SIMULATION ON THE EU CROSS-BORDER CARE DIRECTIVE

Brussels, 24 November 2011

FINAL REPORT

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Executive Summary

The Directive on the application of PatientsôRights in Cross-Border Healthcare has proved to be one of the most controversial pieces of European healthcare legislation in recent years, and many significant questions remain on its possible impact.

At the end of 2011, different stakeholder groups from six countries participated in a simulation to tackle the key issues raised by the Directive, discussing how they would respond in reality to these situations. The aim was to build a stronger understanding of the likely future impact of the Directive and to forecast potential issues as the Directive is put into practice.

The simulation paints a picture of the Directive that differs from the discussions that dominated in the run up to its adoption into European law. In some areas there was a striking consensus, which suggests that the Directive will bring substantial legal certainty. Perhaps surprisingly this includes areas where tensions in implementation may have been predicted such as on the articulation between the Directive and Regulation 883/04, but where, in practice, pragmatic solutions are being found.

For other issues, there was a large consensus within stakeholder groups but equally large divergent approaches between stakeholder groups. For instance, whereas purchasers and public authorities made clear that for the care to be reimbursed, it should comply with the conditions as defined by the patients Member State, the providers were equally clear that they would not adapt procedures or processes to the conditions of the foreign health insurer or payer of the cross border patient. As long as the number of cross border patients remains low this potential clash is expected to be solved pragmatically on a case-by-case basis.

Some areas within the Directive, in particular the ones which are the result of heavy political wrangling, were not seen to have much relevance at the practical level. This includes the provisions allowing Member States under certain conditions to prevent high inflows of patients. It was clear from the simulation that few if any Member States have means of following the number of foreign patients using health care in their country, let alone a system for regulating that flow, and thus it is difficult to see how these theoretical protections could be translated into practice.

However, in other areas the implementation of the Directive may have an important and largely unpredicted impact on domestic health policy, driving towards greater clarity on the definition of the benefit package for citizens and on the provision of information to patients.

Yet, the most striking set of conclusions from the simulation relates to the potential burden for patients travelling under the Directive. Patients will bear the responsibility for many of the elements involved in accessing planned treatment across borders. The responsibility to find information on potential treatments, the burden of proof in demonstrating to insurers that the treatment has been carried out and the responsibility to submit the correct documentation clearly was seen to lie with patients

Patients who go abroad for treatment under the directive with public cover, in many ways are treated as if they are not part of the social system. Providers do not comply with the tariffs agreed within the Member State of treatment as they do for patients receiving care under the regulation. They freely set their tariffs and request supplements as they would for domestic

private patients. Patients in effect are perceived as consumers shopping around with their óvoucherô.

Without an institutionalized relationship between the payer and the provider in which the provider commits to comply with certain conditions and the payer assumes responsibility for the care provided, the patient is likely to be left to defend his or her own interests. Within the simulation National contact points and other institutions seemed unable to bridge this gap or to have any certainty on what they might do and how they might do it.

Given the size of the burden for patients it is therefore likely that the Directive will only be used when there is really no alternative, better-managed option to receive the treatment, or by patients who do not understand the responsibility on their shoulders and the risks they take.

Introduction

I Political and policy background ï the Directive on PatientsôRights

The Directive on the application of PatientsôRights in Cross-border Healthcare has proved to be one of the most controversial pieces of European healthcare legislation in recent years. Although the costs for people crossing borders for planned healthcare is estimated to be less than one per cent of health budgets annually, it took from July 2008 until March 2011 to agree on the legislative proposal. The debate itself on the correct legislative framework for this kind of cross-border healthcare began in earnest at the end of the 1990s.

In part, the controversy arises from its long history. The legislation has not been drafted in a vacuum, but has had to align previous Court of Justice of the European Union (CJEU) rulings on cross-border care and run alongside Regulation 883/04 (which substitutes Regulation No 1408/71 on the coordination of social security schemes). After the creation of the internal market, a number of cases on cross-border care were brought before the European Court of Justice (ECJ): Kohll and Decker (C-158/96, 1998), Geraets-Smits and Peerbooms (C-157/99, 2001), Muller Fauré and Van Riet (C-385/99, 2003) and Watts (2006) to name but a few. In them, the ECJ emphasized the applicability of the fundamental freedoms, enshrined within the EC Treaty, for statutory health care services. The result was a lack of legal clarity, but one in which the ECJ had made a number of important judgements that have shaped subsequent options for future legislation. The choice has therefore not been between perfect and imperfect legislation but between an imperfect legal framework and no framework at all.

In addition, the Directive touches on a number of issues that have an impact beyond cross-border healthcare *per se*. In looking at improving clarity for patients crossing borders the Directive raises questions on eHealth, on patient safety and quality, on waiting lists and on rare diseases, amongst others. The role of EU legislation and its potential expansion into areas more traditionally covered by Member States under the subsidiarity principle mean that it could be argued that the Directive is more significant for the door it pushes open to EU policy makers on broader health policy questions than for the regulation of planned cross-border movement itself.

Member States now have until October 2013 to transpose the Directive into national legislation.

II Why hold a cross-border healthcare simulation?

Beyond the heat of the political debate, many significant questions remain on the possible impact of the Directive and how to implement it. Although there was no shortage of voices in the debates in the run up to the Directiveôs adoption, there have been relatively few attempts to understand the impact of the Directive in practice and how key players in the health system (from patients to health insurers to providers and public authorities) are likely to react to its provisions.

The aim of the cross-border healthcare simulation has been to do just that: to build a stronger understanding of the likely future impact of the Directive and to forecast potential issues as the Directive is put into practice. The intention has been that those taking part and the EU health policy community as a whole will gain new insights into how different countries and stakeholders are approaching the implementation of the Directive as well as into different ways of resolving potential bottlenecks. It is hoped that this will feed into EU level debates on implementing the Directive.

The Simulation Approach

I Scope

The simulation covered six EU countries: Belgium, France, Germany, The Netherlands, Luxembourg and Spain. The countries were chosen because they are a cluster of countries with relatively important movements of patients between them. Most of them share borders and languages and several arrangements for cross-border care have been set up between them. Spain occupies a particular place in the cluster, as it provides care to many long-term residents and tourists from the more northern countries and it is also confronted with these long-term residents requesting to go back to their country of origin for treatment. The country mix was also designed to reflect different health systems and cultures, from health insurance to ñNHS-typeò models.

Using three case studies written specifically for the event, different stakeholder groups from the six invited countries worked together on key issues raised by the Directive (including information for patients, interaction with Regulation 883/04, prior authorization and rare diseases). The stakeholder groups discussed how they would respond in reality to these situations. The simulation was the first of its kind at EU level.

The case studies were designed to help explore some of the difficult questions in the implementation of the Directive that are relevant across many different European Member States. They were not based on actual cases, but were designed to reflect real questions and dilemmas in applying the Directive. For consistency, MS A was used to designate the country where the patient is insured or in other words is affiliated (A) for healthcare cover. This country would thus pay for the cross-border healthcare and usually is the country where the patient is a resident. MS T was used to designate the country where the patient is to be treated (T). The case studies were designed to reflect the range of health systems attending the simulation (NHS-type and social insurance), so there are differences between the MS A and MS T in the different case studies.

