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EDITORIAL COMMENTS

Towards an improved framework for cross-border healthcare

If there is one area where the European Union can prove its relevance to the ordinary citizen, it is likely to be its involvement with healthcare, especially the cross-border delivery of such services in one Member State to persons affiliated with a public health scheme of another Member State. The establishment of a Community framework for cross-border healthcare, as set out in the Commission's proposal of 2 July 2008 for a Directive on the application of patients' rights in cross-border healthcare,[1] aims to provide greater clarity about rights to reimbursement for healthcare provided in other Member States, and to ensure that the care delivered to persons from other Member States is of high quality, safe and efficient. It is not difficult to applaud this initiative.

In Europe as well as elsewhere, healthcare has long been essentially an activity of local dimension and local impact. Today, it is fast becoming a global business. Doctors and nurses from developing countries are recruited by rich countries. The outsourcing of record-keeping and consultations over the electronic highway constitute a huge global industry. A flood of patients from rich countries now seek medical treatment in countries other than their own. Especially from the United States, millions of "medical refugees" travel to foreign countries for treatment. Many of them are uninsured or underinsured. The best hospitals in Asia and Latin America rival or surpass many hospitals in the rich world for safety, quality and price. It is estimated that Americans can save 85 percent if they desert the troubled health system back home and shop around for savings elsewhere. By one estimate, the number of Americans who travel for care will soar from 1 million in 2007, to 10 million by 2012. By that time medical tourism will deprive American hospitals of some USD160 billion of annual business.[2]

Although this trend of globalization does not leave Europe unaffected, for the average European the need to leave his or her country of residence in search of adequate healthcare is not an equally pressing matter. Most people in Europe are not uninsured or underinsured. At present the number of patients in the European Union who travel voluntarily to third countries is insignificant. The number of those who travel to other Member States to undergo medical treatment is similarly unimpressive: the pertinent figure appears to be less than 1 percent of the insured persons. This percentage is liable to increase if obsta-

1. COM(2008)414 final.
2. See *The Economist*, 14 Aug. 14, 2008, Briefing on Globalisation and healthcare.

cles to cross-border healthcare are removed. Indeed, the quality of medical services is not invariably of a sufficiently high standard in individual Member States. Countries may experience capacity problems, and limited access to certain types of treatment (waiting lists) may cause great harm to patients. However, the State-funded health-insurance systems in the European Union as a rule are not encouraging their patients to travel and get treatment abroad. Since their attitude in this respect limits patients' freedom of choice and shields national public health system from a certain measure of salutary competition from other Member States, any initiative allowing the market freedoms to be enjoyed more fully will help improve consumer welfare in this field and should be welcomed.

There is no doubt that the Court of Justice has greatly advanced the promotion of free movement of patients.[3] The main text of secondary law dealing with cross-border healthcare is Article 22 of Regulation No. 1408/71.[4] According to this provision any insured person in need of medical treatment during a stay in another Member State is entitled to the benefits in kind which the host State provides to its own insured persons or to cash benefits which are to be paid by the home State and which permit patients to defray the cost of healthcare in the host State. In addition, these benefits are also available to persons wishing to travel to another Member State in order to receive treatment there and who successfully apply to the competent institution of their home State for authorization to receive such healthcare services abroad. The Court of Justice has interpreted Article 49 of the Treaty extensively and it has considerably circumscribed the discretion given to Member States in Article 22 of Regulation 1408/71 regarding the situations in which they may refuse to grant such an authorization.

Let us briefly recall the main elements of the case law:[5] Health services, including hospital services are services within the meaning of Article 49 of the

3. For an excellent overview of the case law in this area, see Hatzopoulos and Silveira da Cunha, "The ECJ case law on cross-border aspects of health services", Briefing note for the EP Committee on Internal Market and Consumer Protection (January 2007), IPOL/A/IMCO/NT/2006-22 (Doc EP 382.183).

4. Council Regulation No. 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, O.J. 1971, L 149/2. The Regulation was last amended by Reg. (EC) No. 1992/2006, O.J. 2006, L 392/1. See also Art. 20 of Reg. (EC) No. 883/2004 on the coordination of social security systems, O.J. 2004, L 166/1. The latter Regulation replaces Reg. No. 1408/71, but will only apply after the entry into force of an implementing regulation (Art. 91).

5. See in particular Case C-158/96, *Kohll,* [1998] ECR I-1931, Case C-120/95, *Decker,* [1998] ECR I-1831, Case C-368/98, *Vanbraekel,* [2001] ECR I-5363; Case C-157/99, *Smits and Peerbooms,* [2001] ECR I-5473; Case C-56/01, *Inizan,* [2003] ECR I-12403; Case C-8/02, *Leichtle,* [2004] ECR I-2641; Case C-385/99, *Müller-Fauré and Van Riet,* [2003] ECR I-4503, and Case C-372/04, *Watts,*[2006] ECR I-4325.

