



# **Europeanization of national health systems**

## ***National impact and EU codification of the patient mobility case law***

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## Executive summary

In March 2011 the Directive on the application of Patients' Rights in Cross-Border Healthcare (hereafter the Directive) was signed into EU law <sup>(1)</sup>. This Directive is the result of a lengthy and laborious policy process aimed at finding adequate responses to the rulings of the Court of Justice of the European Union (CJEU) with regard to reimbursement of health services outside the state where the patient is socially insured.

The CJEU made clear that health care, when it is provided for remuneration, is an economic activity to which the Treaty provisions on the freedom to provide services are applicable. The Court ruled that making the reimbursement for care received in another Member State (MS) subject to the requirement that the patient must first receive authorisation from his domestic social protection system is an obstacle to freedom of movement, which can be justified for hospital care but not for ambulatory care. Up until then, planned treatment abroad could only be reimbursed based on Regulation 883/2004 on the coordination of social security schemes (hereafter the Regulation), provided that the patient first received prior authorisation from the financing institution to which (s)he is affiliated <sup>(2)</sup>.

Health policy makers have been considering since how to cope with the implications of this case law, which has created a great deal of legal uncertainty. The Member States' main fear was that this internal market approach would jeopardise national sovereignty over healthcare and undermine national regulation with respect to public health services, as certain rules could be targeted as unjustified obstacles to the free movement of goods and services. This may lead to the Member States losing control over areas such as healthcare priority setting and capacity planning.

Several policy initiatives have been taken at EU level in an attempt to put forward policy responses to the legal uncertainty and the pressure on the regulatory powers of health authorities. The initial policy response was to support cooperation in the field of healthcare and to monitor the impact of the EU on healthcare systems. However, when the European Commission included healthcare services in its proposal for a services directive -the so called "Bolkestein Directive"- health policy makers called for a specific legal initiative on the health sector. In July 2008, two years after healthcare services had been excluded from the scope of the Services Directive, the Commission adopted a proposal for a Directive on the application of Patients' Rights in Cross-Border Healthcare. The provisions were presented as 'patients' rights' and the removal of all references to health 'services' dispelled the concerns that it could be considered as a resurgence of the Bolkestein Directive. It took another couple of years before the EU institutions agreed on the draft, which was finally approved in March 2011. Member States have until October 2013 to transpose the Directive into national legislation.

The Directive aims to codify the case law by clarifying the rights of patients to seek health care in another EU Member State and to ensure the proper conditions for receiving that care. It is structured around three main areas. First, it provides a specific framework for reimbursement of care received abroad; secondly, it addresses the question as to which MS, in the case of cross-border care, should be responsible for ensuring quality and safety standards, information, redress and liability as well as privacy protection; and thirdly, it aims to encourage European cooperation on health care in specific areas.

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1. Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, O.J. L 2011 88/45-65.
  2. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, O.J. L 166, 30 April 2004.

To assess the potential impact of the application of the free movement rules to healthcare and of increased patient mobility, we distinguished four different types of impact: on health systems; on patients' access to care; on quality of care and patients' rights and finally, on healthcare workers.

Our analysis of the potential impact on health systems focused on the regulatory powers of health authorities under the free movement principles and looked at the way in which the Directive succeeds in preserving these powers. Indeed, healthcare systems are characterized by extensive regulation aiming to address the important market failures in this sector and to ensure the most cost-effective use of the limited public financial means. These regulatory frameworks risk coming under pressure through the application of the EU principles on the free movement of services.

In this respect, a first finding is that the Directive succeeds in providing legal certainty on the interpretation of important aspects of the Court rulings with regard to patient mobility. This includes the circumstances under which healthcare payers can make the reimbursement of care provided abroad subject to prior authorisation. However, the Directive carefully avoids addressing the application of the free movement principles beyond the issue of patient mobility, to deal with providers wishing to temporarily provide services or permanently establish in another Member State and the potential deregulatory effect thereof. Furthermore, given the lines drawn by the Court, a secondary legislation instrument proves to be unable to address some of the major concerns that drove the policy debate since the initial Court rulings. In particular, this concerns the reimbursement of care provided by non-contracted providers abroad, and possibly also at home. When compared to the initial Commission proposal, the final version of the Directive clearly better preserves the steering capacity of the Member States.

For the healthcare systems, the obligation to reimburse, under the case law and the Directive, care from non-contracted providers abroad is clearly one of the most sensitive issues. As illustrated by the fierce Polish opposition to the then draft Directive, it is feared that Member States would come under pressure to also have to reimburse care from non-contracted providers at home. The case studies show that Member States try to keep some grip on the selection of providers abroad, e.g. by requiring that they are integrated in the statutory system of the Member State of care provision and where the domestic system is based on benefits in kind, the attempt is to channel patients abroad through contracted providers. Also, the procedure based on the Regulation is made more attractive. Some Member States with a benefit in kind system (such as the Netherlands) who decided to reimburse care from providers abroad, indeed also domestically reimbursed care of non-contracted providers under the same conditions. However, they seem to have made these possibilities less attractive than treatment by contracted providers.

When assessing the financial impact on health systems, we found that the cost per health service should not be higher for care provided based on the Directive. However, cross-border care can increase the volume of care to be funded by the healthcare system, when care providers abroad have financial incentives to increase the delivery of care services per patient or when patients go abroad for treatments not timely available at home. Also, with patients going abroad, the available budgets also flow out of the country. This can potentially (for countries with large outflows of patients) reduce the available budgets for investing in the domestic system.

Cross-border care can encourage improvements in the domestic system when (potentially) large outflows of patients reveal weaknesses in domestic systems, in particular on quality and timely access, which are badly regarded by the population. This is illustrated in the Polish case study

where some stakeholders used the negotiations on Directive to plead for improvements in the domestic system. Cross-border care can be used to breach monopolies of domestic providers and to encourage them to perform better. This can put pressure on health workers.

As was illustrated in some of the case studies, domestic actors draw legitimacy from the jurisprudence to further their aspirations and to exit the domestic social system. The case law was used by insurers to acquire new instruments to compete and by providers to acquire more possibilities for commercial behaviour and price increases. Private, commercial providers also reinforced their positions. Examples include:

- threats to question the domestic contracting system, with as a result that compliance has been assured by a strong (and effective) increase of doctor's fees (Luxemburg);
- setting up of a broad coalition pushing for commercialisation of hospital services (Belgium);
- selective contracting by sickness funds in the Netherlands;
- set up and promote domestic healthcare facilities for export (Belgium and Poland).

Also, public authorities make use of the jurisprudence to support domestic reform agendas, such as addressing waiting times, make the health care system more businesslike and increase patient choice (UK) or the introduction of more competition in the system (the Netherlands).

When discussing the potential impact of the Directive on patients' access to care, a distinction should be made between accesses to cross-border care on the one hand and access to care for the majority of patients who stay at home for treatment.

For patients who stay in the domestic system, access to care primarily depends on the capacity of health authorities to steer the health system and to ensure its financial viability, as discussed above. Large net outflows of patients can, in less densely populated areas, with little healthcare supply, provoke closures in the domestic health infrastructure and large outflows of money for treating patients abroad can impede new domestic investments. In the receiving country, large inflows can provoke capacity problems, or providers can have a financial interest to give priority to foreign patients. On the other hand, policies to address long waiting times seem in some Member States to be encouraged by the CJEU case law. Member States confronted with long waiting lists try to reduce the demand for exit, e.g. through contracting the domestic commercial sector.

The impact on access for patients who go abroad is found to be positive: (s)he has closer, quicker or more access to care and can choose between more providers. However, the procedure for cross-border care based on the Directive is in most of these respects less beneficial than the procedure based on the Regulation on the coordination of the social security systems. The Directive provides fewer guarantees than Regulation 883/04 with regard to the financial aspects of access to care. This is also why the Directive gives priority to the reimbursement based on the Regulation when the patient has the right to treatment abroad according to the latter. Furthermore, the Directive does not create new rights for treatment abroad for patients confronted with long waiting lists at home which did not yet exist under the Regulation. However, patients can, through the Directive, acquire access to care that is closer to home, but in another Member State and also provider choice increases.

The impact of cross-border care on equity in access to care was found to be negative. Socially advantaged groups are likely to make more use of the possibilities to receive care abroad. Also, access to cross-border care is easier for patients who are fit to travel and who have no co-morbidity. Cross-border care can incentivise providers to select the easiest to treat patients, whereas they usually are not allowed to do so under the domestic system.

When discussing the impact on quality of care, again a distinction should be made between the

impact on care for cross-border patients and impact on quality for patients who stay at home. In a cross-border context, continuity of care can be problematic. The Directive only partially succeeds in addressing this. Furthermore, the Directive does not provide robust guarantees with regard to the quality and safety of cross-border care and thus patients will have to rely on the quality frameworks of the country of care provision.

For patients who stay at home, cross-border care can also have an impact on quality of care. It can put pressure on established arrangements, such as the GP gatekeeper system in the sending healthcare system, but can also offer opportunities for mutual learning, which can have a positive effect on quality of care and can provide training opportunities for workers.

Cross-border care can have an array of potential impacts on healthcare workers.

Cooperating healthcare professionals, in particular in initiatives allowing organised patient mobility, can learn from each other and new procedures and approaches can be introduced. Many projects allowing patients treatment abroad are embedded in a wider cooperation involving cooperation between health professionals, exchange of knowledge, joint training and education programs, exchange of professionals, experience and best practice.

Medical doctors, in particular specialists providing highly specialist care, consider treating foreign patients as a way to strengthen their reputation and skills as well as to establish links with colleagues abroad. The development of European reference networks between healthcare providers and centres of expertise in the Directive responds to this aspiration.

Cross-border care can increase competition between providers and incentivise them to perform better. It can put pressure on health professionals to treat more patients, and sometimes increasing competition is an underlying motive of purchasers contracting abroad.

When numbers are important, patient mobility can have an impact on employment opportunities and workload. In the receiving country, treatment of patients from abroad could in principle lead to expanding capacity and recruitment of additional staff. However, when there are supply shortages, as is the case in many countries for nurses, it could increase workload.

The sending country, on the other hand, can in principle face closure of specific services. However, health authorities usually prevent unwanted closure of domestic infrastructure.

Healthcare workers can be confronted by patients with expectations and attitudes that differ from domestic patients. They could furthermore be encouraged to acquire skills to communicate with the foreign patients including culture and language.

## Introduction

In March 2011 the Directive on the application of Patients' Rights in Cross-Border Healthcare (hereafter the Directive) was signed into EU law <sup>(3)</sup>. This Directive is the result of a lengthy and laborious policy process aimed at finding adequate responses to the rulings of the Court of Justice of the European Union (CJEU) with regard to reimbursement of health services outside the state where the patient is socially insured.

Health policy makers have been considering since how to cope with the implications of this case law, which has created a great deal of legal uncertainty. The Member States' main fear was that this internal market approach would jeopardise national sovereignty over healthcare and undermine national regulation with respect to public health services, as certain rules could be targeted as unjustified obstacles to the free movement of goods and services. This may lead to the Member States losing control over areas such as healthcare priority setting and capacity planning.

Several policy initiatives have been taken at EU level in an attempt to put forward policy responses to the legal uncertainty and the pressure on the regulatory powers of health authorities. A High Level Group on Health Services and Medical Care (HLG), consisting of senior officials of EU Member States and chaired by the European Commission, was set up in 2004 with the aim of supporting European cooperation in the field of healthcare and to monitor the impact of the EU on healthcare systems.

The setting-up of the HLG did not prevent the European Commission from including healthcare services in its proposal for a services directive, the so called "Bolkestein Directive" <sup>(4)</sup>. After two years of heated policy debate, healthcare services were finally excluded from the scope of this directive. This exclusion did not however eliminate the applicability of free movement rules to health services.

The European Commission therefore announced in 2006 that it would put forward a specific legal initiative on the health sector. After a lengthy and painful policy process, the Commission adopted the proposal for a directive in July 2008 <sup>(5)</sup>. The provisions were presented as 'patients' rights'. The removal of all references to health 'services' dispelled the concerns that it could be considered as a resurgence of the Bolkestein Directive.

Within the Council, five presidencies negotiated the proposal (the French, Tchech, Swedish, Spanish, and Belgian) and in early 2011 the European Parliament, the Commission, and the Council finally agreed on a heavily amended version.

In this paper we look at the EU codification and the national implementation of the CJEU case law with regard to patient mobility and analyse the potential impact of the free movement rules and increased patient mobility on health systems, patients, and workers. After a clarification of the Court rulings and the application of the internal market rules to healthcare, we will explain the content of the Directive on the application of patients' rights in cross-border care. Next we look at the potential impact of these developments and of increased patient mobility. We analyse the

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3. Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, *O.J. L* 2011 88/45-65.

4. Commission of the European Communities (2004), Proposal for a directive of the European Parliament and of the Council on services in the internal market. COM (2004) 2 final of 5 March 2004.

5. Commission of the European Communities (2008), Proposal for a Directive on the application of patients' rights in cross-border healthcare, COM (2008) 414 of 2 July 2008.

impact on health systems; on patients' access to care; on quality of care and patients' rights and on healthcare workers. In five case studies analysing the national impact of the application of the patient mobility case law, we illustrate and some of the effects described above. Finally, we draw conclusions from this analysis.

## The CJEU case law on patient mobility

In a series of judgments over more than a decade, starting with the famous Kohll and Decker rulings in 1998, the CJEU made clear that healthcare provided for remuneration is an economic activity in the meaning of the EU Treaty, irrespective of how and by whom it is funded and irrespective of the way Member States organise and finance their social security systems<sup>(6)</sup>.

Since healthcare is considered an economic activity, it has to comply with the EU Treaty rules on the freedom to provide cross-border services and the freedom of establishment. As part of the single market, these freedoms aim to boost the EU economy by removing obstacles to trade between Member States. The freedom of establishment guarantees the ability of care providers to establish themselves in a stable and continuous way in one or more Member States. The freedom to provide services, on the other hand, guarantees for providers, once established in a Member State, the freedom to provide - on a temporary basis - services in other Member States without having to establish in the Member State of service provision. This freedom also includes the freedom to provide cross-border services at a distance, e.g. through the internet, and the freedom for the recipient of a service (in healthcare this is the patient) to go to the Member State of the service provider without being obstructed by restrictions.