Stakeholders were divided into five groups to discuss the case studies: public authorities; health insurers/purchasers (2 groups); healthcare providers; and patient (organisations). Each case study had a number of questions specific to each group to probe their responses to the issues presented. The full list of questions is given in appendix 2. The questions focus principally, but not solely, on the aspects related to reimbursement of care in the Directive. They include issues on granting prior authorization; referring patients abroad; adapting medical procedures or prescribing behaviour to patients coming from abroad; drafting and controlling invoices; providing information to patients on quality and safety and on reimbursement issues; understanding the position of the private and not contracted sector; integrating foreign supply in domestic planning policies; limiting the inflow of foreign patients; reimbursing for treatment of rare diseases; charging tariffs to patients from abroad; evaluating reimbursement levels and conditions and understanding the interaction between the Directive and Regulation 883/04.

The simulation was facilitated by two experts from the field, Nick Fahy, formerly of the European Commission and now an independent consultant, and Prof. Francis Colardyn, former Chief Executive of the University Hospital of Gent. The tables were hosted by a table chair and a rapporteur made notes of the discussion. To promote an open discussion, the simulation was held under a variation of ñChatham Houseò rules, so that the discussion has been reported, but not attributed to individual participants.

II Case Studies

Case Study 1: Prior Authorisation for Hospital Care

Patient X, who is entitled to health care benefits at the expense of MS A, is in need of orthopaedic surgery (hip replacement). In MS A, health care is provided for both by the statutory health care system and private health care providers, for which there is no intervention in the costs by the statutory health care system.

Patient X requests for a prior authorisation to travel to MS T with the purpose of receiving the treatment concerning the hip replacement in a private hospital not integrated in the statutory healthcare system of MS T. After careful examination of the request, the medical officer of MS A concludes that the treatment is provided for by the statutory health care insurance of the MS A, and that given the current state of health of patient X and the existing waiting times for hip replacements in MS A, the necessary treatment cannot be provided by the statutory health care system of MS A within a time which is medically justifiable.

However, the treatment can be provided for in a private hospital of MS A within a time limit which is medically justifiable (= no waiting list). The private hospital in MS T applies a different procedure and uses different prostheses (more expensive) for the treatment then the ones that are defined in the benefit package of MS A. Furthermore MS A does not, contrary to MS T, have an explicit catalogue of benefits and tariffs for individual treatments.

The treating hospital in MS T sometimes ï when there is a high demand ï temporarily hires the services of orthopaedists who are established in MS C. MS T is unable to provide information on whether these orthopaedists have received any disciplinary sanctions. The hospital and treating doctors provide patient X after treatment with an invoice which does not make clear which exact medical procedures have been applied, and in a language that is not understood by the institution of MS A responsible for the reimbursement of the costs of health care.

Case Study 2: Rare Diseases

The child of a young family suffers of the syndrome of West, a form of epilepsy. This disease fits the definition of a rare disease (max. 5 patients in 10.000 inhabitants), but is quite common.

In MS A, in principle only the drug Vigabatrin is reimbursed. The treating doctor in MS A prescribed however a drug called Zonegran, which is much more expensive. This drug costs ú 1.300/year. It is reimbursed by the national health insurance of MS A only if the alternative, cheaper products (Vigabatrin) proved ineffective and if the child followed a Ketogenic diet. In the neighbouring MS T, the drug is reimbursed without conditions. The child has not been treated by Vigabatrin nor followed a Ketogenic diet. The treating doctor advised the parents to purchase the product in MS T.

In order to refine the diagnosis, the parents would like to have some genetic tests done. Because the tests do not exist in their own country, MS A (nor are included in the domestic benefit package), they would like to have them done in an expert centre integrated in a network of centres of excellence in MS T (ambulatory tests).

The parents contact their health insurance fund to ask the authorisation to buy the drug and to have the genetic tests in MS T done. They have already made an appointment in the centre for within five days. The tariffs that the specialists in this clinic apply are the ones applicable for private patients. The parents ask if the supplements of the specialists, above the statutory cover, are reimbursed.

Case Study 3: Inflows and Outflows

Mrs X, a 60 year old woman from MS A was referred to hospital by her family doctor with severe pain in one knee. She is generally in good health, apart from her longstanding osteoarthritis. The orthopaedic surgeon she saw at the hospital Y has recommended that she has total knee arthroplasty (TKA- total knee replacement), given that non-surgical interventions have not worked.

X hospital, in MS T, just across the border from hospital Y has a strong reputation for orthopaedic surgery, particularly arthroplasty, where they are piloting new surgical techniques. To build the revenue and reputation of the hospital, the orthopaedic surgeons, together with the hospital chief executive, have decided to raise awareness of their services outside of their own country. In particular, they have targeted other countries and are seeing a growing number of foreign patients travelling to have surgery. These patients are charged 15% more than the domestic tariff for TKA, agreed in the collective social health insurance agreements.

Mrs X is keen to have the operation on her knee. However, the surgeon at Y hospital has put her on a waiting list for surgery. She is unhappy with this, and because of the pain has decided to have surgery at X hospital, which is in MS T, just across the border. However, there are problems at Hospital X. Due to the large inflows of patients from MS A, waiting times for x-rays particularly increased. Patients at Hospital X have found out that foreign patients are being given preferential treatment in terms of scheduling of x-rays etc. It is unclear which criteria are being used. An urgent hospital board meeting has been called to discuss the issue. Local politicians have also become interested in the issue and have asked the hospital for a response.

There are also concerns in her home country, MS A. Staff at Hospital Y are concerned on the potential for this to threaten the long-term viability of the orthopaedic unit. This concern is nourished by rumours that some medical specialists from hospital X plan to set up a private consultations in MS T, aimed to refer the patients to their practice in hospital X. Some of the surgeons at Hospital Y have now stated that they do not want to see any patients who have gone to Hospital X for surgery for their follow up appointments (arguing that there is an MRSA infection risk). The government is discussing mechanisms for refusing prior authorisation for TKA in that region on the grounds of overriding reasons of general interest.

Main Findings

The reportôs main findings are grouped into four sections. The first looks at what the simulation showed about some potential barriers for patients wanting to access cross-border healthcare, including prior authorisation, quality and safety and medical records. The second section picks up on the main reimbursement issues as the Directive is implemented, with particular implications for health insurers/payers, and their relationship with providers and public authorities. The third section takes the question of information, one of the strongest themes to emerge from the simulation discussion, looking at information on treatment and quality, on reimbursement and the national contact points. Finally, the fourth section looks at some of the potential challenges to health systems that the simulation suggested would be posed by the implementation of the Directive.

I Barriers for Patients?

Prior authorisation

Prior authorisation was one of the topics most debated as the Directive made its way through the Council of the EU, as Member States and the Commission sought to find an accommodation between the principle of freedom of movement upheld by the ECJ (limiting prior authorisation to what is necessary in the general interest) and the desire in certain MS to retain control over the movement of patients. The Directive states the general principle that MS are not permitted to make the reimbursement of costs of cross-border healthcare subject to prior authorisation (Art. 7), whilst defining some important exceptions, in particular for hospital inpatient care (Art. 8).

Despite this, discussions within the simulation suggested that in practice patients will request prior authorisation (also for ambulatory care) rather than travelling without it. One insurer was clear, for example, that they always advised patients to talk with them prior to care abroad, whether or not prior authorisation is required. Members of the patientsô stakeholder group confirmed that in the event of uncertainty in the information available they would seek prior authorisation ñto be on the safe sideò.

