

# EPF Workshops on Cross-Border Healthcare – 1st Stop: Croatia

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## Meeting Report

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## 1 Introduction

### 1.1 GENERAL BACKGROUND INFORMATION ON THE WORKSHOP

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.

EPF has undertaken considerable work, in cooperation with our members, with the EU Institutions on the Directive prior to its adoption, and has subsequently produced and disseminated a toolkit explaining the Directive and presented it 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 and the European Commission is due to report on the implementation of the Directive by October 2015, it is now particularly timely to organise dedicated national workshops to ‘raise the bar’ in terms of comprehensive knowledge and awareness among patient communities.

### 1.2 TARGET AUDIENCE

The workshop was aimed at patient leaders from Croatia who have the capacity to transfer learning and knowledge from the conference to peers within their organisation and networks (such as board representatives, directors, policy and communication specialists within the organisations). A representative of the Croatian National Contact Point was invited with the aim of facilitating contacts with patient groups within Croatia.

### 1.3 STRUCTURE OF THE WORKSHOP

The workshop was conducted in English, with simultaneous interpretation in Croatian.

The event was structured around presentations and interactive discussions with the participants, as well as working groups.

## 2 The first Directive to focus on “Patients’ Rights” – What does this really mean for patients?

**Camille Bullo**, EPF, introduced the workshop and explained its objectives.

### 2.1 OBJECTIVES OF THE WORKSHOP

- To raise awareness and knowledge about the CPHC Directive and patients’ rights enshrined within this legislation;
- To ensure understanding about the scope of the Directive and its application at national level;

- To ‘unpack’ various aspects of the Directive which have wider policy and systems implications of interest to patients (eHealth provision, HTA provision, general provisions on Quality of Care and Patient Safety, specific provisions linked to Rare Diseases etc.);
- To facilitate greater understanding regarding the role on National Contact Points and how patient groups could support their effectiveness;
- To agree an approach to evaluate the impact of the legislation from a patients’ perspective, on a longitudinal basis;
- To create an informal network of patient leaders interested and committed in CBHC to monitor developments over the coming years;

Participants were invited to introduce themselves (see list of participants in the annexes).

## 2.2 THE EUROPEAN COMMISSION’S PERSPECTIVE

The European Commission’s perspective on the Directive was presented by **John Rowan from the European Commission’s Directorate General for Health (DG SANTE)**. He gave three headline messages regarding the Directive:

- **The patient’s right to choose to receive healthcare from a provider outside his/her country** has been confirmed and clearly explained. The Directive has not created patients’ rights out of nothing: part of the foundation was provided by cases at the European Court of Justice that established a series of rights, and certain aspects of access to healthcare provision have been addressed since the early 1970s under the EU Regulations on the coordination of social security systems.<sup>1</sup>
- **Information to patients is a crucial aspect.** One important theme running through the Directive is patient empowerment, i.e. providing patients with the right information to enable them to make informed choices about their rights and the treatments to which they are entitled.
- **The Directive establishes a minimum set of patients’ rights throughout the EU for the first time.** In many Member States this might not change things in practical terms, but it represents significant progress at the level of EU health policy.

The basic principles governing cross-border healthcare are: patients have the right of reimbursement (under certain conditions) when they receive healthcare in another Member State; the level of reimbursement is up to the cost of the treatment at home; and the legislation of the Member State of treatment applies in relation to quality and safety standards, with a requirement for transparency regarding those standards.

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<sup>1</sup> Regulation (EC) No 883/2004 and Implementing Regulation (EC) No.987/2009, as amended. Information on the EU social security regulations is available here.



### 2.2.1 PRIOR AUTHORISATION

During the negotiations on the text of the Directive, concerns were voiced by some Member States regarding the possibility of national healthcare systems coming under extra pressure due to cross-border demand for treatments. As a result, the Directive specifies that in some cases, Member States can require patients to ask for prior authorisation before travelling for treatment.

Prior authorisation may be required for healthcare that involves (a) an overnight hospital stay, and/or (b) highly specialised and cost-intensive healthcare (“hospital care”). The logic for this is to strike a balance between the patient’s right to free movement and the need for Member States to plan and invest in certain treatments and to ensure that this planning and investment should not go to waste.