The Court ruled that making the reimbursement for care received abroad subject to the requirement that the patient must first receive authorization from his domestic social protection system is an obstacle to freedom to provide services. However, this barrier may be justified for intramural care by the need to ensure the provision of a balanced medical and hospital service accessible to all, and the maintenance of a treatment facility or medical service on national territory.

As a consequence, statutory social protection systems have to reimburse their affiliates for health care provided in another Member State up to the level of reimbursement provided by their own system, if this care is included in the domestic benefit package. If the costs actually incurred are lower than that amount, reimbursement can be limited to the actual costs.

For hospital care, Member States may require that this reimbursement be subject to prior authorization. This authorization must be given if the domestic system cannot provide the same or equally effective treatment within a medically acceptable time limit, considering the patient's medical conditions, course of illness, nature of disability, as well as the degree of pain.

The conditions on which benefits are granted pursuant to the legislation of the State of affiliation remain enforceable where treatment is received abroad, provided that these conditions are necessary to protect a general interest objective and are proportional to this objective. The Court accepted in this respect for instance the requirement that a general practitioner should be

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6. CJEU, Case C-120/95 *Decker v. Caisse de Maladie des Employés Privés* [1998] ECR I-1831; CJEU, Case C-158/96 *Kohll v. Union des Caisses de Maladie* [1998] ECR I-1931; CJEU, Case C-157/99 *Geraets-Smits and Peerbooms* [2001] ECR I-5473; CJEU, Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509; CJEU, Case C-372/04 *Watts* [2006] ECR I-4325; CJEU, Case C-444/05 *Stamatelaki* [2007] ECR I-3185.

consulted prior to consulting a specialist.

However, not all national conditions and formalities, even though they apply in a non-discriminatory manner, can be upheld in a cross-border situation. The most notable exception is the requirement to only be treated by a contracted provider. The Court ruled that if the assumption of the cost of treatment given by (both domestic and foreign) providers who are *not* contracted by the sickness fund or health system is made conditional on the granting of prior authorisation, then this is liable to affect foreign providers more than providers established in the State of health insurance. This condition is therefore seen as an obstacle to the free movement principles <sup>(7)</sup>. This applies even if foreign providers have the same possibility to enter into contracts. Foreign providers are thus in principle entitled to be placed on the same footing as domestic contracted providers, even if they do not have to comply with the requirements included in the contracts with which domestic providers have to comply, in particular with regard to price setting.

This contrasts with the classical EU mechanism under which patients are entitled to reimbursement of treatment abroad, based on Regulation 883/2004 (formerly Regulation 1408/71) on the coordination of social security schemes (hereafter the Regulation) <sup>(8)</sup>. This Regulation entitles patients whose treatment becomes necessary during a stay in another Member State (for example people travelling, studying, or working abroad) to the same benefits as patients insured in the host Member State.

For patients who want to go abroad to receive planned care, the Regulation enables, in principle, the funding of this care provided that the patient has received prior authorisation from the financing institution to which (s)he is affiliated. This authorisation is based on an authorisation form commonly known as the E112. Such an authorisation must be given when the care is included in the benefit package of the Member State of affiliation, and when adequate or equivalent care is not available within a reasonable time period in the country of affiliation. Member States can however also decide to allow patients to go abroad in other circumstances based on this procedure.

Under the Regulation the patient is treated in the host Member State as if he were socially insured in that Member State. This means that care providers have to be integrated in the publicly funded system of their own Member State and have to comply with the according legal framework when they treat foreign patients. Consequently, tariffs and the content of care are defined by the rules that apply when providers deliver statutory care to domestic patients.

The Court however stipulated that the provisions on the free movement of services act as a complement to the rights of E112-holders. If, for a holder of a form E112, the amount reimbursable under the legislation of the State where treatment is received is lower than the amount payable under the legislation of the State of affiliation, the patient should receive a complement in order to guarantee him a level of coverage which is at least equivalent to the level of cover provided by the legislation of the State of affiliation <sup>(9)</sup>. This is relevant when the insured person was required to make a financial contribution to the cost of treatment abroad.

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7. Case C-157/99, *Geraets-Smits and Peerbooms*, at 66-68.

8. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems, OJ L 166, 30.4.2004, p. 1.

9. CJEU, Case C-368/98 *Vanbraekel* [2001] ECR, at 45.

<b>Reimbursement of planned treatment in another EU Member State (MS)</b>		
	<i>CJEU case law (and Directive 2011/24/EU)</i>	<i>Regulation 882/2004 (=E112 form)</i>
<i>Prior authorisation</i>	Can only be requested in limited circumstances, in particular hospital care or highly specialised care requiring planning	Required
<i>Prior authorisation must be granted</i>	When undue delay for treatment at home	When undue delay for treatment at home
<i>Qualifying providers</i>	All	Only those providing statutory care
<i>Reimbursement level</i>	Of the MS where socially insured	Always most beneficial level: of the MS of treatment or of social insurance
<i>Reimbursement conditions</i>	Of the MS where socially insured	Same as for statutory care in MS of treatment
<i>Payment</i>	Up front payment by patient and reimbursement	Third party payment system (when applicable for socially insured patients in MS of treatment)

## **The Directive on the application of patients' rights in cross-border care**

The Directive aims to clarify the right of patients that seek healthcare in another EU country, thus implementing and clarifying the rulings by the Court of Justice. In this section we will explain the main provisions. The Directive is structured around three main areas. First, it provides a specific framework for reimbursement of care received abroad; secondly, it addresses the question as to which Member State, in the case of cross-border care, should be responsible for ensuring quality and safety standards, information, redress, and liability as well as privacy protection; and thirdly it aims to encourage European cooperation on healthcare in specific areas.

### **Legal basis and scope of application**

Whereas the initial proposal was only based on the internal market provisions of the Treaty on the Functioning of the European Union, the adopted text has a double legal basis: the internal market article (Art 114, former Art 95) and the public health article (Art 168, former Art 152). The latter was added under political pressure to not only approach the issue from an (internal) market perspective, but to complement this by health policy objectives. Furthermore, the Public Health legal basis was needed for the provisions encouraging cooperation between Member States.

Contrary to the initial Commission proposal, the Directive does not only apply to health services provided by health professionals to patients to assess, maintain, or restore their state of health, but also to the prescription, dispensation, and provision of medicinal products and medical devices (Art 3, a).

Services in the field of long-term care, the allocation of and access to organs for the purpose of organ transplants and public vaccination programs against infectious diseases are excluded

from its scope (Art 1).

### **Rules on reimbursement of costs of cross-border healthcare**

According to the Directive, the Member State in which the patient is covered for healthcare (the Member State of affiliation) has to ensure that the costs incurred for treatment in another Member State are reimbursed, if the healthcare in question is among the benefits to which the patient would have been entitled if the treatment was provided in its own Member State. The costs have to be reimbursed up to the level of costs that would have been assumed, had this healthcare been provided domestically, without exceeding the actual costs of healthcare received. The reimbursement of these costs can be made subject to the same conditions, criteria of eligibility and regulatory and administrative formalities, as would be imposed if this healthcare were provided in the Member State of affiliation (Art 7). Member States have to establish transparent mechanism for calculation of costs for cross-border healthcare that are to be reimbursed (Art 7,6).

The Directive maintains the possibility to require prior authorization as a condition for reimbursement for specific types of cross-border care. This is the case for healthcare made subject to planning requirements and involving overnight hospital accommodation for at least one night or requiring the use of highly specialized and cost-intensive medical infrastructure or equipment (Art 8.2(a)).

Reimbursement for costs of cross-border healthcare can furthermore be subject to prior authorization when it involves treatments presenting a particular risk for the patient, the population, or when the treatment is to be provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care (Art 8,2 (b) and (c)).

Prior authorization may be refused when the healthcare can be provided domestically within a time limit which is medically justifiable (Art 8,6), but must be granted when this is not the case (Art 8,5). Prior authorization may furthermore only be refused when (Art 8,6):

- the patient will be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable;
- the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;
- this healthcare is to be provided by a healthcare provider that raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision.

Measures (including prior authorization systems and administrative procedures regarding cross-border healthcare) need to be proven necessary and proportionate to the objective to be achieved and may not constitute a means of arbitrary discrimination (Art 7.11; 8.1 in fine and Art 9.1).

Next to the specific rules defining the conditions under which healthcare may be subject to prior authorisation, a general exception allows Member States to limit reimbursement of cross-border care on the basis of overriding reasons of general interest, such as planning requirements (Art 7.9). However, it is unclear how this “one size fits all” provision should be interpreted and applied.

Where the patient is entitled to cross-border healthcare under both the Directive and the Regulation (EC) on the coordination of the social security systems, and if the application of the Regulation is more advantageous to the patient, the patient’s attention should be drawn to this

by the Member State of affiliation (rec. 31) and the prior authorization should be granted and the benefits provided in accordance with the Regulation unless the patient requests otherwise (Art 8,3).

### **Responsibilities of the respective Member States**

According to the Directive, the Member State where the patient is affiliated for health cover has to (Art 5):

- provide patients on request with information on their rights and entitlements to receiving cross-border healthcare, in particular as regards to the terms and conditions for reimbursement of costs and procedures for appeal and redress if patients consider their rights have not been respected;
- ensure that, where a patient has received cross-border healthcare, the same medical follow-up is available as would have been if that healthcare had been provided on its territory;
- patients who seek to receive or do receive cross-border healthcare have remote access to or have at least a copy of their medical records.

The responsibility to ensure the proper conditions for the care provided to a cross-border patient and to guarantee quality and safety lies with the Member State of treatment. According to the Directive (Art 4,1), the care the patient receives has to be provided in accordance with the legislation in the Member State of treatment and in accordance with the standards and guidelines of quality and safety as applicable in that Member State. The Member State of treatment has to ensure that patients receive, upon request, information on these standards and guidelines. Member States also have to cooperate on standards and guidelines on quality and safety (Art 10,1).

The Member State of treatment has furthermore to ensure transparent complaint procedures and redress mechanisms, systems of professional liability insurance or similar arrangements, privacy protection with respect to the processing of personal data, as well as the right to have access to his personal medical record (Art 4.2). This Member State also has to ensure that healthcare providers provide patients with relevant information including on treatment options, on the availability, quality and safety of the healthcare they provide, on prices, as well as on their authorization or registration status (Art 4.2). Upon request of the authorities of other Member States, they have to make available information on the right to practice of health professionals listed in national or local registers established on their territory (Art 10,4).

Member States have to designate one or more national contact points (NCP) which should provide patients and health providers upon request with the information the respective Member States of treatment and affiliation have to provide (Art 6). NCP have to cooperate closely with each other and with the Commission to exchange information including on provisions with supervision and render mutual assistance to clarify the content of invoices (Art 10,1).

### **Cooperation in healthcare**

The chapter on cooperation in healthcare (Chapter IV) within the Directive deals with a series of different areas:

- Member States have to facilitate cooperation in cross-border healthcare provision at regional and local level. (Art 10, 2). The Commission will encourage Member States, particularly neighbouring countries, to cooperate in border regions and to conclude agreements among themselves (Art 10, 3).
- Member States have to ensure that prescriptions issued for a medicinal product or a medical device in another Member State can be dispensed on their territory in compliance with their

national legislation (Art 11). Any restrictions on **recognition of such prescriptions** have to be limited to what is necessary and proportionate to safeguard human health, and may not be discriminatory unless based on legitimate and justified doubts about the authenticity, content, or comprehensibility of an individual prescription. The Commission will adopt measures to facilitate the recognition of such prescriptions and to exclude specific categories of medicinal products or medical devices from the recognition.

- The Commission will support Member States in the development of **European reference networks between healthcare providers and centres of expertise** in the Member States, in particular in the area of rare diseases (Art 12). These networks aim to improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise.
- The Commission will support Member States in cooperating with the development of diagnosis and treatment capacity for **rare diseases** (Art 13).
- A voluntary **network** connecting national authorities responsible for **eHealth** will be set up to support and facilitate cooperation and the exchange of information among Member States (Art 14). The eHealth network aims in particular to draw up guidelines on data that are to be included in patients' summaries and on methods for enabling the use of medical information for public health and research, and to support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.
- The Union will also support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary **network** connecting national authorities or bodies responsible for **health technology assessment** (Art 15). The network aims to support Member States in the provision of information on the relative efficacy and effectiveness of health technologies, to enable an effective exchange of this information, and to avoid duplication of assessments.

### **Implementing acts and transposition**

A Committee, consisting of representatives of the Member States and chaired by the Commission representative will assist the Commission in adopting the delegated acts (Art 16, 17). Member States have to adapt their national regulations, and administrative provisions necessary to comply with the Directive by 25 October 2013 (Art 21).

Every 3 years, the Commission has to conduct an assessment of the systems and practices put in place in the Member States and to draw up a report on the operation of the Directive. This report should in particular include information on patient flows, financial dimensions of patient mobility, the implementation of prior authorization systems, and on the functioning of the European reference networks and national contact points. The Commission can, where appropriate, make proposals to modify the systems of prior authorization (Art 20).

### **Potential impact of the application of the free movement rules and of increased patient mobility**

Patients prefer to be treated as close to home as possible, by professionals who speak their language, in a health system with which they are familiar, surrounded by their relatives and friends. Patient mobility is therefore expected to remain a relative marginal phenomenon. However, it can be important in certain regions, in specific healthcare facilities, or for specific

treatments<sup>(10)</sup>. Furthermore, the application of the rules on the free movement of services to healthcare and the application of the provisions of the Directive can have important impacts on health systems irrespective of the number of patients that move across-border. Both the Directive and the application of the free movement rules to healthcare provision can become a lever to change domestic policy and practice.

The impact of funding planned care in another EU Member State on health systems, patients, and workers, can be different depending on the procedure through which the patient receives this care abroad. Apart from the possibilities to receive reimbursement based on the EU Treaty provisions on the free movement implemented in Directive, patients can get access to care abroad based on the Regulation; healthcare purchases can directly contract with healthcare services in another Member State or patients can pay the treatment out of their pocket (and possibly receive reimbursement from their private, non-statutory health insurer). Because the applicable tariffs, the reimbursement level, the qualifying providers, and the third party payer systems differ between these types of arrangements, the potential impact can vary.