The simulation also showed that prior authorisation may be used by insurers/payers as a tool to specify reimbursement. Some insurers suggested including reimbursement conditions in the authorisation (e.g. requirements with regard to the treatment and the invoice). Furthermore, health insurers insisted that the patient needs a medical report from a physician indicating the medical need for the treatment abroad, and according to some of them, the demand for prior authorisation should be done by a physician. A request by a patient (or his parents) was not considered sufficient. In some countries, health insurers would request the patient/the referring physician to indicate the institution/provider that would provide the treatment, in other countries they would do so only under the Regulation.

The simulation revealed that, despite the formal legal position on prior authorisation, it may become normal for patients to request prior authorisation or prior advice before travelling under the Directive.

Medical records

The medical record lies at the heart of safeguarding patient safety throughout cross-border healthcare. The Directive emphasises the importance of a smooth transfer of medical information for continuity of care in cross-border cases, balancing this with the right of individuals to have their data protected. The Directive outlines specific responsibilities for the MS of affiliation and MS of treatment. The MS of affiliation is obliged to ensure that patients have remote access to or a copy of their medical records (Art.5,d); the MS of treatment is obliged to provide a written or electronic record of the treatment delivered abroad.

However current practice is far from what is envisaged in the Directive. The healthcare providers acknowledged that providing patients with a copy of their medical record is mandatory by law in all European countries and the providers claimed that they would share this with their patient. But strikingly, all the patient representatives reported problems in accessing their medical records. Patients highlighted that in some cases it is not possible to have one single medical file, even when treated in the same hospital but in two different departments. The question of ownership of the medical record was also raised. Although patients asserted that the medical record in theory belongs to them, the citizen, as the information contained in it concerns the individual patient, in practice patients recognised that the medical record is usually considered the property of the physician. In some countries patients can have a copy of the record but not access to the comments of the doctors. In addition, healthcare providers also highlighted the issue of translation, and argued that without it the medical file would have no use. Providing a summary or referral letter was not seen as a problem (and is often deemed sufficient, in addition to MRIs, X-rays etc.), but the costs of translation would entail costs that are not usually covered by health insurers.

Reflecting on the possibility of having health records in electronic format, many patient representatives expressed concerns with regard to the protection of personal data, in particular that sensitive health information stored electronically could end up in the hands of unauthorised parties.

Language

Language was another theme running through each of the case studies within the simulation. It was highlighted by patients as one of the major barriers: ñlanguage is the biggest barrierò, commented one, and another: ñEven if the information about a provider is available on the internet, if I donôt understand the language I cannot make any use of itò.

The question of accountability for the correctness of translated documents was raised but remained unsolved, in particular with regard to medical records. Major questions were raised

on who should pay for translation if it is needed (whether the patient file, invoice, or information on quality and safety). The principle argued consistently by most of the simulation participants was however that the patient should bear the costs.

Quality and safety

The primary focus of the simulation was on reimbursement, but the issue of quality and safety was a significant point of discussion, where it intersected with the option to withhold prior authorisation or refuse reimbursement for treatment. Although weaker than the original legislative proposal from 2008, the Directive has retained certain provisions on quality and safety.

According to the Directive, cross-border healthcare shall be provided in accordance with standards and guidelines on quality and safety laid down by the MS of treatment. Nevertheless, the MS of affiliation can refuse prior authorisation when a patient will be exposed to a patient safety risk ñwith reasonable certaintyò and when a healthcare provider raises ñserious and specific concernsò relating to quality and safety standards (Art.8,6°).

The simulation findings raise significant doubts on how well these provisions will operate in practice given current information and data systems. First, who should check? Participants pointed out the responsibilities of the MS of treatment to provide quality and safety information; however, it was unclear whether health insurers would be responsible for verifying the information before granting or refusing prior authorisation. Insurers were understandably reluctant to be accountable for this, particularly given the weakness of some available information and lack of an agreed cross-border framework for evaluating quality and safety standards. Health insurers also considered that they should be able to rely on the health authorities of the MS of treatment for verifying health professional qualifications.

Second, how would you check? Even if clear responsibilities for verifying quality and safety information are set out, it was unclear how health insurers would do this in practice. There was disagreement on whether prior authorisation could be refused on quality and safety grounds, with the balance of opinion that prior authorisation could not be refused as it would be difficult to prove whether quality and safety criteria are met or not, and therefore the arguments on overriding reasons of general interest would not apply. In this scenario, given that prior authorisation should be given unless there is clear evidence that quality and safety criteria are not met (i.e. what must be shown is the lack of patient safety/quality), this could expose patients to safety risks.

It is thus likely that these provisions of the Directive will not be applied in practice. They could however be used by health insurers to advise their patients to always ask for prior authorisation and to ask their referring doctor to recommend a healthcare provider abroad.

The simulation also raised questions on follow up and aftercare. Providers may refuse to give follow-up care (even if there is no legal basis for doing so), and insurers may refuse to cover

redress treatment. It was mentioned that in one country hospitals consider that the risk of MRSA infections is too high to treat patients who come back after treatment abroad. Furthermore, it was highlighted that insurers may refuse reimbursement if their patients go to a domestic provider for ñdamage repairò when a treatment abroad was not done well (e.g. dental care). Public authorities argued that, in the end, they would be responsible if a patient would not receive the necessary follow-up care after a treatment abroad.

II Reimbursement Challenges

Domestic conditions for reimbursement

One of the dilemmas highlighted through the simulation is the extent to which care abroad should conform to domestic conditions for reimbursement and the benefit package. According to the Directive, the MS of affiliation may impose the same conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if this healthcare were provided in its territory (Art. 7,7°). Participants agreed that the care provided abroad should not necessarily be the same but similar to the one reimbursed at home. A number of health insurers argued that prior authorisation could be used by insurers to specify the care that would be reimbursed (i.e. applying conditions). However, healthcare providers were unanimous in stating that they would not adapt treatment procedures to the requirements of foreign insurers, except perhaps for minor changes in pre-hospital pathways.

This raises a potential risk for patients, that, even if prior authorisation is granted, reimbursement may not follow if there is a disagreement between the insurer/payer and the provider. The discussions also highlighted that health professionals do not consider it their role to take into account reimbursement conditions abroad when discussing a therapy with the patient.

Reimbursement of non-statutory providers

The simulation also raised questions on non-statutory providers and their integration within cross-border healthcare.

On the question of applying the Directive or the Regulation, there was a unanimous view that non-statutory providers in another MS could be used under the Directive. The view of public authorities and health insurers was that the non-statutory provided care would be reimbursed. Under the Regulation, providers must in principle be integrated into the statutory system, although Member States can decide to allow exceptions to this principle.

However, there was a preference within the simulation to ensure treatment of the patient at home, through a private provider if the patient cannot be treated by a domestic statutory health provider without undue delay. For patients, where there was a unanimous agreement on this point, the reason behind it was principally a preference to be treated at home, close to

family and carers. Health insurers also supported either encouraging patients to get treatment within a private hospital in the MS of affiliation or to go to a private but contracted hospital abroad, allowing easier reading of invoices and providing treatment that corresponds to national tariffs and procedures in the MS of affiliation. For public authorities the picture was more complex. Most did not intervene strongly on cross-border contracting; in a number of the MS it was made clear to insurers that they were permitted to contract in this way, though in practice numbers remained relatively low.

