EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare: Legislation Guidance for Patient Organisations

Updated version – November 2013

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1 Introduction

The EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare came into force on 25 October 2013. This guide provides basic information about the rights of patients under the Directive, as well as opportunities for patient involvement in implementing it at national level. For more details on the content of the Directive please see "EPF recommendations for the implementation of Directive 2011/24/EU".[1]

1.1 HOW DID THE DIRECTIVE COME ABOUT?

The EU Treaty states that the organisation and financing of the healthcare system and the delivery of healthcare are the responsibility of the EU Member States.[2] However over the years European health systems and policies have become more interconnected due to many factors, including increasing cross-border movement of patients and health professionals, and the dissemination of new medical technologies.

EU citizens already have the right to access healthcare in other Member States in some circumstances. EU Regulation No. 1408/1971[3] is often referred to in this context, but a modernised regime on the coordination of social security systems has applied in the EU since 1 May 2010. It includes the consolidated regulations (EC) No. 883/2004 and its Implementing Regulation (EC) No. 987/2009.[4]

UNPLANNED TREATMENT – THE EUROPEAN HEALTH INSURANCE CARD.

People travelling to other Member States for a temporary stay or on holiday can make use of their rights through the European Health Insurance Card (EHIC). This card replaces the previously used form E111. The EHIC gives you access to public-sector healthcare during a temporary stay in another Member State under the same conditions and at the same cost (free in some countries) as citizens of that country.[5]

PLANNED TREATMENT WITH PRIOR AUTHORISATION.

Previously, the only way for patients to access pre-planned treatment abroad would be with prior authorisation granted by the health insurance institution in their country through the E112 form.

[1] Available on our website: http://www.eu-patient.eu/whatwedo/Policy/Patients-Mobility/
[2] Article 168 of the Treaty on the Functioning of the European Union (TFEU), formerly Article 152 of the Treaty Establishing the European Community (TEC).
[3] This Regulation coordinates national social security legislation in order to protect the social security rights of persons moving within the European Union. Source: http://europa.eu/legislation_summaries/employment_and_social_policy/social_protection/c10516_en.htm
[4] Available here: http://ec.europa.eu/social/main.jsp?langId=en&catId=867
[5] For more information about this: EHIC webpage

The health insurance institution would certify that it would cover the cost of the treatment abroad. In practice, one of the main problems with this system has been the complicated administrative procedures to obtain the prior authorisation, and the long waiting lists for patients before getting the authorisation. Lack of information about patients' rights in this context and the financial and practical aspects was also a barrier.

This led to some patients bringing their Member State to the European Court of Justice (ECJ). On the basis of EU internal market rules, they asked for the right to access healthcare products and services in other Member States than their own. Since 1998, several judgements of the ECJ confirmed that patients have, in certain cases, the rights to access healthcare services in other Member States than their own, with the cost being carried by their own health system. Possibly the most famous case is that of Mrs Watts, a UK citizen who was refused prior authorisation to get a hip replacement abroad but did so anyway because she would have had to wait too long to get the operation in the NHS..[6] Another well-known ruling concerned the cases of Mr Kohll and Mr Decker, two Luxembourg nationals. The court decided that in their specific cases, prior authorisation to obtain healthcare abroad was an unjustified restriction to the freedom to provide services.[7]

There was a need to clarify patients' rights through EU legislation, based on this "case law" of the European Court of Justice. Directive 2006/123/EC[8] on services in the internal market (the so-called "Bolkestein Directive") tried to address this issue. Nevertheless, the European Parliament and the Council excluded health services from the directive, considering that patients are not ordinary consumers but are in a vulnerable position because their health is at stake. Health was therefore not considered merely a commercial commodity. They invited the commission to come forward with a specific initiative addressing health services.

So, in 2008, after a public consultation on health services in cross-border healthcare, the European Commission put forward a legislative proposal for a directive. After a long negotiation between the Institutions, the directive was adopted by the Council in February 2011. It entered into force on 25 October 2013.

1.2 WHY IS THIS DIRECTIVE IMPORTANT FOR PATIENTS?

The Cross-Border Healthcare Directive clarifies the legal rights of patients. In principle there should be no need to seek prior authorisation, but the directive allows for prior authorisation for certain types of care. The Directive covers both public and private healthcare providers, and requires Member States to provide information to patients and the public on their rights and options.

The directive is not perfect – the text evolved significantly during its long "legislative journey" of two and a half years. The final document is in many respects a compromise that falls short of EPF's ambitious vision.[9] Nevertheless, it is an important milestone for patients.