We will discuss these different potential impacts of the Directive, of increased patient mobility, and the application of the free movement rules to healthcare services below.

### **Impact on health systems**

This section analyses the potential impact of increasing patient mobility and the application of the free movement rules on health systems. We focus on the regulatory powers of health authorities under the free movement principles and look at the way in which the Directive succeeds in preserving these powers. In particular we analyse the extent to which health authorities can, under the Directive, control inflows and outflows of patients, define conditions for reimbursing care, and define the pool of providers whose care qualifies for reimbursement. We furthermore analyse what could be the impact on public expenditures for care and domestic price setting. Also the potential impact of organised cross-border care, which can be different from the impact of individual patients searching for care abroad, is discussed. Finally, we explain how the free movement principles can impact on cost calculation mechanisms.

### **The capacity of health authorities to steer the system**

From the onset, the political debate on the implications of the jurisprudence did not focus primarily on the potential impact in terms of the number of patients travelling for healthcare abroad, but rather on the implications for the organization of the national healthcare systems and the financial impact.

Healthcare systems are characterized by extensive regulation aiming to address the important market failures in this sector and to ensure the most cost-effective use of the limited public financial means. These regulatory frameworks risk coming under pressure through the application of the EU principles on the free movement of services.

Gradually it has become clear that the implications of the CJEU go far beyond the issues related to patient mobility. Not only do the rules on reimbursement of care for patients going abroad potentially form an obstacle to free movement, but other regulations limiting access to health care services or restricting the exercise of these activities can also form a barrier to the single market. The threshold for applying the free movement rules is low. Even if the Court accepts

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10. Rosenmøller M., McKee M., Baeten R. (eds.) (2006), Patient Mobility in the European Union: Learning from experience, European Observatory on Health Systems and Policies, Copenhagen.

general interest objectives as a justification ground for hindrance to the free movement, health authorities face a relatively high burden of proof <sup>(11)</sup>.

The potential deregulatory effect stemming from the removal of unjustified restrictions to the free movement principles could cripple the steering instruments used by health authorities. The fear that legal uncertainty might lead to creeping deregulation and the concern to lose the steering capacity over the healthcare systems was one of the main drives behind the Directive. However, the adopted text only deals with patient mobility and carefully avoids addressing the potential deregulatory effect of the application of the free movement principles on providers wishing to temporarily or permanently provide services in another Member State.

The long-term effects of these developments remain rather unpredictable. They could create more diversity in health care provision and more fragmented health care systems. Moreover, increased choice for patients and providers might challenge public support for the equity and solidarity principles underpinning many European health care systems.

### **Controlling outflows**

To ensure access to care and the long-term financial viability of the health systems, health authorities need the power to prioritize and manage resources and plan services. Large net outflows of patients, could for instance lead to closure of domestic infrastructure, which might decrease local access to care. This is why access to planned treatment abroad based on the Regulation is subject to prior authorization from the institution where the patient is covered for healthcare.

Also, in existing arrangements relaxing access to care abroad, measures are taken to prevent closure in the domestic health infrastructure. This counts in particular in less densely populated areas. For instance, contracts of a Dutch health insurer with Belgian hospitals to treat patients from the Dutch region Zeeuws-Vlaanderen, were limited to those treatments which could not be provided in the local domestic hospital <sup>(12)</sup>. Similarly, a cross-border care agreement at the Belgian-French border allows French patients access to the closest Belgian hospital. However, patients living closer to the French local hospital are excluded from the arrangement because French health authorities fear that they would have to close services in the local hospital when outflows would become too important <sup>(13)</sup>.

This is the reason why the extent to which Member States would retain the possibility to require prior authorization for treatment abroad, in particular for hospital care, was among the most controversial issues of the proposed Directive. As explained above, the Directive maintains the possibility to require prior authorization as a condition for reimbursement of specific types of cross-border care, in particular for hospital care or care requiring the use of highly specialized and cost-intensive medical infrastructure or equipment, when it is subject to planning (Art 8.2(a)). Prior authorization may be refused when the healthcare can be provided domestically within a

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11. See: Gekiere W., Baeten R. and Palm W. (2010), Free movement of services in the EU and health care. In: Mossialos et al. (eds), *Health Systems Governance in Europe: the role of European Union law and policy*, Cambridge University Press, Cambridge, 461-508.

12. Glinos IA, Boffin N and Baeten R. (2005), Contracting Cross-border Care in Belgian Hospitals: An analysis of Belgian, Dutch and English Stakeholder Perspectives. Brussels, Observatoire social européen.

13. Kiasuwa, R. and Baeten R. (forthcoming), Cross-border hospital collaboration in the region of the Ardennes, at the French-Belgian border. In: I. Glinos and M. Wismar, eds. *Cross-border hospital collaboration in the EU*, WHO on behalf of European Observatory on Health Systems and Policies, Copenhagen.

time limit which is medically justifiable (Art 8,6), but must be granted when this is not the case (Art 8,5).

Whereas the initial Commission proposal required Member States, before introducing a system of prior authorization, to provide evidence that the outflow of patients due to cross-border hospital care undermines, or is likely to undermine, the financial sustainability of health and social security systems overall or the organization, planning and delivery of health services, the adopted text leaves more room for health authorities to justify their systems of prior authorization. Furthermore, many health authorities argued since long to assimilate, for the application of the prior authorization system, healthcare requiring the use of cost-intensive medical infrastructure with hospital care. This is now obtained through the Directive. The element of planning has thus become the decisive factor for determining the remaining scope of prior authorization rather than the setting where the care is delivered (outpatient vs. inpatient). The Directive leaves it to the Member States to define the services that fall under these categories of healthcare subject to planning. Yet, they need to notify the Commission about it (Art 8.2 in fine).

### **Controlling inflows**

Conversely, in the host Member State, cross-border care can lead to supply shortages and capacity problems.

Several studies mention that receiving hospitals may lack readily available bed space and that this can prolong waiting time for local patients <sup>(14)</sup>. Faced with potentially large inflows of foreign patients for planned care, some health authorities took measures to control inflows in order to avoid potential domestic supply shortage. For instance, Austrian health authorities opposed direct contracting between German sickness funds and Austrian hospitals <sup>(15)</sup>. The example of organ transplants for Italian patients done abroad in the late 1980s may be outdated, but it remains illustrative because the supply of this type of care is, by its very nature, limited. 40% of cadaver kidneys available for transplants in France and 50% of kidney transplants in Austria were used for Italian patients. As a result, tariffs charged by French organ transplant facilities to Italian patients were almost doubled in 1993 <sup>(16)</sup>.

The possibility to intervene if inflows would exceed existing capacity therefore was another issue heavily debated in the Council in the run up to the Directive. As a result, the Directive provides that Member States can, in exceptional cases, adopt measures to ensure sufficient and permanent access to healthcare within their territory. Such measures have to be limited to what is necessary and proportionate (Art 4,3°). However, it is likely that this provision will not be applied in practice. Even if public authorities voice the concern that high inflows could affect access to care for domestic patients, a simulation on the implementation of the Directive suggests that they do not have the means to collect information on the number of foreign patients using health care in their country, let alone a system for regulating that flow <sup>(17)</sup>.

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14. Glinos et al., 2005.

15. Nebling T, Schemken HW. (2006), Cross-border contracting: The German experience. In: Rosenmüller et al, 2006: 137-156.

16. France G.(1993), Cross-border Care: The Italian Experience. In: Paper presented to the Conference Healthcare Financing and the Single European Market - Working Group "Cross-border Care", Brussels.

17. Jelfs, E. and Baeten R. (2012), R. Simulation on the EU Cross-Border Care Directive, Final Report OSE, EHMA, AIM, 38p. Available at:

## Conditions for reimbursement

Criteria and conditions for funding healthcare are crucial to guarantee the most cost-effective use of limited financial resources. The CJEU rulings did challenge national requirements, since it was not clear which domestic conditions could be justified for care provided abroad. This led to considerable legal uncertainty. Since the first Court rulings, Member States feared in particular that they could not impose on and monitor whether providers were respecting cost containment measures abroad in the same way as they could in the case of domestic providers <sup>(18)</sup>.

Under the Directive, Member States may maintain general conditions, criteria for eligibility, and regulatory and administrative formalities for receipt of healthcare and reimbursement of healthcare costs also for patients seeking healthcare in another Member State. Such conditions may not be discriminatory nor constitute an obstacle to the free movement, unless they are objectively justified by planning requirements (Rec. 37 and Art 7,7). The Directive explicitly mentions that the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care can be imposed on an insured person seeking reimbursement of the costs of cross-border healthcare, if such requirement is also applicable at home (Rec. 37).

The possibility to maintain conditions for reimbursement of care that form an obstacle to the free movement, can thus only be justified in the general interest when they aim to plan healthcare. However, many thresholds for funding treatment do not directly relate to planning requirements, but do nevertheless form key elements of the system of controlling access to care and are instruments to control costs and avoid wastage of financial resources. As an example, conditions may be imposed regarding the reimbursement of expensive pharmaceutical products (such as that an alternative, cheaper product proved ineffective). If such domestic reimbursement conditions cannot be imposed for pharmaceuticals dispensed in another Member State, this can have an important impact on healthcare budgets.

Furthermore, as showed in the already mentioned simulation on the Directive, healthcare providers seem not willing to adapt treatment procedures to the requirements of the foreign payer of the patient <sup>(19)</sup>. An example illustrating a similar behaviour relates to Dutch patients consulting Belgian specialists. In Belgium, patients have direct access to specialists, whereas in the Netherlands the condition to consult a general practitioner before consulting a specialist applies. Belgian specialists do not require a referral letter from patients coming from the Netherlands and do not have any incentive to do so. Dutch patients try to formalize the situation on their return by asking their Dutch GP for a referral letter retrospectively <sup>(20)</sup>.

## Qualifying providers

After the initial Court rulings, Member States' greatest concern, in particular countries where healthcare under the social protection system is provided by a limited group of (contracted or public) providers or by providers who adhered to a collective agreement, was that it would no longer be possible to exclude (private) providers from their social protection system. If they were

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[http://www.ose.be/files/publication/2012/CrossBorderHealthcareSimulation\\_FinalRep\\_09052012.pdf](http://www.ose.be/files/publication/2012/CrossBorderHealthcareSimulation_FinalRep_09052012.pdf)  
(accessed 17 September 2012).

18. Palm W. et al (2000) Implications of recent jurisprudence on the coordination of healthcare protection systems, General report produced for the Directorate General for Employment and Social Affairs of the European Commission, 99-100.

19. Jelfs and Baeten, 2012.

20. Glinos et al., 2005.

to fund care from non-contracted providers abroad, they feared the possibility of coming under pressure to reimburse care from domestic non-contracted providers, who do not have to comply with all the conditions defined in these contracts or agreements (in particular, the set tariffs) <sup>(21)</sup>.

Since reimbursement of cross-border care under the Directive in principle follows the rules of the Member State of affiliation, it could be argued that private (non-contracted) providers could be excluded from coverage. This would fall under the application of the provision that the same conditions, criteria for eligibility and regulatory and administrative formalities, can be imposed by the Member State of affiliation as the ones applied if healthcare is provided in its territory. The Court of Justice nevertheless specified that denying reimbursement of foreign private or non-contracted providers is to be considered a disproportionate measure <sup>(22)</sup>.

Until the very last moment in the debate on the Directive in the Council, the choice of the providers to be covered by the Directive was the major outstanding issue. Many Member States preferred to exclude non-contractual healthcare providers from the scope of the Directive, since, in their view, this would give rise to “reverse discrimination” because treatment of such providers is not reimbursed at national level, while they would have to reimburse it in cross-border situations <sup>(23)</sup>. This issue was the main reason behind the failure of the Swedish proposal for a compromise at the end of 2009 <sup>(24)</sup> and was at the core of the Polish objection to the Directive, as highlighted in the case study below.

Even if the Directive does not oblige Member States to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State (Art 1.4), it is well possible that the implementation of the Directive will increase pressure on Member States to also provide access domestically to such providers. Indeed, this is what happened in Germany and the Netherlands when they implemented the Court rulings: by providing access to non-contracted providers abroad, they extended this possibility to domestic non-contracted providers (see also below in the case study on the Netherlands) <sup>(25)</sup>.

Most Member States, when starting to implement the Court rulings, searched for creative ways to channel patients away from these non-statutory providers abroad. Most of them made treatment abroad by providers integrated in the statutory system of the Member State of care provision more attractive, or they made it more attractive for patients to be treated by contracted providers abroad (see for instance the case studies on Luxemburg and the Netherlands below) <sup>(26)</sup>.

## Treatment costs

When patients are treated abroad under the Directive, this should not impact the cost of individual treatments, as the public intervention is limited to the reimbursement tariffs of the

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21. Palm et al. 2000, 99-100.

22. Case C-157/99 *Geraets-Smits and Peerbooms*; CJEU, Case C-496/01 *Commission v France* [2004] ECR I-2351 and *Stamatelaki*.

23. Slegers, M. (2009) Employment, Social Policy and Health Council, Cross-border healthcare and maternity leave on agenda, *Europolitics*, 27 November.

24. Press release of the Council meeting Employment, Social Policy, Health and Consumer Affairs, Brussels, 30 November - 1 December 2009, p.13.

25. Baeten R., Vanhercke B. and Coucheir M. (2010) The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law, *OSE Paper Series, Research paper N° 3*, July 2010, 30 p.

26. Baeten et al. 2010.

country where the patient is covered for health insurance. However, cross-border care can increase the volume of care to be funded by the healthcare system, when care providers abroad have financial incentives to increase the delivery of care services per patient or when patients go abroad for treatments not timely available at home. It can lead to multiple – and possibly superfluous – medical procedures. For example, Belgian doctors seem to disregard tests already done in the Netherlands and Dutch doctors consider scans and radiographs carried out in Belgium for Dutch patients superfluous <sup>(27)</sup>. In Denmark, public hospitals suspect that private and foreign providers that are contracted by public purchasers carry out more tests before and after treatment than would be done in a public institution <sup>(28)</sup>.