Invoices

The Directive states that the MS of treatment have to ensure that healthcare providers provide clear invoices (Art. 4,2°,b). It also contains a particular provision on cost calculation in a cross-border context, stating that Member States of affiliation should have a transparent mechanism through which reimbursed costs should be calculated and that the mechanism should be based on ñobjective, non-discriminatory criteriaò which should be made available in advance (Art. 7.6).

Nonetheless, the challenges around transparent and accurate invoicing were a running theme through all three case studies. First, it was questioned how insurers can know exactly what care has been provided and how to control/supervise whether it has been actually provided. The health insurers outlined a number of different approaches to this. For example, the insurer can contact the provider prior to treatment or after treatment for specifications. Health authorities suggested that, even if providers could be expected to clarify bills, there is no way to oblige them to provide more information than they would provide for domestic patients. However, the providers suggested different responses to this: private providers suggested that it was not a problem to adapt invoices to requirements of insurers (and would bill the patient for this), whereas public providers argued that they would not make major efforts with regard to adapting invoices. Some health care providers suggested to draft the invoice in English in the case of a patient coming from another member-state.

The picture is complex. For example, insurers highlighted that they refund care at domestic tariffs, whereas some elements of the care (or aftercare) that is included in the domestic tariff has not been provided by the foreign provider, for example follow up treatments and rehabilitation. With the diversity of financing approaches and cost calculation across the EU, this is a difficult issue. For countries with an explicit catalogue of benefits (a nomenclature for health treatments), such as Belgium and Luxembourg, it is easier to evaluate procedures and treatments that apply in cross-border care.

Perhaps the most interesting element of this discussion was on where final accountability lies for accurate information. Although public authorities were clear that they would assist patients in securing accurate information and that it is the obligation of the health insurers to help the patient if he/she cannot get all the necessary information himself, both public authorities and health insurers argued strongly that the final responsibility for accurate invoices lies with the patient who will be asked to provide the correct information, proofs on the care that has been provided and the content of the invoice. As one observed, ñIn essence,

it is a matter of *who carries the burden of proof* when a bill is not specific enough to allow reimbursement according to national tariffsò. When you have a claim ï and the claim (or entitlement) of the patient clearly exists under the Directive ï then it must be up to the *claimant* (i.e. patient) to provide necessary information. Nevertheless, even if in theory an unclear invoice could lead to a refusal of reimbursement, in practice payers assured that they would find a way to reimburse the patient.

Patients might thus face serious challenges to obtain a clear invoice and could bear an inappropriately heavy burden for accessing planned healthcare abroad under the Directive. There is therefore an important challenge to provide transparent invoicing and pricing systems (what is in, what is not in the price) .

Tariffs and supplements: non discrimination

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 Member States and for domestic patients in a comparable medical situation, or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients (Art. 4,4°). This provision has important implications for the issue of tariffs and supplements for cross-border healthcare, explored in one of the case studies through the scenario of a hospital charging foreign patients 15% more than the domestic tariff.

Participants agreed that tariffs charged cannot be higher than the ones charged for domestic patients in the MS of treatment. However, this raised questions on which domestic tariffs were being applied ï those for socially insured patients/the collectively agreed tariffs between health insurers and providers or those for private patients/applied by providers who do not adhere to the collectively agreed tariffs? Discussions with the healthcare providers suggested that private tariffs would often be used for foreign patients travelling under the Directive (in contrast to patients travelling under the Regulation). For care which is not in the benefit package a private price will always be charged. According to most authorities/ insurers, under the Directive private tariffs in the MS of treatment have to be reimbursed up to the level of the reimbursement tariff in the MS of affiliation. Health insurers of some Member States would however not pay for these supplements. Some would even pay higher tariffs then the reimbursement tariff in the MS of affiliation, when the patient went abroad because of waiting lists at home. Some health insurers would, in some specifically defined exceptional circumstances, also reimburse accommodation and/or transport.

A second issue raised by a number of the insurers related to the amount of information available, and in particular, how insurers would know whether or not the tariff charged is higher than that for domestic patients.

Information systems available to public authorities or insurers are thus not adequate to allow comprehensive understanding of the tariffs charged, and this is all the more the case for patients treated abroad. If foreign patients would in principle pay ñprivate tariffsò, patients risk having to pay high prices out of their pocket, without having been informed about this

prior to their treatment (even if, according to the Directive healthcare providers should provide clear information on prices (Art. 4,2°)).

III Information, Information, Information

One of the clearest themes to come through the simulation was the need for independent information for the Directive to function well, information that is currently often not available even domestically: on reimbursement, treatment, quality and safety and the national contact points. Although it was a particular concern for the patientsô group, it has implications for all actors in the cross-border healthcare process.

Information on reimbursement

Information on how cross-border care works in practice, its administrative procedures and who is going to pay the bill and under which conditions was identified as important information needed by patients seeking care abroad.

According to the Directive, it is the responsibility of the MS of affiliation to ensure that there are mechanism in place to provide patients with such information (Art.5,b). Patients highlighted that decisions on the different administrative options for cross-border care, particularly the application of the Regulation or the Directive were too complex for patients, and that this decision should be taken by the competent authorities and not ñput on the shouldersò of the patients or their carer. This was also the view of patients in decisions on whether prior authorisation should be sought. Patients emphasised a preference for the legal instrument which implies less complex procedure and that assures a swift reimbursement. Health insurers would inform patients about the differences between the Regulation and Directive procedure, in particular with regard to up-front payments versus third party payer systems.

The health providers within the simulation did not consider it the role of clinicians to provide information on reimbursement issues (or indeed even to take them into account when proposing a treatment). This leaves health insurers and the national contact points (NCPs) specified in the Directive as the main information points. However, some patients were concerned that health insurers might not offer impartial advice. As one patient representative commented, ñThey are a natural source of information but not idealò. Patients were therefore keen to argue for an independent source of advice.

Information on treatment and quality/safety

Information on treatment, and specifically its quality and safety was an important theme in the discussions across the case studies, particularly for the patientsô stakeholder group.

The Directive requires the MS of treatment to give patients from other MS information on the safety and quality standards that it uses and which providers are subject to them (Art. 4,2°). Furthermore, the MS of treatment shall ensure that healthcare providers provide relevant information to help individual patients to make an informed choice, including on treatment options and quality and safety of the healthcare they provide. The limitation on the requirement is that the MS cannot oblige healthcare providers to give more information to foreign patients than they already give to domestic patients (Art. 4, 2°, b).

Patients were clear on the need for information about the quality levels of hospitals, highlighting the need for comparative analysis and indicators. A patient representative said: ñI'd like to know whether the hospital abroad is better than the one in my home countryò. The need to ñtranslateò information into lay language for it to be usable was also underlined, with patients reflecting that even when it is available currently citizens tend not to use performance information to choose their healthcare provider.

However, the healthcare providers underlined the difference between informed consent (i.e., the patient agreeing to the treatment having been made aware of the risks) and informed decision making, where patients are aware of alternative treatments and or/procedures. Healthcare providers took responsibility to deliver care based on informed consent (though it was also noted that how informed consent is recorded often differs, with some countries insisting on written consent and others only on oral agreement). However, in the case of cross-border care, healthcare providers saw national contact points as having the duty of informing patients on alternative curative options, in order to secure that independent information is provided. Although there is logic to this, it is important to note that the patients in the simulation put doctors at the top of the list of sources of information on cross-border care, and this is also the approach of the Directive. We thus see a gap between the legal provision and the preparedness of the providers. It can be wondered whether national authorities will be able to make health providers comply with this duty and how they would be able to monitor whether providers assume this responsibility. Given that this ñpatient rightò is rather formulated as a duty for the authorities and not as an enforceable right of the patient, patients might in reality not be able to obtain this information when they seek care abroad.