A request for authorisation may be refused under certain conditions: for example, if there is no undue delay in accessing treatment, i.e. if the treatment in question can be given to the patient in their own country within a medically reasonable time-limit. The definition of a “medically reasonable time-limit” depends on the needs and circumstances of the individual patient. Any refusal must be properly reasoned – there must be an individual assessment of the patient’s situation, resulting in a specific and detailed rationale for the treatment timeframe, which is then communicated in a transparent manner to the patient and can therefore be challenged if necessary.

### 2.2.2 INFORMATION TO PATIENTS PROVIDED BY NATIONAL CONTACT POINTS

Information to patients is crucial, so there is an obligation for each Member State to set up at least one National Contact Point (NCP). A Member State can set up more than one NCP depending on how it has structured its healthcare system, e.g. to reflect regional/federal competencies.

NCPs must be able to inform patients who want to go abroad regarding their rights and entitlements as well as the processes for prior authorisation, reimbursement and appeal; and to tell incoming patients what to expect – how the healthcare system works, the quality and safety standards that apply, and about the complaint and the redress procedures that are available. The role of NCPs also includes practical support relating to invoices: they must be able to help a patient deal with invoices from another country by liaising with the NCP in the country of treatment.

NCPs have an obligation to consult with stakeholders, especially patient organisations as well as healthcare providers and insurers. They should be dynamic organisations rather than simply a webpage with some information.

Healthcare providers also have obligations under the Directive. Importantly, they must provide information on: treatment options; the quality and safety standards they apply; prices; their authorisation status; insurance and liability cover.<sup>2</sup> Once again, the objective is to ensure that the patient is able to make a properly informed choice.

### 2.2.3 PRICES AND REIMBURSEMENT TARIFFS

There are three main points to this provision in the Directive. The principle of non-discrimination means that providers must apply the same fees to incoming patients as for domestic patients. The reference-point for setting reimbursement tariffs must be treatment in the home country given by a contracted or public provider, depending on the health system.<sup>3</sup> There must be transparency on the “basket of benefits” and reimbursement tariffs – answering the basic question: which treatments, and how much.

### 2.2.4 MINIMUM PATIENTS' RIGHTS

Although the Directive sets a minimum standard for patients' rights, it also contains certain new or enhanced rights: the right to appeal authorisation and reimbursement decisions; the right to a transparent complaints procedure and to seek redress; the right to privacy; the right to access a copy of one's own medical records for all treatments; and non-discrimination on the basis of nationality regarding access and prices.

A few years ago, many Member States still considered that the EU had no real role in health systems, which were regarded as a national responsibility with no European dimension. There is now a law at European level which sets out patients' rights and applies to every patient and every treatment in the

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<sup>2</sup> All treatment providers must be covered by liability insurance or an equivalent guarantee.

<sup>3</sup> There have been cases where Member States set the reimbursement tariff using the cost of private treatment as a reference-point, thus creating an artificially low reimbursement tariff.

EU. This provides a firm basis for developing a European approach to health systems policy in the years to come.

### 2.2.5 WHAT IS NEW COMPARED TO THE SOCIAL SECURITY REGULATIONS?

The system for cross-border healthcare under the Regulations worked fairly well for unplanned care, such as patients using their European Health Insurance Card (EHIC) abroad, but not for planned care. The Directive introduced specific measures to ensure the system works also for planned treatment – such as the heavy emphasis on information to patients on their rights, the obligation for transparency by Member States, and the various procedural guarantees.

There are some important differences between the EU social security Regulations – which still apply<sup>4</sup> – and the new Directive:

- The Regulations only cover public-sector or contracted providers, while the Directive covers all providers in the EU, both public and private.
- Under the Regulations, prior authorisation is always required for planned care, but is the exception under the Directive – in fact, some Member States have chosen not to use prior authorisation at all.
- The Regulations cover patient costs in full (with prior authorisation), while the Directive covers only to the level of the treatment in the home Member State. The logic is that cross-border treatment should be cost-neutral to national health systems.