Conversely, when patients are treated abroad under the Regulation or based on a cross-border contract between a healthcare purchaser and provider, the costs for the statutory payer can be either higher or lower than the price they would pay domestically. Examples of purchasers that have contracted care abroad at a cheaper price than the domestic official tariff include: Danish counties that contracted German hospitals where prices are 10% lower than the Danish DRG-rates <sup>(29)</sup>; tariffs in health facilities for rehabilitation care in the Czech Republic that tend to be 30 to 40 % cheaper than in Germany <sup>(30)</sup>; and prices in Belgian hospitals that are on average 10% lower compared to the prices in the Netherlands <sup>(31)</sup>. These differences in prices can be due to different tariff systems. In Belgium and Germany, tariffs do not or only partially include hospitals' capital investment costs <sup>(32)</sup>. Salaries can also differ considerably.

Under the Regulation, the costs to be assumed by the public authorities can also be higher as the costs of care reimbursed at home. This is in particular the case when patients from EU 10 Member States receive treatment in a healthcare facility in a EU 15 Member State, where prices are overall much higher. In principle patients do only have the right to reimbursement of planned treatment under the Regulation with prior authorization from their funding institution. However, the establishment of European Reference Networks of healthcare facilities providing highly specialized care under the Directive might make it more difficult for health authorities to refuse prior authorization in such centers with an EU label, when the care is not available at home. This raises important questions of the need for EU-wide solidarity to fund the care provided through the centers integrated in these networks.

### **Impact on domestic prices**

When foreign patients, or their purchasers, are prepared to pay higher tariffs than the official tariffs applicable in the domestic statutory system, providers can have an incentive to give priority to treating these 'better paying' patients from abroad. As an example, in Belgium, there has been a concern that treating foreign patients could lead to increasingly commercial behaviour of the (not-for-profit) providers and an upward pressure on the prices for domestic statutory care. Therefore, Belgium signed an agreement with England's Department of Health, framing the treatment of English NHS patients in Belgian hospitals, according to which Belgian

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27. Glinos I.A. and Baeten R.(2006), A Literature Review of Cross-Border Patient Mobility in the European Union. Brussels, Observatoire Social Européen.

Visser L. (2001), Grensoverschrijdende zorg - een lust of een last? Management Gezondheidszorg, Erasmus Univ Rotterdam.

28. Glinos and Baeten, 2006.

29. Glinos and Baeten, 2006.

30. Nebling and Schemken, 2006.

31. Glinos et al. 2005.

32. Baeten R., McKee M., Rosenmüller M. (2006) Conclusions. In: Rosenmüller et.al, 2006:179-187.

tariffs had to apply and English patients were not to get priority over Belgian patients <sup>(33)</sup>. Also, for cross-border contracts between Dutch insurers and Belgian hospitals, a Belgian sickness fund is often involved as a third contracting partner and also watches that the Belgian official tariffs apply <sup>(34)</sup>.

According to the Directive, the MS of treatment has to ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other MS and for domestic patients (Art 4,4°). We discuss this more in detail below, under “Financial access to cross-border care.

### **Money leaving the system**

If patients go abroad due to weaknesses in the domestic system, the funding also goes abroad and can impede improvement in the domestic system, especially when it concerns care with high investment costs. As an example, substantial interregional patient movements within Italy (where regional health authorities are responsible for funding healthcare) from southern to northern and central regions further aggravated inequalities in access to healthcare as well as disparities in regional public accounts <sup>(35)</sup>.

Conversely, the willingness to go abroad for treatment can also push for more investments in the domestic system. For instance, in Estonia, where the population demonstrated a high willingness to be treated abroad, some policy-makers made use of these developments to launch the debate on the need to direct more resources into domestic healthcare <sup>(36)</sup>. Also, policies to address long waiting times seem in some Member States to be encouraged by the CJEU case law, because, according to the Court, patients have the right to be treated abroad if they cannot be treated at home with undue delay <sup>(37)</sup>.

### **Potential impact of organised cross-border care**

Although the Directive does in the first place set rules for individual patients who want to receive treatment abroad, a specific provision addresses organised cross-border healthcare collaboration. The Directive urges Member States, with the support of the Commission, to facilitate cooperation in cross-border healthcare provision at regional and local level, in particular in border regions and to conclude agreements among neighbouring countries (Art10, 2 and 3).

Many collaboration projects allowing patients from a defined region access to care abroad emerged in the past. Such cooperation projects can have several impacts on healthcare systems.

First, they can lead to efficiency gains and economies of scale when providers on both sides of a border agree on a task division or decide to share investment costs. Especially in less densely populated areas these initiatives can lead to benefits for the involved healthcare systems as a whole. As an example, an agreement across the French-Italian border merged the facilities and

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33. A Framework for cross-border patient mobility and exchange of experience in the field of healthcare between Belgium and England. Brussels, 2003.

34. Glinos et al., 2005.

35. Giannoni M. (2006) Universality and decentralization: The evolution of the Italian healthcare system. *Eurohealth*. 12(2):10-3.

36. Jesse M. and Kruuda R. (2006), Cross-border care in the north: Estonia, Finland and Latvia. In: Rosenmöller et al, 2006.

37. Baeten et al, 2010.

competences of a French hospital in Menton with two Italian hospitals, as well as one Italian dialysis centre<sup>(38)</sup>. Also, the use of a radiotherapy machine at a German hospital in Schleswig-Holstein, is co-financed by the Danish Southern Jutland Health authority<sup>(39)</sup>. Healthcare payers can also make use of care infrastructure abroad when patients are too few to support the domestic infrastructure, such as the Maltese ‘treatment abroad’ programme which sends patients abroad when investment costs are too high, patients are too few and professional staff – if employed to perform this type of services – would quickly become deskilled<sup>(40)</sup>.

Secondly, such arrangements can breach any ‘monopoly’ position that may exist for domestic providers. As a consequence, domestic providers can be encouraged to perform better, lower prices, reduce waiting times and improve services. For instance, pushing domestic providers to improve their health services was one of the motives for the English NHS (UK) to conclude cross-border contracts with French and Belgian hospitals<sup>(41)</sup>.

Thirdly, they can challenge existing contracting systems. In most Member States with a social health insurance system, agreements between providers and purchasers on tariffs and content of care are negotiated collectively between the associations of sickness funds and the associations of providers in order to avoid the emergence of dual healthcare systems. Cross-border care can challenge these collective arrangements as they are not simply transposable to contracting foreign providers. Consequently, purchasers may contract selectively with foreign purchasers, even when they are not permitted to do so domestically. This happened both in Germany and the Netherlands<sup>(42)</sup>.

Fourthly, they can weaken the position of central authorities towards local actors in healthcare systems. Most projects for cross-border care are initiated by local actors. However, legislation and conditions for funding care, accreditation of providers, and prior authorization mainly originate from central authorities, as does often the financial responsibility for paying the care abroad. Many projects for cross-border collaboration challenge this central legislation or require particular local interpretations. In some Member States this has led to initiatives from central authorities to re-establish their grip on the local actors in the field of cross-border care. For instance, France and Belgium concluded a Bilateral Framework agreement and henceforth, the collaboration agreements between the local French and Belgian actors in the border region have to comply with the provisions of this agreement<sup>(43)</sup>.

### **Cost calculation mechanism**

In many EU healthcare systems patients have access to care free of charge and healthcare facilities are state owned or remunerated at a flat rate, a lump sum based on the population size they serve. As a consequence, there is no clear price nor reimbursement rate of individual treatments in these so called benefit in kind systems.

However, according to the Directive, Member States have to establish transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed (Art 7,6). This

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38. Glinos and Baeten, 2006.

39. Augustin, U., D. Panteli, and R. Busse (forthcoming), German radiation therapy for Danish cancer patients – a 13-year long border-region success story, in: Glinos and Wismar (eds.), forthcoming.

40. Muscat AN, Grech K, Cachia JM, Xuereb D. (2006), Sharing capacities - Malta and the United Kingdom. In: Rosenmüller et al, 2006: 119-136.

41. Glinos et al., 2005.

42. Nebling and Schemken, 2006 and Glinos et al., 2005.

43. Kiasuwa and Baeten, forthcoming.

provision might be very challenging for some Member States and could in the long run, herald a transformation in the way healthcare providers are funded, including domestically.

The complexity of this issue is illustrated in two case studies below. In the UK, an advice of the Department of Health of 2010, states that, “Where there is no tariff, a price will need to be calculated, and average costs which can be shown to have been reasonably calculated may be used,” to determine the reimbursement level for care received abroad. The advice continues that, “If commissioners are however unable to work out an objective cost, or appropriately decode EU receipts for health care, they may face the prospect of reimbursing the full costs of treatment”<sup>(44)</sup>. Similarly, in the Netherlands the level of assumption for care abroad for patients with a benefit in kind policy is not defined but should, “Not be such as to create a de facto obstacle to the provision of care in another Member State” (see Dutch case study below).

### **Impact on patients’ access to care**

When discussing the potential impact of the Directive on access to care, a distinction should be made between access to cross-border care on the one hand and access to care for the majority of patients who stay at home for treatment.

For patients who stay in the domestic system, access to care primarily depends on the capacity of health authorities to steer the health system and to ensure its financial viability, as discussed in the previous section. Large outflows of patients can, in less densely populated areas, with little healthcare supply, provoke closures in the domestic health infrastructure and large outflows of money for treating patients abroad can impede new domestic investments. In the receiving country, large inflows can provoke capacity problems, or providers can have a financial interest to give priority to foreign patients. On the other hand, policies to address long waiting times seem in some Member States to be encouraged by the CJEU case law.

To analyse the impact on access to care for patients going abroad for treatment, we will compare the possibilities created by the Directive with the already existing opportunities under the Regulation.

### **Financial access to cross-border care**

The Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person (rec. 33). Cross-border healthcare shall be reimbursed up to the level of costs that would have been assumed, had this healthcare been provided domestically, without exceeding the actual costs of healthcare received (Art 7.4). As a consequence, the patient charge can be lower for treatments in Member States where the applicable prices are lower than in the Member State of affiliation, but the patient charge could be prohibitive for treatments in Member States where the applicable prices are higher than in the Member State of affiliation.

According to the non-discrimination principle, the Directive forbids healthcare providers to apply a different scale of fees for patients from other Member States (Art 4.4). This does not however

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44. Department of Health (2010), Cross Border Healthcare & Patient Mobility. Revised Advice on Handling Requests from Patients for Treatment in Countries of the European Economic Area, Guidance for the NHS, 2010, Point 8.14  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_115256](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256) (accessed 02 August 2012).

mean that they have to comply with the tariffs applied to statutorily covered care for domestic patients. Providers can freely set their tariffs and request supplements if they are allowed to do so for domestic “private” patients. As illustrated in the case studies on Belgium and England below, national health authorities determined, based on this article of the Directive, that health providers should assume that patients wish to be treated in the same way as domestic statutorily covered patients. However, in a simulation on the application of the Directive, healthcare providers suggested that private tariffs would most often be used for foreign patients travelling under the Directive, rather than those that apply for socially insured patients or the collectively agreed tariffs between health insurers and providers<sup>(45)</sup>. The Directive thus seems to be unable to prevent an upward pressure on prices when inflows of patients would be important.

By contrast, according to the Regulation, care is funded according to the level applicable in the Member State of treatment, and patients are, based on the principle of non-discrimination, equally treated with the patient who is socially insured in the state of treatment. Hence, statutorily agreed tariffs and the applicable user charges will also apply to cross-border patients. If, however, for a patient who has received (or should have received) a prior authorization under the Regulation, payment turns out to be lower than what would have been paid if treatment had been given in the state of affiliation, the patient is entitled to an additional reimbursement. This additional funding should cover any user charge he would have been exposed to in the state of treatment, up to the level of the difference between both tariffs<sup>(46)</sup>. The Regulation, combined with this case law, thus guarantees the patient always the most beneficial reimbursement tariff (either by the country of treatment or by the country of affiliation)<sup>(47)</sup>. Furthermore, as opposed to under the Regulation, the patient who seeks treatment abroad under the Directive has in principle to first pay for his treatment and only receives reimbursement upon his return home.

The Regulation thus provides more guarantees for financial access to care abroad than the procedure based on the Directive. The potentially more beneficial rights is why the Directive gives priority to the reimbursement based on the Regulation when the patient has the right to treatment abroad according to the latter (recital 29, 31, 41 and Art 8.3).

Under both, the Directive and the Regulation, patients can have to bear additional cost, which they would not have to bear if they were treated at home. These include travel cost, possibly travel and accommodation for an accompanying person, and translation costs (eg of the medical file). Some Member States do reimburse some of these costs, in particular when the treatment is not available at home. For instance, the Irish National Treatment Purchase Fund and Malta fund under certain conditions travel and accommodation for an accompanying person<sup>(48)</sup>. Malta furthermore invested in portable medical equipment, together with mechanisms for ensuring accommodation and remuneration for the accompanying hospital team members when necessary<sup>(49)</sup>.

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45. Jelfs and Baeten, 2012.

46. Case *Vanbraekel and Watts*; However, the Court denied the application of this additional reimbursement bonus for unscheduled care during a temporary stay in another Member State, basically since in those cases a patient - given the urgency of treatment – could not actually choose between treatment at home or in the country of stay and therefore no hindrance to the principle of free provision of services can be found (CJEU, Case C-211/08 *Commission/Spain*, [2010] ECR I-0000).

47. Baeten R and Palm W (forthcoming), Preserving general interest in healthcare through secondary and soft EU law: the case of the Patients’ rights Directive in: Neergaard et al. (eds.), *Social Services of General Interest in the EU*, T.M.C. Asser Press.

48. Glinos and Baeten, 2006.

49. Muscat et al. 2006.

## **Geographical access to care**

Evidence shows that patient flows are numerically the most important in border regions and between neighboring countries <sup>(50)</sup>. Border-region populations are often more familiar with and willing to use health care facilities across the frontier. This is especially the case when populations on both sides of the border have strong cultural, linguistic and historical ties.

