EPF Cross Border Healthcare Conference

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EPF Regional Conference on the EU Directive on Cross-Border Healthcare

Conference Report

Brussels, 9-11 December 2013

Participating countries: Belgium, France, Germany, Luxembourg and The Netherlands

Contents

Introduction

One of the main factors governing the impact of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare – the "cross-border healthcare Directive" – will be the degree to which patients are enabled to understand the legislation and benefit from it.

In cooperation with its members, EPF undertook considerable work with the EU Institutions on the Directive prior to its adoption, and subsequently produced a toolkit explaining the Directive, which was disseminated in June 2012. The toolkit was presented at various events throughout the European Union in which patient leaders were involved, to raise awareness during the transposition phase. As this phase ended on 25 October 2013, it is now particularly timely to organise dedicated regional conferences to 'raise the bar' in terms of comprehensive knowledge and awareness among patient communities.

About the conference

This conference is the first in a series of EPF regional conferences for patient communities on the cross-border healthcare Directive. The conference was aimed at patient leaders from the five participating countries – Belgium, Luxembourg, The Netherlands, France and Germany – who have the capacity to transfer learning and knowledge from the conference to peers within their organisations and networks. Participants commit themselves to active follow-up after the event.

The expected outcomes of the conference were:

Clear identification of the roles of patients' organisations in supporting patients' access to cross-border healthcare;

An informal network of patient leaders in each Member State with a strong knowledge base and understanding of the legislation and with the capacity:

- to discern the new rights for patients deriving from the Directive compared to (previously existing) rights under the Social Security Regulation;
- to interact with national government representatives and other stakeholders on the issue and contribute to the effective implementation of the Directive;
- to explain to fellow patient leaders in their Member State facts about cross-border healthcare and how it works in practice;
- to support the effective dissemination of information to the wider patient community in the Member State;
- to be a potential resource to National Contact Points to ensure the information they produce is fit for purpose from a patient's perspective;

- to participate in monitoring the implementation of the Directive from the perspective of patients and provide feedback to EPF and the European Commission.

The Conference lasted one and a half days and was conducted in English. It was structured around thematic plenary sessions and interactive debates with the audience, as well as parallel working groups followed by a closing plenary which presented the key conclusions and proposals on the way forward.

The level of detail contained in this report is intended to capture the priorities and nuances in the different perspectives expressed during the Conference.

Executive summary

With the Cross-border Healthcare Directive, the rules on patient access to healthcare have been clarified and are now in force. However, much work still remains to be done, especially to inform patients of their rights and to explain what is covered and how they might go about exercising their rights.

One of the main functions of the Conference was to enable the European Patients' Forum to help build networks of patient leaders in the Member States who can guide patients on their journey through a complicated system. In so doing, they can contribute towards refining and improving the legal framework and its application, in order to ensure that the system does not constitute a barrier to access to cross-border healthcare.

The Conference received a strong message from DG SANCO that the Commission wants the patient community to be assertive and clear in voicing the patient perspective in terms of what patients want, what is going well and what is going wrong.

There is very real interest among patients' organisations to understand the scope and technical details of the Directive and how these might be implemented in practice, also in comparison with social security legislation. They now have a clearer view of the intention behind the wording of the text from a legislative perspective, and where possible challenges may arise in reality.

Clearly, the Directive is work-in-progress, especially when we consider the incomplete transposition process and the delays in setting up National Contact Points (NCPs). The Directive is about patients' rights, so patients' organisations have a crucial role to play in monitoring progress on specific aspects (e.g. prior authorisation and NCPs) and providing detailed and timely feedback to the Commission and national representatives.

The critical role of the NCP in the effective implementation of the Cross-Border Healthcare Directive was amply demonstrated by the contributions of all participants. A breakout group discussion during Session Two generated a quality criteria "wish-list" for NCPs from the point of view of the patients' organisation. This is a powerful practical tool which patients' organisations can use with some leverage in relation to competent authorities.

In one sense, the lack of substantial progress on NCPs in most Member States can be said to have a positive aspect: it gives patients' organisations a clear-cut opportunity to respond to the

Commission's invitation to provide detailed practical feedback to both the Commission and national authorities that can form part of the planning, setting up and subsequent development of the NCPs in many Member States.

Sessions Three and Four generated serious and detailed discussion about the practical process of obtaining cross-border treatment, also focusing on quality of care, transparency of safety and quality standards and the contribution of European Reference Networks (ERNs) to improving the quality of diagnosis and treatment. The discussion raised a number of key issues and specific recommendations, highlighting the opportunities of the Directive to create change, and in particular some of the ways in which patients' organisations might play an active part in that change in order to provide the care that is needed, reduce existing disparities and improve the quality of care across Europe. At the same time, the discussion served to shed light on some of the flaws and core challenges contained in the Directive as it stands today, in a context of disharmony between national systems both in terms of the availability of treatments and divergent clinical guidelines for the treatment of specific conditions.

There is a gap in the policy-making of Member States but also the European Commission in terms of how to support patients' organisations in Europe – there is no clear vision from them on how to do this. This first in a series of conferences on the Cross-border Health Directive has already highlighted the valuable contribution that patients' organisations can make towards ensuring that this Directive, as well as other health-related EU legislation, reflects the realities of living with a disease and has the maximum positive impact on the lives of European citizens.

With this conference, EPF together with patient communities in the participating countries have taken the first steps towards promoting stronger awareness of this landmark Directive and its implications for patients, as well as creating a network of patient leaders who are committed to disseminating information to their peers and working together with the National Contact Points in their Member States to support effective implementation.

During the next two years, EPF and its members will monitor the impact of the legislation closely from a patients' perspective and ensure that the grassroots patients' experiences will inform the European Commission's first progress report, due in October 2015.

Session 1: The first Directive to focus on "Patients' Rights" – what does this really mean for patients?

Objectives:

- *To provide a clear overview of the scope of the Directive and its application*
- *To highlight its strengths but also potential barriers in implementation, and new rights compared to existing social security legislation*

Moderator Tamsin Rose described the context for the Conference by referring to the fact that although the 1992 Treaty on European Union (the Maastricht Treaty) was the first EU treaty to mention health protection, the subsequent absence of political guidance and the fact that Member States remain responsible for healthcare meant that European policy on the reimbursement of healthcare was being addressed by the European Court of Justice on a case-by-case basis.

With the Directive, the rules on access to healthcare have been clarified. However, much work still remains to be done, especially to inform patients of their rights and to explain what is covered and how they might go about exercising their rights.

One of the main functions of the conference is to enable the European Patients' Forum to help build networks of patient leaders in the Member States who can guide patients on their journey through a complicated system. In so doing, they can contribute towards refining and improving the legal framework and its application, in order to ensure that the system does not constitute a barrier to access to cross-border healthcare.

A. THE EUROPEAN COMMISSION'S PERSPECTIVE

The European Commission's perspective on the Directive was presented by **Nathalie Chaze** from the European Commission's Directorate General for Health and Consumers (DG SANCO). The headline messages regarding the Directive at this stage are:

- the patient's right to choose to receive healthcare from a provider outside his/her country has been confirmed, increased and clearly explained. The system is therefore moving from a process where decisions are made **for** patients to one where decisions are made **by** empowered patients;
- patients' ability to choose – their empowerment – depends on the quality and quantity of information they receive regarding the health systems and treatments that are available on a European scale. One of the biggest challenges of the Directive will be how that information is provided to patients;

- the Directive establishes a minimum set of patients' rights in the EU. Some Member States may choose to exceed them (some already do), but others "may be more cautious in their choices" – pressure from patients' organisations will therefore be a factor. Also, despite the principle of subsidiarity, health is considered to be an economic activity under the Treaty, and so is subject to legal enforcement regarding citizens' freedom of movement.

The basic principles governing cross-border healthcare are: patients have the right of reimbursement when they receive healthcare in another Member State; the level of reimbursement is up to the cost of treatment at home; and the legislation of the Member State of treatment applies in relation to quality and safety standards.

Prior authorisation

The rationale for the Directive's provisions on prior authorisation was that Member States feared an undue financial burden on their health systems caused by an increased outflow of patients from abroad; the Commission therefore inserted safeguards for Member States through a limited provision for prior authorisation, while aiming to guarantee the maximum possible patients' rights. The result is that some Member States may have longer lists than others in terms of care that is subject to prior authorisation.

Prior authorisation may be required for healthcare that involves (a) an overnight hospital stay, and (b) highly specialised and cost-intensive healthcare. If an overnight stay is normal in the home country, then prior authorisation may be necessary when seeking treatment abroad. Treatments in these categories must be clearly defined; for example, there must be transparency on what "cost-intensive" means exactly.

