

EPF Workshops on Cross-Border Healthcare – 4th Stop: Bulgaria

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 Bulgaria 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 Bulgarian National Contact Point was invited with the aim of facilitating contacts with patient groups within Bulgaria.

STRUCTURE OF THE WORKSHOP

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

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

Margarida Silva, EPF, 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;
- 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 in each country 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?

Camille Bullo, 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 apply⁴ – 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 Bulgaria 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 Bulgaria 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.

3 The crucial role for the National Contact Points

3.1 BRAINSTORMING SESSION ON THE IDEAL NCP...

The 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 Bulgaria?**

Conclusions regarding these questions were reported by each participants 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 Bulgarian NCP to quickly seek for an information they do not have.

3.2 PRESENTATION FROM THE BULGARIAN NATIONAL CONTACT POINT

Todor Boukovski and Petya Sotirova from the National Health Insurance Fund, gave a presentation on their role as National Contact Point and how they intend to work with patient organisations.

Petya Sotirova thanked the participants for their very useful ideas and said she hoped for a mutual and complementary co-operation between the National Contact Point and patient organisations.



3.2.1 STRUCTURE

Petya Sotirova explained that the National Contact Point is part of the National Health Insurance Fund, and is split in two subdivisions: a sub-directorate dealing with international issues and requests from abroad, and a sub-directorate for questions from Bulgarians living in Bulgaria or abroad.

3.2.2 ACCESSIBILITY

In order to ask their questions, Bulgarian citizens can use different ways:

- A free phone number has been set up;
- Citizens can also ask their questions via an online centre (answers are provided within three working days);
- There is also a physical reception, accessible to all, where citizens can come and ask for help.
- The Bulgarian NCP is present across Bulgaria, through the regional Health Insurance Funds offices: the regional Health Insurance Funds offices can answer the simpler questions. When there is a complicated case, it is referred to the National office.

3.2.3 QUALITY OF INFORMATION

- The Bulgarian National Contact Point can only give information on healthcare providers who are registered within the National Health Insurance Fund.
- They cannot give the name of a single healthcare professional, but can provide a list of doctors with contact details.

3.2.4 DISSEMINATION OF INFORMATION

- Unfortunately, for now, the dissemination is inadequate, as it is present only via the website which is not really accessible.

3.2.5 COOPERATION WITH PATIENT ORGANISATIONS

- The NHIF is ready to cooperate with patient organisations. Mr. Boukovski suggests that patient organisations provide a link to the NHIF cross-border healthcare webpage on their own websites.

- They also express their availability to organise meetings and consult with patient organisations to coordinate input on certain specialisms. However, Mr. Boukovski explains their capacity of action is very limited when it comes to recommending a specialist abroad: there are many specialists in Europe and in order to provide a quality recommendation, one has to know the patient's dossier.

3.3 DISCUSSION

- **Question: How many requests did you have to answer since the National Contact Point has been set up?**

Answer from the National Contact Point: The National Contact Point has been set up 18 months ago, in October 2013. There have been 7 requests for prior authorisation, 5 were refused, and 2 were accepted.

There has been only one query from Europe to get healthcare in Bulgaria. However, there have been 3400 phone calls on the free phone number, mainly from Bulgarians from abroad who come to Bulgaria to seek for healthcare.

One participant comments that this very low number shows that there is a need to advertise the directive among the general public and to open out a debate with healthcare professionals and politicians.

- **Question: Does the Directive make sense for Bulgarian patients given that the level of reimbursement in Bulgaria is often much lower than anywhere else in Europe?**

Answer from the National Contact Point: the NHIF is aware that the level of reimbursement in Bulgaria is a restraining factor. Patients have to travel, and the prices are higher in other European countries. In that context, the regulation may offer a better coverage than the directive.

In the future, the NHIF may undertake the liberalisation of the reimbursement level to ensure that patients are not reimbursed only at the level of the Bulgarian reimbursement system. However, it is still too premature to say when this will happen. This is a very political issue.

- **Stanimir Hasurdjiev, NPO**, proposes the NCP to work in cooperation with the National Patient Organisations on the implementation of the directive. NPO has set up a call centre which will provide information to patients on treatments available in Bulgaria and other key issues in several languages. They are also planning to launch a media awareness campaign.

4 The Patient Journey in Cross-Border Healthcare

In the afternoon, participants broke into four 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

- The decision should be based on the healthcare professional's advice and qualitative evaluation.
- The patient should be familiar with the directive and decide whether it is better for him/her to go and seek for healthcare abroad under the directive or regulation.
- The patient should conduct an analysis of the pro and against arguments
- The patient should find information about health professionals abroad (friends, patients who have experienced this).

4.2 BEFORE LEAVING

- The patient should make sure s/he has secured the funding for the travel and accommodation, and if necessary interpretation
- The patient should make sure s/he takes some useful contacts of people on the spot (Patient organisation, Bulgarian Embassy).
- S/he should have his/her medical record translated.

4.3 WHEN YOU ARE ABROAD

- Are the tests included in the price of the treatment?
- What happens if you have to stay longer than foreseen?
- What happens in case of complications? Whom should you address?
- How to make sure there is “informed consent” abroad, when you are discussing in a foreign language?

4.4 RETURNING HOME

- You need to make sure you have the necessary documents to be submitted for reimbursement
- You need to know how to apply for appeal in case something went wrong

4.5 RECOMMENDATIONS

- Awareness needs to be raised about the directive: in particular, there should be information available about the differences between the regulation and the directive, and how to decide which tool is the best for the patient according to his/her condition;
- There should be a list of documents that should follow the patient during his/her journey;
- There should be a unified invoicing system;
- Informed consent must be the rule, even abroad, even when speaking a different language. The support from interpreters may be needed.

5 Conclusions, Take Home Message and Next Steps

Moderator Margarida Silva invited the participants to share the message they will be taking away and what actions they will be taking when 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: via media actions, by publishing links on their own website.

Some participants proposed to draft a guide on the differences between the regulation, the directive and the European Health Insurance Card.

Camille Bullo, EPF, 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 Bullo 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, 30 March 2015