### 2.2.6 CO-OPERATION BETWEEN HEALTH SYSTEMS

There is a general obligation for Member States to co-operate on guidelines and standards for quality and safety; European Reference Networks (ERNs), especially to ensure that expertise and information on rare diseases is shared across Europe in order to improve diagnosis and access to treatment; Health Technology Assessment (HTA), for which voluntary networks already exist and are working, aiming in particular to eliminate duplication of effort among 28 separate HTA bodies and to improve HTA capacity in specific Member States;<sup>5</sup> and eHealth, for which there is a Steering Group working on a common eHealth policy across the EU. The Directive also addresses the need to promote more co-operation between Member States on cross-border healthcare in border regions. This is likely to come onto the political agenda in 2015, as more Member States realise that such co-operation offers particular benefits. Working examples – both good and bad – already exist to feed this discussion.

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<sup>4</sup> For more information see the EPF guidance document.

<sup>5</sup> There is a continuing debate on the acceptable extent of co-operation and harmonisation of HTA at the European level. A consensus is emerging at least on applying a shared approach to the purely scientific analysis of health technologies, but how that information is used by each Member State still varies. Member States have tended to guard their prerogatives regarding the pricing of medicines, but in recent years there has been a significant political shift in terms of increased transparency on the content of price negotiations.

### 2.2.7 THE NEXT STEPS

The Commission's check on transposition of the Directive by Member States is ongoing, involving a detailed assessment of all the notified measures for Member States in terms of completeness and compliance.

Monitoring by individuals and stakeholders is also very important, to help assess how the Directive is working on the ground. The Commission holds national governments to account in terms of meeting their responsibilities as framed by law; it is therefore very important that the Commission receives feedback from patient organisations and individual citizens in terms of what is happening in practice, how individual cases are being handled, etc., so that it can fulfil this crucial function.

The reflection process on the functioning of the NCPs is ongoing. Individual NCPs are already consulting each other on how best to present information on national health systems, quality and safety standards, etc., so a more systematic approach across Europe would raise the general standard of information being made available to patients.

This monitoring feedback will be incorporated into the regular reporting by the Commission to the European Parliament and Council. The first formal progress report with recommendations is due to be published by 25 October 2015, but the Commission aims to publish it in the summer of 2015.

This series of workshops involving patient organisations will provide valuable input to the Commission, as it works to ensure that there is a fruitful discussion at the political level on how to improve cross-border healthcare.



## 2.3 THE PATIENT'S PERSPECTIVE

The patient's perspective was given by **Bojana Santic from RODA**, a Croatian patient organisation dealing with medical issues affecting families and parents' rights (infertility, hospitalisation...).

Bojana said that before the Directive, there was already a right set out in the social security Regulations for patients to access healthcare in other Member States, but this only applied in particular cases. The European Court of Justice's rulings led to an accumulation of case-law but no clear overall understanding of patients' rights. Therefore, the main aim of the cross-border healthcare Directive was to clarify the legal rights of patients across the EU.

The Directive is not perfect: it is in many respects a compromise from the patient perspective – gaps and areas of uncertainty remain – but nevertheless, it is a very important milestone for patients as the key benefits outlined by the European Commission showed.



### 2.3.1 WHY IS THE DIRECTIVE IMPORTANT TO CROATIAN PATIENTS?

There are a number of specific issues in the national context to which cross-border healthcare could provide the solution: a lack of specialists; long waiting-lists for consultations in some specialisms;

unmet demand for dental care and treatment for rare diseases; high cost of modern treatments and high co-payments.

The Directive therefore offers important advantages, such as the patient's enhanced right to choose, and more flexible options for patients to get medical services as soon as possible. However, patients in Croatia and elsewhere face crucial barriers to access: the requirement for upfront payment, low health literacy, and a basic lack of information about the Directive.

Support is equally important as information: will the NCPs become an "enabling service" for patients or a "gatekeeping mechanism" that negatively affects access? One approach that would influence this outcome would be to establish a continuous and transparent dialogue between patient organisations and Ministries of Health and NCPs. So far, the involvement of patient organisations in this respect has been fairly low.

