: hospitals receive a pre-set price per case treated according to the DRG for that case.

⁶⁵ Langenbrunner J, Orosz E, Kutzin J, Wiley M (2005) Purchasing and Paying Providers. In Figueras J, Robinson R, Jakubowski E (eds.) *Purchasing to Improve Health System Performance*, Maidenhead: Open University Press, pp. 236-264.

3.5 Implications of the evidence on competition in health care: a summary

The evidence to date suggests that market competition in the delivery of health care makes an ambiguous contribution to the objective of an efficient and equitable health care system. This may appear surprising given the general impression that introduction of competition in other markets is often associated with lower costs and greater consumer choice. A central reason for the observed difference between health care and other industries is that asymmetric information leads to more serious market failures than in other markets. Competition for patients where quality is largely unobservable means that hospitals delivering lower quality may succeed at the expense of those with high quality standards. Publicly available data on quality are limited. It remains to be seen whether improved and easily accessible information on the quality of hospital services will in future have more impact on patient choice and the competitive behaviour of providers. In the US, where performance data have been available for a longer period than in most European countries, the evidence suggests use of the information by patients and insurers is limited.

A particular problem in health care is that where patients are insured (public or private insurance), competition for patients often results in cost increasing treatments. Some cost increasing treatments may be cost-effective but many are not. At the point of use, the cost-effectiveness of treatment is of little interest to an insured patient. Competing for patients can lead to industry wide cost increases rather than the cost reductions observed in other sectors.

There is also a political cost of competition in health care that is rarely present in other markets. The evidence suggests that the most effective form of competition in delivering lower costs and perhaps higher quality is payer driven competition which requires restrictions on patient choice. This has proved to be politically unpalatable. In addition, in most developed countries, there is a social commitment to universal coverage and access on the basis of medical need rather than income. This requires restraining some of the more obvious forms of competitive behaviour such as risk selection, cream skimming and concentration on lucrative markets.

The implications of the available evidence for the EU agenda are important. In all the relevant decisions of the ECJ, the Court has stressed the importance of maintaining health care systems with universal access and hence the need for Member States to control costs. The contribution of more competitive markets in health care to securing the objectives of the Single

Market may not just be more limited than in other sectors of the economy, but also inconsistent with this overall objective.

4. THE SINGLE MARKET AND COMPETITION LAW

When discussing the impact of the EU on national health care systems, it is important to distinguish between:

- i) ECJ judgements on free movement of goods, services, capital and labour;
- ii) EC Competition Law.

The ECJ judgments on the rights of patients under Article 49 to obtain care from providers in other Member States only apply to cross-border treatment. As the Court repeated in the *Watts* case, Article 49 does not apply to transactions within a Member State. For example, nothing prevents a Member State from organising its health care system in a way that offers patients no choice of domestic provider, whilst the same patients may simultaneously have a right to a choice of provider from another Member State. Member States are free to organise their systems on an integrated basis, with no competition, or to promote competition between providers and/or insurers. It is up to Member States to decide how their health care systems are structured. In practice there is wide variation within the EU over the extent to which each Member State, as a matter of domestic policy, chooses to adopt more or less competitive models of health insurance and health care delivery. This reflects national policy decisions, not Single Market regulation.

However, EC Competition Law is a different matter. Where countries introduce elements of competition into their health care systems, Competition Law will apply. For example, the principles of Community Competition Law are embedded in domestic UK Competition Law (The Competition Act 1998). The competition rules therefore apply to behaviour within the UK and not just to cross-border issues. In *Bettercare Group Ltd v. Director General of Fair Trading*⁶⁶, Community criteria for defining an undertaking and economic activity were applied to a competition dispute between a Northern Ireland NHS purchaser and Northern Ireland private sector providers by the UK Competition Commission Appeals Tribunal. The subsequent *FENIN* judgement⁶⁷ has raised some questions relevant to the

⁶⁶ *Bettercare Group Ltd v Director General of Fair Trading*, Case 1006/2/1/01, 1 August 2002. Competition Commission Appeals Tribunal. www.catribunal.org.uk.

⁶⁷ Case T-319/99 *Federacion Nacional de Empresas de Instrumentacion Cientifica, Medica Tecnica y Dental (FENIN) v Commission of the European Communities* 4 March 2003.

interpretation of European law by this domestic Tribunal. There are differences between EC Competition Law and Single Market legislation, but legal commentators see an evolving convergence between EC competition rules and Single Market rules⁶⁸. Developments of case law in this area can have important implications for governments that choose to adopt pro-competitive structures for their health care systems.

The UK presents an interesting example of problems that may be ahead. The UK is the relevant Member State but it is composed of four nations that, since devolution, have adopted very different ways of organising their health care services⁶⁹. Scotland has adopted an integrated, non-competitive approach to delivery of health care while England is implementing a market based system for delivering (but not for insuring) publicly funded health care. The English reforms increase the likelihood that English NHS services may be more subject to Community competition and Single Market rules than services provided within some other nations of the UK. A few examples of issues that could arise are listed below.

4.1 Diversity of providers

In England it is government policy to encourage a diversity of providers. This includes encouragement of overseas companies to provide hospital services, diagnostic services and primary care for NHS patients. On the face of it, this policy is in accord with EU policy on free movement of capital. However, several problems could arise for the English Department of Health (DH).

(i) State aids

The DH wants the hospital market to be “contestable”. There could be arguments as to whether there is a “level playing field” between NHS Trusts (publicly owned bodies providing hospital and community based health care services), the UK private sector and other European providers. One potential issue is the cost of capital. NHS Trusts can borrow at a real interest rate of 3.5%, significantly below the cost of capital to the UK private sector (around 15%). However, the issue is not clear. NHS Trusts with Private Finance Initiative (PFI) contracts pay much higher implicit interest rates (around 19%) and it is unknown what the cost of capital is for potential European market entrants.

⁶⁸ O’Loughlin R (2003) *EC Competition Rules and Free Movement Rules: An Examination of the Parallels and their Furtherance by the ECJ Wouters Decision*, E.C.L.R.: 62-69. Krajewski M, Farley M (2004) *Limited Competition in National Health Systems and the Application of Competition Law: AOK Bundesverband Case*, 29 E.L. Rev. December: 842-851.

⁶⁹ Greer SL (2004) *Four Way Bet: How Devolution Has Led to Four Different Models for the NHS*. The Constitution Unit, University College London, London.