Authorisation may be refused if there is no "undue delay" in accessing treatment, but any refusal must be properly reasoned – there must be an individual assessment of the patient resulting in a specific/detailed rationale for the treatment timeframe, which is then communicated to the patient and can therefore be challenged if necessary. How Member States choose in practice to interpret the various definitions and other aspects of prior authorisation needs to be monitored closely by patients' organisations.

Arguably, patients with rare diseases probably need cross-border healthcare more than other patients, but the political negotiations on the Directive ruled out a specific provision on prior authorisation for rare disease patients. The agreed compromise was to issue a call to Member States to put in place a specific procedure that answers this serious need (e.g. involving assessment by disease specialists rather than generalists, as a matter of course), and DG SANCO will monitor the Member States response to that call – patient feedback would also be welcome in this regard.

National Contact Points to provide information to patients

The Directive sets a new standard in enabling patients to make an informed choice, specifically through the obligation for each Member States to set up a National Contact Point (NCP). NCPs must be able to inform patients who want to go abroad (regarding rights and entitlements, reimbursement and appeal processes), and to tell incoming patients what to expect (quality and safety standards and systems, complaints and the redress procedure, health providers' right to practice). They must provide information on request regarding the accessibility of hospitals for persons with disabilities. NCPs may also resolve possible issues with other Member States' NCPs or

social security systems. NCPs have an obligation to consult with patients' organisations, healthcare providers and healthcare insurers.

Healthcare providers must provide information on: treatment options; quality and safety; prices; authorisation status; insurance and liability cover. Patients should have access to care on the basis of non-discrimination. This applies especially to prices and reimbursement tariffs: providers must apply the same scale of fees as for domestic patients or be able to justify any difference (there is a large and well-established body of jurisprudence to support this requirement). The reference-point for setting reimbursement tariffs must be treatment in the home Member State. There needs to be transparency on the "basket of benefits" and reimbursement tariffs in a way that the patient can understand (i.e. avoiding giving information that is too general or too detailed). This is another aspect of the Directive that needs to be monitored in practice, so feedback from patients' organisations will be welcome.

The Directive sets a minimum standard for patients' rights, including: the right of appeal on authorisation and reimbursement decisions; the right to access information on safety and quality standards and guidelines; the right to a transparent complaints procedure and to seek redress (all health providers must be covered by liability insurance or an equivalent guarantee); the right to privacy; the right of access to/copy of medical records; and non-discrimination on the basis of nationality (including for prices).

What is new compared to the social security Regulations?

Prior to the Directive, EU citizens already had the right to access healthcare in other Member States in some circumstances governed by the EU Regulations on the coordination of social security systems.[1] The Regulations will continue to exist and benefit patients, but there are some important differences between these and the new Directive.

- The Regulations only cover public-sector or contracted providers, while the Directive covers all providers in the EU;
- Prior authorisation is the norm for planned care under the Regulations, but the exception (if used at all) under the Directive;
- The Regulations cover patient costs at the level of the Member State of treatment, the Directive at the level of Member State of affiliation (the "home" Member State);
- The Directive introduces significant "flanking" measures: information; procedural guarantees, etc.

The next steps

The Commission is disappointed to note that some Member States have still not transposed the Directive after two and a half years, and will launch infringement procedures in 2014 where necessary. Similarly, a significant number of Member States have made little or no progress on National Contact Points, so one of the useful aspects of the CBHC Conference is to focus on this issue and provide feedback from patients' organisations ahead of the Commission's reporting and

[1] For more information on this, please see the EPF Toolkit available at http://www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/

recommendations to the European Parliament and Council. The first progress report is due to be published on 25 October 2015.

B. THE PATIENT'S PERSPECTIVE

The patient's perspective was given by **Isabelle Riquier**, a French national living in Germany with Multiple Sclerosis.

She explained that she is not a cross-border patient by choice – rather, this was imposed by her life circumstances and healthcare coverage. She and her husband (an independent consultant) have always worked and lived outside France; they have no link with France other than their health insurance. As French nationals living abroad, they are covered by specific French health/social security structures such as FOM[2] and (more recently) the Caisse des Français de l'Etranger (CFE). The advantage of these structures is that they cover French nationals in whichever country they settle, with no interruption in the coverage when moving. Isabelle's husband was obliged to make social security contributions when professionally active in Spain and Slovenia; these provided complementary health cover at a relatively high cost, but the couple never used it.

Isabelle was living in Slovenia when she was diagnosed with Multiple Sclerosis in October 2010. She and her husband decided to move to Germany in 2011 (Isabelle speaks German) to seek appropriate treatment, but at that time they had no intention of settling in Germany – it was supposed to be a transition period. They did not subscribe to German health insurance, as her husband had registered his professional activity in Tunisia in order to be closer to his core business in Francophone Africa.

Their main health insurance (CFE) is dedicated to French nationals living abroad and gives 100 percent coverage for Multiple Sclerosis – but based on the French cost and when treatment is performed in France. Isabelle initiated treatment by self-injection in Germany, but very quickly the substantially higher cost of the medicine in Germany led her to source the medicine for her treatment in France, in order to have the 100 percent coverage by CFE. Still, it was relatively easy for her to travel occasionally to France to obtain the medicines.

When Isabelle's treatment shifted to monthly perfusions in hospital, initially she received this in Munich. However, the substantially higher medicine cost (and the fact that hospital treatment in Germany is not covered by CFE) soon made this unmanageable, and she began to travel to Strasbourg to receive hospital treatment there.

[2] Mutuelle Familiale France et Outre-Mer

Globally, the monthly treatment is cheaper in Germany than in France, but CFE does not consider the totality of the monthly expenses and instead applies its reimbursement on the different costs. Unfortunately, the medicine represents the biggest part of the expenses in Germany (see table 1).

Table 1: treatment costs in France vs Germany

	STRASBOURG	MUNICH
Medicine (Tysabri)	€1,837.80	€2,385.66
Hospital stay	€1,127.38	€92.96
Transport cost	around €200.00	€5.00
Total amount	**€3,165.18**	**€2,483.62**

Due to CFE's insistence that its reimbursement procedure does not cover 100 percent of the costs generated in Germany (despite the clear financial benefit if it were to do so), Isabelle is now obliged to travel each month to Strasbourg for her monthly perfusion in order to get full coverage from CFE, including travel expenses.

The monthly round-trips are having a negative impact on Isabelle's treatment and are excessively tiring (she wakes up at 4.30am and gets back at 10.30pm). They also prevent her from having appropriate follow-up with a medical consultant. Finally, a significant difference in costs between France and Germany does not allow her to have complementary health treatment such as physiotherapy; her complementary insurance does not cover treatment abroad, and as a patient with a pre-existing chronic condition she is unable to get a new complementary insurance.

Isabelle and her husband have no intention of returning to France. Their professional lives are abroad and if they returned only on health grounds they would no longer have CFE coverage, nor would they be covered by the French social security system (in the absence of professional activity in France). She can receive excellent treatment in Munich and would choose to do so if the treatment were properly reimbursed.

How could the Directive help in Isabelle's case? She would:

- have the opportunity and choice to be treated in Germany or any other EU country within the framework of the global monthly expenses covered in France;
- avoid wasting her energy on exhausting travel (from which she needs a week to recover) and greatly reduce the heavy administrative burden of getting travel reimbursement from CFE;
- have a more balanced life, without always worrying about the next trip, and be able to resume a better level of professional involvement with her husband;
- have the cost of her treatment reimbursed in line with the reality of the expenses. Why be obliged to go to France and spend more money instead of receiving treatment in Germany for less money?

- have a National Contact Point for obtaining appropriate advice; in their current situation, Isabelle and her husband suffer from the absence of relevant contacts able to help them to find a solution.[3]

Implementation of the Directive would therefore lead to three types of benefits for Isabelle and the healthcare system: a health outcome benefit, a quality-of-life benefit and a cost/financial benefit.

Isabelle's case raises some further questions:

- Will the Directive take chronic diseases such as Multiple Sclerosis, with high monthly expenses, into consideration?
- Will chronic diseases receive particular attention under the Directive with regard to the cost burden on the patient, by implementing direct payments between the home health insurer and the treating hospital for patients living abroad?

C. PLENARY DEBATE

Isabelle Riquier's experience already highlights the very uneven levels displayed by Member States in terms of establishing NCPs and transparency – currently, it is no surprise that even the larger Member States present a labyrinth of confusing, sometimes insufficient and sometimes too detailed information to patients. One factor in the unevenness of transparency today is the fact that some Member States did not allow cross-border healthcare at all before the Directive, while others did. This points to the major challenge for all Member State to create a culture of transparency and co-operation regarding patients who are already vulnerable due to their ill-health, and so may not have the capacity to battle bureaucracy for their rights. Generally, healthcare systems are not used to being transparent, they are reluctant, especially on how they operate, individual patient rights, the availability/cost of care and on access; implementing the Directive will require stakeholders to address this resistance to change.