[6] See C-372/04.
[7] See C-120/95 and C-158/96
[8] See http://europa.eu/legislation_summaries/employment_and_social_policy/job_creation_measures/l33237_en.htm
[9] http://www.eu-patient.eu/Documents/Press/PressReleases/Press_Release_CBHC_statement_final.pdf

SOME OF THE KEY BENEFITS FOR PATIENTS ARE:

- Recognition for the **first time** in EU law that patients have a right to cross-border healthcare and are entitled to be reimbursed for it;
- **Right to information** on cross-border healthcare, and the creation of **National Contact Points** in each Member State to provide this;
- Right of patients to obtain a copy of their medical record and to get appropriate **medical follow-up in the home country;**
- **Recognition** of prescriptions made abroad ;
- **Transparency** on the quality and safety standards for healthcare that apply in each Member State;
- **Legal basis** for European co-operation on eHealth and Health Technology Assessment;
- **Better cooperation** between Member States in rare diseases, including establishing a legal basis for European Reference Networks and centres of excellence.

Although cross-border healthcare touches directly only a minority of patients, the co-operation aspects in the legislation have potential to contribute in the long term to better access and better quality of healthcare across Europe.

1.3 PATIENT ORGANISATIONS' ENGAGEMENT IS KEY TO SUCCESSFUL IMPLEMENTATION

Many of the provisions of the Directive are optional for Member States to implement. Others leave room for interpretation. So, much depends on the way Member States choose to implement the directive. The full impact of the new laws will only become clear in the course of the coming years.

In order to make sure that the Directive is implemented in Member States in a way that benefits patients, it is essential that patient organisations at national level involve themselves actively in the implementation and monitoring.

2 Key dates

2 July 2008
Publication of the European Commission's legislative proposal

19 January 2011
Adoption by the European Parliament

28 February 2011
Adoption by the Council of the European Union

9 March 2011
Publication of the legislation in the EU official Journal

25 October 2013

Entry into force. From this date onwards patients are able to use their rights under the Directive.

25 October 2015
First progress report by the European Commission. This first report, two years after entry into force, will be a key opportunity to assess whether the Directive is a success from a patient perspective.

Member States are obliged to help the Commission by providing all available information they have; therefore patient organisations should liaise with their national authorities and with the European Patients' Forum to provide their views on the strengths and weaknesses of the Directive.

3 Key points in the legislation

3.1 SCOPE (ARTICLE 1)

The Directive covers all healthcare services, including diagnosis, treatment, prescription and dispensation of medicines and medical devices (but not reimbursement) and including eHealth services (Article 1(2), recital 26). The Directive does not apply to long-term care or support for people in their daily routines (such as in care homes). It also does not apply to allocation of organs for transplants or national vaccination campaigns (Article 1(3)). The directive does not affect Member States' laws and regulations relating to the organisation and financing of healthcare generally, as that is a national competence (Article 1(4)). Definitions of key terms, such as "healthcare", "insured person" and "Member State of affiliation" are provided in Article 3.

3.2 THE PRINCIPLE OF NON-DISCRIMINATION (ARTICLE 4)

The Directive is based on the principle of non-discrimination: healthcare providers that provide cross-border healthcare are not allowed to charge higher fees for overseas patients than for domestic patients. Member States are also not allowed to treat overseas patients differently from domestic patients (Article 4(3) and 4(4)).

Member States have a right to introduce restrictions the cross-border healthcare only for "overriding reasons of general interest, such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources" (Article 7(9), Recital 11, 12). Healthcare providers are not obliged to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by significantly increasing waiting times (Recital 21).

Any restrictions imposed by Member States have to be explained and justified to the European Commission (Article 7(11)). The restrictions imposed by Member States should not create unjustified barriers to free movement of provision of services (Article 7(11), Recital 11).

3.3 REIMBURSEMENT (ARTICLE 7)

It is important to be aware that the decision on what healthcare is reimbursed, and at what level, is entirely up to each Member State. Member States are free to determine the details of their own Social Security "benefits basket"– i.e., which benefits are provided, the conditions of eligibility, and the reimbursement status of the benefits (Article 7(3)).

Member States must though provide clear information to patients regarding reimbursement (see section 3.6 on "information to patients").

3.3.1 WHAT CARE CAN BE REIMBURSED?

In principle, patients are entitled to reimbursement for cross-border healthcare if they would be entitled to reimbursement of that healthcare at home. The treatment must therefore be part of the healthcare benefits "basket" in the home Member State (Recital 33). Where exactly the same treatment does not exist, the directive says that consideration should be given to the corresponding benefit for the patient (Recital 34).