Relaxing access to care abroad in border areas can be particularly important in sparsely populated border areas. For example, cross-border arrangements allowed the population of a border region in the Republic of Ireland to go to a hospital in Northern Ireland for oral and maxillofacial surgery, saving some patients to travel almost 320 km. to Dublin and patients suffering from renal diseases in the final stages obtained access to haemodialysis services in Northern Ireland, saving them about 100 km of travel to Dublin 2-3 times a week <sup>(51)</sup>. Such arrangements can be particularly beneficial for vulnerable groups <sup>(52)</sup>.

The Directive allows patients access to care that is closer to home, but in another Member State, than alternative care in the Member State of affiliation. By removing the barriers to funding such treatments, the Directive thus improves geographical access. This counts in particular for ambulatory care, for which patients can receive treatment abroad without prior authorization.

## **Timely access to care**

Cross-border care can be a tool to overcome domestic waiting list problems. According to the Directive, the Member State of affiliation may not refuse prior authorization if it cannot provide the treatment to which the patient is entitled, on its territory within a time limit which is medically justifiable (Art 8.5). Based on the CJEU rulings, a similar provision was already incorporated in the Regulation. It requires that Member States accord authorization for care abroad when the treatment in question is part of the benefit package in the state where the patient is covered for health and cannot be provided there within a time limit which is medically justifiable (Art 20.2 in fine of the Regulation) <sup>(53)</sup>. In this respect, the Directive does thus not provide for rights which were not already guaranteed through the Regulation <sup>(54)</sup>.

## **Access to highly specialized treatment**

The diagnosis and treatment of some conditions require an important concentration of both financial resources and professional skills. In particular, smaller EU countries, such as Luxembourg and Malta, that are not able to provide the whole range of health services within their borders, are used to send their patients abroad for specific highly specialised care <sup>(55)</sup>.

With the aim to improve the access to diagnosis and the provision of high-quality healthcare to patients who have conditions requiring a particular concentration of resources or expertise, the Directive provides for the development of European reference networks between healthcare

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50. Rosenmüller et al, 2006.

51. Jamison J, Legido-Quigley H, Mckee M. Cross-border care in Ireland. In: Rosenmüller et al, 2006.

52. See e.g. Hayes ABD, Gray AM (2002). Building for the Future: Cross-Border Co-operation in Health. The Cross-Border Acute Project - Phase II., University of Ulster, Ulster.

53. The provisions on undue delay were strengthened after the *Müller-Fauré* Case.

54. Baeten and Palm, forthcoming.

55. Muscat et al, 2006 and Kieffer R.(2003), L'impact de la jurisprudence européenne sur la politique sanitaire et sociale au Luxembourg. In: *Les rendez-vous européen de la Santé transfrontalière: Libre circulation et régulation*. Lille, France, 2003.

providers and centres of expertise in the Member States. These networks should in particular be set up in the area of rare diseases (Art 12). They could also be focal points for medical training and research, information dissemination, and evaluation.

The Directive does not specify how the care provided in these centers should be paid for, and nothing in the Directive obliges Member States to include treatments provided in these centers in their benefit package. These provisions do thus not improve access to care. However, it is likely that the creation of the networks would increase pressure on the respective statutory systems to include the treatments they provide in their benefit package.

### **Patient choice**

Access to care abroad, under the Directive or through other arrangements, increases patient choice. Patients can go to providers in another system, possibly with different treatment procedures and with different characteristics.

Several sources indicate a link between dissatisfaction with the domestic health care system and the willingness to go abroad for treatment. Also, people who have settled down in another EU Member State often prefer to return to their country of origin when they need health care (<sup>56</sup>).

### **Equity in access to cross-border care**

It has been reported frequently that wealthier patients and patients with good overall health conditions are more likely to make use of the possibilities for cross-border care.

Not only the costs the patients have to bear themselves can be prohibitive, but going abroad for care also requires important skills such as language knowledge and the ability to self-manage the care. The lack of information, not only in terms of the possibilities to reimbursement of cross-border care but also in terms of the availability and quality of care, has been identified as an important obstacle discouraging people to receive cross-border treatment.

The Directive includes provisions to help individual patients make an informed choice. The information duty covers a whole spectrum of issues, including rights and entitlements, applicable procedures and mechanisms, as well as availability, provider status, prices etc. The burden for patients to look for all this information themselves is high and apart from the challenge to provide all this information in a clear, transparent and timely manner, the language barrier may still be a problem. There is no obligation for Member States to deliver information in languages other than the official languages of the Member States concerned (Art 4.5). The simulation on the Directive, already mentioned above, also indicated that patients bear the responsibility for many of the elements involved in accessing planned treatment across borders. This includes finding information on potential treatments; the burden of proof in demonstrating to insurers what exact treatment has been carried out. National contact points and other institutions seem unable to bridge this gap (<sup>57</sup>).

Access to healthcare abroad can also be more difficult for people with complex health problems or chronic diseases. Patients need to be fit to travel and providers can have financial incentives to select the easiest to treat patients. Furthermore, patients with complex and chronic conditions need more long-term care and a multidisciplinary approach, which can be problematic in a cross-border setting.

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56. Glinos and Baeten, 2006.

57. Jelfs and Baeten, 2012.

## Impact on quality of care and patients' rights

The Directive provides measures aiming to protect the individual patient (as a consumer of services), in order to ensure the proper conditions for receiving care abroad and to build trust and confidence to allow patients to seek treatment across the EU. The Directive suggests that all Member States should have standards and guidelines on quality and safety of care (Art 4,1). Member States shall furthermore render mutual assistance as is necessary, including cooperation on standards and guidelines on quality and safety (Art 10). However, the provisions of the initial proposal for a Directive, granting the Commission, in cooperation with the Member States, the power to develop guidelines to facilitate the implementation of the provisions on quality and safety, were not acceptable for Member States. It is therefore not clear what level of quality and safety measures would be required and how this would be supervised or exacted. As a result, the Directive fails to ensure quality and safety of cross-border care and the patient will have to rely on the nationally set standards in the host Member State.

Continuity of care has been reported as a problematic issue in a cross-border context. Gaps in the cross-border pathway include: a lack of communication between referring and treating professionals; differences in MRSA protocols<sup>(58)</sup>; lack of knowledge about specialists; lack of insight into the complete cross-border patient pathway; uncertainties about tasks and responsibilities; and problems with the availability at home of drugs and medical devices that were prescribed abroad <sup>(59)</sup>. The Directive addresses some of these issues, by ensuring patients' access to his personal medical record and by promoting the cross-border recognition of medical prescriptions. Many other aspects are however not addressed.

Measures to protect the patient include: besides measures to guarantee quality and safety of care received, also transparent complaint procedures and redress mechanisms; systems of professional liability insurance or similar arrangements; privacy protection with respect to the processing of personal data, as well as the right to have and to access a personal medical record (Art 4.2). Although these provisions in principle only relate to cross-border care, they should apply to all patients alike and thus also domestic patients should be able to benefit from the obligations imposed on Member States <sup>(60)</sup>.

## Impact on healthcare workers

Cross-border care can have an array of potential impacts on healthcare workers.

Cooperating healthcare professionals, in particular in initiatives allowing organised patient mobility, can learn from each other and new procedures and approaches can be introduced. For instance, a Norwegian project allowing patients to go abroad for elective surgery found that contacts with foreign hospitals had given Norwegian providers insight into new treatment methods and had contributed to better treatment procedures in domestic hospitals <sup>(61)</sup>. Nurses involved in dermatology clinics in a cross-border project between Northern Ireland and the

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58 MRSA (Methicillin-resistant Staphylococcus aureus) is a bacterium responsible for several difficult-to-treat infections in humans.

59. Baeten, R. (2011), "Past impacts of cross-border health care", in Wismar et al., (eds.), *Cross-border Health Care in the European Union: Mapping and analysing practices and policies*, Observatory Study Series No. 22, European Observatory on Health Systems and Policies, pp.255-287.

60. Palm W. and Baeten R. (2011), The quality and safety paradox in the patients' rights Directive, *Eur J Public Health*, 21 (3): 272-274.

61. Glinos and Baeten, 2006.

Republic of Ireland judged that they acquired new skills <sup>(62)</sup>. A Belgian hospital reported that they had to contact social services in a more systematic way and at an early stage before discharging Dutch patients and that this process impacted their attitudes toward discharge procedures for Belgian patients <sup>(63)</sup>.

Many projects allowing patients treatment abroad are embedded in a wider cooperation involving cooperation between health professionals, exchange of knowledge, joint training and education programs, exchange of professionals, experience and best practice. For instance, in the border region between the Netherlands, Belgium, and Germany, twice yearly, psychiatry students from four hospitals worked for three weeks in one of the other collaborating psychiatric institutions, and the hospitals alternate in organizing joint patient discussions every trimester <sup>(64)</sup>. Often, healthcare professionals work at both side of the border in two collaborating institutions and sometimes in jointly set up healthcare infrastructure. For instance, an Austrian emergency helicopter service at Suben Heliport (AT) is staffed by both German and Austrian personnel and transports patients to nearby hospitals on both sides of the border <sup>(65)</sup>.

Cross-border care can allow continuity for both patients and workers. For instance, an Austrian hospital has been under reconstruction for an extended period of time, during which Austrian doctors and nurses have worked at the German hospital, at a distance of 2 km, that received Austrian patients <sup>(66)</sup>. It can also ensure continuity for patients, during workers' actions, as demonstrated in the Republic of Ireland where the services of a hospital in Northern Ireland were purchased during a nurses strike <sup>(67)</sup>.

Medical doctors, in particular specialists providing highly specialist care, consider treating foreign patients as a way to strengthen their reputation and skills as well as to establish links with colleagues abroad <sup>(68)</sup>. The development of European reference networks between healthcare providers and centres of expertise in the Directive responds to this aspiration. The European reference networks also aim to become the focal points for medical training and research, information dissemination, and evaluation.

Cross-border care can increase competition between providers and incentivise them to perform better. It can put pressure on health professionals to treat more patients, and sometimes increasing competition is an underlying motive of purchasers contracting abroad. The increased competition also explains why referring health professionals from the sending country can be reluctant to cooperate; they perceive the foreign doctors as rivals <sup>(69)</sup>.

Competition can also play a role with regard to salaries, as illustrated by a cooperation at the Latvian-Estonian border. The Estonian hospital expressed an interest in employing medical doctors and nurses from the Latvian side, with 30% higher salaries on the Estonian side <sup>(70)</sup>.

When numbers are important, patient mobility can have an impact on employment opportunities and workload. In the receiving country, treatment of patients from abroad could in principle lead

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62. Hayes ABD, Gray AM. (2000) Laying Foundations: Cross-Border Co-operation in Health. The Cross-Border Acute Project, University of Ulster, Ulster.

63. Glinos et al., 2005.

64. Glinos, I. A.(2011), Cross-border collaboration, in Wismar et al., 2011, pp.217-254.

65. Glinos, 2011.

66. Glinos, 2011.

67. Hayes and Gray, 2000.

68. Glinos et al., 2005.

69. Glinos and Baeten, 2006.

70. Glinos and Baeten, 2006.

to expanding capacity and recruitment of additional staff. However, when there are supply shortages, as is the case in many countries for nurses, it could increase workload.

The sending country, on the other hand, can in principle face closure of specific services. However, health authorities usually prevent unwanted closure of domestic infrastructure. Conversely, large patient flows are often the result of deliberate policies to close domestic small health institutions in rural areas <sup>(71)</sup>.

Healthcare workers can finally be confronted by patients with expectations and attitudes that differ from domestic patients. They could furthermore be encouraged to acquire skills to communicate with the foreign patients including culture and language.

## **Case studies: national impact of the application of the patient mobility case law <sup>(72)</sup>**

This section analyses how Member States reacted to the judgments of the European Court of Justice (and national court rulings) with regard to reimbursement of care provided in another Member State and to the proposed Directive. Furthermore, it provides some examples on how actors involved in the national health care systems tried to take advantage of the newly created opportunities. The analysis is based on 5 case studies that reflect the great variety of healthcare systems that exists within the EU.

### **Belgium**

In Belgium, an explicit catalogue of benefits defines the tariffs of individual treatments, including reimbursement levels. Health providers and health insurers/sickness funds, define these prices and reimbursement tariffs in collective agreements. Health professionals can individually adhere to these agreements. However, and this is specific for Belgium, all care is reimbursed at the same level, whether or not professionals adhere to the agreements and providers who do not adhere have freedom of price setting. This makes the Belgian system the most “fit” to the rulings with regard to the reimbursement of care provided in another Member State, at least for ambulatory care.

This probably explains the promptness of the Belgian reaction to the CJEU case law, implementing the most important aspects. The National Institute for Health and Disability Insurance (NIHDI) issued already in 1998 a Circular, with the aim of giving an interpretation of CJEU case law <sup>(73)</sup>. Pursuant to this Circular, insured persons were entitled, subject to certain conditions but without prior authorisation, to be reimbursed for the costs of cross-border non-hospital care. Subsequent Circulars have progressively broadened this right, without however changing the approach in any fundamental way <sup>(74)</sup>. The currently applicable Circular states that non-hospital treatments in other Member States are reimbursed at the rates of the Belgian sickness insurance, provided that the conditions for assumption which exist in Belgium (e.g. authorisation) are fulfilled. Pharmaceutical products purchased in another Member State qualify

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71. Glinos and Baeten, 2006; Kiasuwa and Baeten, forthcoming.

72. The Polish case study has been carried out by Kinga Zdunek. The other case studies draw on Baeten et al, 2010. The Dutch case study has been updated based on information provided by Dr. Hans Vollaard and for the Belgian case study information was provided by Chris Segaert.

73. INAMI Circular nr. 98/258 of 05 August 1998.

74. The current Circular is the one of 16 March 2006, VI nr. 2006/117, complemented by one of 7 June 2008, extending the procedure without authorisation to the 3 EER States and Switzerland.

for reimbursement if its characteristics are identical to a pharmaceutical reimbursed in Belgium. The definition of hospital care was extended in 2006, and the Circular now lists several treatments that do not involve overnight stay but which require, “a hospital infrastructure with all the equipment which normally can be found in a hospital to provide them”<sup>(75)</sup>. Interestingly, this approach of assimilating care needing highly specialised equipment with hospital care was later adopted in the Directive.