Participants from the Netherlands noted that the Dutch healthcare system is becoming more differentiated in terms of forms of treatment (and therefore access); the privatisation of health insurance 6 to 7 years ago has affected access to treatment, for example by removing free access to certain hospitals. The question raised was how the Directive might impact the choices of insured patients in terms of cross-border access to treatment, given that in the cross-border context patients have a free choice of provider but in the national context of the Netherlands they do not.

The Watts case[4] indicated that: Member States are free to place restrictions on their own citizens within national systems, but this does not affect EU law in terms of access, hence the right of even their own citizens to access care from a private provider on a cross-border basis. Similarly, irrespective of the restrictions that might be operated nationally by health insurers, they cannot apply the same approach to cross-border treatment. In terms of non-discrimination, Member States

[3] It should be noted that recently Isabelle was able to have useful and helpful contact with the German National Contact Point, but so far she has no information from the French Ministry of Health and Social Affairs regarding a French NCP.
[4] ECJ judgement C-372/04.

are also required to put in place a system of liability insurance (or its equivalent) in order to give guarantees to cross-border patients.

Other questions addressed prior authorisation and divergent clinical guidelines in different Member States. There is already evidence of problems and delays in obtaining prior authorisation in some Member States, so a recognised timeline would be useful to patients. As the Directive is now in force, patients' rights exist and Member States must demonstrate due diligence in responding within a reasonable time to requests for prior authorisation. The Commission would very much appreciate feedback from patients in order to assess the effectiveness of this aspect of the Directive.

There is also disharmony between national systems both in terms of the availability of treatments and divergent clinical guidelines for the treatment of specific conditions; for example, chemotherapy for colorectal cancer has assumed the character of personalised medicine in Germany, which is far from being the case in Latvia. This is a specific health inequality affecting patients with chronic diseases. Travelling abroad for treatment can impact a patient's professional as well as personal life, e.g. when an employer is not happy with an employee having to travel frequently for treatment of a health problem.

The lack of harmonisation of guidelines gives even greater importance to the patient obtaining accurate information on quality standards abroad from the NCP. The Commission does not aim for harmonisation of clinical guidelines across Europe (it cannot dictate to Member States what they offer, especially when there are national budget issues); rather, it believes that the European Reference Networks established under the Directive and patient feedback may reduce the disparities in guidelines and improve the quality of care across Europe.

In response to a question regarding long-term care, it was clarified that chronic and long-term conditions are covered by the Directive – it is long-term ancillary care (e.g. social support, nursing homes) that is not covered. Also, access to clinical trials is not normally part of the "basket of benefits" and therefore is not covered by the Directive – patients would need to look more towards the future Clinical Trials Regulation.

Finally, there are questions as to how medical records travelling across borders will be treated between national systems. Will there be a reliable standard of translation? Also, the languages of the local and cross-border care providers can be a determining factor in a patient's choice, so information on these needs to be made available in advance.

D. MAIN OUTCOMES

There is very real interest among patients' organisations to understand the technical details of the Directive and how these might be implemented in practice. They now have a clearer view of the intention behind the wording of the text from a legislative perspective, and where possible challenges may arise in reality.

Clearly, the Directive is work-in-progress, especially when we consider the incomplete transposition process and the delays in setting up NCPs. It is about patients' rights, so patients' organisations have a crucial role to play in monitoring progress on specific aspects (e.g. prior authorisation and NCPs) and providing detailed and timely feedback to the Commission and national representatives.

Session 2: The crucial role of National Contact Points (NCP) and creating a model that meets the needs of Patients

Objectives:

- *To recognise the critical role of the National Contact Point in the effective implementation of the Cross-Border Healthcare Directive*
- *To understand the purpose, potential and role of patients' organisations in supporting and monitoring the development of the National Contact Points*

At the start of this plenary session, participants broke out into small groups of five people each to discuss the following questions:

1. What would a model National Contact Point look like?
2. What are the quality criteria and critical success factors?
3. How should patients' organisations be involved in the effective evolution of National Contact Points in the participants' five countries?

Conclusions regarding these questions were reported by each group and then discussed. The synthesised list of conclusions can be clustered as follows:

Fundamental principles

- The NCP should adopt a multi-stakeholder approach (e.g. co-operation with the domestic social security system, active involvement of patient groups/experts/health professionals);
- It should demonstrate independence and transparency.

Accessibility and availability:

- The NCP should be easily accessible (aim to be barrier-free);
- It should have a website, free telephone line, free 24-hour emergency hotline, email, and physical premises with disabled access (for patients who may not be able to contact the NCP via the internet or by phone);
- The website should:
    - be easy to find;
    - be easy to understand, including FAQs and guides;
    - have content that is informative and clearly-structured;
    - explain the benefits of the Directive;
    - clearly indicate patient's rights;
    - include a check-list for application by patients.

Visibility

- Care should be taken to select a national name that is easily identifiable both domestically and from abroad;
- Information about the NCP and how to contact it should be widely available;
- Information/awareness campaigns (e.g. in hospitals, doctors' surgeries) during launch and after, setting specific targets (e.g. NCP should be known by 80 percent of the public by the end of year one).

Operation

- Responsiveness is crucial: the NCP should respond quickly (or at least within a reasonable time, e.g. one to two weeks), replying to all questions;
- Information provided should be clear to lay people – "designed for and by patients";
- Process should be patient-friendly, also allowing for individualised guidance (case managers);
- Process should take a multi-language approach, requiring an in-house pool of language skills, and address cultural sensitivities; languages should be the mother tongue(s) of domestic patients, foreign languages for visiting patients plus English.

Quality standards

- The NCP must be perceived as being reliable, providing accurate information;
- It should have at least a basic knowledge of procedures abroad, including the quality standards of treatment according to country; failing that, it should know who to ask;
- Staff should be educated and well-trained to respond to enquiries;
- There should be adequate staffing according to demand, and specific personnel tasked with resolving issues between NCPs;
- A quality control system should be in place to monitor performance indicators such as response time to applications; quality control must incorporate patient involvement, e.g. satisfaction questionnaire.

Action at the European level

- There is a clear need to address disparities between Member States and issues arising from national competence in health. Measurable progress could be achieved through:
    - Ensuring interoperability of databases, aiming for a degree of integration;
    - EU funding to support the functioning of NCPs;
    - Co-ordination between NCPs, e.g. by creating a European NCP "forum" or network to provide support and promote best practices;
    - Feedback, reporting and evaluation (after 12-18 months) at European level;
    - Benchmarking process at both national and European level; specific targets could be set for convergence on response-times and quality standards;
    - Providing a forum for exchange of experiences between patients;

- Providing a European contact-point for patients and other stakeholders (e.g. via EPF or European Commission);
- Addressing complaints at European level, not national level.

A. PRESENTATION OF THE BELGIAN NATIONAL CONTACT POINT

The Belgian NCP was presented by **Chris Segaert**, International Relations Advisor at the National Institute for Health and Disability Insurance (NIHDI).

Information

The Belgian NCP provides information to Belgian patients and health professionals on: rights to cross-border healthcare and reimbursement; a shortlist of forms of healthcare subject to prior authorisation (including overnight stay in hospital) and how to apply for it; a restricted list of services requiring heavy medical equipment (e.g. PET scans), due to these being subject to a programming policy in Belgium; procedures for appeal; specific situations such as temporary stay and planned healthcare, but not healthcare entitlements when Belgian patients move to live abroad.

The Belgian NCP provides information on the Belgian healthcare system to foreign insured patients who are considering medical treatment in Belgium, for example: patients' rights; the right of healthcare providers (both physical persons and institutions) to provide services and possible restrictions; a list of all types of healthcare providers permitted to practice in Belgium under national law; accessibility of hospitals for persons with disabilities; complaints procedures and procedures to seek redress; possibilities to seek remedies in case of harm; quality and safety standards; and regarding Belgian invoices.

The NCP does not provide information on: patients' rights and entitlements in other Member States or the healthcare systems in other Member States (patients are referred to the NCP of the relevant Member State); long-term care (home care services, nursing homes, etc.); complementary healthcare insurance; organ donation; nursing facilities for persons with disabilities, childcare, etc.

Organisation and funding

Although Belgium is a small country, it is also a complex country from the political/cultural point of view. Its federal composition already makes Belgium a "little Europe": it has seven health ministries with competence in one way or another on different levels, requiring inter-ministerial conferences to co-ordinate policy and practice on healthcare issues.

A Protocol Agreement was signed on 24 June 2013 between the federal government and the federated entities concerning the organisation and financing of the NCP. It created a single NCP for Belgium to speak and act with overarching competence over the regional health authorities. It is co-ordinated by the Federal Public Service for Public Health and jointly funded by FPS Public Health, NIHDI, and the federated entities.

How the contact centre works

Patients can contact the NCP by telephone, email or using a web form on the NCP website in four languages: Dutch, French, German and English.