### 2.3.2 A CRUCIAL CONCERN: EQUITY OF ACCESS

The Directive is based on the principles of non-discrimination, universality, access to good quality care, equity and solidarity – but in reality, the requirement for patients to pay upfront for treatment will be a barrier for many patients. Normally, the patient must pay the treatment costs upfront and claim reimbursement afterwards. As we know, the amount to be reimbursed is equivalent to the cost of the same or similar treatment "at home", so if the treatment abroad is more expensive the patient is left with more out-of-pocket cost; but if it is cheaper, then the whole cost can be covered. However, the patient can never benefit financially from the reimbursement, and we must also remember that the patient's travel and other costs are not covered.

A Member State is obliged to cover only the cost of treatment itself but it can decide to reimburse the full cost of the treatment and extra costs if it so chooses. Member States must have a transparent mechanism for reimbursement – it must be based on objective, non-discriminatory criteria and it must be publicly available.<sup>6</sup>

Sometimes it may be better for the patient to access treatment abroad under the social security Regulations rather than the Directive, as was explained by the European Commission. This may be a better option for patients with rare diseases, for example, where the treatment may not be available in the home country. The important point to bear in mind is that **the NCP must inform the patient which option is better for them.**

Member States can even choose to opt for a direct payment mechanism to transfer costs across borders. Patient organisations can and should advocate in favour of these options to their governments in order to improve equity of access.

The transparency provisions have much more potential than just to inform patients who are considering treatment abroad: patients and patient organisations can use them to get informed about their rights, the safety and quality of treatment, and how it compares to other Member States. This information can then be used to advocate for better quality and more equitable access also "at home".

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<sup>6</sup> Article 7 of the Directive

This can stimulate providers in Croatia to strive to improve quality, which is important for patients who access care “at home”.

### 2.3.3 IMPLEMENTATION AND MONITORING – THE NEXT STEPS

The first implementation report by the European Commission is a key opportunity to assess whether the Directive is a success from the patients’ perspective. Member States must help the Commission by providing all the information they have, but patient organisations should also take up the Commission’s invitation to give their feedback on the strengths and weaknesses of the Directive to both the Commission and national authorities, both directly and via EPF. In practical terms, patient organisations can:

- Engage with the NCP and give feedback on how it functions to serve patients;
- Ask their government to set up a system for direct payments and/or prior notification;
- Give feedback to EPF and the European Commission on all aspects of implementation – how it works for patients, and when it does not;
- Provide information on cross-border healthcare on their organisation’s website, including links to useful sources of information;
- Check the information provided on quality and safety standards: is it useful, is it understandable? How can it be used to call for improvements in quality of care in your country?
- Use the EPF tools, such as the guidance document and policy recommendations!

### 2.4 KEY POINTS FROM THE DISCUSSION

- *Are second opinions and diagnostics covered under the Directive?* It depends on whether they are included in the basket of benefits of your country. Croatian patients are allowed to visit a different doctor to get a second opinion in their home country, therefore they are allowed to do this abroad.
- *The directive cannot overcome the reimbursement decisions made by the Member States:* in some countries, better drugs are available from the first stage of a disease, while they are offered to Croatian patients in the second stage of the disease only (“Some people have to wait to get worse to access drugs”). While the directive creates the right for Croatian patients to seek healthcare abroad, it will not impose on Croatia the rules that other Member states have chosen to adopt.
- *The issue of lack of trust in Croatian healthcare professionals* appears to be one of the recurrent reasons why Croatian patients seek for healthcare abroad. The European Patients’ Forum is currently preparing a campaign on empowerment that will also focus on improving the relationship between healthcare professionals and patients.
- *Equity* is at the core of the discussions following the presentations of the European Commission. Participants have mixed opinions on whether the directive is actually useful for Croatian patients, as they still think receiving treatment in Croatia is the cheaper option. Cross-border healthcare seems to be an option “*for wealthy people only*”. Participants are then invited to look

at the other benefits of the directive, including the opportunity to access transparent information about the quality and safety standards of their home country, and the launch of a cooperation between Member states on different issues of importance (HTA, e-health, rare diseases...).

