EPF Workshops on Cross-Border Healthcare – 6th Stop: Romania

Meeting Report

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1 Introduction

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.

TARGET AUDIENCE

The workshop was aimed at patient leaders from Romania 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 Romanian National Contact Point was invited with the aim of facilitating contacts with patient groups within Romania.

STRUCTURE OF THE WORKSHOP

The workshop was conducted in English, with simultaneous interpretation in Romanian.
The presentation of the Directive by the EPF representative as well as the presentation of the National Contact Point were given during the plenary session, attended by around 100 patient representatives. The interactive sessions on the ideal National Contact Point and on the patient Journey took place within a smaller group of around 15 representatives from patient organisations. The workshop concluded with proposals on the way forward.

OBJECTIVES OF THE SESSION

Dorica Dan, from the **Romanian Alliance of Rare Diseases,** introduced the session and explained its objectives.

- To raise awareness and knowledge about the CBHC 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.

2 The first Directive to focus on "Patients' Rights" – What does this really mean for patients?

Camille Bullot, EPF, gave a presentation on the Directive and its meaning for patients.

2.1 HEADLINE MESSAGES

She gave five 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: 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.

- **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.** Patients will have a right to a copy of the medical record; to appropriate medical follow-up; the prescription made abroad will have to be recognised. 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 Directive states that **quality and safety standards for healthcare have to be transparent.**

- Finally, the Directive also provides **legal basis for co-operation between Member States on eHealth and HTA, rare diseases and quality/safety standards.**

2.2 BASIC PRINCIPLES OF THE DIRECTIVE

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;
- The legislation of the Member State of treatment applies in relation to quality and safety standards, with a requirement for transparency regarding those standards.

2.3 PRIOR AUTHORISATION

Prior authorisation is not the rule.

However, 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.

2.3.1 WHEN CAN MEMBER STATES REQUIRE PRIOR AUTHORISATION?

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.

2.3.2 CAN A REQUEST FOR AUTHORISATION BE REFUSED?

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.

2.4 PRICES AND REIMBURSEMENT TARIFFS

2.4.1 HOW MUCH WILL I PAY?

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.
- In any case, there must be transparency on the "basket of benefits" and reimbursement tariffs – answering the basic question: which treatments, and how much.
- What about travel costs? Member States are obliged to cover only the cost of treatment but they can decide to reimburse the full cost of the treatment and extra costs.

2.4.2 DO I HAVE TO PAY UPFRONT?

One of the main gaps of the Directive is that patients will have to pay upfront and claim back the expense afterwards. This creates a problem in terms of equity of access: indeed, although the directive states that there should be no discrimination, upfront payment will be a barrier for many.

There is a provision by which Member States can arrange direct payment (the Member State of affiliation pays the cost of the treatment directly to the Member State where the patient receives the treatment), but this is a voluntary provision.

Patient organisations should challenge their national authorities and advocate in favour of direct payment to increase equity of access.

2.5 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. Once again, the objective is to ensure that the patient is able to make a properly informed choice.

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

2.7 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[4] – 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.

2.8 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;

- 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.

2.9 SOME CONCERNS… BUT AN IMPORTANT STEP FORWARD

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 Romania 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.

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

In conclusion, 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.

2.10 DISCUSSION

Question: What happens in the case of emergencies, i.e. if you have a ski accident abroad?

Answer: The Directive is meant to address the needs of people seeking for care abroad in planned situations, that is, when you go abroad with the purpose of seeking for healthcare. In case of an emergency, the European Health Insurance Card (EHIC) is the right tool to use.

Question: If the treatment does not exist in Romania, on which basis will the level of reimbursement be based? Will I be entitled to reimbursement at all?

Answer: in case a treatment does not exist at home, the authority in charge of the reimbursement (the National Health Insurance Fund) will look for a comparable treatment included in its basket of benefits and reimburse the patient according to the level of reimbursement applicable for this similar treatment.

Question: If a test for rare diseases is available abroad and not in Romania, can I get the test abroad? Will I be reimbursed?

Answer: The directive covers everything from diagnostic to follow-up, so it is possible to go abroad for a test. However, the level of reimbursement will be based on the level of reimbursement in the case of a test at home. If that test does not exist, then we are in the case addressed in the previous question. For rare diseases, the Social Security Regulation is often a better option. Although prior authorisation is needed, its scope is wider and it can cover additional costs such as travel and accommodation costs.

3 The crucial role for the National Contact Points

3.1 PRESENTATION FROM THE ROMANIAN NATIONAL CONTACT POINT (NCP)

Andreea Gărăiacu, Head of the NCP, gave a presentation on the role of the Romanian National Contact Point and how they intend to work with patient organisations.

3.1.1 STRUCTURE

The Romanian National Contact Point was set up on 5th May 2014, within the National Health Insurance Fund. It is funded by the National Health Insurance Fund.

3.1.2 ACCESSIBILITY

There are five executives working daily within the National Contact Point. They speak Romanian as well as English.

The National Contact Point has its own web-site page - www.cnas-pnc.ro – on which you can find:

- Information on what type of healthcare subject to prior authorisation and on the criteria to be met in order to obtain prior authorization;
- The methodology for reimbursement of costs occurring when accessing cross-border healthcare, and the level of reimbursement.

Information can be obtained:

- by written request addressed to the National House for Health Insurance;
- by fax: 0372.309.283;
- by e-mail: pnc@casan.ro;

A free phone number has also been set up. It is available between 10.00 and 16.00.