When the patient contacts the NCP, s/he communicates with specifically-trained staff in the front office. A very complicated question will be referred by the front office to service specialists in the back office. If the question calls for further input, it will be referred to Team Leaders heading teams that are each expert in particular services. The answer is finally given to the patient by the front office, which always acts as the interface between the patient and the NCP/competent authority.

A central Service Agreement signed at the federal level provides for quality control and benchmarking criteria, e.g. for response times, quality of response. Although quality standards are set at the federal level, they are most often monitored at the federated entity level, which can apply additional standards.

The website

The NCP's website, www.crossborderhealthcare.be, was given an English name in order to avoid the Dutch/French/German language debate. It provides general information in the four languages, and more detailed information on the websites of the competent authorities/administrations (in the languages of these competent authorities/administrations). For personalised advice, patients are referred to their healthcare insurance fund, which is the entity in Belgium that knows the most about the patient's file.

The site provides: information to Belgian patients and health professionals on entitlements to cross-border healthcare; information to foreign insured persons on the Belgian healthcare system; contact details of NCPs in other Member State; and details of the competent authorities/administrations involved. Given the gaps in available information, parts of the website are still under construction and so overall it is a work-in-progress.

Consultation with stakeholders

No official consultation with stakeholders took place prior to the creation of the Belgian NCP, although some stakeholders (e.g. healthcare insurance funds) had informal input. Currently a "roadshow" is underway, presenting the NCP to the national Commission for Patient Rights (29 November 2013), the umbrella organisation of national healthcare funds (January 2014), and the Observatory for Patient Mobility (which monitors the inflows of foreign patients and the impact on the accessibility for Belgian patients in hospitals). Evaluation will be carried out in the future, taking into account the feedback of all stakeholders, the general public and others.

B. PRESENTATION OF THE INTERIM REPORT OF THE EUROPEAN COMMISSION BEHAVIOURAL STUDY ON INFORMATION AND CROSS BORDER HEALTHCARE

The European Commission recently initiated a study on the National Contact Points (NCPs), following a first feasibility study commissioned in 2011. The interim results of this in-depth behavioural study were presented by **Dr Charlotte Duke**, Partner at London Economics Ltd.

The objective of the study was to use behavioural economics to pre-test some concepts and thus inform the development of NCPs. The method chosen was to implement an online experiment to address two key areas:

- Key drivers and barriers to choosing healthcare treatment in another European country; and
- How information is presented on healthcare websites: the impact of framing on understanding and choice to remain at home or to seek healthcare in another European country.

The process

Pairs of hypothetical NCP portals – a home country NCP and cross-border country NCP – were set up based on the requirements under the Directive, plus previous Commission data on what has been done so far regarding NCP websites. Each NCP had three pages of information, with links between them such that participants could browse in a natural fashion moving backwards and forwards between the pages and the home and cross-border NCP. Each cross-border country NCP contained a link to "Quality and Safety" and a link to a list of providers.

Framing of the webpages

- Design: The reimbursement page was re-framed to highlight possible advantages of going cross-border rather than only focusing on reimbursement;
- Language: Each home country NCP was available in English and the language of the respondent's home country. The cross-border NCP was also provided in the language of the respondent's home country;
- Complexity: The reimbursement page was modified to include more detailed and complex information on medical treatments, to test how much was too much information;
- Information source: Details on cross-border providers' legal requirements and validation processes were provided by the home NCP instead of the cross-border NCP.

Choice between providers

Respondents were asked to indicate which of two specific healthcare options (home/cross-border) they would be more likely to choose in a given scenario (with variations in waiting time, cost, travel distance, etc.). Based on prior research, the experiment took root-canal dental treatment, hip replacement treatment and heart bypass surgery as its three representative test services.

Country pairings for the experiment were selected based on existing evidence of cross-border healthcare provision and using expert advisor opinion. Individual pairings (country of origin/target country) were: Denmark/Germany, Estonia/ Finland, Germany/Netherlands, Italy/Austria, Poland/Germany, Spain/Germany, Sweden/Denmark and Czech Republic/Austria.

Key drivers and barriers for citizens

Motivation for seeking cross-border healthcare: to receive a treatment that is not available in domestic country (64 percent); to receive better quality treatment than at home (34 percent), to receive treatment more quickly than at home (29 percent), to receive cheaper treatment than at home (25 percent), to receive a treatment from a renowned specialist (24 percent). Twenty percent

of respondents indicated they would not choose to travel to another EU country to receive medical treatment.

Cost to the patient was the greatest driver of choice. If cost of domestic treatment relative to cross-border cost is doubled, citizens are roughly 40 percent more likely to choose cross-border – this was highly statistically significant in all regression specifications used.

Waiting time was the second greatest driver of choice in the experiment. If domestic waiting time relative to cross-border waiting time is doubled, citizens are roughly 20 percent more likely to choose cross-border – this was highly statistically significant in all regression specifications used.

Relative trust and confidence varied according to the nature of the treatment: respondents expressed low confidence in domestic and high confidence in cross-border country for root-canal dental treatment, but high confidence in domestic and low confidence in cross-border country for heart bypass surgery.

Key drivers and barriers: Other findings

- Language is an important barrier (linked with possible familiarity with the country and customs). Respondents who spoke the language (and perhaps had some familiarity of the culture) of the cross-border country were more likely to choose the cross-border option;
- Men were more likely to choose cross-border option (this supports previous findings by Eurobarometer)[5];
- Respondents who are more risk-averse were less likely to choose the cross-border option.

Framing of information on websites

- Specific framing of the information on the mock-up websites did not have a statistical impact on respondents choice in the experiment;
- However, respondent understanding (measured in an incentivised quiz), tended to be lower when information on treatment options was presented in more complex terminology.

So what does this mean for NCP websites?

- Access to information on costs and waiting time should be available through the portal;
- Trust is a major factor: websites should provide clear information about healthcare providers in other Member States including liability insurance, quality and safety standards; they should also provide reviews (case studies) of other patients' experiences in the cross-border country;
- Information that is not too complex for users.

Phase II of the experiment will explore the complexity and the framing of the information in much greater detail. It will involve a survey and experiment hosted on some of the existing NCP sites,

[5] See, for example, Flash Eurobarometer 210, "Cross-border health services in the EU. Analytical report", 1 June 2008.

conducted end-February through March 2014. Phase II will seek engagement with organisations (e.g. DG SANCO, EPF) to promote the study and encourage participation.

C. PLENARY DEBATE

The representativeness of the sample was queried by some participants. It is important to note that the 5,000-6,000 respondents to the study represented the general population, rather than just patients.

When 64 percent of respondents are motivated to seek cross-border healthcare because treatment is not available in their home country, this does not differentiate between the general patient population and patients with rare diseases, who all too often are compelled to seek treatment abroad because it does not exist in their home country – but they can only do so if they pay for themselves upfront, so poorer patients are barred from access. So to quote a figure of 64 percent can be misleading and create false expectations among patients generally. Furthermore, the study and the selected scenarios (dental treatment, hip replacement) did not specifically address the life situations and concerns of patients living with one or more chronic diseases.

The question was raised as to who is responsible for making the decision on access to cross-border healthcare. The Belgian NCP's representative explained that it can give advice but not a decision on where a patient should go for cross-border healthcare; rather, it refers the patient to the competent authority. The danger is that the patient may then face heightened bureaucracy and lengthy delays from the competent authority, or may have a lack of trust in a health insurer's answer. What should the patient do then – who will advise her/him? This will need to be clarified.

Participants noted the lack of consultation before the Belgian NCP was set up. The reason for this gap was two-fold: the particular challenge of forging consensus among several authorities regarding the many practical and political aspects of the proposal, and the very short time-frame for consulting all stakeholders (particularly the patients' organisations), given that final agreement to set up the NCP was only obtained in June 2013 (just four months before the 25 October deadline).

Another hurdle to setting up the Belgian NCP was funding: the national government's response was that it had no budget for it, so funding had to be carved out of the existing budgets of the federated entities. On that basis, the estimated budget for 2014 is of the order of just €80,000 (primarily allocated to the contact centre). If and when the money runs out in 2014, the authorities involved will have to negotiate new emergency funding. This underlined the recommendation made by the participants that funding should be available at EU level to support the functioning of NCPs.

D. MAIN OUTCOMES

The critical role of the National Contact Point in the effective implementation of the Cross-Border Healthcare Directive was amply demonstrated by the contributions of all participants in the small breakout groups as well as the featured presentations.

In one sense, the lack of substantial progress on NCPs in most Member States can be said to have a positive aspect: it gives patients' organisations a clear-cut opportunity to respond to the

Commission's invitation to provide detailed practical feedback to both the Commission and national authorities that can form part of the planning stage in setting up NCPs many Member States as well as their future development.