## 3 The crucial role of the National Contact Points

### 3.1 BRAINSTORMING SESSION ON THE IDEAL NCP...

The participants were asked to reflect and discuss the following questions in pairs:

1. What would a “model” National Contact Point look like?
2. What are the quality criteria and critical success factors?
3. How should patient organisations be involved in the effective evolution of National Contact Points in Croatia?

Conclusions regarding these questions were reported by each participant to the whole group. The synthesised list of conclusions can be clustered as follows:

#### ASSISTANCE

- The NCP provides assistance to fill in the forms for medical treatment abroad;
- It assists patients in contacting the other NCPs (language-wise).

#### ACCESSIBILITY AND AVAILABILITY

- The NCP takes a proactive role in raising awareness about the directive: information must be available at healthcare institutions (in leaflets, brochures, etc. for people who are not familiar with internet);
- The web page of the NCP includes a list of the other NCPs and a link to their websites;
- Information is available in all EU languages;
- There should be the opportunity to contact the NCPs (at home and abroad) other than via email, for example through “Skype calls”;
- The NCP’s web page includes a search engine for treatments and diagnosis.

#### AN AWARENESS-RAISING AND EDUCATIONAL ROLE

- The NCP provides trainings and education on the cross-border healthcare directive for GPs and physicians, as they are in regular contact with patients and should be able to inform them of the opportunity to get healthcare abroad, when appropriate;
- The NCP should play a role in sharing experiences and best practices of other member states (especially regarding treatment of mental illnesses, state of de-institutionalisation, self-help...);

- It should collect feedback from patients having benefited from cross-border healthcare in order to better inform patients seeking healthcare abroad in the future.

## QUALITY OF INFORMATION

- The employees of the NCP should have broad competences and be able to give medical, legal advice but also advice on quality and safety;
- The NCP provides information about the costs of procedures, the reimbursement rates, and an accurate description of the procedures;
- It also offers comparable data and statistics about the procedures performed by the different healthcare providers and about the frequency at which these procedures are performed;
- There should be a possibility to compare the prices of procedures between the different health providers across the EU, in order to help the patient to decide;
- It provides information on quality and safety standards. A “European Yellow pages of healthcare providers” and their quality standards could be created;
- General data about the state of waiting lists (in Croatia and abroad) should be made available;
- The NCP should provide assistance in finding an alternative solution and legal advice in case the request to get healthcare abroad is refused.

### 3.2 PRESENTATION FROM THE CROATIAN NATIONAL CONTACT POINT

**Dubrakva Pezelj Duliba, Head of the Croatian National Contact Point**, introduced the activities done by the Croatian NCP.

The NCP started functioning on 25<sup>th</sup> October 2013. The activities of the Croatian NCP are currently coordinated by one person within the Croatian Health Insurance, but there are agents dispatched locally who can answer the questions raised by patients in five different languages (Croatian, English, Italian, German and Hungarian).



The NCP is accessible via phone and email. So far, the NCP has received about 1200 calls. The questions raised by patients and citizens ranged from enquiries on patients' rights in other member states, to questions on the contractual status of Croatian and foreign healthcare providers, through questions on the communication with other NCPs.

In the future, the Croatian NCP plans to be able to respond to information requests on the quality of providers in Croatia and abroad. They are checking the opportunity to work jointly with other NCPs on that issue.

Improving the communication with patient organisations is also one of the priorities of the NCP. So far, the NCP has received no information on the number of people actually going abroad or coming in for treatment. This is mainly due to the fact that there is currently no system to measure the number of people who went abroad or came in.

## 4 The patient journey in cross-border healthcare

In the afternoon, participants discussed the four major stages of the patient journey:

- **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.
- **Before leaving:** What practical arrangements patients need to think about before leaving.
- **When accessing care abroad:** What information patients need to know regarding the Member State of treatment and healthcare providers, e.g. quality and safety standards, administrative processes, prices and payment, etc.
- **When returning home:** issues regarding reimbursement; complaints and redress mechanisms; continuity of care; cross-border prescriptions.