(ii) Insolvency and takeover

The DH has stated that NHS Trusts that face insolvency will not be bailed out. However, legislation stipulates that if an NHS Trust is dissolved, its assets and liabilities are to be transferred to another NHS Trust or DH organisation. What if a European provider wanted to enter the market by purchasing the assets of a failing English NHS Trust? In most markets it is common for a company wishing to enter a new market to do so by takeover or purchase of the assets of a failing or under-performing existing producer. In recent years there have been several ECJ judgements related to restrictions on investment in industries of particular public sensitivity. The issue has been whether powers reserved by governments to control investment, mergers and disposal infringe treaty obligations on the free movement of capital. The cases to date have dealt with restrictions on investment and takeover in privatised public utilities, arrangements generally referred to as “golden shares”⁷⁰. However, in all these decisions the Court has pointed to the nomenclature that clarifies the meaning of “capital movements”⁷¹. In particular, direct investments include:

- Establishment and extension of branches or new undertakings belonging solely to the person providing the capital and the acquisition in full of existing undertakings;
- Participation in new or existing undertakings with a view to establishing or maintaining lasting economic links.

Some NHS assets have been transferred to new Independent Sector Treatment Centres (ISTCs) to assist market entry. Since published DH policy is to encourage diversity of providers and contestability, it is possible that the existing legislative restriction on which companies can takeover NHS assets could be challenged. Transfer of assets from public to private sector companies, within a planning framework, will not be without precedent. In Germany several regional (Länder) governments are looking at selling public sector hospitals in financial difficulty to private sector companies.

4.2 The National Tariff

In the past the UK government has argued before the ECJ that there were no prices for NHS services relevant to reimbursement of a patient who wished to be treated in other Member States (*Kohll and Decker*). England now has a published price list for hospital services. Full implementation of the National Tariff

⁷⁰ See for example, Case C-463/00 *Commission of the European Communities v Kingdom of Spain* 13 May 2003 and Case C-98/01 *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland* 13 May 2003.

⁷¹ Annex I to Council Directive 88/361/EEC of 24 June 1988.

could have further implications for the way the ECJ and competition authorities view the activities of English NHS Trusts. The UK Office of National Statistics (ONS), in agreement with Eurostat, currently classifies NHS Trusts and NHS Foundation Trusts as non-market parts of general government. In July 2003 the ONS announced that in accord with Eurostat rules “Once the National Tariff system has been achieved, all English NHS Trusts and NHS Foundation Trusts will be classified as market bodies, i.e. public corporations.”⁷² In future cases where there is argument as to whether NHS organisations are engaged in “economic activity”, the criteria used to define NHS Trusts as market bodies may be considered relevant to the question whether they constitute “undertakings” within the terms of Community law.

4.3 Patient choice and national policy

From 2006, all ISTCs and private sector hospitals that wish to treat English NHS patients at National Tariff prices have the right to be included in the choice menu. Given that all willing UK private providers are included, it will not be possible to exclude any willing provider in other Member States. A possibly contentious issue is the requirement that a willing provider be subject to inspection by the English Healthcare Commission. If, say, a French hospital wishes to treat NHS patients at National Tariff prices but is excluded from the market unless it submits to what is likely to be an onerous system of inspection by a UK regulatory authority, this requirement could be seen as an attempt to protect the domestic market.

4.4 Contestability and planned capacity

The DH has made it clear that it expects English NHS Trusts to compete – though not on price – for patients, both among themselves and with the private sector, and that this market is to be “contestable” – i.e. hospitals that fail to remain solvent if they do not attract sufficient patients will not be bailed out. The DH has not yet published its new rules on insolvency but it is difficult to see how credible threats of contestability can be reconciled with the idea that planned capacity is to be protected from the impact of patient choice. In the past the UK has invoked, as a justification for restricting cross-border movement of patients (prior authorisation), the possibility of financial undermining of planned capacity – that is a hospital could find itself with too few patients to remain viable. If the DH is willing to accept this consequence of its domestic choice regime for hospitals, it could reduce the credibility of arguing

before the ECJ that patients exercising choice for cross-border treatment must be restricted on the grounds that it could undermine the financial viability of particular hospitals.

5. CONCLUSIONS: FUTURE DEVELOPMENTS, RISKS AND UNCERTAINTIES

A number of key messages emerge from this review.

The difficulties which Member States face with current EU health policy are easy to appreciate. As has been seen, there is a tension between the market-oriented economic growth objectives of the single market and the cost-containment objectives of Member States for expenditure on solidarity-based health care delivery. The uncritical application of Treaty articles to the health sector is not just unhelpful but could prove counterproductive if efficiency and solidarity were to be undermined as a result. Where maintenance of solidarity in predominantly publicly funded health care systems requires measures that conflict with Single Market objectives, there needs to be political agreement on the nature of exceptions required for health care.

In addition, competition has important limitations when applied to delivery of health care. “Managed care” seeks to overcome several well known sources of market failure in health care markets using instruments such as gate-keeping, selective contracting, prospective prices, utilisation review and pharmaceutical formularies. All EU countries use some of these techniques for managing the market or are introducing some of them. Managing the market can include continuous adjustment of the implicit benefit package, for example waiting times and speed of access to new technologies, to contain health care expenditure within public budgets. Competition between payers (sickness funds/insurers) can undermine solidarity unless highly regulated. On existing evidence, competition between providers is most effective in reducing costs when associated with restrictions on patient choice. If the Court were to extend further the rights of patients to socially-financed cross-border health care, for example into services currently covered by contracts between providers and third party payers, it could be unwittingly undermining the crucial role of the payers. Member States differ significantly in the extent to which they wish to expand or contract patient choice. This is an important aspect of subsidiarity and affects the extent to which competition for patients is acceptable. Paradoxically, the research evidence that payer driven competition between providers requires a restriction of patient choice is a pro-competition

⁷² Office of National Statistics, *National Accounts Sector Classifications of NHS Foundation Trusts and NHS Trusts*, PSCC case 2002/22 of 2 July 2003.

based argument for a prior authorisation system, rather than the planning based argument currently adopted by the Court.

Health care is, of course, not the only regulated sector where market mechanisms are of limited applicability. Articles 16 and 86 of the Treaty allow for special consideration of *Services of General Interest (SGI)*, which have since been defined by the Commission as ones in which “universal service, continuity, quality of service, affordability, user and consumer protection” are defining objectives. In such cases there is a need to ensure that what the Commission describes as “public service missions” are not compromised by the application of market mechanisms. Specifically, Article 86(2) provides that the rules on competition apply to undertakings entrusted with the operation of services of general economic interest only as long as they do not obstruct the performance of these services, although a proviso in the Treaty also notes that “The development of trade must not be affected to such an extent as would be contrary to the interests of the Community”.

However, designating health an SGI still leaves open and vague how the trade-off between competition and public service objectives is to be addressed, and does not address the issue of the crucial role played by public finance in health care and the consequent need for clear and explicit limits on the erosion of national control and accountability. On the contrary, designating health an SGI opens the prospect of Commission-led, sector-specific regulation and supervision in a policy area whose importance to the individual citizen, and consequent political profile for national governments, makes it one of the most sensitive sectors to deal with at international level.