The healthcare providers illustrated a variety of approaches to informing patients on quality and safety of care, ranging from health providers who do not provide patients with information on treatment options to providers who publish information publicly. Healthcare providers generally agreed that they would provide patients coming from abroad with information on the treatment provided that they already made available to domestic patients, but argued for an independent intermediary between providers and patients. In particular, healthcare providers noted that quality of care is often based on quantitative indicators (e.g. mortality, length of stay) and that although this information is usable for health insurers it is often difficult to understand for patients. Healthcare providers also highlighted moves towards accreditation (e.g. JCI, ISO-9001) as ñtokens of qualityò to be advertised to patients. However questions were raised on whether accreditation is transparent enough to be fully understood by patients, or whether the meaning of accreditation findings would need to be

made available by an independent party. Here again national contact points were cited as a potential actor.

Also health insurers were reluctant to provide information on treatment or on quality and safety in the MS of treatment. They wondered who would be legally responsible should something go wrong.

Interestingly, the comparative analysis and indicators on quality was the main focus for better information for patients. On the question of the extent to which patients need information on the records of healthcare professionals there was less agreement. The Directive has a specific provision relating to health professionals directly, introducing the right for the MS of affiliation to receive upon request confirmation that the treatment is being delivered by a legally practicing health professional (Art. 10,4°). Also providers from the MS of treatment have to provide upon request information on their authorization or registration status (Art. 4,2°,b). Some patients supported access to this kind of information, but others argued that it is the responsibility of the hospital to ensure that the people working there are fit to practice. ñI never asked my own doctor at home about his record. I donôt think I would ask this information from a doctor in another countryò, commented one participant.

This area raises important questions both on the variation in practice between countries and providers on information to patients, and on the extent of the information that the MS of treatment will in practice give to patients wanting to access care abroad. Although the Directive does not explicitly require it, implementing the Directive may push Member States to release more information on patient safety and quality of institutions than is currently available.

The role of the National Contact Points versus insurers and providers

The simulation suggested that the Directive will also pose significant challenge to health systems in determining who will provide information, both on reimbursement and on safety and quality. In this, two particular facets of the discussion were relevant.

First, there was a disjunction in perception on independence and transparency of information between patients and health insurers. For patients, the most important question was the transparency and independence of the information they received, which was reiterated throughout the three case studies. The health insurers were recognised by patients to be the ñmost knowledgeableò party on cross-border healthcare, and the insurers themselves assumed throughout the discussions that they would be a crucial port of call for patients looking for neutral information. However there was a concern among the patients that the information provided by health insurers, in particular when they have financial incentives, is not neutral. ñIt is an issue of trust.ò This is an indication of an important challenge for health insurers to deal with if they wish be seen as a source of transparent and neutral information.

Second, the simulation underlined the importance of defining whose responsibility it is to provide information in different domains, particularly between the MS of treatment, the MS of affiliation, the health insurer/payer and the healthcare provider. The Directive states: ñThe

MS of Treatment has responsibility for informing patients on relevant information on safety and quality standards enforced on its territoryò. This is relatively clear as a responsibility, though health insurers expected to be contacted by patients when that information was either difficult to understand or untranslated.

What is less clear is the demarcation of responsibilities between health insurers/payers and public authorities in the MS of affiliation. There is an obligation for Member States to ensure that national contact points should be established, and that these should, in cooperation between them, provide information on the main aspects of cross-border healthcare (Art. 6). The location of the NCPs is unspecified: ñThe MS should decide on the form and number of their national contact pointsò (Rec. 49). There was disagreement highlighted on where the NCPs should sit, particularly on whether ministries or health insurers should act as NCPs in certain MS. The patients within the simulation suggested that patients do not expect the contact points to provide legal assistance in case of medical errors or help them to make the complaint. However patients were clear that they need people who can answer their questions and not bureaucrats who do not know and cannot provide any useful information.

The most sensitive domain with regard to information related to treatment options and quality of care. Neither providers from the MS of treatment nor the health insurers from the MS of affiliation want to take the responsibility for this kind of information and suggested that the NCP of the MS of treatment could assume this role. It is however questionable whether these NCP would be able to assume responsibility for this information. Who would be accountable if the information is wrong? As argued by the patients, it is likely that they will in the first place rely on their treating/referring doctor for this kind of information, which is what they would also do for a treatment at home. We can expect that, without sound international collaboration and networking between referring and treating providers, this could prove a significant barrier to patient mobility.

One way forward suggested by some of the health insurers was that the MS of treatment should provide the information on quality/safety of the provider (translated if necessary); the health insurer/payer in the MS of affiliation should provide information on prior authorization, reimbursement and all financial aspects; and the public authority in the MS of affiliation should provide further general information on cross-border care. However, if implemented, this approach needs to take into account the perception of patients expressed within the simulation that health insurers may not provide transparent and neutral information.

With uncertainty on what information NCPs might provide and where they might be located, this should be closely monitored as the Directive is implemented to ensure that patients can receive the information that they require.

IV Managing the Health System

The simulation showed that the implementation of the Directive has important implications for managing health systems, even though the volumes of cross-border care under the Directive are expected to be relatively small in most countries and regions. In particular, the simulation looked at how the Directive and Regulation will work together, questions on access to care and patient inflows and rare diseases. The simulation showed that most public authorities have developed pragmatic approaches to working with some of these system issues, in particular with dealing with managing the Directive and Regulation in parallel. Indeed on other issues, where some Member States had strongly argued for particular provisions in the Directive, the simulation showed that public authorities would probably not make use of these provisions in practice. However, the simulation also showed some potentially unexpected consequences of the Directiveôs implementation, in particular on areas where the Directive may act as a lever on domestic health policy beyond the legal provisions.

The Directive and the Regulation – systems in parallel

One of the key issues submitted to the simulation was the tension between the Directive and Regulation (EC) No 883/2004 on the coordination of social security systems (the Regulation), and the challenge of working both systems in parallel. According to the Directive, when the conditions set out in the Regulation are fulfilled, prior authorisation should be granted and the benefits provided in accordance with the Regulation unless otherwise requested by the patient (Rec. 46 and Art. 8, 3°).

A number of elements in the case studies were designed to test this tension ï particularly in case studies 1 and 2, with questions on granting prior authorisation and treatment for rare diseases. Although there were differences, a clear approach to testing cases of cross-border care from the perspective of the public authorities emerged in the discussions. First, public authorities would test cases to see if they were eligible under the Regulation; second, if not eligible under the Regulation they would test for eligibility under the Directive (e.g. for non-statutory providers as in case study 1); third, they would test for any relevant national legislation (for example solidarity funds to fund cases of treatment for rare diseases across borders). Patients challenged this approach and had some concern that health insurers could advise patients to go abroad under the Directive, in case the costs would be lower for them under this procedure as compared to the Regulation.

Access to care and high inflows of patients

According to the Directive, inflows of patients may create a demand exceeding the capacities existing in a MS for a given treatment. Therefore, the MS of treatment should retain the possibility, in exceptional cases, to remedy the situation on the grounds of public health (Rec. 21) and may adopt measures regarding access to treatment to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate (Art. 4,3°). The Directive also states that nothing in this Directive should

oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients (Rec. 21).