The outcomes of the discussion were then reported to the full group. The questions 1 (When deciding) and 2 (Before leaving) were treated simultaneously by the participants.

## CRITICAL ISSUES

### WHEN DECIDING AND BEFORE LEAVING

- What will happen in case of complications?
- How do I choose a doctor abroad? What kind of criteria should I base my decision on? Is there somewhere I can find experiences and testimonies from patients who visited the clinic previously?
- Where can I find detailed information on the procedure, its cost, and entitlement to reimbursement?
- Will I need someone to accompany me through the journey?

## DURING THE STAY

- What should I do in case of complications? Should I come back or not?
- Will I be transported home? Will this be covered?
- How do I overcome the language barriers between me as a patient and the healthcare professionals?
- Will the medication I am prescribed abroad be available in my country?

## AFTER RETURNING HOME

- Where do I apply for reimbursement? Who is my interlocutor?
- How long will I have to wait for reimbursement?
- Which documents do I need to submit?
- In case something went wrong, are there any complaint mechanisms?
- Am I entitled to follow-up treatment and control visits?

## RECOMMENDATIONS

### WHEN DECIDING / BEFORE LEAVING

- **Information on the procedures, treatments, and quality and safety standards of healthcare providers** should be given by the National Contact Point in order for the patient to be able to make an informed choice;
- **A check-list of issues to consider throughout the journey** should be made available for patients. Given the diversity of national contexts, this check-list should be designed at national level by the National Contact Point and patient organisations together;
- **Experiences from patients** with similar conditions having sought for healthcare abroad should be made available by patient organisations and the National Contact Point.

### DURING THE STAY

- **Interpreters** should be available to facilitate the communication between the patient and the healthcare provider and make sure there is informed consent from the patient's side;
- A leaflet should be given to the patient by the hosting healthcare provider. It should gather all information relevant to the stay of the patient abroad, including details on its procedure, rules of the hosting healthcare provider (can the person accompanying me stay in my room?) in its own language;
- Ideally, healthcare providers abroad should appoint a **liaison person for foreign patients**, to help them throughout their journey. This person would support them with all aspects of their stay abroad, including accommodation and local transportation.

## AFTER RETURNING HOME

- A mechanism to **collect the feedback from patients returning home** after a cross-border healthcare experience should be developed and implemented;
- **A leaflet should be produced to inform and support patients** through the reimbursement process (whom do I need to send invoices to? What papers do I need to send?).

## 5 Conclusions, Take Home Message and Next Steps

**Moderator Camille Bullo** invited the participants to tell the group what message they will be taking away and what actions they will be returning home.

All participants said they had learned a lot about the directive.

They committed to different actions to raise awareness about the directive and to spread knowledge within their own networks and beyond: organising a roundtable with the city of Zagreb, working together with the media to produce a TV report, disseminating printed materials...

Some participants regretted the lack of visibility of the NCP, as well as the lack of a cooperation between patient organisations themselves, and between patient organisations and the Croatian NCPs on the other side. They all agreed to strengthen this cooperation and the communication between the NCP and patient organisations. To this end, a list of the contact details of the participating organisations will be sent to the attendees.

**The National Contact Point** welcomed the initiative of this workshop, and the opportunity it provided to listen to “the other side”. According to the NCP, there is still a lot to do for all Croatian patients and citizens to be aware of the opportunities created by the Directive.

Participants regretted the lack of capacity within their own department. More people need to be dedicated to the work of the NCP if we want to meet the expectations of the patients.

**Camille Bullo, EPF**, thanks the participants for their enthusiasm and active participation, and invited the participants to think of the wider implications of the directive.

Even though patient mobility and cross-border healthcare remains an option for a limited number of patients only given the shortcomings of the directive, it also is an opportunity for patients to advocate for better healthcare and more transparency on the quality and safety standards in their own country.

She announced that a conference gathering patient leaders and representatives from the NCPs across the 28 countries would take place in early July in Brussels. This will be the occasion to take stock of the state of implementation of the directive and to share some feedback with the European Commission on its benefits but also on the recommendations that can be made to further advance patients’ rights in Europe.

CB, 29/01/15