The main fear of Member States has been that the Court judgements are the thin end of the wedge, and could in the extreme be used to argue in favour of harmonised EU health services provision. There are a number of pressures in this direction in addition to those already identified and Article 152 of the Treaty, which was considered explicitly by the Court in the *Watts* case, seems to offer only limited protection against this. One area of future uncertainty is the difficulty of defining, and possible creep in the understanding of, “ambulatory care”⁷³ and hence in the range of services for which patients might be entitled to automatic reimbursement if purchased abroad. An increasing number of services, previously provided within hospitals, are now being supplied in other settings and this trend is likely to continue.

Another fundamental question concerns basic entitlements. In its judgements the Court has made clear, and the draft Directive on patients’ rights in cross-border health care confirms, that the availability of a treatment in some Member States is not relevant to whether the treatment is included in the benefit package of another Member State – each Member State defines the benefits for its insured population. In future an issue may not be whether a particular treatment is available but acceptability of the level of service. The Court has not provided a definition of “undue delay” but, as adopted by the draft Directive, has clearly moved in the direction of some measurement of health state. This was obvious in the *Watts* case when the Court said that the level of pain and ability to carry out usual professional activities were relevant to decisions on the availability of “normal” treatment. No-one questioned that treatment for severe arthritis was an insured benefit of an English NHS patient. The issue was the degree of deterioration in health required before treatment was offered. The Judge suggested that the *threshold* for treatment in this case was so low that it could be inconsistent with the Article 152 requirement for a high standard of health care.

Defining the threshold for treatment is as much a part of the system for controlling access to insured health care as the decisions on what treatments to offer. In line with the Court judgements, the draft Directive requires Member States to ensure that any administrative decisions regarding the use of health care in another Member State are subject to administrative review and are capable of being challenged in judicial proceedings. It is easy to speculate that such proceedings would offer patients the opportunity to bring continuing pressure on the thresholds of care which are established, to the extent that this could impinge on an important aspect of national autonomy. For example, there has been debate in England over the degree of deterioration in eyesight before treatment is offered for macular degeneration. If the decision were that treatment to prevent loss of sight in one eye while vision remains in the other eye is not a cost-effective use of NHS resources, could an ECJ or domestic judge decide the consequent disability for patients was inconsistent with the Article 152 commitment to a high standard of health care?

The provisions in the draft Directive, including for mutual recognition of prescriptions, are also of relevance to a topic of considerable current interest in the UK: that of so-called “top-up” payments⁷⁴. At the time of writing, the English Department of Health is conducting a review into whether “top-up” payments

⁷³ C-385/99 *V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen*, 13 May 2003.

⁷⁴ “NHS scandal: dying cancer victim was forced to pay.” *The Sunday Times*, 1 June 2008.

by patients are admissible in the case of expensive treatments, forming part of an overall package of care, where those treatments are not recommended by NICE^{75,76}. The context for this review is the recent experience of cancer patients who, having asked to pay privately for expensive anti-cancer drugs which Primary Care Trusts will not fund, have found themselves asked to pay for all their cancer treatment, including the NHS part. It seems conceivable that cross-border health care could play a part in the development of such two-part treatment patterns, with patients going abroad to get whole packages of care, of which only part would be reimbursable by the NHS.

On a more general level, the Court judgements have given publicity and profile to inequalities in provision, and in entitlements to cross-border care between Member States which can only become more transparent once the draft Directive is agreed and transposed into national law. These considerations could elevate the debate to one concerning the sovereignty of Member States to define the health care package, which becomes a question of the role of integration (what is to be harmonised across Europe) rather than one of free movement or of Competition Law.

On the other hand, many Community policies have implications for control of health systems, so this is not new and indeed it could be argued that the draft Directive, following the Court, has been more scrupulous in respecting the characteristics and provisions of each national health care system than other Community institutions where directives and industrial policies directly impact on health care. All

Member States have the option of “proofing” their domestic health systems against the application of Community Single Market rules and Competition Law by tightly defining and constraining domestic entitlements and by adopting non-market means of health services delivery. Currently the UK does neither, and recent policies of the DH applied to the English NHS enlarge significantly the scope for application of Single Market rules and Community Competition Law.

It is important to distinguish between the independent movement of patients for cross-border treatment and the internal policies of Member States that may embrace cross-border contracting and inward direct investment by overseas providers of health care services. In practice, the internal policies of Member States have much more effect on the degree of competition emerging in health care than do judgements of the ECJ.

The likely influence of the Directive on cross-border patient flows must also be kept in perspective. Within Europe numbers of patients travelling far from home within their own countries or across borders have been insignificant and there is no evidence of an impact on provider competition. It is possible that planned changes in payment systems in several Member States may increase the economic impact of patient choice in local markets. The importance of the Directive for the health care systems of Member States is more likely to be revealed in the extent to which national systems are restructured to avoid future legal challenge rather than in the number of patients treated cross-border.

⁷⁵ Richards C, Dingwall R, Watson W (2001) Should NHS Patients Be Allowed to Contribute Extra Money to their Care? *BMJ*, 8 September 2001; 323: 563–565.

⁷⁶ “A review of the consequences of additional private drugs for NHS care” at http://www.dh.gov.uk/en/Aboutus/MinistersandDepartmentLeaders/Nationalclinicaldirectors/DH_086040

GLOSSARY OF RELEVANT TREATY ARTICLES

The European Union has been established on the basis of a succession of Treaties, beginning with the European Coal and Steel Community (ECSC), which was signed in 1951 by the six founder members: France, Germany, Italy, Belgium, the Netherlands and Luxembourg. In 1957 the European Atomic Energy Community (Euratom) was founded and also the European Economic Community (EEC). 1986 saw the signing of the Single European Act, which set a deadline of 1992 for the completion of the single European market, and in 1992 the Treaty on European Union (Treaty of Maastricht) was signed. In 1997 the Treaty of Amsterdam was signed, by which time the number of Member States had grown to 15 including, in addition to the original six, Austria, Denmark, Finland, Greece, Republic of Ireland, Portugal, Spain, Sweden and the United Kingdom⁷⁷.

The following Articles refer to the Consolidated Version of the Treaty Establishing the European Community, which incorporates provisions introduced by the entry into force of the Treaty of Amsterdam on 1 May 1999. As a result of the incorporation of new provisions, articles have been renumbered. As is conventional, the former numbers are inserted in brackets. Article 2, which establishes the mission of the Community, is set out in full, as occasionally are other articles where this seems important to enable the reader to better judge the arguments set out in the main text of the paper.

Treaty articles constitute the foundation stones of European law. Article 249 (ex Article 189) establishes the differing procedures for the promulgation of legislation. Thus:

“In order to carry out their task and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions.”