Session 3: Parallel Workshops – The Patient Journey in Cross-Border Healthcare

On the afternoon of the first day, participants split into three parallel groups, with 10 or so people in each group. The parallel sessions were then repeated to enable participants to attend two out of three groups. The outcomes were reported in plenary session on the morning of day two.

Objectives:

- *To address specific aspects of the Directive from the perspective of "the patient journey"; to provide more detailed information on which aspects of the Directive are relevant at different stages and what specific information needs patients will have*
- *To generate a discussion identifying critical issues from a patient's point of view, and develop recommendations for Member States and patients' organisations in this regard, to create a sense of "ownership"*

Workshop A – Before leaving/when deciding whether or not to seek cross-border healthcare:

Prior authorisation; rights under the Directive versus the Regulation; referrals/dialogue with health professionals; assessing medical need; what information patients need to make a decision; and what they need to think about before leaving.

Workshop B – When accessing care abroad:

What information patients need to know regarding the Member State of treatment and care providers, e.g. quality and safety standards, administrative processes, prices and payment, etc.

Workshop C – When returning home:

Issues regarding reimbursement; complaints and redress mechanisms; continuity of care; e-prescriptions.

Session 4: Feedback from the Workshop rapporteurs on the key issues and recommendations from Session Three

Objectives:

- *To reinforce information gleaned on the thematic topics and the issues raised*
- *To enable the participants to obtain a clear overview on the outcomes of the workshop in which they were not involved*

A. WORKSHOP A: BEFORE LEAVING/WHEN DECIDING

(Findings of Groups 1 and 2 combined)

Information

- Where do I get my prior authorisation and what do I need to do?
- Where is the care/treatment I need? The patient's physician will not necessarily be able to answer this;
- Easy access to lists on reimbursement, costs, etc.;
- Specifying "undue delay" on a case-by-case basis;
- Patient experience of other NCPs should be shared.

Key issues

- Own patient's money is needed/involved (upfront payments);
- Is follow-up prescription medicine paid for and available in the home country?
- Additional reimbursement (e.g. if you need to duplicate or translate your medical record)?
- (Un)certainty of exchange of digital/medical record;
- Translation: medical file and hospital/consultation and cost;
- Time, especially possible delays to treatment due to poor response time by NCP;
- Where is my specific treatment available?
- Who will review my prior authorisation?
- Is the safety and quality of hospitals monitored?

Recommendations

- An independent board of people who review prior authorisation requests;
- Information given by the NCP should be informed by patients' organisations;
- Checklist for getting service abroad, what steps to take, what information to gather;
- Quality of hospitals, waiting-lists, success rates, and doctors via reliable, non-biased information – preferably via NCP;
- Soft data and questions regarding specific providers and/or experiences via patients' organisations.

B. WORKSHOP B: WHEN ACCESSING CARE ABROAD

Key issues (Group 1)

- Information on the different clinical/treatment guidelines applied in Member States, especially where more than one step is needed for diagnosis;
- Information to find health professionals/institutions that provide quality care in your disease-area – how do you know that a professional is appropriately qualified?
- Communication and language barriers;
- Discrimination by healthcare staff;
- Transfer of information (medical records), e.g. accurate translation, portability;
- Information on waiting-lists in target country;
- Logistics for patients: travel, accommodation, etc.

Key issues (Group 2)

- Language/cultural barriers – including dealing with allergies, dietary issues, etc.;
- Unexpected problems – e.g. treatment is not what was discussed, longer stay, extra costs, safety concerns, etc.;
- Logistics – e.g. travel support, accommodation of carers, etc.;
- Possible discrimination by staff as “health tourist”;
- Different patient rights in different Member States;
- Reimbursement concerns (may still arise).

Recommendations (Group 1)

- Care providers to provide multilingual information for patients; information about health professionals’ language skills to be made available in advance;
- Mechanism for facilitating the “logistics“, including Member States to support reasonable extra costs (travel, disability);
- EU database of healthcare providers (including qualifications and experience) for patients by disease-area;
- European Reference Networks can recommend guidelines for one country that can be recognised and used in other countries;
- Develop best practices for transfer of patient data: safe, effective and respecting patients’ privacy.

Recommendations (Group 2)

- Medical expertise should travel rather than patients, whenever possible;
- Quality of care guidelines could be improved at European/international level with patient input;
- Development of European Reference Networks;
- Disease-specific “travel” guides developed by patient groups (possibly with industry, e.g. apps);
- Hotline for emergencies;
- Possibility of complementary insurance to cover unexpected situations?

- Support person (e.g. peer-to-peer, buddies) who can help with problems, e.g. logistics, communication, etc.

C. WORKSHOP C: WHEN RETURNING HOME

(Findings of Groups 1 and 2 combined)

Key issues

- Clarity on reimbursement (should also be considered before leaving/when deciding);
- Continuity of care, access to medication;
- Collaboration/communication as early as possible between all stakeholders, based on trust;
- Different jurisdictions: language, but also redress, data protection, drug use, hygiene regulations;
- Quality of care vs quality of life (the emotional/psychological aspects of getting care abroad);
- Infection risk (e.g. MRSA);
- More general concerns about the Directive.

Recommendations

- Reimbursement procedures: specific cross-border healthcare tariffs could guarantee good follow-up and continuity of care;
- Harmonisation of procedures and guidelines (eHealth, hygiene, data protection, etc.) – or at least synergies and convergence based on best practice and trust;
- Cross-border healthcare Ombudsman to oversee redress – immediate trouble-shooting (e.g. via hotline), not legal wrangling after the event;
- Multi-stakeholder approach – trust and synergies.

Session 5: Quality of Care and Patient Safety

A. QUALITY OF CARE AND PATIENT SAFETY – CORNERSTONES OF THE LEGISLATION

Objectives:

- *To ensure a full understanding of: the provisions in the Directive focusing on quality of care, transparency of safety and quality standards; the impact of this for the patient seeking treatment abroad; and the wider policy context*

Achim Kautz of the European Liver Patient Association (ELPA) focused on two crucial aspects of the Directive.

Article 4 of the Directive specifies that "*Member States retain responsibility for providing efficient and quantitatively adequate healthcare to citizens on their territory*". Providers of cross-border healthcare services should also ensure that patients have all the necessary information to make an informed choice with respect to: treatment options and their availability; quality and safety of the healthcare; invoices; and prices and reimbursement policies. Article 4(2) specifies that Member States must provide information to patients on their national standards and guidelines on quality and safety. They are also required to cooperate with each other in the area of safety and quality standards and guidelines (Article 10).

Member States are therefore obliged to publish their safety and quality standards and guidelines. This transparency is potentially a huge step towards patient empowerment, as patients can compare standards and patients' organisations can use this information to advocate for better quality healthcare both at home and abroad.

However, what is missing from the Directive is a definition of "quality and safety". Instead, the Directive states that cross-border healthcare must be provided to patients in accordance with the safety and quality standards and guidelines that are in place in the Member State of treatment, and where applicable in accordance with EU legislation (Article 4(1)). This is an area where patients' organisations can play a valuable role, defining some criteria for "safety" and "quality" which the Commission could adopt.

Also missing is a definition of "transparency". It was already evident, before the Directive came into force, that national standards are hard to identify and sometimes inconsistent. If this uncertainty is preserved in the Directive, how can issues relating to standards be tackled when things go wrong? What happens then?

The Directive is based on the principle of non-discrimination: patients should be treated equally irrespective of their origin (overseas or domestic) or ethnic background (Article 4(3)), and providers must not apply higher fees for overseas patients (Article 4(4)). As has already been highlighted in the workshops, when foreign patients experience discrimination, this is almost invariably expressed in a lower quality of care.

So, how are patients to find the "provided information" referred to in the Directive? Achim gave a living example: "A short while ago, I asked a colleague to look on the internet for a link to the German NCP. After two days of looking, she found the only one on the europa website, at http://europa.eu/youreurope/citizens/national-contact-points/germany/index_en.htm#health. The trouble is, when we clicked on the link indicated for the NCP website, we got the message: "10.4.5 404 Not Found", i.e. the server has not found anything matching the requested URL. No indication was given as to whether the condition was temporary or permanent."

If even basic information cannot be accessed at the start of a patient's search, then clearly there will be problems with awareness of the Directive itself. The challenges were described very well in the workshops. They start with: How to find the right information? It is hard for a patient to find national standards of quality and safety, and it is even harder to find the standards of quality and safety in another Member State – even if you speak the language.

Extremely few patients are trained to the point where they are able to compare the standards of care of two Member States. Achim pointed out: "There are some 158 liver diseases, ranging very widely from extremely rare to very common. Even after many years in the field, it is hard for me to compare the standards of care for all the different liver diseases – for a normal patient, it is impossible."

Regarding continuity of care, the Directive states that "*if a medical follow-up proves necessary after their return home, the home country must provide the same follow-up as for treatment received at home*". But what if the medication is not available or the guidelines are completely different in the home country?