For hospital care, prior authorisation is required. Belgian insured persons who go abroad with a E112 form and have to pay user charges are entitled to an additional reimbursement insofar as the level of cover (the amount publicly funded) under Belgian legislation is higher than the level of cover provided under the legislation of the State of treatment.

Whereas Belgium does not face important outflows of patients, the increasing inflow of patients from abroad has been the subject of heavy political debate. There is a concern that treatment of foreign patients could lead to increasing commercial behavior of the (mainly not for profit) domestic providers. The Federation of Enterprises in Belgium (FEB, *Fédération des entreprises de Belgique*) launched the debate on opening up the Belgian health care market to foreign patients, referring to the possibilities created by the CJEU rulings (De Greef and Thomaes, 2006)<sup>(76)</sup>.

This initiative had two consequences. First, a law has been adopted to change the rules for hospital funding, making a legal distinction between patients covered by the Belgian public system and (foreign) patients that are considered as “private” patients and to whom higher tariffs can be charged<sup>(77)</sup>. That way, hospitals have more incentives to attract foreign patients. “Private” patients were so far not known in the Belgian system, as all care providers in Belgium are integrated in the publicly funded system. The legitimation for the changed legislation was that the Belgian tariffs do not cover real costs. However, due to political disagreement and technical problems, this law was changed fundamentally afterwards, prior to its entry into force on 1 July 2010. The firm distinction between Belgian insured patients and foreign insured patients was deleted, one of the reasons being that it was not in line with EU-law. The current legal framework provides the possibility – under strict conditions - to install a higher (hospital) tariff to be charged to patients insured in non-EEA countries (but no legislative measures have been taken yet to make this possible).

Secondly, a series of public and not for profit hospitals, including several major university hospitals, created - at the initiative of the aforementioned FEB - an association called “Healthcare Belgium”, with the aim to promote Belgian health care abroad. This is the first time that hospitals, traditionally organised in umbrella organisations of the not-for-profit sector, organised themselves at the initiative of the national organisation of Belgian enterprises, which suggests a shift of approach, towards more commercial behaviour.

Because Belgium is confronted with important inflows of patients in some regions and in some health care facilities, Belgium was one of the countries that pleaded most, during the negotiations on the Directive, to include a provision allowing Member States to keep control over inflows. This finally resulted in Art 4,3° of the Directive, offering Member States the possibility to intervene when numbers would exceed available capacities (as discussed above).

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75. INAMI Circular VI nr. 2006/117 of 16 March 2006.

76. De Greef, S. and Thomaes, R. (2006), *Dare & Care: Internationalisering van de Belgische medische sector*, VBO, Brussels.

77. Loi du 4 juin 2007 modifiant la législation en vue de promouvoir la mobilité des patients, *Moniteur Belge* 25 July 2007.

Domestically, EU Directive facilitated the adoption, in the national convention for doctor fees, of the principle that doctors who acceded to the convention should also apply the agreed fees to EEA nationals. This non-discrimination clause will furthermore be incorporated in the Belgian health insurance Act <sup>(78)</sup>.

## Luxemburg

As Luxemburg was directly involved in the initial Kohll and Decker cases, the national authorities examined the consequences of the decisions promptly and thoroughly. The Union des Caisses de Maladies (UCM), the social security authority that was a party in these court cases, issued its opinion as early as May 1998. A new procedure was introduced whereby medical devices, pharmaceuticals, and out-patient care are reimbursed without prior authorization <sup>(79)</sup>. Interestingly, this procedure has not been incorporated into national legislation. Patients are informed about the possibility and the procedure in an official note that is attached to the negative reply on a request for a E112 form for ambulatory care <sup>(80)</sup>.

For assumption of the costs of hospital treatment abroad, prior authorisation remains required. Reimbursement extends to co-payments and co-insurance rates levied in the Member State where treatment is obtained, minus the co-payment charged under Luxembourg legislation <sup>(81)</sup>. Accommodation expenses and costs of an accompanying person can also be assumed under certain conditions <sup>(82)</sup>. Hospital care, however, is to be provided by a provider integrated in the statutory system of the country of care provision. This illustrates our assertion above that Member States want to keep control over the selection of the providers for which they do reimburse care abroad and try to channel patients away from the non-statutory providers abroad. Luxemburg justifies this by stating that the Luxemburg health insurance does not dispose of tariffs for hospital care, and that a lot of these treatments are even not available in Luxemburg and do not have a domestic tariff <sup>(83)</sup>. Reimbursement is consequently based on the official tariffs of the country of care provision. Only when the authorised treatment cannot be performed by a health care provider operating within the framework of the statutory social security system of the Member State of treatment, reimbursement is guaranteed according to Luxemburg tariffs <sup>(84)</sup>. Luxemburg argues that hospital treatment in Luxemburg is not a service provided against remuneration and thus implicitly suggests that hospital treatment does not fall under the scope of the free movement rules (Gouvernement Luxembourgeois, 2007).

The main result of the Kohll and Decker judgments for Luxemburg was however a major confrontation with its medical corps. In Luxemburg all health professionals are compulsorily submitted to collective agreements between the professional groups and the public health insurance system. The agreement system that is in place since 1930 requires the professionals to comply with imposed tariffs and other conditions. Following the Court rulings, the health insurance system was however obliged to reimburse costs of providers abroad, even though these providers were not bound by the official tariffs, or by any other constraint imposed by the agreement system. The Luxemburg medical profession perceived the opening of borders and

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78. De Mars B et al. (2011), Elective care for foreign patients: impact on the Belgian healthcare system, KCE Reports 169, p. 144.

79. Palm et al., 2000; Kieffer, 2003.

80. Written exchange, legal advisor, Caisse nationale de la santé Luxembourg (Gesondheetskeess), 04 August 2009.

81. Code des Assurances Sociales, Article 26 § 1.

82. Ibid, Article 28.

83. Kieffer, 2003.

84. Code des Assurances Sociales., Article 26.

the reimbursement of care provided by foreign providers not bound by the agreements as (reverse) discrimination. Consequently, negotiations to adapt the medical agreement were suspended. In particular, the discussions concerning the introduction of profiles of medical activity to trace abuse of the system were blocked. Furthermore, Luxembourg physicians were calling to abandon the compulsory agreement system. This was at stake in a doctors' strike 2000. In response, the government was forced to increase reimbursement fees on average 6.5%. The Court rulings thus seriously damaged the cooperation between the doctors and the public health insurers <sup>(85)</sup>.

The lack of domestic availability of certain treatments, combined with the fact that all patients live close to a border, make Luxembourg a country where the likelihood that patients will try to use the newly created possibilities for care abroad is very high. This explains why Luxembourg, even if it did implement the Court rulings to a large extent, tries to make the procedure based on the case law and the Directive less attractive than the procedure it traditionally applies based on the Regulation. Luxembourg basically makes the "Regulation" based procedure as attractive as possible financially, by providing reimbursement of additional costs. Also, the administrative handling of the procedure based on the Court rulings is less attractive. As stated by the president of the Union des Caisses de Maladies during a hearing in European Parliament, "there is the risk also, and a real risk, that such doctor's bills will not be given favourable treatment when presented in Luxembourg to the insurance organisations. That is why we recommend that patients should (...) use their E112 form" <sup>(86)</sup>." Similarly, the Luxembourg authorities seem to somewhat "hide" the existing Treaty based system. Patients are only informed about its possibilities when their application based on the Regulation based procedure failed.

### **Poland** <sup>(87)</sup>

Poland did so far not implement the CJEU case law, claiming that the rulings did not apply to its health care system <sup>(88)</sup>.

However, since its accession, Poland is confronted with practices of inappropriate use of the provisions of the Regulation. In principle, the Regulation provides for reimbursement of treatment that becomes medically necessary during a temporary stay abroad. This provision is used by Polish women living near the German border to give birth in German hospitals, where prices are substantially higher than in the Polish public system. The women do not pay anything, but Poland's National Health Fund is supposed to compensate Germany for the costs of the care received. Poland considered taking action against these practices <sup>(89)</sup>.

In the process of its adoption, the proposal for a Directive provoked an array of sometimes heavy reactions from different stakeholders pointing to the risks and opportunities of the Directive. In the end, Poland was one of the countries that voted in February 2011 against the Directive in the Council (together with Austria, Portugal and Romania). Some stakeholder groups successfully used the forthcoming implementation of the Directive to push for the realization of their aspirations.

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85. Kieffer, 2003.

86. Kieffer, R. (2005), The impact of Kohll and Decker rulings on national health care systems: the example from Luxembourg,. EPP-ED Public Hearing "Patient Mobility in the EU", European Parliament, Brussels, Thursday 3 March 2005, Transcripts. URL: [http://www.iese.edu/en/files/Health\\_Activities3\\_tcm4-14206.pdf](http://www.iese.edu/en/files/Health_Activities3_tcm4-14206.pdf) (accessed 28 June 2010).

87. This case study has been carried out by Kinga Zdunek.

88. Interview with a civil servant of the Polish Ministry of Health, 22 March 2012.

89. <http://wyborcza.pl/1,86871,5089182.html> and <http://www.krakowpost.com/article/761> (accessed 20 September 2012).

The proposal for a Directive was considered as a serious threat to the Polish health care system. It was not that much the funding for outpatient treatment sought abroad, which was expected to remain relatively low, that worried the authorities. It was estimated that 16% of the insured persons in the border areas would make use of the possibilities to go abroad for ambulatory care, which would cost approximately 180 mln PLN (43 mln €) <sup>(90)</sup>. It was however feared that by reimbursing care provided by non-contracted care providers abroad, citizens would also demand to be reimbursed for care by non-contracted domestic healthcare providers <sup>(91)</sup>. This was estimated to cost about 3,2 mld PLN (or 776 mln €), approximately 7% of the 2007 total income of Polish National Health Fund. Furthermore, it could affect the relationship between the insured citizens, the public payer, the statutory health insurance, and private health insurance <sup>(92)</sup>. The draft Directive was strongly criticized by previous Polish minister of health, Ewa Kopacz, who claimed in June 2010 that it could provoke the crash of Polish health budget. She argued that unlimited demand for healthcare would provoke uncontrolled flows of money and that it would negatively affect the contracts concluded with the national providers and reinforce the problem of waiting lists <sup>(93)</sup>.

In a reaction, the Polish Chamber of Physicians and Dentists (Naczelna Izba Lekarska) <sup>(94)</sup> expressed its satisfaction with the proposed Directive and hoped that free movement of patients between countries could be beneficial for the Polish healthcare system as well as for doctors and dentists <sup>(95)</sup>. A few weeks later, the Doctors' Trade Union of Poland <sup>(96)</sup> directed an open letter to Polish Prime Minister Donald Tusk titled, "There Is No Freedom Without Solidarity, There Is No Solidarity Without Freedom," in which they call upon the Prime Minister to adapt the Polish healthcare to the Directive, which would, according to them, force to implement measures which are awaited since many years such as:

The abolishment of administrative limits for funding healthcare services by the National Health Fund <sup>(97)</sup>;

- A fair valuation of health care services;

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90. Małgorzata Budzyńska (2008), *Transgraniczne świadczenie usług zdrowotnych w UE – stan obecny i perspektywy* Biuletyn Analiz. Nr 21. UKIE (Cross-border services in Healthcare in EU – current state and perspectives, governmental bulletin of analysis) [http://www.biuletyn.polskawue.gov.pl/HLP/banal.nsf/0/4C477FF5B31ADD5DC12575380038138C/\\$file/04\\_M.Budzy%C5%84ska\\_Opieka%20zdrowotna.pdf?Open](http://www.biuletyn.polskawue.gov.pl/HLP/banal.nsf/0/4C477FF5B31ADD5DC12575380038138C/$file/04_M.Budzy%C5%84ska_Opieka%20zdrowotna.pdf?Open) (accessed 28 February 2012).

91. Machalska, M. (2009), "Dans quelle mesure la nature du système des soins de santé favorise une Européanisation approfondie ?", Etude de la mobilité transfrontalière des patients au sein de l'Union Européenne, College of Europe, Mémoire présenté pour le Diplôme d'Etudes Européennes Approfondies, Bruges.

92. Małgorzata Budzyńska, 2008.

93. Press conference, Ewa Kopacz o leczeniu za granicą: swobodny przepływ pacjentów oznaczałby krach zdrowotnego budżetu (Ewa Kopacz comments the procedures of seeking the treatment abroad: free movement of patients would mean the crash of Polish health budget), Rynek Zdrowia, Warsaw 10<sup>th</sup> June 2010, Ministry of Health (<http://www.rynekzdrowia.pl/Polityka-zdrowotna/Ewa-Kopacz-o-leczeniu-za-granica-swobodny-przeplyw-pacjentow-oznaczałby-krach-zdrowotnego-budzetu,18819,14.html>) (accessed 28 August 2012).

94. A self-regulatory professional body.

95. Stanowisko Nr 38/10/P-IV Prezydium Naczelnej Rady Lekarskiej z dnia 11 czerwca 2010 w sprawie projektu dyrektywy w sprawie stosowania praw pacjenta w transgranicznej opiece zdrowotnej (The official position of the Polish Chamber of Physicians and Dentists from 11 June 2010 on the proposal for a Directive on cross-border care) [http://www.nil.org.pl/\\_data/assets/pdf\\_file/0016/6208/ps038-10-P-VI.pdf](http://www.nil.org.pl/_data/assets/pdf_file/0016/6208/ps038-10-P-VI.pdf) (accessed 28 February 2012).

96. Grouping the employed doctors, working in the public healthcare sector.

97. The NHF finances health services according to its financial resources

- A realistic estimation of the financial resources needed to be spent on health to cover the basket of guaranteed health services;
- Renounce to “offer competitions” organized by the National Health Fund, which are a potential platform for corruption and distortion of competition, by the arbitrary choice of providers;
- The implementation of an efficient registry system for medical services and control of the validity of their license by the National Health Fund <sup>(98)</sup>.