Regulations are directly applicable in all Member States without the need for additional domestic legislation. Directives are binding on (some or all) Member States as to the end to be achieved, whilst leaving choice as to the form and method open to Member States. Directives have to be transposed, therefore, into domestic law. Decisions are binding in their entirety on those to whom they are addressed. Recommendations and Opinions have no binding force.

Much of the discussion in the main text of this book relates to single market legislation, namely legislation relating to the four freedoms of movement, of: goods,

services, labour and capital. A very large body of supporting secondary legislation (regulations, directives, etc.) has been built up in support of the main Treaty articles. For reference, the policies and legislation in these areas can be located via the Internal Market website of the European Union (<http://europa.eu>).

The interpretation of Community Law is a matter principally for the European Court of Justice, to whom national courts may refer questions for legal interpretation. The Court is generally perceived to have pursued a vigorous policy of integration over the years, and to have taken on the task of giving flesh and substance to the outline positions set out in the Treaties.

Article 2 (ex Article 2)

“The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing common policies or activities referred to in Articles 3 and 4, to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States”.

Article 3 (ex Article 3)

Establishes the internal market, general prohibition of restrictions on trade, areas to be the subject of common policies, and that the activities of the Community shall include “a contribution to the attainment of a high level of health protection...”

Article 4 (ex Article 3a)

Includes provisions on the introduction of a single currency.

Article 5 (ex Article 3b) (on subsidiarity)

Establishes that:

“The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein.

In areas which do not fall within its exclusive competence, the Community shall take action insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can,

⁷⁷ To which have now been added: Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia.

therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty.”

Article 14 (ex Article 7a)

Includes that:

“The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty.”

Article 16 (on services of general economic interest)

“Without prejudice to Articles 73, 86 and 87 [which refer to state aids, public services and competition law] and given the place occupied by services of general economic interest in the shared values of the Union, as well as their role in promoting social and territorial cohesion, the Community and the Member States, each within their respective powers and within the scope of application of this Treaty, shall take care that such services operate on the basis of principles and conditions which enable them to fulfil their missions.”

Articles 28 (ex Article 30), 29 (ex Article 34) and Article 30 (ex Article 36) (regarding the free movement of goods)

“Quantitative restrictions on imports and exports and all measures having equivalent effect shall be prohibited between Member States. These provisions do not preclude prohibitions on trade which can be justified on grounds of public morality, public policy or security, the protection of health and life of humans, animals or plants, etc....as long as such prohibitions or restrictions do not constitute arbitrary discrimination or a disguised restriction on trade between Member States.”

Articles 39 to 42 (ex Articles 48 to 51) (on the freedom of movement of workers)

These establish that freedom of movement of workers shall be secured within the Community, including the abolition of any discrimination based on nationality, and by adopting such measures in the field of social security as are necessary to provide freedom of movement for workers, including migrant workers and their dependants. Regulation 1408/71 provides supporting legislation conferring the transferability between Member States of social security rights.

Article 43 (ex Article 52) (on the Right of Establishment)

This article prohibits restrictions on the freedom of establishment of nationals of a Member State in the

territory of another Member State, including restrictions on the setting up of agencies, branches or subsidiaries by nationals of any Member States established in the territory of any Member State.

“Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms...”

In support of this Article, two mutual recognition Directives, 89/48 and 92/51 were also passed allowing for the mutual recognition of diplomas and educational training.

Article 49 (ex Article 59)

Prohibits restrictions on freedom to provide services within the EU.

Article 50 (ex Article 60)

Establishes that:

“Services shall be considered to be “services” within the meaning of this Treaty where they are normally provided for remuneration, insofar as they are not governed by the provisions relating to freedom of movement for goods, capital and persons...”

Without prejudice to the provisions of the Chapter relating to the right of establishment, the person providing a service may, in order to do so, temporarily pursue his activity in the State where the service is provided, under the same conditions as are imposed by the State on its own nationals.”

Article 56 (ex Article 73b)

Establishes the abolition of all restrictions on the movement of capital between Member States and between Member States and third countries.

Article 81 (ex Article 85)

Establishes as incompatible with the common market:

“all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development, or investment;
- (c) share markets or sources of supply;
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”

Article 82 (ex Article 86)

“Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market insofar as it may affect trade between Member States...”

Article 86 (ex Article 90) (on services of general economic interest)

Includes that:

“Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in this Treaty, in particular to the rules on competition, insofar as the application of such rules does not obstruct the performance in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Community.”

Article 87 (ex Article 92) (on State Aids)

This establishes that any aid granted by a Member State, or through State resources in any form whatsoever, which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods, shall, insofar as it affects trade between Member States, be incompatible with the common market, subject to some exceptions, as long as they do not distort trade or discriminate on the basis of the origin of products.

Article 98 (ex Article 102a) (on economic policy)

“...The Member States and the Community shall act in accordance with the principle of an open market economy with free competition, favouring an efficient allocation of resources, and in compliance with the principles set out in Article 4.”

Article 152 (ex Article 129) (on the Community’s formal health policy)

“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 health, preventing human ill-health 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 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 organizations 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 States 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 harmonization 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 organization 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.”

Article 153 (ex Article 129a) (on consumer protection)

“1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests.

Consumer protection requirements shall be taken into account in defining and implementing other Community policies and activities.”

ANNEX – SUMMARIES OF RELEVANT ECJ CASES

28 April 1998 Case C-120/95 *Nicholas Decker v Caisse de Maladie des Employés Privés* of Luxembourg.

Mr Decker, a Luxembourg national, had been refused reimbursement by his medical insurance fund of the cost of a pair of spectacles which he had purchased from an optician established in Arlon, Belgium, on a prescription from an ophthalmologist established in Luxembourg. The grounds for refusal were that the spectacles had been purchased abroad without the prior authorization of the Fund, a decision which Mr Decker contested on the grounds that the decision amounted to a barrier to the free movement of goods under Articles 28 (ex-Article 30) and Article 30 (ex-Article 36) of the Treaty.

Among the many submissions by Member States governments, the Luxembourg, Belgian, French and UK governments submitted that the national Luxembourg rules which required the medical treatment abroad to be authorized in advance did not fall within the scope of the Treaty articles governing free movement of goods, in that they concerned social security which was reserved to national competence.

In its Judgement, the Court affirmed that Community Law does not detract from the powers of the Member States to organize their social security systems, and that in the absence of harmonization at Community level, it is therefore for the legislation of each Member State to determine “the conditions concerning the right or duty to be insured with a social security scheme”. However, it noted that Member States must comply with Community Law when exercising those powers. As the Court had held in other instances, measures adopted by Member States in social security matters are subject to Treaty rules on the free movement of goods. The fact, therefore, that national rules fall within the field of social security could not exclude the application of Article 28 of the Treaty.