3.1.3 QUALITY OF INFORMATION

The National Contact Point provides information to patients provided on:

- Treatment options, availability, information about quality and safety standards for healthcare provided in Romania;
- Clear invoices and clear information on prices;
- Authorised medical services providers, their registration within specialised organisations;
- National standards and guidelines on quality and safety of health services
- Accessibility of hospitals for persons with disabilities;
- Information on patients' rights, complaints procedures and redress mechanisms, as well as legal and administrative options available to settle disputes, including in the event of complications arising from cross-border healthcare;

- Information regarding to the terms and conditions for reimbursement of costs and procedures for accessing healthcare abroad.
- Prescriptions issued in Romania or in another EU Member States.

The National Contact Point cooperates with the National Contact Points in other Member States of the European Union on standards and guidelines on quality and safety. They also cooperate with the national health insurance funds and offer each other mutual assistance to clarify the content of payment documents.

The National Contact Point also organises the translation of some documents in the official languages of the other Member States of the European Union.

3.1.4 COOPERATION WITH PATIENT ORGANISATIONS AND OTHER STAKEHOLDERS

The National Contact Point has concluded Memoranda of Understanding with several associations of healthcare professionals. They intend to conclude partnerships with patient organisations in the near future.

The National Contact Point cooperates with the National Health Insurance and the Ministry of Health, especially in the context of the periodic reports on the implementation of the Directive.

3.2 DISCUSSION

Question: How many people have accessed the National Contact Point so far?

Answer: there have been 600 requests since the creation of the National Contact Point.

3.3 BRAINSTORMING SESSION ON THE IDEAL NCP…

The participants were broken into two groups and asked to reflect and 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 patient organisations be involved in the effective evolution of National Contact Points in Romania?**

Conclusions regarding these questions were reported by each participant in plenary session. The synthesised list of conclusions can be clustered as follows:

PROFILE OF THE NCP: A MULTIDISCIPLINARY AND MULTILINGUAL TEAM

- The NCP team is composed of individuals with mixed backgrounds, including experts from the National Health Insurance Fund, and representatives from patient organisations;
- There should be an effort to strike a balance in representation between the different organisations;
- The NCP should think of creating regional antennas, who would be able to give more details on healthcare providers.

QUALITY OF INFORMATION

- Information should be provided by disease area;
- Specific information should be given about deadlines and timelines;
- The NCP should be able to give references of generalist and specialist practitioners.

RESPONSIVENESS

- There should be a “priority” line for urgent cases: questions should then be answered within 3 to 5 days;
- As a general rule, questions should be answered within a maximum of 14 days.

AN AWARENESS-RAISING AND PROACTIVE ROLE

- The NCP should organise an awareness-raising campaign to inform the population of the benefits offered by the Directive. Media and municipalities also have a role to play in relaying the information;
- They should display information on their website, but not only. They should be reachable via a free phone number;
- The target group to the information campaign of the NCP should be the general public and also healthcare professionals and healthcare providers, not only patient organisations;
- The information should be available in several languages and in an understandable manner (not bureaucratic language);
- The NCP should provide a system by which patients can evaluate their services and provide feedback;
- There should be a network of NCPs across Europe, enabling the Romanian NCP to quickly seek for an information they do not have.

4 The Patient Journey in Cross-Border Healthcare

Participants broke into two groups again and 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 in the plenary session.

4.1 WHEN DECIDING

- It is important to determine precisely **the cost and the length** of the treatment to avoid surprises.
- The fact that cultural differences (affecting the treatment protocol or not) may exist between the home country and the country of treatment should also be taken into account when making the decision on whether or not to seek for healthcare abroad.

4.2 BEFORE LEAVING

- Is it possible for the physicians (the one at home and the one abroad) to liaise to ensure continuity of care?
- Will language be a barrier?
- The patient must plan carefully his/her own transportation and logistics.
- How do I choose my healthcare provider abroad? Who can advise me?

4.3 WHEN YOU ARE ABROAD

- What happens if I miscalculated the costs?
- What happens if I need to extend my say?
- What happens in case of complications and/or malpraxis?
- Is there an intermediary to support me in the communication with the healthcare professional (interpretation?)
- Who is accountable for the information provided beforehand and the reality?

4.4 RETURNING HOME

- How do you ensure monitoring and follow up?
- What papers do you need for reimbursement? Do you need to get them translated?
- How long do you have to wait in order to be reimbursed?

4.5 RECOMMENDATIONS

- Participants agree that a guide for patients should be drafted and disseminated by patient organisations. This guide should contain practical information and a check-list of the things to consider before seeking for cross-border healthcare.
- A clarification on the different instruments which exist to go and seek for healthcare abroad would also be very much welcome. When is it relevant to use the European Health Insurance Card? When is it more convenient to use the Social Security Regulation, and when is the Directive the best option?
- Participants also argue that some of the optional provisions of the directive should be implemented, such as direct payment, and the coverage of travel and accommodation costs, currently included in the Directive on a voluntary basis.

5 Conclusions, Take Home Message and Next Steps

Camille Bullot from the European Patients' Forum invited the participants to share the message they will be taking away and what actions they will be taking when returning home.

Camille thanked the participants for their enthusiasm and active participation, and invited the participants to think of the wider implications of the directive.

The Directive is not a panacea: however, 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.

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 conferences 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.

Camille Bullot announced that a conference gathering patient leaders and representatives from the NCPs across the 28 countries would take place on July 2nd 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, 04 May 2015