Similarly, in an open letter directed to Polish Members of European Parliament, representatives of patient’s and doctor’s organizations <sup>(99)</sup> tried to convince the decision makers that free movement of patients will be beneficial for both Polish healthcare system and health workforce <sup>(100)</sup>.

Interestingly, the adoption of the Directive provoked heated discussions on abortion. Abortion is prohibited in Poland except in the following cases: the woman's life or health is endangered; the pregnancy is a result of a criminal act on the proviso that it doesn't exceed the 12<sup>th</sup> week of pregnancy; or when the fetus is seriously malformed <sup>(101)</sup>. In all those cases it is publicly reimbursed. The Polish Federation for Woman and Family Planning (FEDERA) claimed that in practice doctors are extending the time of procedures, what blocks access to abortion, even in cases where it is legally allowed <sup>(102)</sup>. FEDERA argued that the Directive could facilitate access to abortion in other Member States and hence ensure real access to services which are theoretically guaranteed in the family planning law. They expressed the hope that the Directive will stimulate the main public payer to enable Polish woman to exercise the right to abortion domestically to avoid an outflow of patients <sup>(103)</sup>.

In May 2010 the Medical Tourism Chamber of Commerce (Izba Gospodarcza Turystyki Medycznej) called on the Minister of Economy to recognise medical tourism as an export

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98. *Nie ma wolności bez solidarności, nie ma solidarności bez wolności!* List otwarty do Premiera Donalda Tuska, 8 July 2010 (There is no freedom without solidarity, there is no solidarity without freedom. Open letter to Prime Minister Donald Tusk) [http://www.ozzl.org.pl/images/stories/Nie\\_masolidarnosci\\_bez\\_wolnoci.pdf](http://www.ozzl.org.pl/images/stories/Nie_masolidarnosci_bez_wolnoci.pdf) (accessed 28 February 2012).
99. Polish Chamber of Physicians and Dentists, Doctors’ Trade Union of Poland, Adam Smith Centre, Institute of Patient Rights and Health Education, Federation of Polish Patients, National Association of Non-public Hospitals.
100. Piszą listy, bo chcą otwartych granic dla leczenia, Rynek Zdrowia, (letters pleading for the borders to be opened for treatment) 30.09.2010 <http://www.rynekzdrowia.pl/Prawo/Pisza-listy-bo-chca-otwartych-granic-dla-leczenia,102211,2.html> (accessed 28 February 2012).
101. Ustawa o planowaniu rodziny, ochronie płodu ludzkiego i warunkach dopuszczalności przerywania ciąży z dnia 7 stycznia 1993 r. (Family Planning, protection of human fetus and abortion law) <http://mopr.szczecin.pl/dokumenty/ustawa-o-planowaniu-rodziny.pdf> (accessed 28 February 2012).
102. Dyrektywa UE może umożliwić Polakom korzystanie z legalnej aborcji ? Rynek Zdrowia, (Can the Directive allow Polish women to exercise the right for legal abortion?) 12 May 2011 <http://www.rynekzdrowia.pl/Polityka-zdrowotna/Dyrektywa-UE-moze-umozliwic-Polkom-korzystanie-z-legalnej-aborcji,108927,14,0.html> (accessed 28 February 2012).
103. Nowa Dyrektywa unijna o transgranicznej opiece zdrowotnej a dostęp kobiet do legalnej aborcji, Warszawa, 12 May 2011.(FEDERA stand: The New EU directive on cross-border Healthcare and the right to legal abortion) [http://federa.org.pl/dokumenty\\_pdf/prawa\\_pacjenta/dyrektywa\\_transgraniczna\\_notatka.pdf](http://federa.org.pl/dokumenty_pdf/prawa_pacjenta/dyrektywa_transgraniczna_notatka.pdf) (accessed 28 February 2012).

specialty, arguing that the Directive is a milestone in medical tourism development <sup>(104)</sup>. As a result, medical tourism was included in the project “Promotion of the Polish economy on international markets” co-financed by European Regional Development Fund <sup>(105)</sup>. Currently, important investments are made to receive foreign patients. For example, the company Dalimex is building a medical facility offering medical services particularly aimed at foreign patients in Lublin. This investment is strongly linked with the newly created airport in Lublin <sup>(106)</sup>.

The Directive encourages cross-border cooperation in border regions. In this context, it is relevant to mention that at the end of 2011, a cross-border framework agreement on emergency medical services was signed between Poland and Germany. Interestingly, this agreement was inspired by a similar agreement between Germany and France (which in turn was inspired by an agreement between France and Belgium). The agreement covers the cross-border areas of 3 Polish regions and aims to provide emergency medical services. The services will be provided by the nearest emergency unit, regardless of the location of the accident <sup>(107)</sup>. The debate on such cooperation started in 2002 <sup>(108)</sup>.

The public interest in the implementation process of the Directive seems low. Interest groups are much more involved in the dialogue with policy makers <sup>(109)</sup>.

## The Netherlands

The case of the Netherlands is an interesting one for more than one reason. First, two landmark CJEU rulings (*Geraets-Smits and Peerbooms* and *Müller-Fauré and Van Riet*) have their origin in this Member State, which, as will be demonstrated below, went to great effort to comply with the principles stemming from these judgments. Second, the country has (had) a problem with waiting lists, which, being a major push factor for the cross-border movements of patients, might help to explain the abundance of national court cases addressing the right to seek health care outside the national territory. Thirdly, the Netherlands held a unique position among other Member States in that about 30 % of the population were not compulsorily insured for health care and were expected to take out private health insurance. As a result, this category of persons did not fall within the ambit of former Regulation 1408/71 (now Regulation 883/04). This situation has come to an end on 1 January 2006, with the entry into force of the new Health

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104. Zachodni emeryci leczą się w Polsce bo tu jest tanio, Rynek Zdrowia, (Western Pensioners are treated in Poland because it is cheaper) 7 May 2010, <http://www.rynekzdrowia.pl/Finanse-i-zarzadzanie/Zachodni-emeryci-lecza-sie-w-Polsce-bo-tu-jest-tanio,17953,1.html>

105. Promotion of Poland as an attractive and business-friendly country with a huge investment potential, Ministry of Economy: <http://www.forum-ekonomiczne.pl/public/upload/ibrowser/InwestujMedycyna.pdf>

106. Dalimex przyspiesza z budową kompleksu przy ul. Obywatelskiej, Dziennik Wschodni, 15 September 2011 (Dalimex speeds up the construction of facility on Obywatelska Street) <http://www.dziennikwschodni.pl/apps/pbcs.dll/article?AID=/20110915/LUBLIN/504119237>

107. Komunikat prasowy MZ: Minister Zdrowia Bartosz Arłukowicz oraz Federalny Minister Zdrowia Daniel Bahr podpisali Umowę ramową między Rzeczpospolitą Polską a Republiką Federalną Niemiec o współpracy transgranicznej w ratownictwie medycznym (press release: Minister of Health Bartosz Arłukowicz and Federal Minister of Health Daniel Bahr signed the Framework agreement on cross-border cooperation in emergency cases between Poland and Germany) <http://www.mz.gov.pl/wwwmz/index?mr=&ms=&ml=pl&mi=&mx=0&mt=&my=&ma=18981>

108. Odpowiedź podsekretarza stanu w Ministerstwie Zdrowia - z upoważnienia ministra - na interpelację nr 5232 w sprawie polsko-niemieckiej współpracy w dziedzinie ochrony zdrowia w obszarze przygranicznym, 20 October 2008 (Reply of undersecretary of state in Ministry of Health – act with Minister authorization – on parliamentary question Nr 5232 on Polish-German cooperation on Healthcare in cross-border areas) <http://orka2.sejm.gov.pl/IZ6.nsf/main/566A81C5>

109. Interview with a civil servant of the Polish Ministry of Health, 22 March 2012.

Insurance Act<sup>(110)</sup>, pursuant to which the entire population is obliged to take out sickness insurance with one of the competing private health insurance companies. The distinction between the compulsorily insured with a sickness fund and privately insured was thus abandoned. From the outset of the legislative process leading to the 2006 reform, due attention has been paid to the compatibility of the future scheme with Community internal market requirements.

According to the Dutch interpretation of the initial *Kohll and Decker* rulings in 1998, the Dutch system of contracting was in conformity with EU law. Health insurers could conclude contracts with foreign providers if there is a need for it, while they may not refuse to contract with a provider solely on the grounds that the provider is located in another Member State. In addition, no distinction could be made between domestic and foreign non-contracted providers in those cases where patients had the right to go to non-contracted providers with prior authorisation from their insurer<sup>(111)</sup>. In 2002, sickness funds were advised to conclude contracts with foreign providers if they planned to systematically offer their members access to cross-border health care<sup>(112)</sup>. In a later stage, this advice was incorporated in law. Again, as was the case in Luxemburg, the concerned foreign hospitals must provide care within the framework of the social security system applicable in the country of care provision<sup>(113)</sup>. The justification given for this requirement is to ensure at least the quality level deemed in the state of treatment is acceptable<sup>(114)</sup>. The Dutch practice to contract with foreign providers was not only inspired by the Court rulings. The domestic political pressure to address the waiting times certainly pushed the Netherlands to look for appropriate answers by offering its citizens treatment abroad<sup>(115)</sup>.

After the *Geraets-Smits and Peerbooms* and *Müller-Fauré and Van Riet* Court rulings it became clear that the approach of contracting abroad had to be complemented by a second approach of pure reimbursement of care. The traditional Dutch approach already embraced a dual system with benefits in kind for sickness fund patients and reimbursement system for privately insured patients. Reimbursing care abroad was thus not completely alien to the system and privately insured under the so-called WTZ framework had already obtained the right to receive reimbursement without prior authorisation for extramural care<sup>(116)</sup>.

The possibility has been created from 2005 onwards also for sickness fund patients to obtain care from a provider which is not contracted by the sickness fund, at home or abroad, under certain conditions<sup>(117)</sup>. For intramural care from a non-contracted care provider, prior authorisation remained necessary<sup>(118)</sup>. Following several national court rulings, it was furthermore stipulated that that hospital treatment abroad could no longer be refused if the patient could not be treated in a contracted hospital within waiting times corresponding to the Dutch norms defining acceptable waiting times (Treek norms)<sup>(119)</sup>.

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110. Zorgverzekeringswet Act of 16 June 2005, *Staatsblad* 2005, 358.

111. Ziekenfondsraad (1998), Grensoverschrijdende zorg: arresten Decker en Kohll, Aan de uitvoeringsorganen ZFW en AWBZ, Circulairnummer ZFW/38/98, AWBZ/31/98, 15 July 1998.

112. CVZ, Circulaire 02/021 met betrekking tot grensoverschrijdende zorg, 02 May 2002.

113. Ziekenfondswet, Article 1 as amended by the Law of 9 December 2004.

114. Zorgverzekeringswet, *Kamerstukken II*, 2003-04, nr. 29.763, 3, 80.

115. Glinos *et al.*, 2005.

116. Email communication from Dr. Hans Vollaard, 13 March 2012.

117. Arrangement of 16 August 2005 on the implementation of Article 9 ZFW and Article 10 AWBZ, Article 2 § 1.

118. Ziekenfondswet, Article 3 § 1 and 9, §3 as amended by the Law of 9 December 2004.

119. CVZ, Tweede aanvullende circulaire in zake arrest Müller-Fauré en Van riet n.a.v. uitspraken Centrale Raad van Beroep d.d. 18 juni 2004, Circulaire 04/45, College voor zorgverzekeringen, Diemen, 1 september 2004 [http://www.cvz.nl/resources/circ0445\\_tcm13-9078.pdf](http://www.cvz.nl/resources/circ0445_tcm13-9078.pdf)

As of 1 January 2006, a new sickness insurance system has been introduced. The entire population is now obliged to take out sickness insurance with one of the competing private health insurance companies and contains a uniform arrangement of insured persons' entitlements. All insured persons have henceforth a choice between a so-called restitution policy: a benefit in kind policy or a combination of both. Based on the health care reform sickness funds are furthermore no longer obliged to engage contracts with all domestic care institutions, such as hospitals.

If the insured person has opted for a restitution policy, (s)he can turn to any provider of health care anywhere in the world and is entitled to the reimbursement of the costs incurred<sup>(120)</sup>. However, the health insurer is not obliged to reimburse costs which are higher than what can be deemed reasonably appropriate in the Dutch market circumstances<sup>(121)</sup>.

In principle, the insured person who has opted for benefits in kind policy has to turn to those providers of care – either domestic or foreign – whom are contracted by the health insurer. He has however the right to go to a provider – either domestic or foreign – who is not contracted by the health insurer and be reimbursed an amount which is determined by the insurer in its policy (full or partial)<sup>(122)</sup>. Noticeably, this right has been incorporated in order to comply with the Court rulings and create new rights not only for patients searching for treatment abroad, but also for patients that are treated in the domestic system<sup>(123)</sup>. Interesting furthermore is that the law does not stipulate a minimum level of assumption: the explanatory statement to the health insurance law (ZVW) confines itself to stating that the level of assumption should not be such as to create a *de facto* obstacle to the provision of care in another Member State<sup>(124)</sup>. It does not however, really seem to aim to encourage patients to make use of this procedure.

It follows from the above that under the new Dutch scheme, according to which the authorization requirement is abolished altogether, the distinction between intramural and extramural care is no longer relevant. Furthermore, there is no longer a need to interpret the concept of undue delay.

The Dutch government and parliament did not see a cross-border healthcare Directive necessary for the Netherlands itself. They considered (and still consider) the Health Insurance Act of 2006 as fully consistent with the EU case law concerning cross-border healthcare. They were however in favour for a Directive to oblige those member states that did not (fully) comply with the EU case law yet. However, they resisted the inclusion of long-term care in the directive, and cooperation with an obligatory nature concerning ehealth or quality of care, expressing concerns about "creeping" European interference on healthcare issues. They favoured transparency in quality and pricing, allowing patients to make a better choice<sup>(125)</sup>.