And what if something goes wrong? It is recommended in the Directive that patients contact the National Contact Point to get information on complaint procedures and seeking remedies in the country of treatment. But in real life, said Achim, "no patient is able to find the way through the bureaucratic jungle; and then if the response time is too long for a chronic patient, then he or she might be dead before getting even an initial answer." This is another aspect on which patients' organisations can make a valuable contribution, by providing easy-to-understand information for their patient communities.

Some conclusions:

1. At this stage, it is hard to get all necessary information regarding the quality of care and patient safety. Solution: Many more NGOs and public health institutions – but also GPs and health insurance providers – must be trained to provide the best information. In parallel, the information should be much easier to find via the internet.

2. Different guidelines and different interpretations of guidelines make some medical help impossible. Solution: An easy-to-understand toolkit should be produced that explains all the issues regarding safety and guidelines and enables the patient to compare both aspects.

3. For most patients, the language barrier is the biggest obstacle. Solution: NCPs should be able to refer to translators, but also to "culture translators".

In summary: the Cross-Border Healthcare Directive is a very good initiative, but at this stage it is "like a child who has just learned to walk." Patients have the power to put pressure on the Commission to

carry out very urgent fine-tuning of the Directive, as one step towards the same high quality and safety in healthcare standards across Europe, and towards ensuring that every European citizen has the same access to the medication s/he needs. There is a lot for patients' organisations to do.

B. EUROPEAN REFERENCE NETWORKS

Objectives:

- *To discuss European Reference Networks (ERNs) and their contribution to improving the quality of diagnosis and treatment*

Flaminia Macchia of EURORDIS focused on the role of European Reference Networks in delivering cross-border healthcare.

European Reference Networks (ERNs) have already existed for some years. The process started in 2004 with the High Level Group on Health Services and Medical Care, continued with the Working Groups on European Reference Networks, and culminated in the Cross-Border Healthcare Directive which gave a legal basis to the creation of ERNs of healthcare providers and Centres of Expertise – in particular in the area of rare diseases – based on voluntary participation.

According to the summary report of the replies to the European Commission's Public Consultation on the Implementation of European Reference Networks, "*The main added value of the European Reference Networks and of the Centres of Expertise is the* ***improvement of access to both diagnosis and*** *high-quality, accessible and cost-effective* ***healthcare*** *for patients who have a medical condition requiring a particular concentration of expertise or resources, particularly in medical domains where expertise is rare.*" But although the focus of ERNs currently is rare diseases, they provide a model that in future could be applied to other chronic conditions to enhance the quality of care across Europe.

There are over 6,000 diseases which are designated as rare. This poses particular challenges: patients are rare, and so experts and expertise are also rare. Centres of Expertise reveal where the expertise lies and gather together the existing experience to improve patient care. Nationally-designated Centres of Expertise therefore form the core of the ERNs, which will also include healthcare providers, labs where genetic testing is done, patient groups and individual experts. Member States are encouraged to foster participation of Centres of Expertise and healthcare providers in the ERNs; offers of funding would be the most obvious incentive.

To organise common healthcare pathways at national and European levels, it is necessary to build networks. Centres of Expertise can have very different structures by country – ERNs therefore need to be flexible to integrate those differences. ERNs have a key role in facilitating patient mobility as provided for in the Directive – but experts should also be prepared to travel between Centres of Expertise, to encourage mobility of expertise.

What would be expected to form the core tools and activities of the ERNs?

- Disease registries: international terminology to support interoperability as part of a global data-sharing effort;
- ERNs should promote the use of lab testing facilities which participate in Quality Assurance programmes (e.g. EuroGentest);[6]
- ERNs should develop a mechanism for sharing good practice guidelines for diagnosis and care between Member State;
- Training and education tools to raise standards of care;
- Multi-stakeholder evaluation of ERNs (including patients' organisations) with indicators covering processes, outcomes and impact (including patient-reported outcomes);
- Communications infrastructures to ensure visibility of the ERNs, their processes and accessibility (own website and Orphanet);
- Cross-border referral mechanisms to help operate the Cross-Border Healthcare Directive and the Regulation on the coordination of social security systems to their full potential;
- In all of these areas, telemedicine is crucial to supporting remote patient consultations, training and education.

Going forward, the focus will be on implementation, so what should be envisaged regarding ERNs for rare diseases at the national level is to: integrate different national structures; identify and access adequate funding; ensure real patient involvement; provide comprehensive care; and promote research (ideally, a rare disease ERN should be able to lead a clinical trial). As a minimum common denominator, an ERN should gather a critical mass of patients to support research and be able to develop and share best practices.

Another important aspect is that patients should be meaningfully involved at all levels of activity, from managing an ERN to membership of steering committees/Board/project groups (active and equal participation in governance and evaluation). In fact, participation by patients' organisations should be a prerequisite for an ERN to receive funding. Conversely, an ERN's budget should include funding for patients' organisations to allow full participation, as well as networking between patient groups representing the conditions covered (e.g. in the form of a Federation).

Flaminia highlighted that "Rome was not built in a day":

- Implementation of the Directive will be stepwise and progressive, starting from the most advanced and organised groups; ERNs will not spring up fully-formed;
- Pilot projects led by the European Commission;
- It is better to identify short-, medium- and long-term priorities and do them well rather than try to do everything at once;
- Patients' priorities include: best-practice guidelines for diagnosis and care; networking between healthcare providers and patient groups; clinical research, registries, clinical trials; social care.

[6] See http://www.eurogentest.org/index.php?id=138

ERNs are still in the making. Within the framework of the Directive, in 2014 the European Commission will adopt: a list of criteria that ERNs must fulfil; a list of criteria that healthcare providers must fulfil to join an ERN; and criteria for evaluating ERNs. Member States should be able to implement those measures, e.g. identify Centres of Expertise on the basis of the adopted criteria.

Also in 2014, the Commission will launch a call for ERN candidatures. Member States, Centres of Expertise and existing Networks should be prepared to participate. Are they ready in your country?

In 2015, in a call under Horizon 2020, the Commission will fund a pilot to define validated models of organisation of ERNs.

The vision of patients with rare diseases:

- All rare diseases covered by at least one ERN which will focus on groups of diseases such as rare hematologic diseases, genodermatoses, rare pulmonary diseases, etc. Every patient with a rare disease should have a "home" ERN;
- ERNs should deliver and disseminate structured healthcare pathways through a high level of integrated expertise to improve diagnosis and care to the best European standards;
- In the future, 20 to 30 rare disease ERNs to be established: "*Based around the concept of medical specialties and body systems, diagnostic and therapeutic areas can be identified each covering a wide range of rare diseases.*"[7] These would also include one ERN for undiagnosed patients;
- Rare disease ERNs must be multidisciplinary to address multisystem disorders and must include social care; networks should encompass Centres of Expertise, healthcare providers, social workers, patients' organisations, genetic testing labs, research groups, etc.

C. PLENARY DEBATE

The role of patients' organisations was discussed. The challenges posed to the patient's journey by an "imperfect" Directive imply a further burden on the capacity of patients' organisations – especially when one considers that 90 percent of them are voluntary, so members are called upon to contribute their time and energy on top of the commitments of a normal life and managing a disease. If patients' organisations are to be involved in the process of working with the NCPs, then they need support – including financial support (e.g. from the government for a secretariat) – to build their capacity. One possible solution would be to hold an annual meeting or conference of patients' organisations at the national level to review the situation and decide how best to work with the NCP in terms of practical issues arising from different aspects of the patient's journey.

One aspect that has not yet been addressed clearly enough is the costs relating to recovery from major surgery such as a splenectomy/colectomy or hip replacement, which might take up to a year

[7] EUCERD Recommendations to the European Commission and the Member States on European Reference Networks for Rare Diseases (RD ERNs), 31 January 2013.

or even more. In Germany, there are specialised rehab clinics that substantially improve a patient's recovery and quality of life. Are such essential costs all covered by the current definition of reimbursable costs (continuity of care)?

Regarding greater harmonisation of safety and quality standards, the currently ongoing Joint Action on Patient Safety and Quality of Care[8] funded under the health programme involves all 28 Member State governments and a number of stakeholders (doctors, nurses, pharmacists and health managers, as well as EPF representing patients). One of the goals of the 3-year project is to look at common definitions and principles around quality and safety. Perhaps insufficient linkages have been made with the potential outcomes and outputs of this Joint Action and the quality and safety aspects of the Cross-Border Health Directive: it could potentially make a major contribution towards the effective implementation of the Directive. It was suggested that EPF could encourage more conversations between the people in Member States responsible for the Directive and those responsible for the Joint Action.