Treaty; there is no need to distinguish between care provided in a hospital environment and care provided outside such an environment. A medical service does not cease to be a provision of services within the meaning of the Treaty because it is paid for by a national health service or by a system providing benefits in kind. For cross-border medical services to come within Article 49 there is no need to make a distinction by reference to whether the patient pays itself the costs incurred and subsequently applies for reimbursement or whether the sickness fund or the national budget pays the provider directly.

The requirement of an authorization to be obtained by a person wishing to be eligible for the reimbursement of medical costs incurred in another Member State deters insured persons from approaching providers of medical services established in another Member State and therefore constitutes, for these medical service providers and for their patients, a restriction on the freedom to provide services. However, for overriding reasons of national policy this type of restriction can be justified in regard to hospital services. Access to non-hospital services cannot be restricted for such reasons.

As regards *hospital services*, in view of the necessary planning in order to ensure sufficient and permanent access to a balanced range of high quality hospital treatment as well as to control costs and to prevent as far as possible any wastage of financial, technical and human resources, a requirement under a national health system that the assumption of costs of hospital treatment provided in another Member State must be subject to prior authorization, appears to be a measure which is both necessary and reasonable. It can be regarded as an overriding reason in the general interest capable of justifying a barrier to the freedom to provide services.[6] However, such an authorization may only be refused in concrete cases if the proposed medical treatment cannot be regarded as normal in the professional circles concerned or if it cannot be demonstrated that the insured person's medical treatment renders the service in question necessary. The latter condition is to be construed restrictively. It means that a refusal because of lack of medical necessity is only justified if the same or an equally effective treatment can be obtained at a (domestic) establishment having a contractual arrangement with the insured person's sickness insurance fund and if such treatment will be delivered without undue delay. The Court has clearly indicated that economic considerations should not play a role in that appraisal. Whether or not the waiting time before a patient can receive the required treatment is reasonable, i.e. that the delay is not undue, should be determined exclusively in the light of each patient's medical condition.

6. *Smits and Peerbooms*, cited *supra* paras. 56–80*; Müller-Fauré and Van Riet*, cited *supra,* paras. 93–98.

As regards *non-hospital services* sought by a patient in a Member State other than its own, the Court has not accepted that there could be a valid justification for a requirement of prior authorization. Costs for non-hospital care, made within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation, must be reimbursed by the health organization of the State of affiliation. They cannot possibly be regarded as posing a serious threat to the financial balance of social security systems.

In the wake of this case law, there has been a flurry of activity. Although the rulings of the Court were clear in the individual cases that gave rise to them, there was much uncertainty as to how they would apply more generally in practice. Later studies ordered by the Commission have shown that many Member States have so far failed formally to amend their legislation and practices. Because the case law had left many questions unresolved it was soon recognized that the ensuing legal vacuum called for specific legislative action. In 2003 the Health Ministers requested the Commission to explore how legal certainty for patients and stakeholders in the field of cross-border care could be improved. The Commission complied with this request by including in its proposal for a directive on services in the internal market provisions codifying the rulings of the Court of Justice in applying free movement principles to health services.[7] However, the European Parliament and the Council were not happy with the lack of precision in this proposal and these provisions were deleted from the draft directive. It was broadly felt that the specificities of health services, in particular their technical complexities, the sensitivity for public opinion and their intimate links with publicly financed social security schemes, could not sufficiently be taken into account in a directive applying generally to the liberalization of services in the common market. Following the subsequent adoption by the Council in June 2006 of Conclusions on common values and principles in EU Health Systems[8] and reports and resolutions of the European Parliament adopted in 2005 and 2007,[9] and after receiving input from relevant stakeholders such as health organizations represented in the Open Health Forum and the High Level Group on Health Services and Medical Care, the Commission put forward its new proposals for a Directive to clarify the Court's rulings and amplify and intensify cooperation between Member States.

The legal basis of the proposal is Article 95 of the Treaty. The Commission cautiously points out that the proposed provisions are needed for the function-

7. COM(2004)2 of 13 Jan. 2004.
8. O.J. 2006, C 146/1.
9. See in particular the European Parliament resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market, P6 TA (2007)0201.

ing of the internal market. They aim to bring about an efficient cross-border healthcare and free movement of health services and a high level of health protection. These measures may entail certain adjustments to the national healthcare and social security systems but this does not mean that they undermine the sovereign powers of the Member States in the health field.[10] According to Article 152(5) EC, Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and the delivery of health services and medical care. These limitations on Community powers are fully respected: it is up to each Member State to determine the rules governing the rights or duties under their social security system, the healthcare cover and the conditions under which benefits provided by their sickness insurance scheme are granted.