With regard to the role of 1408/71, on which the Luxembourg prior authorization system was closely modelled, the Court noted: (i) the fact that a national measure is consistent with a piece of secondary legislation does not remove it from the scope of the Treaty provisions; and (ii) that the purpose of Regulation 1408/71 is to allow an insured person access to medical care in another Member State on the same terms as the nationals of that Member State, but without incurring additional expenditure.

On the application of Article 28 governing the free movement of goods, the Court said that Regulation 1408/71 does not prevent the reimbursement of the

cost of medical care on conditions prevailing in the Member State of insurance, even without prior authorization. Furthermore, the Court found that making the acquisition of medical goods in another Member State subject to prior authorization, whilst the acquisition of the same goods in the Member State of insurance was not subject to such a requirement, constituted a barrier to the free movement of goods. Since the costs to the Luxembourg medical system were the same in both cases, a prior authorization procedure could not be justified by the need to control health care expenditure, by the need to avoid undermining the financial balance of the social security system or on other public health grounds.

28 April 1998 Case C-158/96 *Raymond Kohll vs Union des Caisses de Maladie*, Luxembourg

Mr Kohll, a Luxembourg national, had been refused authorization by his Luxembourg medical insurance association to obtain treatment for his daughter from an orthodontist established in Trier, Germany, on the grounds that national rules, which were consistent with Regulation 1408/71, did not justify the treatment being obtained outside Luxembourg. He appealed against the decision on the grounds that the rules in question were not consistent with Articles 49 and 50 (ex-Articles 59 and 60) of the Treaty.

Questions referred to the ECJ were:

1. Do Articles 49 and 50 of the Treaty preclude rules under which reimbursement of the cost of medical benefits in another Member State is subject to prior authorization?
2. Is the maintenance of a balanced medical and hospital service accessible to everyone a justification for a system of prior authorization?

The Court began its Judgement by reaffirming that, according to settled case law, Community Law does not detract from the powers of Member States to organize their social security systems and that in the absence of harmonization it is for the legislation of each Member State “to determine the conditions concerning the right or duty to be insured with a social security scheme and the conditions for entitlement to benefits”. However, it is for Member States to comply with Community Law when exercising those powers.

The Court also reaffirmed that the “special nature” of certain services does not remove them from the ambit

of the fundamental principle of freedom of movement and the fact that the Luxembourg rules in question fall within the sphere of social security does not exclude the application of Articles 49 and 50 of the Treaty. It also affirmed that the fact that national rules are consistent with secondary legislation does not have the effect of removing that measure from the scope of the provisions of the Treaty. Article 22 of Regulation 1408/71 does not regulate, and does not therefore prevent, the reimbursement by Member States at the tariffs in force in the competent State, of costs incurred in connection with treatment provided in another Member State, even without prior authorization.

Noting that Article 49 precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State, the Court judged that the Luxembourg rules requiring prior authorization for the reimbursement of costs of medical care obtained in another Member State clearly did deter patients from approaching providers of medical services established in another Member State and constituted, for them and their patients, a barrier to freedom to provide services. The Court dismissed the arguments of some Member States, that the financial balance of the social security system might be upset, noting that the financial burden on the Luxembourg budget would be the same, given Mr Kohll's request to be refunded at the national tariff of Luxembourg.

12 July 2001 Case C-157/99 B.S.M. Geraets-Smits vs Stichting Ziechenfonds VGZ and H.T.M. Peerbooms vs Stichting CZ Groep Zorgverzekeringen

Mrs Geraets-Smits, a Dutch national who suffered from Parkinson's disease, had been refused reimbursement by her insurance association in the Netherlands of the costs of care received at the Elena-Klinik in Kassel, Germany. The grounds for refusal were that the specific clinical treatment she received was not regarded by the Dutch authorities as "normal treatment within professional circles concerned" – a necessary condition for the care to be reimbursable by the sickness fund under Dutch legislation. Furthermore, satisfactory treatment was available in the Netherlands at an establishment having contractual arrangements with the sickness insurance fund.

Mr Peerbooms had fallen into a vegetative state following a road accident and was transferred to the University Clinic in Innsbruck, Austria where he was given special intensive therapy using neurostimulation. This treatment was experimental and not available to anyone over 25 years of age in

the Netherlands. Mr Peerbooms' neurologist requested reimbursement of the costs of the treatment from his Dutch insurance fund, which refused to pay on the grounds that the type of treatment was not regarded as normal within the professional circles concerned and that, in any case, adequate treatment could have been obtained in the Netherlands from a care provider and/or an establishment with which the insurance association already had a contract to provide care.

Questions referred to the ECJ were:

1. Are the national rules in the Netherlands, which make prior authorization necessary to obtain medical care from another Member State, incompatible with Articles 49 and 50 of the Treaty?
2. What is the answer to Question 1 where the authorization is refused because the relevant treatment in the other Member State is not regarded as "normal in professional circles"? Is it relevant whether the treatment in question is reimbursed under the social security system of the other Member State?
3. What is the answer to Question 1 where the treatment abroad is deemed to be normal and to constitute a benefit, but is refused on the ground that timely and adequate care can be obtained from a contracted Netherlands care provider and treatment abroad is therefore not necessary for the health care of the person concerned?
4. If the requirement to obtain prior authorization constitutes a barrier to the freedom to provide services under Articles 49 and 50 of the Treaty, are there overriding reasons in the general interest to justify such a barrier?

In submission to the Court a number of Member States' governments held that hospital services do not constitute services within the meaning of Article 49, particularly where, as under the Dutch system, benefits are provided in kind and free of charge, where patients do not make direct payments to their service provider, and on the grounds that the definition of services must include the concept of for-profit and remuneration.

The Court dismissed these arguments by reference to previous case-law: that medical activities fall within the scope of Article 49; that the special nature of social security law does not exclude the application of Articles 49 and 50; that the medical treatment at issue was in fact paid for directly by the patients; and that the Treaty articles do not require that the service be paid for by those for whom it is performed. Payments made by the Dutch sickness funds, although

made at a flat rate, clearly do constitute consideration for hospital services and represent remuneration for the hospital which provides them, which can be said, therefore, to be engaged in an activity of an economic character.

The Court ruled that Dutch law, requiring a patient to obtain prior authorization for care from another Member State, constituted a barrier to freedom to provide services. Possible justifications proposed by the Court for such a barrier included the possible risk of seriously undermining a social security systems' financial balance. They also included the objective of maintaining balanced medical and hospital service open to all "even if this objective is intrinsically linked to the method of financing the social security system". A further justification for a restriction on the freedom to provide medical and hospital services could be the maintenance of treatment capacity or medical competence on national territory, which is essential for the public health and even the survival of the population.