It is wrong however to assume that public authorities have easy access to robust data on patient flows that would support these decisions. Indeed the simulation found that public authorities only have limited information on patient in/outflows. Some public authorities had no access to information on the number of foreign patients accessing care in their MS, or on waiting times, and are therefore unable to know if there are access problems due to high inflows. Many MS saw no legal basis nor incentives for controlling inflows. Patients did strongly believe that it is the responsibility of the authorities to manage the patientsô flows and the possible problems arising from cross-border health care, ensuring equal access to treatment for all. Health authorities mentioned healthcare providers as the party with responsibility to ensure that domestic patients were not disadvantaged by foreign patients. Healthcare providers, even if they did not consider it acceptable that domestic patients (as taxpayers) would have to wait unduly, due to inflows of foreign patients, they did not suggest stopping to admit foreign patients when they could not any more guarantee timely access to care for domestic patients. They rather suggested to increase capacity or to reallocate patients to other hospitals. The non-statutory providers did however see inequalities in access to care as ñjustifiedò.

If MS are to restrict inflows of patients, public authorities will thus need to establish new information systems that will allow MS to justify restrictions. However, it is more likely that this provision from the Directive will not be applied in practice. Public authorities and providers voice the concern that high inflows could affect access to care for domestic patients. Nevertheless, they seem not to be motivated to take effective action. It is rather surprising that public authorities, who insisted on inserting this provision in the Directive, seem now not to have the tools or the incentives to intervene.

Rare diseases

In the later stages of the legislative passage of the Directive, the provisions on rare diseases were subject to particularly heated debate. The final, adopted Article (Art.13) states that the Commission will support MS in cooperating in the development of diagnosis and treatment capacity, supporting health professionals to diagnose rare diseases (especially through the Orphanet database and European reference networks) and raise awareness of the possibilities offered under Regulation 883/2004 for referring patients to other MS even for diagnosis and treatments unavailable in the MS of affiliation.

In the rare diseases case study, public authorities and health insurers from different countries took a variety of approaches to reimbursement. Most of the public authorities would follow the test of first consulting if the reimbursement could come through the Regulation (and that reimbursement would not be given as treatment/tests is not in the national benefit basket). The second test is whether the Directive applies. Most agreed that under the Directive the drug or test discussed in Case Study 2 would not be reimbursed, for the same reason. The third test applied was national law, i.e. specific provisions by country. Here there was some

scope in some countries to reimburse treatment abroad if medically necessary (on a case-by-case basis), even if not in the domestic benefit package, through solidarity funds or other mechanisms. In this case, higher tariffs could also be reimbursed.

Challenges to domestic healthcare policy?

One of the most interesting elements highlighted by the simulation is the potential for the Directive to become a lever to change domestic policy and practice beyond the strict legal scope of the Directive. Four domains were highlighted in particular:

European Reference Networks (ERN): A number of participants, particularly health insurers, were clear that if ERNs were established it would ñcompletely changeò the picture on reimbursement for treatment and services currently not reimbursed within MS health systems. As a number of participants observed, it is difficult to see how in practice MS could refuse to reimburse treatment and services with the EU ñlabelò of an ERN, even if theoretically it is possible for MS to refuse reimbursement for treatments that are too far removed from those applied in the MS of affiliation. Public authorities in the simulation stressed that the reimbursement decision would depend on whether treatment is based on international medical standards and considerations of cost effectiveness. This increased pressure is a significant potential impact from the Directive.

Transparency in cost calculation, calculation of reimbursement tariffs and invoices: The major questions raised on how costs and reimbursement tariffs are calculated in cross-border cases (discussed in section II) also pose questions within countries. Healthcare providers observed that the Directive might challenge current cost calculation mechanisms and argued that the Directive might provide an opportunity to clarify invoices also at national level.

Information on quality, prices and healthcare professional records: In a similar vein, the questions on information (on quality, prices and the records of health professionals) might also benefit domestic patients and provoke a culture shift on information. In practice, part of the difficulty in providing information to patients crossing borders is that the information is often not given to domestic patients or even not available. With clear expectation within the Directive that patients will be able to access information on which to base a decision, one of the major impacts of the Directive in the medium term may be to challenge current information provision domestically as well as across borders. As suggested by the providers, the Directive might also push initiatives for accreditation of healthcare services such as hospitals.

Public hospitals, private sector behaviour: One of the most striking themes coming out of the discussion with healthcare providers was the extent to which hospitals providing publicly covered care modelled behaviours much closer to those typically adopted by the private sector in responding to cross-border patients travelling under the Directive. For example, hospitals and hospital doctors would most often charge these patients higher tariffs then the ones agreed within the domestic health insurance system; providers would not take into account reimbursement conditions applicable in the country of affiliation (whereas for domestic patients they do comply with domestic conditions). Furthermore, it is likely that

they will charge patients who request additional services such as translation or adapted invoices, as non-statutory providers do. If providers start to develop such behaviour for patients from abroad, this could encourage them to also provide ñadditional servicesò to domestic patients at their request if they are willing to pay for them.

This makes the case for seeing the Directiveôs impact not only in the strict legal provisions that it contains but also in its potential to shape culture and practice in healthcare at national level in areas in which the EU does not have binding powers. This is despite the Directiveôs clear statement that it ñshall not affect laws and regulation in Member States relating to the organisation and financing of healthcare in situations not related to cross-border healthcareò. For their potential to change health system culture, these consequences should perhaps be regarded as some of the most significant impacts of the Directive. At both national and European level, these consequences should be monitored as the Directive is implemented.

Conclusions

The cross-border healthcare simulation paints a picture of the Directive that differs from the discussions that dominated in the run up to its adoption into European law. It suggests that some of the provisions strongly argued for as the Directive made its way through the legislative process may be less important in practice. It also suggests a number of areas where the Directive may have an unexpected impact, particularly on domestic health policy. Most significantly of all, the simulation challenges public authorities, health insurers and healthcare providers to work to ensure that patients travelling under the Directive do not bear an unfair burden in managing their own care.

Legal certainty

In the simulation and in this report we mainly focused on the outstanding and potential problematic issues of the Directive. However, we should start by saying that there was a striking consensus both within stakeholder groups and between stakeholder groups on several important questions submitted to the participants. These included issues on whether prior authorisation should be sought for the specific case; whether reimbursement was possible and whether it was possible under the Directive or under the Regulation. Our first conclusion should therefore be that the Directive is expected to bring substantial legal certainty for the actors, where the last decade was marked by legal uncertainty.

For other issues, there was a large consensus within stakeholder groups but equally large divergent approaches between stakeholder groups. The most notable example here relates to the conditions for reimbursing care. Whereas purchasers and public authorities made clear that for the care to be reimbursed, it should comply with the conditions as defined in the MS of affiliation, the providers were equally clear that they would not adapt procedures to conditions of the health insurer of the foreign patient. This suggests an emerging clash between the stakeholders. We can expect this clash to be solved in a pragmatic way when numbers remain low (insurers being motivated to serve their clients), and possibly by cross-border contracts when numbers of patients flows are expected to become important. However, if the divergent conditions would themselves lead to important patient flows, health insurers will probably be compelled to close the gap.