The proposal is structured around three main themes. It first sets out common principles to be embedded in all EU health systems. This involves determining which Member State is responsible in any case of cross-border healthcare for ensuring compliance with common principles and defining a minimum core set of common principles. Such principles include common standards for quality and safety, rules on giving patients access to the key medical, financial and practical information they need for making a rational and informed choice between different providers in their own country and in other Member States, arrangements for transferring patients' records so as to ensure continuity of healthcare, mechanisms for ensuring that patients can seek redress and compensation if they suffer harm when healthcare is provided in a cross-border situation, and so on.

A second set of rules provides a framework for cooperation in regard to issues such as the recognition of prescriptions in another Member State, the development of European reference networks for highly specialized healthcare requiring a particular concentration of resources or expertise (European centres of excellence), and the establishment of a Community network on health technology assessment. Another important focus for cooperation is the area of E-health. Member States' health systems have widely different and incompatible formats and standards for information and communication technologies (ICT). These differences create obstacles to cross-border healthcare provision and risks to health protection. The proposal aims at harmonization in this area, but this will be limited to ensuring the interoperability of ICT-schemes which Member States may have chosen to introduce.

The third – and central – theme of the new directive seeks to clarify (or rather to systematize) the case law of the Court of Justice as regards the entitlement of patients to receive healthcare in another Member State and to have the

10. See Case C-372/04, *Watts*, para 146.

cost of such treatment refunded. Under the directive, patients will be entitled to obtain reimbursement up to the amount that would have been paid had they received that treatment at home. The Member States may not make reimbursement of costs of non-hospital care provided in another Member State subject to prior authorization. In regard to hospital care, however, such a system of prior authorization may be introduced if the financial balance of the social security system and the process of planning and rationalization threaten to be undermined by an outflow of patients.

It is important to note that the proposal does not aim to replace or to modify the existing framework for cross-border healthcare set forth in Regulation No.1408/71. This regulation organizes the coordination of the national social security schemes. Provisions regarding entitlements provided for by the proposed directive and the provisions of Regulation No. 1408/71 are alternative mechanisms for the assumption of medical costs incurred in other Member States. So the patient has a choice: an insured person either benefits from the mechanism of that regulation or that person chooses for the system of the proposed directive.

The difference between those two options resides in the requirement of *prior authorization*. As indicated earlier on, a person wishing to go to the territory of another Member State to receive treatment appropriate to his or her condition may request an authorization pursuant to Article 22 of Regulation No. 1408/71 (the E112 system). In that case the patient is entitled to treatment in accordance with the legislation of the "host" State and will receive reimbursement according to the tariffs in force in that State. This rule of full reimbursement applies both to non-hospital care and to hospital care. Obviously, this option may be advantageous for a medical tourist. The cost of treatment – and the amount reimbursable – under the legislation of the State where the treatment is received may be higher than that applicable for the same treatment in the State of affiliation. It may also be the case, as in *Vanbraekel,*[11] that the cost of treatment in the State of treatment is lower than in the Member State in which the patient is insured. Article 22 of Regulation No. 1408/71 does not require – nor does it prohibit – that the patient be paid an additional reimbursement covering the difference between the lower cost of the care in the country of treatment and that to which he or she would have been entitled if the care had been provided in the home State.[12] Under Article 49 EC, however, entitlement to such additional reimbursement appears to exist.[13] So, if Article 22 of

11. Case C-368/98, *Vanbraekel*, [2001] ECR I-5363.

12. Ibid., para 37.

13. "Article 59 [now Article 49] of the EC Treaty is to be interpreted as meaning that, if the reimbursement of costs incurred on hospital services provided in a Member State of stay, calculated under the rules in force in that State, is less than the amount which application of the leg-

Regulation No. 1408/71 applies and provided that authorization (when required) is granted, a patient from another Member State is never out-of-pocket. By virtue of Article 49 he or she may even enjoy a windfall.[14]

On the other hand, patients who do not rely on Regulation No. 1408/71 and who go for healthcare to another Member State without having obtained the authorization envisaged in Article 22 of that Regulation, may be less well off. The proposed new directive clarifies that in respect of both hospital care and non-hospital healthcare provided in another Member State, in situations where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation, the insured person is entitled to reimbursement of costs incurred in accordance with the tariffs applicable for the same treatment in the Member State of affiliation (Art. 6). This is not to the patient's advantage if treatment in his own country is less costly than that in the country where the medical services are provided. He has to foot part of the bill himself. In addition, the Member State of affiliation may have limitations on the choice of providers , conditions of eligibility or other planning mechanisms which are applied domestically. These may also be imposed on patients seeking healthcare in another Member State, provided these conditions respect internal market freedoms and are necessary, proportionate and non-discriminatory.

