EPF Workshops on Cross-Border Healthcare – 2nd Stop: Spain/Portugal

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 Spain and Portugal 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 Portuguese National Contact Point was invited with the aim of facilitating contacts with patient groups within Portugal.[1]

STRUCTURE OF THE WORKSHOP

The workshop was conducted in English, with simultaneous interpretation in Spanish and Portuguese. The event was structured around thematic plenary sessions and interactive debates with the participants, as well as working groups followed by a closing plenary, which presented key conclusions and proposals on the way forward.

OBJECTIVES OF THE SESSION

Maria Dolors Navarro, President of the Spanish Patients' Forum, welcomed the participants to the meeting.

Nicola Bedlington, EPF Secretary General, introduced the session and explained its objectives.

- 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;

[1] Unfortunately, the Spanish National Contact Point was unable to send any representative to the meeting because of conflicting appointments.

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

2.1 THE EUROPEAN COMMISSION'S PERSPECTIVE

The European Commission's perspective on the Directive was presented by **Ms Maria Iglesia Gomez, Head of the Health Systems Unit within DG SANTE, European Commission.**

She 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.

- **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.

2.1.1 PRIOR AUTHORISATION

When can member states require 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.

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.

In any case, Maria Iglesia Gomez made it very clear that prior authorisation must remain the exception.

2.1.2 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.[2] Once again, the objective is to ensure that the patient is able to make a properly informed choice.

2.1.3 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. There must be transparency on the "basket of benefits" and reimbursement tariffs – answering the basic question: which treatments, and how much.

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

2.1.5 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[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.

2.1.6 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;
- 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.

2.2 THE PATIENTS' PERSPECTIVE

The patient's perspective was given by **Guadalupe Morales, from the Fundación Mundo Bipolar,** a Spanish patient organisation dealing with bipolar disorders.

Guadalupe explained 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.

2.2.1 WHY IS THE DIRECTIVE IMPORTANT TO SPANISH AND PORTUGUESE PATIENTS?

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 Spain 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.

2.2.2 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.

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

2.2.3 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 their 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!

2.3 MAIN POINTS FROM THE DISCUSSION

A question on whether the evaluation will take into account the inclusion of patient groups is asked. Maria Iglesia Gomez answers that the Directive prescribes the consultation of National Contact Points with patient organisations. Therefore, during the compliance check, this point will be analysed.

Participants are puzzled by the lack of definition of "highly-specialised healthcare", for which prior authorisation is needed. Maria Iglesia Gomez explains this is left to the interpretation of Member

States. Participants are concerned this imprecision may lead member states to refuse the authorisation to patients under the pretext the technology used is too specialised.

A participant then asks about how the directive articulates with the pharmaceutical market and prices of medicines across Europe. The Head of Unit of the European Commission Maria Iglesia Gomez reckons that this is a complicated question. The determination of the price of medicines is the fruit of a negotiation between the Member States and pharmaceutical companies. Therefore the European Commission has very little margin for action. An important tool in that field is the Directive on transparency, by which member states have to communicate the price applied in their respective country. Yet, the European Commission is often being asked to intervene. During the Italian Presidency of the European Council, some recommendations were formulated on this issue. The EU is also working on the development of a mechanism for public procurement.

Spanish participants also raise the fact that the gaps of the Spanish health system, organised regionally with different rules for each autonomous region. The cross-border healthcare directive seems to make it easier for Spanish patients to seek for healthcare in another country than to get treatment in a different region.

Finally, participants express concerns on whether the directive will have an impact on the quality of their healthcare system, by creating more inequalities between the domestic population and patients from abroad, to the detriment of the domestic patients. This concern is heightened by the current trend towards privatisation of public services.

3 The crucial role for the National Contact Points

3.1 BRAINSTORMING SESSION ON THE IDEAL NCP…

Moderator Camille Bullot, EPF Membership Officer, introduces the session. Participants were broken into four 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 Spain and Portugal?**

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

Transparency and independence

- The NCP should be independent from the government.

A proactive role in the dissemination of information

- NCPs should be proactive and raise awareness about the directive among different audiences, including healthcare professionals.

Availability and accessibility

- The NCP should be reached through different channels according to the target, especially since lots of patients are at risk of social exclusion (leaflets, emails). A European hotline should be set up for patients from across Europe to benefit from equal access to the same information. A physical point of contact should also be set up;
- The information should be delivered in the patient's mother tongue;
- Information should be delivered through different channels: the NCP but also through patients' or users organisations, who speak the same language as the patients.

Quality and timely information

- NCP should be able to inform patients about the amount they will be reimbursed;
- They should inform the patients about the maximum time for which they can receive the treatment (before it's considered long-term care and falls out of the scope of the directive);
- NCP should deliver the information in a timely manner;
- They should inform patients of ways and possibilities to cover the extra costs (such as travel and accommodation).

Cooperation with patient organisations

- The role of patient organisations is essential: NCPs should organise regular meetings with patient organisations;
- They should organise trainings for patient organisations and the general public.

3.2 PRESENTATION FROM THE PORTUGUESE NATIONAL CONTACT POINT

Ricardo Mestre and Sofia Caetano from the Healthcare Management and Funding Department of the Portuguese Health Ministry, present the activities led by the Portuguese National Contact Point.

The Portuguese National Contact Point was set up in August 2014 and therefore has a limited experience. Portugal has set up three NCPs: on the mainland, in Madeira, and in the Azores.

Information on the directive is displayed on a dedicated website. For questions and requests, the Portuguese NCP is accessible via email.

Sofia Caetano and Ricardo Mestre explain the role of the Portuguese National Contact Point. They also express their readiness to cooperate with patient organisations.

The presentation of the Portuguese National Contact Point is available on the event's webpage.

4 The Patient Journey in Cross-Border Healthcare

In the afternoon, participants broke again in groups 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

- Is the treatment available in your home country? Abroad?
- Do I need prior authorisation?
- What is the total estimated cost (healthcare + travel + accommodation)?
- Does the cross-border healthcare apply to clinical trials?
- Do I need to have my health records translated? If so, do I need a certified translation? How much is it going to cost?

4.2 BEFORE LEAVING

- Do I have insurance of the quality and safety standards of the healthcare provider abroad? Where is this information available?
- Will I be able to communicate with the health professionals abroad?

- Is medication going to be the same abroad?
- May I bring an accompanying person?
- What about the transportation's conditions

4.3 WHEN YOU ARE ABROAD

- What if something goes wrong?
- How do I overcome the communications' barrier?

4.4 RETURNING HOME

- Am I entitled to any follow-up? How do I ensure a proper follow-up and communication with the healthcare professionals abroad once I am back home?

5 Conclusions, Take Home Message and Next Steps

Nicola Bedlington, EPF Secretary General, invited the participants to share the message they will be taking away and what actions they will be taking when returning home.

Participants all 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.

One participant suggested that patient organisations should send a few requests to their country's National Contact Point and evaluate the answer. This feedback would then be forwarded to EPF and the European Commission's.

Participants agreed over the need to have common and consistent criteria to evaluate the directive at European level.

Concerns were expressed once again over the differences in access to healthcare and the impact on equity of the directive: indeed, for some participants, only the richer patients will be able to seek for cross-border healthcare through the directive.

Nicola Bedlington thanked the participants for their enthusiasm, 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.

Nicola Bedlington 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, 31 March 2015