The Court accepted that, by comparison with medical services provided by practitioners in their surgeries or at the patient's home, medical services provided in a hospital take place within an infrastructure which has very distinct characteristics, including the number of hospitals, their geographical distribution, the model of their organization and the equipment with which they are provided, and that these were issues for which planning, including the Dutch system of contractual arrangements between sickness funds and care providers, had to be possible. Apart from ensuring that there is sufficient and permanent access to a balanced range of high-quality hospital treatment, such planning assisted, the Court said, in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources, which it accepted was a particularly important issue in the hospital care sector.

It agreed, therefore, that a system of prior authorization was necessary if patients were to seek hospital services outside the contractual system, arguing that "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 rationalized, stable, balanced and accessible supply of hospital services would be jeopardized at a stroke".

However, the Court then went on to consider what characteristics of a prior authorization system would be acceptable under Community Law, arguing that these must meet conditions of proportionality, and

must be no more than is sufficient to meet the overall objectives of having the prior authorization system in the first place. For any prior authorization system to be justified, it must be based on "objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of national authorities' discretion, so that it is not used arbitrarily." Such a scheme must also be based on "a procedural system which is easily accessible and capable of ensuring that a request for authorization will be dealt with objectively and impartially within a reasonable time and refusals to grant authorization must also be capable of being challenged in judicial or quasi-judicial proceedings."

The Court reaffirmed that it is for the legislation of each Member State to organize its national social security system and to determine the conditions governing entitlement to benefits. For example, it had already upheld in previous jurisprudence that it was not incompatible with Community Law for a Member State to establish limitative lists excluding certain products from reimbursement, with a view to limiting costs. Community Law "cannot in principle have the effect of requiring a Member State to extend the list of medical services paid for by its social insurance system: the fact that a particular type of medical treatment is covered or not covered by the sickness insurance schemes of other Member States is irrelevant to this issue." However, such exclusions had to be made according to objective criteria, and certainly not on the basis of the origin of the products.

In the case of the Netherlands, the basic qualifying condition for entitlement to benefits, that the treatment in question could "be regarded as normal in the professional circles concerned" applied whether the treatment was to be provided by a contracted establishment or not, within or outside the Netherlands. However, the Court judged that the criteria justifying a prior authorization procedure, particularly of non-discrimination, could only be met if the interpretation of "normal in the professional circles concerned" referred to treatment which was sufficiently tried and tested by international medical science and not confined to what was regarded as normal only in Dutch medical circles.

Non-discrimination in the application of prior authorization also requires that, when treatment is not available without undue delay (a direct translation from the Dutch national law) from a contracted provider, patients may be authorized to seek treatment from an uncontracted provider without reference to whether the uncontracted provider is Dutch or from another Member State. "Once it is clear that treatment covered by the national insurance system cannot be provided by a contracted establishment, it is not acceptable that national hospitals not having any contractual arrangements with the insured person's

sickness fund be given priority over hospitals in other Member States” (para 107).

12 July 2001 Case C-368/98 Van Braekel and Others vs Alliance Nationale des Mutualités Chrétiennes (the ANMC)

This case was brought by Mr Abdon van Braekel and his six children, as heirs of Ms Jeanne Descamps, a Belgian national residing in Belgium and insured under the ANMC. In February 1990 she sought authorization from the ANMC to undergo orthopaedic surgery in France for bilateral gonarthrosis, which she subsequently obtained despite being initially refused authorization. Authorization under Regulation 1408/71 was subsequently given retrospectively. The reimbursable cost of the operation would have been FRF 38,608.99 under French legislation, and was FRF 49,935.44 under Belgian rules.

The questions which the ECJ was asked to clarify were:

1. Must the costs of hospital treatment be reimbursed in accordance with the scheme of the State of the competent institution or in accordance with that organized by the State on whose territory the hospital treatment has taken place?
2. Is a limitation of the amount reimbursed under the legislation of the State of the competent institution permitted, having regard to Article 36 of Regulation 1408/71 which refers to reimbursement in full?

In its reasoning, the Court noted that the national rules under which Ms Descamps was retrospectively granted prior authorization under Regulation 1408/71 were less restrictive than those which apply under Article 22 (2) of that Regulation. The Court noted in this regard that the provisions of Article 22 (2) of Regulation 1408/71 are designed to limit the circumstances in which authorization may be refused. The fact that in this case authorization was granted on the basis of a national law having different provisions still constituted an authorization with the meaning of Article 22 (1) (c) of Regulation 1408/71.

Normally, reimbursement would have been at tariffs prevailing in the Member State of treatment. In this case, however, Belgian tariffs were lower than French tariffs. The Court noted that Article 22 of Regulation 1408/71 does not prevent reimbursement at tariffs in force in the competent State where such tariffs are more beneficial. Nor does the Article require such additional reimbursement.

The Court went on to consider whether such an obligation to reimburse more beneficial tariffs might arise under Article 49 (ex-Article 59) of the Treaty. The specific question which it considered was whether the fact that national legislation does not guarantee a person covered by its social insurance scheme, and authorized to receive hospital care abroad, a level of payment equal to that to which he would have been entitled if he had received hospital treatment in the Member State in which he was insured, entails a restriction of freedom to provide services within the meaning of Article 49.

It concluded that “there is no doubt that the fact that a person has a lower level of cover when he receives hospital treatment in another Member State than when he undergoes the same treatment in the Member State in which he is insured, may deter, or even prevent, that person from applying to providers of medical services established in other Member States and constitutes, both for insured persons and for service providers, a barrier to freedom to provide services.”

Consequently, the Court authorized payment for the service at the rate of the competent Member State in this case where it was higher than the cost of treatment in the host Member State.

13 May 2003 Case C-385/99 V.G. Müller-Fauré and E.E.M van Riet

Ms Müller-Fauré, a Dutch national insured in the Netherlands, underwent non-emergency dental treatment whilst on holiday in Germany and subsequently applied to her insurer, the Zwijsrecht Fund, for reimbursement of the costs of the treatment, only part of which was covered by her medical insurance.

Ms van Riet had treatment in Deurne hospital, Belgium, for pain in her right wrist which her doctor had claimed could be carried out sooner than in the Netherlands. Her sickness fund in Amsterdam refused to reimburse the costs of the treatment on the grounds that there was no emergency nor necessity to obtain the treatment abroad, since appropriate treatment could be obtained in the Netherlands within a reasonable period (the waiting time was about six months).

The national court contended that the conditions for the application of Article 22(1)(a), Article 22 (1) (c) and Article 22 (2) of Regulation EEC 1408/71 were not met, but raised the question whether national rules requiring that patients may only seek care from a service provider in another Member State which has already entered into an agreement with the patient’s insurer are compatible with Articles 49 and 50 of the

Treaty and, if not, whether the national rules were justified. Did the fact that the Netherlands operates a medical system of health care benefits in kind make any difference to the outcome? Could the Court clarify what it meant by “without undue delay” in its Smits-Peerbooms judgement?