Politically important, not applicable in practice…

The simulation suggests that for a number of areas within the Directive, although provisions have been made in the legal text for political reasons, they seem not to be readily applicable in reality. This is particularly the case for the provisions on managing or preventing high inflows of patients (Art. 4,3°) and refusing prior authorisation on the grounds that quality has not been guaranteed (Art. 8,5°,c) and thus will most probably remain ñdead letterò, at least for the foreseeable future.

The simulation also shows areas where tensions in implementation may have been predicted but where pragmatic and practical solutions are being found. In particular, Member States

have developed ways in which to run the provisions of the Regulation and the Directive in parallel (testing first if the Regulation applies and second the Directive), with national legislation used as a third test, for example in specific solidarity funds for rare disease patients.

Spillovers into the national system

The simulation suggests that implementation of the Directive may also shape health systems in some ways that go beyond the strict provisions of the text. The prospect of ERNs and the pressure to reimburse care with a European label regardless of the domestic reimbursement provisions is a particular example. So too the Directiveôs assumption on information (that it should be transparent and easily available to patients) poses important questions to health insurers, providers and public authorities that resonate beyond cross-border care.

Managing the burden for patients

The most striking set of conclusions from the simulation relates to the potential burden for patients travelling under the Directive. Throughout the discussions it was clear that patients will bear the responsibility for many of the elements involved in accessing planned treatment across borders. The responsibility for finding information on potential treatment will lie primarily with patients. The burden of proof in demonstrating to insurers that the treatment has been carried out and the responsibility to submit the correct documentation will lie with patients. This suggests that although the Directive will formally guarantee patientsô rights to planned cross-border healthcare, it may not readily succeed in really promoting the freedom of patients to access care in another MS.

Even if Directive patients go abroad for treatment with public cover, in many ways they are treated as if they are not part of the social system. Instead of complying with the tariffs agreed on with the health insurance system of MS of treatment, providers freely set their tariffs and request supplements if they are allowed to do so for domestic ñprivateò patients. Providers will charge for any additional costs such as translation and adapted invoices. Patients have the burden of proof on clarifying invoices and the content of the provided care. They will have to seek information themselves on treatment options and even on whether the provider is allowed to exercise its profession. The patient is considered as a consumer shopping around with his ñvoucherò.

The Directive tried to mitigate some of the effects created by the Court rulings. However, given the basic logic underlying the Directive, based on the principles of free movement, the Directive seems to only marginally succeed in this attempt. Without an institutionalized relationship between the payer and the provider, in which the provider commits to comply with certain conditions and the payer assumes responsibility for the care provided, the patient will be left on his or her own. National contact points and other institutions cannot compensate for this lack of management of care. It is therefore likely that the Directive will only be used by patients when there is really no alternative, better managed option to receive the treatment, or by patients who are not aware of the responsibility on their shoulders and

the risks they take. The latter category should be watched over very closely. The recent experiences with the PIP breast implants are illustrative in this respect.

In this sense, it is probably a positive finding of the simulation that patients would in principle always ask for prior authorization or prior advice ñto be on the safe sideò: Patients who travel without prior authorisation take a substantial risk and this should at least allow some management of the cross-border pathway. It is also reassuring that there seems to be a consensus to always look first at whether the patient would have the right to go abroad under the Regulation, under which the patient is considered as a socially insured person of the MS of treatment.

To conclude, the simulation gathered the experts from the involved stakeholder organisations on the Directive and on cross-border care, those who deal with these issues on a daily basis. Nevertheless, important questions remained unsolved. Many experts discovered during the discussions new problems for which nobody had an answer. Practices will need time to become established and consensus on the application will have to be built. Most probably, many issues will be solved in a pragmatic way as long as the numbers of patients making use of this procedure remain manageable. Inevitably, different member states and different stakeholder groups will interpret and use the provisions in a creative way. The Directive is a non-negligible step in the direction towards more legal certainty; it is however also just one step.

Appendix 1: Participants

Baeten	Rita	(Co-organiser) OSE/European Social Observatory	BE
Becker	Amélie	Inspection Générale de la Sécurité Sociale	LU
Bloemheuvel	A.G.	Ministry of Health	NL
Boers	Kris	Permanent Representation of Belgium to the EU	BE
Bremner	Jeni	EHMA/European Health Management Association	BE
Brouwer	Marjan	MS Association The Netherlands	NL
Brunier	Daniel	Ligue Française contre la Sclérose En Plaques	FR
Cazeuneuve	Jérémie	Régime sociale des indépendants/RSI	FR
Colardyn	Francis	(Facilitator) University Hospital Ghent	BE
De Cock	Jo	RIZIV/INAMI/NIHDI	BE
De Toeuf	Jacques	CHIREC asbl	BE
Decoster	Christiaan	Federal Public Service Health, Food Chain Safety and Environment	BE
Dekker	Wout	AIM/Association Internationale de la Mutualité	BE
Destrebecq	Frédéric	(Rapporteur) UEMS	BE
Dewalque	Herman Gerard	Maastricht University Medical Centre	NL
Enderlein	Malte	VDEK	DE
Ewen	Claude	Ministry of Social Security	LU
Fahy	Nick	(Facilitator) Nick Fahy Consulting Limited	UK
Feidt	Tom	LLSP/Ligue Luxembourgeoise de la Sclérose en Plaques	LU
Giepmans	Paul	(Rapporteur) EHMA/European Health Management Association	BE
Glinos	Irene	(Rapporteur) European Observatory on Health Systems and Policies	BE
Greer	Scott	(Observer) University of Michigan	USA
Hoffmann	Paul	Hôpital Kirchberg	LU
Horemans	Christian	(Organising Committee) Union Nationale des Mutualités Libres	BE
Jelfs	Elisabeth	(Co-organiser) EHMA/European Health Management Association	BE
Kessler	Rita	(Rapporteur) AIM/Association Internationale de la Mutualité	BE

Legido-Quigley	Helena	(Table Chair) LSHTM/London School of Hygiene and Tropical Medicine	UK
Lermenier	Gaelle	CLEISS	FR
Lewalle	Henri	(Organising Commitee) Christian Sickness Fund	BE
Machalska	Magdalena	(Organising Committee) AIM/Association Internationale de la Mutualité	BE
Mercier	Fabrice	MGEN	FR
Osterholz	Burchard	GKV-Spitzenverband, DVKA	DE
Otting	Albrecht	Federal Ministry of Labour and Social Affairs	DE
Palm	Willy	(Table Chair) European Observatory on Health Systems and Policies	BE
Passarini	Ilaria	(Rapporteur) BEUC	BE
Peeters	Miek	(Table Chair) Zorgnet Vlaanderen	BE
Radermecker	Didier	UNMS/Socialist Sickness Fund	BE
Ramos Vega	Jose María	FELEM/Federación Española para la Lucha contra la Esclerosis Múltiple	ES
Reker-Barske	Elisabeth	AOK-Bundesverband	DE
Robert	Roger	Catalonian Hospitals Consortium	ES
Rodriguez-Ortiz de Salazar	Begoña	MUFACE/Ministry of Territorial Policy and Public Administration	ES
Schaul	Romain	Caisse Nationale de Santé	LU
Segaert	Chris	(Organising Committee) RIZIV/INAMI	BE
Theisen	Silke	University Hospital Aachen	DE
Van Camp	Luc	ZOL Genk	BE
van der Heijden	Ingrid	Maastricht University - GP vocational training department	NL
Van der Wissel	René	CVZ/College voor Zorgverzekeringen	NL
van der Zanden	Brigitte	EPECS	NL
Van Eck	Bert	Gamma-Knife-Center Krefeld	DE
Van Gastel	Jeroen	Zorgloket Duitsland	NL
Vanhercke	Bart	OSE/European Social Observatory	BE
Vanvinckenroye	Joris	Royal Doctors	BE
Veerkamp	Jan	Zorgverzekeraars Nederlands	NL
Velders	Gert Jan	CVZ	NL
Verschueren	Herwig	(Observer) University of Antwerp	BE

Appendix 2: Case Study Questions

List of questions submitted to case study participants:

Questions Case 1

Public Authorities

- How would you instruct the health insurers/purchasers to calculate the reimbursement tariffs and conditions in such a case, in particular if the foreign invoice does not provide all the details on the provided care but provides an "all in" tariff?
- If there would be important outflows of patients for specific treatments for which there are waiting times, would you consider contracting the domestic private sector or health services abroad?