The Dutch authorities consider that the implementation of the Directive would only require adaptations to the national legislation with regard to the establishment of the National Contact points and the recognition of medical prescriptions issued in another Member State<sup>(126)</sup>. Notable is that Dutch public authorities addressed a proposal to the Polish Ministry of Health, on the provision of healthcare in Poland under the Directive to Polish citizens who migrated to the

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120. Zorgverzekeringswet, ZVW Act of 16 June 2005, *Staatsblad* 2005, 358, Article 11.

121. Besluit zorgverzekering, Article 2.2 § 2.

122. Zorgverzekeringswet, Article 13.

123. Tweede Kamer, 2002-2003, URL: <http://www.st-ab.nl/wetzvwmvt.htm> (accessed 28 June 2010).

124. Kamerstukken II, 2003-04, nr. 29.763, 3, 31 and 110.

125. Email communication from Dr. Hans Vollaard 13 March 2012.

126. <http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2012/05/30/beantwoording-kamervragen-over-europese-richtlijn-patientenrechten-bij-grensoverschrijdende-zorg.html>

Netherlands (<sup>127</sup>).

Concluding, the Netherlands undoubtedly invested the most energy in making its system EU proof. The planned overhaul of its health care system ensured that the marginal costs of implementing the case law - and of making its system “fit” - were considerably lower. Strikingly, the risk for an exodus of patients due to waiting lists did not keep the Netherlands from implementing the Court rulings. Contrary to other countries confronted with long waiting lists and political pressure to address them, there was no domestic parallel sector in the Netherlands of care providers not integrated in the publicly funded system which could have absorbed the waiting list patients (<sup>128</sup>). Therefore, the Netherlands had to turn to foreign countries for extra capacity. Furthermore, the Netherlands needed a larger pool of providers in order to be able to create more competition as an important element of the general reform of the system. The Court rulings were supportive for the domestic policy options: the EU internal market approach fitted well with the rationale of the health care reform in the Netherlands, aiming to create more competition in the system. Also, the Dutch position to compel Member States with the Directive and to push for international transparency in quality and pricing, is in line with the Dutch domestic health care policies, where increasing competition between providers and purchasers and patient choice are high on the political agenda.

The case of the Netherlands also provides some examples of domestic impact of the implementation of the free movement principles. First, the Dutch sickness funds selectively concluded contracts with hospitals abroad at a moment they could not yet selectively contract hospitals domestically. Sickness funds thus successfully used the case law to push through their own aspirations while public authorities found additional legitimacy in the Court rulings for domestic reforms. Secondly, the right for patients with a benefit in kind policy to opt for reimbursement of care was created not only for patients searching for treatment abroad, but also for patients treated in the domestic healthcare system.

## **The United Kingdom**

The initial position of the authorities in the United Kingdom was that the principles on which the Kohll and Decker rulings are based do not apply to the National Health Service. Nevertheless, in practice, regional authorities reimbursed patients in cases which could potentially have ended up before the CJEU, in order to avoid possible precedents (<sup>129</sup>).

After the *Geraets-Smits and Peerbooms* rulings of 2001, defining that in-kind benefit systems fell within the scope of the free movement of services, and that if a Member State could not provide a treatment “without undue delay,” patients had the right to seek treatment abroad, the then secretary of State, Alan Milburn declared that the decision was of great importance and required the NHS to re-examine its practice on the funding of overseas treatment. This was done after initial suggestions that the *Peerbooms* ruling was of limited significance. Montgomery suggests that the Court rulings and political pressure to address waiting lists were used by the government and reinforced its determination to shorten waiting times, make the NHS more businesslike and increase patient choice (<sup>130</sup>). As a consequence, since 2002, the UK allows local health commissioners in England to commission treatments from hospitals within the EU for the

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127. Interview with civil servant of Polish Ministry of Health 22 March 2012.

128. Glinos, I. A., Baeten, R. and Maarse, H., (2010), Purchasing health services abroad: Practices of cross-border contracting and patient mobility in six European countries, in *Health Policy*, Volume 95, Issue 2, pp. 103-112.

129. Palm et al., 2000

130. Montgomery, J. (2005), Impact of EU Law on English Healthcare Law, in Dougan, M. and Spaventa, E. *Social welfare and EU law, essays in European Law*, HART Publishing, Oxford and Portland.

treatment of NHS patients. Since 2004 however, patients were no longer sent through this procedure. It is argued that the procedure was actually set up mainly to put pressure on domestic private providers to lower their prices when contracting with the NHS, which was also part of the NHS reform<sup>(131)</sup>.

Following the *Watts* case, which concerned a UK citizen, the Department of Health issued an advice to local health care commissioners in England on handling requests for care in other European countries, with detailed guidance<sup>(132)</sup>. This advice can be seen as a reaction to the Court criticism that the NHS lacked clear criteria for managing its prior authorisation procedures. It allows for the funding of planned hospital care abroad after prior authorisation, when care cannot be provided without undue delay in the NHS, either through the Regulation based procedure or the procedure based on the Treaty provisions on the free movement. It suggests that the procedure based on the case law is in the interest of the patient only when the treating hospital is not integrated in the public system of the country of treatment.

For ambulatory care, the advice distinguished between services for which it is not necessary for local health care commissioners to put in place prior authorisation; processes such as GP consultations, optometry, pharmacy, and some dental treatments. By contrast, for services whose complexity and cost make them more similar to services provided in hospitals, the requirement for prior authorisation may be justified. The latter might include services subject to referral or which are parts of complex patient pathways. The advice warns that particular care is needed for handling requests for dental care abroad since it is difficult to establish after the event whether any treatment undertaken abroad was clinically necessary and therefore of a sort that would have been provided by the NHS. It is suggested to limit reimbursement to the average cost paid by commissioners for the equivalent NHS course of treatment.

In early 2010, the Department of Health published a new advice and amendments to the NHS Act to clarify the obligations of the Primary Care Trusts with regard to the authorisation and reimbursement aspects of patient mobility and cross-border healthcare, along with Directions by the Secretary of State and updated guidance providing advice and support<sup>(133)</sup>. These rules were drafted in the light of the imminent adoption of the proposal for a Directive, but were also in line with plans to turn some NHS targets, including increasing patient choice into enforceable patient entitlements. One of the biggest issues in England, as in most NHS systems, is how to determine domestic costs. 60% of the healthcare is not covered by a tariff and prices are subject to negotiations and vary geographically. Furthermore, NHS tariffs may cover a package of care, rather than just one procedure, which means costs may need to be “unbundled”<sup>(134)</sup>. According to the 2010 advice, where there is no tariff, a price will need to be calculated, and average costs which can be shown to have been reasonably calculated may be used. If commissioners are however unable to work out an objective cost, or appropriately decode EU receipts for health care, they may face the prospect of reimbursing the full costs of treatment

Compared to the 2007 advice, these documents narrow the definition of health services that can be assimilated to hospital care and for which prior authorisation thus will be required. They now

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131. Glinos et al., 2006.

132. Department of Health (2007), Patient Mobility. Advice to Local Healthcare Commissioners on Handling Requests for Hospital Care in other European Countries following the ECJ's Judgement in the *Watts* case, London, 16 April 2007.

133. Department of Health, 2010; [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_115256](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256) (accessed 02 August 2012).

134. Zanon E. (2012), Health care across borders: Implications of the EU Directive on cross-border health care for the English NHS. *Eurohealth* 2012;17(2-3):34-36

only include medical and dental treatment that involves general anesthesia, epidural anesthesia or intravenously administered sedation, or a service whose provision involves the use of specialised or cost-intensive medical infrastructure or medical equipment.

The documents also provide guidance for the treatment of patients coming from abroad. Lack of service capacity is considered to be the strongest ground for refusing a request for treatment of a non-UK patient. Furthermore, providers who receive requests from EEA patients under the Treaty based route should assume that the patients wish to be treated in the same way as an NHS patient, unless they specifically state that they wish to be treated privately. Providers contracted to the NHS cannot increase the price to an EEA patient simply because they are not an NHS patient as this would be discriminatory under EU law. Providers may, however, make additional charges for services that are not a standard part of the normal treatment arrangements for NHS patients. Patients who specify from the outset that they wish to be treated privately may be charged at the equivalent cost to private patients in England.

It is furthermore argued that for the NHS, it will be a key issue for commissioners to have a clear list of the types of healthcare they do and do not provide. Indeed, NHS systems like the English one do not have a 'basket' of health care to which all patients are entitled. Instead, decisions on eligibility are made locally, taking into account the circumstances of the individual patient (<sup>135</sup>).

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135. Ibid.

## Conclusions

This paper looked at the EU codification and the national implementation of the CJEU case law with regard to patient mobility and analysed the potential impact of the free movement rules and increased patient mobility on health systems, patients and workers.

The fear that legal uncertainty might lead to creeping deregulation and the concern to lose the steering capacity over the healthcare systems was one of the main drivers behind the Directive on Patients' Rights in Cross-border Healthcare. The Directive succeeds in providing legal certainty on the interpretation of important aspects of the Court rulings with regard to patient mobility. This includes the circumstances under which healthcare payers can make the reimbursement of care provided abroad subject to prior authorisation. However, the Directive carefully avoids addressing the application of the free movement principles beyond the issue of patient mobility, to deal with providers wishing to temporarily provide services or permanently establish in another Member State and the potential deregulatory effect thereof. Furthermore, given the lines drawn by the Court, a secondary legislation instrument proves to be unable to address some of the major concerns that drove the policy debate since the initial Court rulings. In particular, this concerns the reimbursement of care provided by non-contracted providers abroad, and possibly also at home. When compared to the initial Commission proposal, the final version of the Directive clearly better preserves the steering capacity of the Member States.

The array of potential impact of the internal market rules and increased patient mobility is very wide, stemming from a number of factors: different incentives in different healthcare systems; different characteristics of the arrangements providing access to care abroad; and further differences between 'sending' and 'receiving' healthcare systems.

For the healthcare systems, the obligation to reimburse, under the case law and the Directive, care from non-contracted providers abroad is clearly one of the most sensitive issues. As illustrated by the fierce Polish opposition to the then draft Directive, it is feared that Member States would come under pressure to also have to reimburse care from non-contracted providers at home. The case studies show that Member States try to keep some grip on the selection of providers abroad, e.g. by requiring that they are integrated in the statutory system of the Member State of care provision and where the domestic system is based on benefits in kind, the attempt is to channel patients abroad through contracted providers. Also, the procedure based on the Regulation is made more attractive. Some Member States with a benefit in kind system (the Netherlands, but also Germany) who decided to reimburse care from providers abroad, indeed also domestically reimbursed care of non-contracted providers under the same conditions. However, they seem to have made these possibilities less attractive than treatment by contracted providers.

When assessing the financial impact on health systems, we found that the cost per health service should not be higher for care provided based on the Directive. However, cross-border care can increase the volume of care to be funded by the healthcare system, when care providers abroad have financial incentives to increase the delivery of care services per patient or when patients go abroad for treatments not timely available at home. Also, with patients going abroad, the available budgets also flow out of the country. This can potentially (for countries with large outflows of patients) reduce the available budgets for investing in the domestic system.

Cross-border care can encourage improvements in the domestic system when (potentially) large outflows of patients reveal weaknesses in domestic systems, in particular on quality and timely access, which are badly regarded by the population. This is illustrated in the Polish case study where some stakeholders used the negotiations on Directive to plead for improvements in the

domestic system. Cross-border care can be used to breach monopolies of domestic providers and to encourage them to perform better. This can put pressure on health workers.

As was illustrated in some of the case studies, domestic actors draw legitimacy from the jurisprudence to further their aspirations and to exit the domestic social system. The case law was used by insurers to acquire new instruments to compete and by providers to acquire more possibilities for commercial behaviour and price increases. Private, commercial providers also reinforced their positions. Examples include:

- threats to question the domestic contracting system, with as a result that compliance has been assured by a strong (and effective) increase of doctor's fees (Luxemburg);
- setting up of a broad coalition pushing for commercialisation of hospital services (Belgium);
- selective contracting by sickness funds in the Netherlands;
- set up and promote domestic healthcare facilities for export (Belgium and Poland).

Also, public authorities make use of the jurisprudence to support domestic reform agendas, such as addressing waiting times, make the health care system more businesslike and increase patient choice (UK) or the introduction of more competition in the system (the Netherlands).

The impact of cross-border care on patients' access to care is positive for the patient who goes abroad: he has closer, quicker or more access to care and can choose between more providers. However, the procedure for cross-border care based on the Directive is in most of these respects less beneficial than the procedure based on the Regulation on the coordination of the social security systems. The Directive provides fewer guarantees than Regulation 883/04 with regard to the financial aspects of access to care. This is also why the Directive gives priority to the reimbursement based on the Regulation when the patient has the right to treatment abroad according to the latter. Furthermore, the Directive does not create new rights for treatment abroad for patients confronted with long waiting lists at home which did not yet exist under the Regulation. However, patients can, through the Directive, acquire access to care that is closer to home, but in another Member State and also provider choice increases.

Cross-border care can also have an impact on access to care for patients who stay in their home system. Large net outflows of patients can lead to closure of domestic infrastructure, which might decrease local access to care for the patients who do not go abroad. In the host system, cross-border care can lead to capacity problems. Both scenarios' can have an impact on workers; it can create employment opportunities, but also increase workload or provoke a loss of employment. Furthermore, the case law seems to have encouraged health authorities to address waiting times. Member States confronted with long waiting lists try to reduce the demand for exit, e.g. through contracting the domestic commercial sector.

The impact of cross-border care on equity in access to care was found to be negative. Socially advantaged groups are likely to make more use of the possibilities to receive care abroad. Also, access to cross-border care is easier for patients who are fit to travel and who have no co-morbidity. Cross-border care can incentivise providers to select the easiest to treat patients, whereas they usually are not allowed to do so under the domestic system.

Continuity of care can be problematic for patients treated abroad, which the Directive only partially succeeds in addressing. Furthermore, the Directive does not provide robust guarantees with regard to the quality and safety of cross-border care and thus patients will have to rely on the quality frameworks of the country of care provision.

Finally, cross-border care can also have an impact on quality of care for patients who stay at home. It can put pressure on established arrangements, such as the GP gatekeeper system in the sending healthcare system, but can also offer opportunities for mutual learning, which can have a positive effect on quality of care and can provide training opportunities for workers.