Identical conditions for reimbursement apply to the provision of non-hospital services and hospital services in another Member State. In line with the case law, the only difference between these two categories is that the reimbursement of the costs of non-hospital care provided in another Member State may never be made subject to prior authorization (Art. 7). By contrast, as regards the costs of hospital care,[15] the Member States may, under strict condi-

islation in force in the Member State of registration would afford to a person receiving hospital treatment in that State, additional reimbursement covering that difference must be granted to the insured person by the competent institution" (*Vanbraekel*, para 53 *in fine*).

14. It is to be noted, however, that the text of recital 24 and Art. 6(3) of the proposed directive make it abundantly clear that the assumption of costs by the Member State of affiliation may not exceed the actual cost of healthcare received. So a patient can never claim an amount which would be higher than the actual cost of treatment abroad. This clashes with the Court's interpretation of Art. 49 in para 53 of the *Vanbraekel* judgment. We do not know whether that judgment still stands. If it does, there is a problem of compatibility between the proposed directive and primary Community law. Obviously the new directive cannot validly restrict the right flowing from Art. 49 for a patient to be refunded the difference between the amount which a treatment undergone at home would have cost and the lower cost actually sustained in connection with treatment in another Member State.

15. The Directive gives a much needed definition of what constitutes "hospital care". This is defined as "healthcare which requires overnight accommodation of the patient in question for at least one night" (Art. 8(1)(a). We presume that "accommodation" must be read as "accommodation in a hospital or similar institution where the care is provided". Otherwise, if a patient visits a doctor on a given day and is asked to return to the doctor's practice the next day for a control

tions, introduce a system of prior authorization to address situations where the financial balance and the planning of an adequate hospital infrastructure threatens to be undermined due to the outflow of patients. As long as a Member State has not availed itself of this opportunity, the insured patient is automatically entitled to reimbursement of the costs which would have been paid for if he had undergone medical treatment in his home country. Again, this may not be sufficient if treatment in the Member State where the medical services were received was more expensive than at home.

It is to be noted, however, that as soon as a patient makes a request for an authorization to receive medical services (hospital care or non-hospital care) in another Member State and the conditions for granting an authorization under Article 22 of Regulation No. 1408/71 are fulfilled, the provisions of the new directive will not apply. Instead, in that case the mechanism of that Regulation will take over (Art. 3(2)). The authorization to receive treatment appropriate to a patient's condition in another Member State must always be granted in circumstances in which the authorization under Article 22 of the Regulation may not be refused. This would be the case where the treatment in question cannot be given within the time medically justifiable, taking into account the patient's current state of health and the probable course of the disease. If these conditions are met, the patient may be better off under the Regulation. Reimbursement will then be on the basis of the cost in the Member State where the treatment was received and it will not be limited to the cost which would have been paid by the social security system of the State of affiliation had the same or similar treatment been provided in its territory. So, generally speaking, a patient planning to obtain hospital care in another Member State will be well advised to verify whether the conditions for application of Article 22 of Regulation No. 1408/71 are fulfilled and to request prior authorization. If such a request is not made, it may nevertheless be presumed that upon being informed by a patient of an intention to receive medical services in another Member State, the competent institution of the State of affiliation will be under an obligation to grant such authorization of its own motion.[16]

Over the years, the Member States have generally applied very restrictive policies with regard to authorizing patients to obtain healthcare abroad. This is

visit, after a good night's sleep in a hotel or in the guest room of a friend, this would qualify as hospital care. It clearly is non-hospital care).

16. Whether such an obligation also exists *ex post*, that is if a person has not complied with a requirement of prior notification of imminent hospital treatment, appears less certain. The proposed directive does not affect the right of a State's healthcare system to stipulate as a condition for reimbursement of medical costs, irrespective of the place where the services in question are delivered, that patients inform their health institution before or within a certain time limit after the treatment is received.

understandable, considering the social importance of the health sector. Yet, it is in the interests of all stakeholders in the European Union to promote more proactive policies for improving cross-border access. Countries with excess capacity in healthcare services should be able to offer these services to patients from countries that experience an excess of demand. This is likely to reduce the length of waiting lists without necessarily leading to a net increase in entitlements. The Court of Justice has so far taken the lead in forcing the Member States to accept that free movement rights have important consequences for cross-border provision of health services. The directive now proposed by the Commission will oblige them to take these rights even more seriously. The draft directive has no pretensions other than that it will establish a Community framework for cross-border healthcare. It is rather sketchy, but its great merit is that it clarifies the legal position on a number of points and that it identifies a series of issues on which further legislative action by the Community and its Member States is urgently needed in the near future.