A problem that is common to 27 out of the 28 Member State is a general decrease of the order of 4 to 10 percent in the healthcare budget for the ministries (the only exception being Germany with a 1 percent increase, which in real terms is less than last year). The problem for each Health Ministry is that many new demands are being placed on the budget at the same time, but its budget was set the year before. So as these demands are addressed in turn, there is less and less available to set aside for setting up and developing a NCP, for example. Patients' organisations should therefore not concentrate on the health ministries, but also go to the social ministries and the justice ministries, because patients' safety is a human right, so maybe those other ministries could spare some funds.

There is a clear link between ERNs and NCPs, in that ERNs (or, if an ERN is not present in a particular country, the most relevant Centre of Expertise) are an obvious source of expert information which NCPs can make available to patients. There must therefore be strong two-way communication between NCPs and those with the relevant knowledge, so NCPs must have access to the right (inter-connected) databases.

D. MAIN OUTCOMES:

Serious and detailed discussion about the practical process of obtaining cross-border treatment has highlighted the opportunities of the Directive to create change, and in particular some of the ways in which patients' organisations might play an active part in that change in order to provide the care that is needed.

At the same time, the discussion has served to shed light on some of the flaws and core challenges contained in the Directive as it stands today.

[8] www.pasq.eu

Session 5: Exploring the role of patients' organisations in securing effective implementation of the Directive

A. THE ROLE OF PATIENTS' ORGANISATIONS – THE CASE OF FRANCE

Objectives:

- *To outline possible actions based on previous experience*
- *To develop a plan of action in terms of cascading knowledge from the conference*
- *To support and to ensure the commitment of the participants to pursue this and be part of an informal network for evaluation.*

Thomas Wiest and **Charlotte Roffiaen** of the Collectif Interassociatif Sur la Santé (CISS) highlighted the role of patient advocacy in achieving progress.

CISS brings together 40 associations with complementary approaches, including associations of patients, seniors, disabled people, families and consumers. It coordinates a network of 25 regional CISS across France, allowing it to be heard when health policies are decided and implemented at the regional level, but also to inform, advise and train representatives of healthcare users who sit in regional, territorial and local bodies.

Cross-border healthcare is already a reality on the basis laid down before the Directive came into force. In 2012, France reimbursed over €481 million for treatments received by French citizens in other EU countries: Belgium €212.5m, Spain €95m, Portugal €77.8m, Germany €27.2m and Switzerland €22.5m. In comparison, France was reimbursed over €615 million. These figures show clearly that most travel for healthcare is to a neighbouring country.

The question today is: will implementation of the Directive change these figures substantially, and would that change be for the better or worse?

Also, is the Directive a solution to the issue of patients foregoing healthcare? In 2013, 33 percent of French citizens did not seek healthcare for financial reasons (up from 27 percent in 2012). A quarter of citizens (25 percent) gave up regular dental care; 17 percent forewent the purchase of optical products; 12 percent gave up medical check-ups; 7 percent the purchase of medicines; and 7 percent forewent heavy treatments.

The global rate for EU citizens foregoing healthcare is 18 percent; so again, the question is whether these figures will change positively in terms of take-up of healthcare, as the Directive is implemented. In this instance, given the fact that upfront payment prior to reimbursement is part of the process under the Directive, it is highly unlikely that patients already excluded from the national system for financial reasons will take up cross-border treatment.

CISS has played a role in the transposition of the Directive in France: t was involved in the consultation on the Decree transposing the Directive on medical prescriptions – but at a very late stage. It has had no involvement in the transposition of the other provisions, especially the NCP, which are still under discussion in the Ministry of Health.

CISS is committed to securing effective implementation of the Directive, and in particular to maintaining pressure on the Ministry of Health, with the following objectives:

- To speed up the transposition process;
- To ensure that it respects the requirements of the Directive and the expectations of patients and users, especially in the fields of: access to information; conditions for prior authorisation; and reimbursement of costs (timing and conditions).

The tools that will be used are: direct contact with the Ministry; dialogue and exchange of information with DG SANCO's Healthcare Systems Unit; exchange of information and good practices with organisations from other Member States; and the media, if necessary. Given that the Commission is willing to take legal action against Member States that have not transposed the Directive (or did so wrongly), dialogue with patients' organisations to highlight issues is increasingly valuable.

CISS is also committed to:

- informing patients on their rights deriving from the Directive: disseminating information on these rights through CISS communication tools (new website, newsletter, factsheets) and DG SANCO's leaflet, even before the Directive was transposed in France;
- training the staff of "Santé Info Service" (CISS hotline) and the CISS member organisations, so that they can advise citizens;
- monitoring the correct implementation of the Directive's provisions on patient rights, collating the requirements of citizens through "Santé Info Service";
- reporting and discussing the cases of bad implementation with the competent public authorities, including the European Commission.

B. PLENARY DEBATE

EPF can and should support CISS and other member organisations in terms of training. Another important role for EPF would be to co-ordinate and promote best practices and to disseminate new information.

CISS does not have a budget for training people for the "Santé Info Service" helpline, but it does dedicate resources to convincing national bodies – including CISS's own board – that European issues matter.

Regarding the way CISS uses the media: France is a fairly conservative country in terms of using the media, so denouncing an authority for (e.g.) non-compliance of a European obligation in a very public way is the weapon of last resort (assuming that gentle PR and/or the collegiate approach has failed). In fact, CISS has a reasonably good relationship with the Health Ministry in terms of channels of communication.

The next annual report of the "Santé Info Service" helpline will be the vehicle for reporting healthcare issues in France and for French citizens, based on the content of calls it has received in the preceding 12 months. It is possible that a specific section of the annual report will highlight/capture evidence of good and bad practice in terms of the Directive.

The French Health Ministry has adopted an approach to discussing and consulting on the creation of an NCP that appears to ignore what patients' organisations might want to see in such a body. This Conference has devised a powerful practical tool in this respect: the quality criteria "wish-list" for NCPs from the point of view of the patients' organisation. This list could be used with some leverage in relation to competent authorities in France and elsewhere.

C. MAIN OUTCOMES:

The quality criteria "wish-list" for National Contact Points from the point of view of the patients' organisation, which was the result of cascading knowledge from the small breakout group discussion during Session Two, is a powerful practical tool which patients' organisations can use with some leverage in relation to competent authorities.

D. TAKE HOME MESSAGES AND CLOSING REMARKS

A strong message from **Natalie Chaze of DG SANCO** was that she wants the patient community to be assertive and clear in voicing the patient perspective to the Commission, in terms of what patients want, what is going well and what is going wrong.

Moderator Nicola Bedlington invited representatives from the various participating countries in turn to tell the Conference what message they will be taking away and what actions they will take on returning home. Some of their commitments are reproduced in the bubble quotes on the next page.

EPF plans to hold three more Conferences on the Cross-Border Healthcare Directive, similar to the current one but drawing some of the lessons learned. The next Conference will be in Athens (7-9 April 2014), followed by Tallinn (early-summer 2014) and finally Ljubljana (October/November 2014).

EPF has a responsibility in terms of keeping this network alive; the first step will be to write the Conference report and have it translated into the participating countries' languages. EPF must also look at devising a tool that will enable all participating patient leaders to keep in touch on issues that began to be discussed in the Conference.

The follow-up to this Conference should include reflection on what EPF's role should be in supporting national patients' organisations in terms of resources – what is feasible and what other avenues might be available – and perhaps involving health professionals more closely on the policy side.

Comments from participants:

"We need to think bigger: once we have some initial conclusions, we should send them to other patients' organisations in The Netherlands and ask for their feedback."

Patient Representative, The Netherlands

"We will use the outcomes of this Conference to discuss with Belgian stakeholders at a meeting already planned for January 2014."

National Contact Point, Belgium

"We are seeking contact with other patients' organisations based on similar diseases, in order to improve representation of those patients and to get more attention from our government. We can also aim to relay some advice to our NCP on that basis."

Patient Representative, Belgium

"Unfortunately I was not here for the first full day of the Conference, but based on today's proceedings, I can take back to my colleagues in the Health Ministry some interesting ideas on how to build capacity for sharing information with the citizens. Luxembourg has not yet transposed the Directive, and the NCP is an issue that is difficult for us to implement, particularly in terms of training up staff. I intend to contact CISS (France) and INAMI (Belgium) to share knowledge and experience on how they did it, in the hope that this will allow us to progress more quickly on an issue that is crucial to proving the added value of the Directive to our citizens."

National health authority, Luxembourg

"The job of co-ordinating with the national authorities on the question of the NCP is too big for one organisation; clearly, using an umbrella organisation would be very useful, while still involving the national organisations."

Patient representative, Germany

"The first thing I must do is write a report on this Conference for my organisation; once completed, that should begin the process of disseminating information about what we have been discussing."

Patient representative, Germany

Giving the closing remarks, Cees Smit from the Dutch Genetic Alliance (VSOP) expressed the hope that national patients' organisations will continue to play a key role in each of their countries regarding further communication and co-operation with other stakeholders in promoting implementation of the Directive and monitoring its impact, both positive and negative.