Questions put to the ECJ by the national court were:

1. Is a national provision which stipulates that a person insured with a sickness insurance fund requires the prior authorization of that fund to seek treatment from a person or establishment outside the Netherlands with whom or which the sickness insurance fund has not concluded an agreement, incompatible with Articles 49 and 50 of the EC Treaty?
2. If so, does a system of benefits in kind constitute an overriding reason in the general interest capable of justifying a restriction on the fundamental principle of freedom to provide services?
3. Does the question whether the treatment as a whole or only a proportion of it involved hospital care affect the answers to these questions?
4. What did the Court mean by “without undue delay” in paragraph 103 of its Smits Peerbooms judgement and must the patient’s medical condition be assessed on a strictly medical basis, regardless of the waiting time for the treatment sought.

In its Judgement, the Court confirmed its Smits-Peerbooms judgement that the requirement for prior authorization for patients to receive services from a non-contracted service provider in another Member State constitutes a barrier to freedom to provide services under Article 49. Article 46 (ex Article 56) permits derogations on grounds of health protection. Member States may therefore restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence on national territory is essential for public health and even the survival of the population.

The Court maintained that a refusal to grant prior authorization taken 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, did not amount to a properly justified restriction on freedom to provide services. The Court noted that the maintenance of waiting times did not seem to be directly related to the need to safeguard the protection of public health, but that, on the contrary, a waiting time which was too long or

abnormal would be more likely to restrict access to balanced, high-quality hospital care.

As regards non-hospital services, the Court conceded that “removal of the condition that there should be a system of agreements in respect of services supplied abroad adversely affects the ways in which health-care expenditure may be controlled in the Member State of affiliation.” However, it went on to stress that even where patients went to another Member State without authorization, they could only claim reimbursement of the cost of treatment within the limits of the cover provided by the sickness insurance scheme. It affirmed that any requirement of the medical system that a general practitioner should be consulted prior to consulting a specialist, applies similarly to care obtained in another Member State.

The Court further argued that, in practical terms, removal of the requirement for prior authorization for that type of care did not seem likely to give rise to patients travelling to other countries in large numbers, given linguistic barriers, geographic distance, the cost of staying abroad and lack of information about the kind of care provided there, such that the financial balance of the Netherlands social security system would be seriously upset and the overall level of public-health protection jeopardized. Care, it noted, 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. Apart from emergencies, the most obvious cases of patients travelling abroad are in border areas or where specific conditions are treated.

On the subject of benefits-in-kind, the Dutch insurance fund and the Netherlands, Spanish and Norwegian governments had argued that the need to establish a mechanism for reimbursement for patients accessing health care in another Member State would oblige the Netherlands to abandon the underlying logic of its health insurance scheme. In reply, the Court observed that Member States had already had to make just such an adjustment for dealing with the reimbursement mechanisms required by Regulation 1408/71. “There is no need, from the perspective of freedom to provide services, to draw a distinction by reference to whether 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.”

It further noted that nothing precludes a Member State with a benefits in kind system from fixing the amounts of reimbursement which patients who have received care in another Member State can claim, provided that those amounts are based on objective, non-discriminatory and transparent criteria.

23 October 2003 Case C-56/01 Patricia Inizan and the Caisse Primaire d'Assurance Maladie des Hauts-de-Seine (CPAM)

Ms Inizan, who was resident in France, asked her French medical insurance association, the CPAM, to reimburse the cost of multi-disciplinary pain treatment which she intended to undergo at the Berlin Moabit hospital in Germany (subsequently Essen Hospital in Germany). Her request was refused by the CPAM in July 1999 on the grounds that the requirements of Article 22(2) of Regulation 1408/71 had not been satisfied. A national court, however, referred the case to the ECJ to clarify whether the requirement for prior authorization constituted a restriction on freedom to provide services under Articles 49 and 50 of the EC Treaty.

Questions referred to the ECJ by the national court were:

1. Is Article 22 of regulation (EEC) 1408/71 compatible with Articles 49 and 50?
2. Consequently, is the CPAM of the Hauts de Seine entitled to refuse Ms Inizan reimbursement of the costs of psychosomatic pain treatment in Essen (Germany), following an adverse opinion from the National Medical Officer?

In its Judgement, the ECJ noted once again that Regulation 1408/71 is not intended to regulate, nor does it therefore prevent, Member States reimbursing the costs of treatment incurred in another Member State, even without prior authorization, at tariffs prevailing in the Member State of insurance. The Court affirmed that the purpose of Article 22 (1) (c) (i) is to confer an entitlement to medical care in another Member State on terms as favourable as those enjoyed by insured citizens of that Member State, thereby facilitating the free movement of insured persons. This constitutes the granting of additional rights over those which insured persons normally have, and the Court maintained that under Article 42 EC (Ex Article 51 EC), the Community legislature may attach conditions to the exercise of those additional rights, including a requirement that prior authorization should be sought. The requirement under Article 36 of Regulation 1408/71, that the insuring institution should reimburse directly the institution of place of stay of a patient who has obtained cross-border health care, requires a level of administrative cooperation between institutions, also thereby helping to facilitate the free movement of patients.

With regard to the second part of the question posed by the national court, the ECJ confirmed that the condition of "undue delay" referred to in *Smits-Peerbooms* is equivalent to "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", which is to be found in Article 22 (2) of Regulation 1408/71.

The Court also confirmed (para 48) that the prior authorization scheme, which Member States are called upon to implement pursuant to Article 22(1) (c) (i) and (2) of Regulation 1408/71, must be based on a procedural system which is easily accessible and capable of ensuring that a request for authorization will be dealt with objectively and impartially within a reasonable time and refusals to grant authorization must also be capable of being challenged in judicial or quasi-judicial proceedings.

The Court (para 50) confirmed that Article 22 (2) of Regulation 1408/71 is not intended to limit the situation in which authorization to receive the benefits in kind may be obtained, and that Member States are free to provide for such authorization to be granted even where the two conditions laid down in Article 22 (2) are not both satisfied.

The Court argued, however, that national provisions in French law, imposing a prior authorization procedure on patients seeking medical care abroad at tariffs prevailing in the Member State of insurance may constitute a barrier to freedom to provide medical services under Articles 49 and 50, acknowledging, however, that since the treatment in question involved hospitalization, such an impediment may be justified. The authorization procedure must, however, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily. Such a system must be based on a procedural system which is easily accessible and capable of ensuring that a request for authorization will be dealt with objectively and impartially within a reasonable time and refusals to grant authorization must also be capable of being challenged in judicial or quasi-judicial proceedings.