Health Insurers/Purchasers (of MS A)

- Would you grant prior authorisation for the treatment in MS T? If you would grant a prior authorisation, would you apply Regulation 883/04 or the Directive?
- Would you request the patient to specify to which hospital in which country he would go before providing prior authorisation? Would you try to convince the patient to go to a hospital integrated in the statutory system of MS T?
- How would you decide on the level of reimbursement if the foreign invoice does not provide all the details on the provided care but provides an "all in" tariff?

Healthcare Providers (including Professionals)

- Would you consider drafting an invoice adapted to the needs of the funding body of MS A, for instance by specifying in wording instead of national codes which treatment has been provided? Would you consider drafting your invoice in English for this purpose?
- What kind of information would you provide patient X upon his request, prior to the treatment, on treatment options, on the quality and safety of the care you provide and on the applicable tariffs?
- Would you consider adapting treatment procedures and conditions to the reimbursement conditions applicable for health cover in MS A? If so, to what extent?

Patients (associations)

- What kind of information would you request before travelling abroad? How would you choose the healthcare provider abroad?
- If reimbursed, would you prefer being treated in a domestic private hospital or in a hospital abroad, if quality is equal?

Additional questions if time allows

Public Authorities

- How would you instruct the health insurers/purchasers to control invoices?
- (*as authority from MS T*) How would you react when the national contact point of MS A asks information, at the request of a patient, on the right to practise of health professionals in the private hospital in MS T?

Health Insurers/Purchasers (*of MS A*)

- How would you assess whether the treatment in MS T met the conditions, criteria of eligibility and regulatory and administrative formalities? Would you request the treatment to be exactly the same as the domestic one? How much leeway would you accept?
- When granting prior authorisation based on the Directive, would you investigate if the private hospital in MS T provides health care that meets the quality and safety standards of care laid down by MS T? And how would you do that? Would you provide information to patient X on the quality and safety of the health care provided by the private hospital in MS T in case this results in a refusal of a prior authorisation?
- How would you (= MS A) provide information to patient X on the rates and the conditions of reimbursement?

Healthcare Providers (including Professionals)

- (*as referring doctor*) Would you advise patient X rather to receive treatment in the private domestic sector or in a foreign hospital if the quality is equal?

Questions Case 2

Public Authorities

- Does the patient need to ask a prior authorisation:
    - If the patient is looking for a clear diagnosis?
    - If the treatment is ambulatory?
    - If a hospitalisation is necessary for the treatment?
- Do you limit the reimbursement to what is foreseen in the health insurance in MS T?

Health Insurers/Purchasers (of MS A)

- Would you consider prior authorisation necessary; would you provide it and if so would you base it on regulation 883/2004 or on the Directive?
    - For the pharmaceutical product
    - For the genetic test
- Would you reimburse the supplements of the specialists? Would you reimburse accommodation and transport for the genetic test and if so, at what tariffs and conditions? What would you base your decision on?

Healthcare Providers (including Professionals)

- *(as provider in MS T)* Would you apply for the genetic tests for these foreign patients the same tariffs as the ones applicable to the domestic socially insured patients, the same as those that apply to domestic private patients, or lower or higher tariffs?
- *(as referring/prescribing doctor)* Would you prescribe such a pharmaceutical product if it is not reimbursed domestically or does not comply with the domestic reimbursement conditions? More generally, would you take into account funding conditions abroad when suggesting a treatment to a patient?

Patients (associations)

- Would you prefer using the procedure based on the Directive or on the Regulation for funding care abroad for a rare disease?
- Would you insist on receiving a copy of your medical file when you intend to consult in a medical centre abroad? Would you like to receive a copy of the medical file of your treatment upon return? Do you think it will be easy to receive these?

Additional questions if time allows

Public Authorities

- Would you consider including the foreign expert centre for genetic tests in your domestic planning and if so, under which conditions?
- What if it concerns an experimental treatment that is not reimbursed in MS T, nor in MS A? Is reimbursement of medical costs possible in this case?

Health Insurers/Purchasers (of MS A)

- Would you reimburse treatment upon return if the prior authorisation was not given within the time limit of 5 days? What reimbursement tariffs would you then apply? Would you provide authorisation *a posteriori*?

Healthcare Providers (including Professionals)

- *(as referring/prescribing doctor)* Would you provide the patient, upon request, with a copy of his medical file when he intends to consult in a medical centre abroad?
- Would you consider adapting treatment procedures and conditions to reimbursement criteria of the health insurance of the patient?

Patients (associations)

- What kind of information would you like to receive before travelling abroad? Do you expect that patients with rare diseases will find the right information via the national contact points?

Questions Case 3

Public Authorities

- *(from MS T)* How would you react if high inflows of patients increase domestic waiting times? What systems/data do you have to measure whether waiting times are rising?
- *(from MS A)* How would you react if outflows of patients threaten the survival of a domestic hospital/hospital unit? What systems/data do you have to defend not allowing cross-border care for "overriding reasons of general interest"? How would you react to treating doctors refusing to provide follow up treatment of patients who went abroad?

Health Insurers/Purchasers (of MS A)

- Would Mrs X need prior authorisation for treatment in your system? If so, what process would Mrs X follow to receive prior authorisation? How would she find out about this process?
- How would Mrs X know what she was entitled to care abroad? What information would be made available to her, esp. on reimbursement?
- Would you pay for the higher tariffs in hospital X if these tariffs correspond with the reimbursement tariffs in MS A?

Healthcare Providers (including Professionals)

- Do you find it acceptable that high inflows of foreign patients would cause access problems for domestic patients? What would you do if CBC patients cause waiting times to rise? Do you have mechanisms to measure/understand this? What processes should providers follow in admitting/prioritising CBC patients for treatment as compared to domestic patients?
- How do you calculate tariffs/pricing for patients from abroad? What data would you use to construct your pricing for foreign patients?

Patients (associations)

- How would you react (as a patient representative of MS A) if high inflows of patients from abroad would cause domestic access problems to care?
- Would you find it acceptable if treating doctors refuse to provide follow up treatment of patients who went abroad? How would you react?

Additional questions if time allows

Public Authorities

- How would you handle the increase in tariff between domestic/non domestic patients?
- What systems/data do you have to define "medically justifiable" time limits?

Healthcare Providers (including Professionals)

- (*from MS A*) Would you find it acceptable if treating doctors in your hospital refuse to provide follow up treatment of patients who went abroad? How would you react?

Patients (associations)

- Where would you look for information to support moving from your domestic health system abroad? What do you know about the national contact point system?