He also hoped that national organisations will maintain contact with EPF and other leading patients' organisations in the implementation of the Directive, specifically committing to be part of the informal network of patient leaders across Europe.

The Commission's report in 2015 will provide a crucial opportunity to review the Directive and propose improvements. As an important first step, national organisations should adopt a pro-active approach towards NCPs and Health Ministries regarding information about this Conference, and should express their willingness to co-operate with other stakeholders in creating optimal information to both patients and healthy citizens.

There is a gap in the policy-making of Member States but also the European Commission in terms of how to support patients' organisations in Europe to function – there is no clear vision from them on how to do this, e.g. how they should be funded in a sustainable way. This first in a series of conferences on the Cross-border Health Directive has already highlighted the valuable contribution that patients' organisations can make towards ensuring that this Directive, as well as other health-related EU legislation, reflects the realities of living with diseases and has the maximum positive impact on the lives of European citizens.

With this conference, EPF together with patient communities in the participating countries have taken the first steps towards stronger awareness of this landmark Directive and its implications for patients, as well as creating a network of patient leaders who are committed to disseminating information to their peers and working together with the National Contact Points in their Member States to support effective implementation. During the next two years, EPF and its members will monitor the impact of the legislation closely from a patients' perspective and ensure that the grassroots patients' experiences will inform the European Commission's first progress report, due in October 2015.

Annex 1 – Conference programme

Day 1 – 9 December

19.30	**Welcome Reception and Buffet** • Quiz on CBHC

Day 2 – 10 December

8.00-9.00	**Registrations**
9.00-10.30	Introductory session – Moderator Tamsin Rose **The first Directive focussing on 'Patient Rights' – what does this really mean for patients?** EC perspective: Nathalie Chaze, DG SANCO European Commission Patient Perspective: Isabelle Riquier, Multiple Sclerosis patient, France **Plenary debate** *Objectives:* • *To provide a clear overview of the scope of the Directive and its application* • *To highlight its strengths but also potential barriers in implementation, new rights compared to existing social security legislation*
10.30-11.00	**Coffee Break and press conference**
11.00-12.30	**The crucial role of National Contact Points (NCP) and creating a framework model that meets the needs of Patients** Moderator: Tamsin Rose **Working groups** – What would a "model" National Contact Point look like **Plenary debate** – What are the critical success factors? How should patients' organisations be involved in the effective evolution of National Contact Points in the five participating countries? **Presentation of the Belgian National Contact Point** - Chris Segaert, NIHDI **Presentation of the Interim Report of the European Commission Behaviouralh study on Information and Cross Border Healthcare** – Dr Charlotte Duke, London Economics Ltd

	Objectives: • *To recognise the critical role of the National Contact Point in the effective implementation of the Cross Border Healthcare Directive* • *To understand the purpose, the potential and the role of patients' organisations in supporting and monitoring the development of the National Contact Points*
12.30-13.30	**Lunch**
13.30-15.00	**Workshops 1 : The Patient Journey in Cross Border Healthcare** Workshop 1.a: **Before leaving/when deciding** whether or not to get cross-border healthcare – prior authorisation, rights under the directive versus the regulation; dialogue with health professionals/referrals, assessing medical need, what information patients need to make a decision, and what they need to think about before leaving – Moderator: Flaminia Macchia, Eurordis Workshop 1.b: **When accessing care abroad** - what information patients' needs to know regarding the member state of treatment and care providers, e.g. quality and safety standards, administrative processes, prices and payment, etc. – Moderator: Kaisa Immonen-Charalambous, EPF Workshop 1.c: **When returning back home** – issues around reimbursement, complaints and redress mechanisms, continuity of care, e-prescriptions – Moderator: Nicola Bedlington, EPF *Objectives:* • *To address specific aspects of the Directive from the perspective of "the patient journey" and will both provide more detailed information on what aspects of the Directive are relevant at different stages and what specific information needs patients will have* • *Aim to generate a discussion identifying critical issues from a patient's point of view, and develop recommendations for Member States and patients' organisations in this regard, to create a sense of "ownership"*
15.00-15.30	**Coffee Break**
15.30-17.00	**Workshops 2: Rerun of workshops 1**
19.30	**Dinner**

Day 3 – 11 December

9.00-9.50	**Feedback from the rapporteurs on the core questions, discussions and recommendations from the workshops** *Objectives:* • *To reinforce information gleaned on the thematic topics and the issues raised* • *To enable the participants to obtain a clear overview on the outcomes of the workshop in which they were not involved*
9.50-10.40	**Quality of Care and Patient Safety – Cornerstones of the legislation** Achim Kautz, European Liver Patient Association (ELPA) **European Reference Networks** Flaminia Macchia, Eurordis *Objectives :* • *To ensure a full understanding of the provisions within the Directive that will focus on quality of care, transparency of safety and quality standards ,and the impact of this for the Patient seeking treatment abroad, and the wider policy context* • *To discuss European reference networks and their contribution to improving the quality of diagnosis and treatment*
10.40-11.10	**Coffee Break**
11.10-12.15	**Exploring the role of patients' organisations in securing effective implementation of the Directive** Speakers: Thomas Wiest and Charlotte Roffiaen, Collectif Inter associatif Sur la Santé (CISS) Moderator: Nicola Bedlington, European Patients' Forum (EPF) *Objectives:* • *To outline possible actions based on previous experience,* • *To develop a plan of action in terms of cascading knowledge from the conference,* • *To support and to ensure the commitment of the participants to pursue this and be part of an informal network for evaluation.*
12.15-12.30	**Take home messages**
12.30-14.00	**Farewell networking lunch**

Annex 2 – List of participants

First Name	**Surname**	**Organisation**
Ton	Akkermans	Dutch Neurofibromatosis Association
Gael	Bassetto	IDF Europe
Nicola	Bedlington	European Patients' Forum (organiser)
Cynthia	Bonsignore	European Patients' Forum (organiser)
Camille	Bullot	European Patients' Forum (organiser)
Anne	Calteux	MINISTRY OF HEALTH
Nathalie	Chaze	DG SANCO European Commission (speaker)
Hilde	De Keyser	Cystic Fibrosis Europe
Michele	Delorme	Schizo? …Oui! Faire face à la schizophrénie
Charlotte	Duke	London Economics (speaker)
Rainer	Goebel	German Leukemia- & Lymphoma Aid
Mala	Heal	EuropaColon
Korn	Henrike	Kopf-Hals-Tumorstiftung
Ottfrid	Hillmann	German Psoriasis Bund e.V.
Kaisa	Immonen-Charalambous	European Patients' Forum (organiser and speaker)
Patrick	Jeannot	MENTAL HEALTH SOLIDARITY
Marleen M	Kaatee	NLV Nederlandse Leverpatienten vereniging
Achim	Kautz	ELPA (speaker)
Klaus	Knops	Multiple Sclerose Liga Vlaanderen vzw
Gertie	Korevaar	Dutch Arthritis Foundation
Michael	Laengsfeld	Pro Retina Germany
Marie Agnès	Letrouit	Schizo? …Oui! Faire face à la schizophrénie
Flaminia	Macchia	EURORDIS (spekaer)

Nora	Mettioui	Flemish League against Cancer (Vlaamse Liga tegen Kanker)
Wolfram	Nolte	EuropaColon Deutschland
Annika	Nowak	DG SANCO European Commission
Stefania	Pirani	International Federation for Spina Bifida and Hydrocephalus
Ananda	Plate	MPE (Myeloma Patients Europe)
Elja Arnet	Reussink	Freya
Isabelle	RIQUIER	MS (speaker)
Daniel	RIQUIER	MS
Charlotte	Roffiaen	Collectif Interassociatif Sur la Santé (CISS) (speaker)
Bianca	Rootsaert	Dutch Coeliac Society
Tamsin	Rose	Tamarack (moderator)
John	Rowan	European Commission - DG SANCO
Roberta	Savli	European Federation of Allergy and Airways Diseases Patients' Associations
Chris	Segeart	INAMI (speaker)
Aline	Simon	Ipsos
Cees	Smit	EGAN - Patients Network for Medical Research and Health
Véronique	Tarasovici	European Patients' Forum (organiser)
Silvia	Van Breukelen	Dutch Genetic Alliance
Astrid	van der Zanden	EPECS
Marcel	Van Hest	NephcEurope
Marieke	van Meel	NephcEurope
Mary Lynne	Van Poelgeest	World Federation Incontinent Patients WFIP
Raymond	Wagener	Inspection Générale de la Sécurité Sociale
Geske	Wehr	European Network for Ichthyosis e.V.
Dieter	Wiek	Deutsche Rheuma-Liga BV e.V.
Thomas	Wiest	CISS (Collectif Interassociatif Sur la Santé)