16 May 2006 Case C-372/04 Mrs Yvonne Watts vs Bedford Primary Care Trust

Mrs Watts, who suffered from arthritis of the hips, was refused authorization by Bedford Primary Care Trust under Regulation 1408/71 to obtain surgery from another Member State, on the grounds that she could receive treatment in a local hospital within the government's NHS Plan targets and therefore "without undue delay". There was a wait of approximately one year for surgery in a local hospital, subsequently revised to 3–4 months as a result of subsequent deterioration in her condition. Mrs Watts nonetheless underwent a hip replacement operation

in Abbeville, France and then proceeded with a claim to be reimbursed by Bedford PCT the cost of the operation in France. Although the national court agreed that her claim for reimbursement fell under the scope of Article 49 of the Treaty, as well as under Article 1408/71, her claim was dismissed, on the grounds that the final waiting time of 3–4 months was not “undue” and did not entitle her, therefore, to have the treatment abroad at NHS expense.

Questions put to the ECJ were:

1. The UK government sought clarification on the question whether Article 49 applied to a State funded national health service such as the UK NHS, as well as to insurance funds such as constituted the Netherlands scheme, having regard to the fact that the NHS has no fund out of which payment could be made to reimburse patients for cross-border health care. Was it material whether hospital treatment provided by the NHS itself constituted the provision of services within Article 49? Does the provision of hospital treatment by NHS bodies constitute the provision of services under Article 49?
2. It asked whether the NHS was obliged to pay for treatment in another Member State which it was not obliged to pay to be carried out privately by a UK service provider.
3. Was it relevant if the patient secured the treatment independently of the relevant NHS body and without prior authorization or notification?
4. Could the Secretary of State for Health rely, as objective justification for refusing prior authorization for hospital treatment in another Member State, on:
 - the fact that authorization would seriously undermine the NHS system of administering priorities through waiting lists?
 - the fact that authorization would permit patients with less urgent medical needs to gain priority over patients with more urgent medical needs?
 - the fact that authorization would have the effect of diverting resources to pay for less urgent treatment for those who are willing to travel abroad, thus adversely affecting others who do not wish or are not able to travel abroad or increasing costs of NHS bodies?
 - the fact that authorization may require the UK to provide additional funding for the NHS budget or to restrict the range of treatment available under the NHS?
 - the comparative costs of the treatment and the incidental costs thereof in the Member State?
5. In determining whether treatment is available “without undue delay” for the purposes of Article 49, to what extent is it necessary or permissible to have regard to:
 - waiting times?
 - clinical priority accorded to the treatment by the relevant NHS body?
 - management of the provision of hospital care in accordance with priorities aimed at giving best effect to finite resources?
 - the fact that NHS treatment is provided free at the point of delivery?
 - the individual medical condition of the patient and the history and probable course of his disease?
6. Are the applicable criteria for Article 22(1)(c) of Regulation 1408/71, particularly “within the time normally necessary for obtaining the treatment in question” identical with those applicable in determining questions of “undue delay” for the purposes of Article 49? If not, to what extent is it necessary or permissible to have regard to the factors governing waiting times previously listed?
7. Should reimbursement of hospital treatment obtained in another Member State be calculated under Article 22 of Regulation 1408/71, that is by reference to the legislation of the Member State where the treatment is provided, or under Article 49 by reference to the legislation of the Member State of residence? How much should be reimbursed where, as in the case of the UK, there is no nationally set tariff for reimbursement of patients for the cost of treatment? Is the obligation limited to the actual cost of providing the same or equivalent treatment in the first Member State? Does it include travel and accommodation costs?
8. Do Article 49 and Article 22 of Regulation 1408/71 impose an obligation on Member States to fund hospital treatment in other Member States without reference to budgetary constraints and, if so, are these requirements compatible with the Member States’ responsibility for the organization and delivery of health services and medical as recognized under Article 152 (5)?

The Court reasserted that the fact that a case falls within the applicability of Article 22 of Regulation 1408/71 does not preclude it from also falling within the scope of Article 49 of the Treaty. A patient has a right to seek medical care from another Member State in accordance with the provisions of the legislation of that Member State (under 1408/71) whilst simultaneously having a right to access health care in another Member State on different conditions under Article 49.

Regarding waiting times, the Court agreed that, where demand for hospital treatment is constantly rising and the supply is necessarily limited by budgetary constraints, national authorities are entitled to institute a system of waiting lists in order to manage the supply of treatment and to set priorities on the basis of available resources and capacities. However, such waiting times should 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 authorization is sought. Waiting times need to be set "flexibly and dynamically" so that the period of wait may be reconsidered in the light of any deterioration in the patient's condition.

The fact that the cost of hospital care obtained in another Member State may be higher than it would have been in a hospital covered by the national system is not a justification for refusing authorization. Nor can justification be refused on the grounds that a financial reimbursement system would have to be established to effect the reimbursement.

The Court reaffirmed that medical services provided for consideration fall within the scope of the Treaty provisions on the freedom to provide services, which include the freedom for the recipients of services to go to another Member State in order to receive those services there, including where reimbursement for hospital treatment is sought from a national health service. In fact, there is no need to determine whether, legally, the provision of hospital treatment by the NHS itself constitutes a service or not.

Article 49 precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provisions of services purely within a Member State. Since it is clear that NHS patients cannot have treatment in another Member State at NHS expense without prior authorization (the fact that NHS patients cannot generally choose when and where hospital

treatment will be provided under the NHS does not of itself constitute a system of prior authorization as to whether treatment can take place) this constitutes a barrier on the freedom to provide services. The fact that the NHS is not obliged to pay for private hospital care in the UK is immaterial to the argument.

The Court noted that as regulations in the NHS do not set out the criteria for the grant or refusal of prior authorization, there is nothing which circumscribes the exercise of discretionary power by national competent authorities. This also makes it difficult to exercise judicial review of decisions refusing to grant authorization. The achievement of fundamental freedoms guaranteed by the Treaty may require Member States to make adjustments to their social security systems.

Where the delay arising from waiting lists exceeds an acceptable period having regard to an objective medical assessment of a patient's medical needs, authorization may not be refused on the basis of those waiting lists, any possible distortion of medical priorities, the need to make specific funds available or cost comparisons with treatment elsewhere.

On reimbursable costs, the Court noted that where a patient has been granted authorization under Article 1408/71, reimbursement should be on the terms of the provider Member State. However, where hospital treatment is provided free of charge, as in the NHS, the requirements of Article 49, that there is no restriction on the freedom to provide services, require that the patient be reimbursed in full the cost of care provided in another Member State.

Whether travel and accommodation costs are reimbursable depends entirely on the rules for doing so in the competent Member State.

Article 152 does not exclude the possibility that Member States may be required under other Treaty provisions, such as Article 49 or Article 22 of Regulation 1408/71, to make adjustments to their national systems of social security. This does not undermine their sovereign powers in the field of social security.

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