3.3.2 HOW MUCH IS THE REIMBURSEMENT?

The amount of reimbursement is the same as "at home" and Member State are obliged to cover only the cost of treatment (Article 7 (4)). It is not possible for a patient to make a profit from cross-border healthcare (Recital 32).

EXAMPLE

- A treatment **costs €100** at home out of which **€80 are reimbursed**. Patient pays: €20.
- In **country A**, the same treatment **costs €120**. The patient will still receive **€80 reimbursement**. The total cost of the treatment to the patient therefore is €40.
- In **country B**, the same treatment **costs €90**. The patient will still receive **€80 reimbursement**. The total cost of the treatment to the patient is €10.
- In **country C**, the same treatment **costs €75**. The patient will receive **only €75**, which is the actual cost of the treatment. The total cost of the treatment to the patient is none.

Other costs, such as travel and accommodation, must be carried out by the patient, unless they get these costs reimbursed at home as well. (These costs are therefore not taken into account in the above examples). However, Member States *are free to decide* to reimburse the full costs of the treatment even if they exceed the normal limit. They may also decide to reimburse extra costs, such as travel or costs resulting from disability (Article 7(4), recital 34). It is important that patients are aware what their country's policy is regarding extra costs.

Member States must have in place a transparent mechanism proposed regulation of costs of cross-border healthcare that are to be reimbursed. This mechanism must be based on objective, non-discriminatory criteria known in advance (Article 7 (6)).

3.3.3 DO PATIENTS HAVE TO PAY UP FRONT?

Normally, patients will have to pay the healthcare costs upfront. They will then be reimbursed by their home Member State.

The directive allows Member States a possibility to reduce the financial burden on patients by making use of *prior notification* (see section 3.4). This could work in two ways (article 9(5)):

- Patient can obtain prior notification and in exchange they can receive written confirmation of the level of reimbursement they are entitled to, before having the treatment. This will help the patient to calculate their costs more accurately.
- Or, a Member State can decide to go further and put in place a mechanism for direct transfer of costs across borders. A mechanism already exists under the arrangements for the coordination of social security systems (EU Regulation No. 883/2004).

Both options are voluntary and Member States are not obliged to use the system for the cross-border healthcare directive. Patient organisations can advocate in favour of this system in their own countries.

3.3.4 CAN REIMBURSEMENT BE REFUSED?

Yes, Member States can refuse to reimburse for certain limited reasons. One reason is if they consider that the service would not have been reimbursed if it had been provided in the home Member State. However, recital 34 clarifies that "[i]f the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross- border treatment sought or received corresponds to benefits provided for in its legislation."

Other reasons for restricting reimbursement for cross-border healthcare may fall under the principle of "overriding reasons of general interest" (see section 3.2). Reimbursement may also be refused, under certain conditions, for healthcare services that are subject to *prior authorisation* (see section 3.4).

3.4 PRIOR AUTHORISATION (ARTICLE 8)

In principle, patients have the right to access cross-border healthcare without notifying the authorities. However, there are certain exceptions for which Member States have the right to put in place a system of prior authorisation.

3.4.1 WHAT HEALTHCARE MAY REQUIRE PRIOR AUTHORISATION?

Member States can require prior authorisation only for certain exceptional cases of healthcare on the basis of "overriding reasons of general interest" explained above. These exceptions are limited to the following (Article 8(2)):

- healthcare involving at least one night's accommodation in hospital
- or healthcare using highly specialised medical infrastructure or equipment. (What is meant by "highly specialised" is not defined in the directive so Member States will have to define that.)
- Healthcare which presents a particular risk for the patient or the general population;
- If the cross-border healthcare provider raises a "serious and specific concern" regarding the quality or safety of care. This would be judged on a case-by-case basis.

Member States will have to publish the precise list of healthcare services that are subject to prior authorisation.

The Directive does not say how long Member States may take to come to a decision regarding prior authorisation. It mentions a "reasonable time", also taking into account any emergency due to the patient's condition (See section 3.5 on "administrative procedures").

3.4.2 CAN THE MEMBER STATE REFUSE PRIOR AUTHORISATION?

Yes, in some cases. In principle, Member States cannot refuse authorisation if the patient is entitled to it under the national law and the treatment cannot be provided at home within a reasonable (medically justifiable) time-limit (Article 8(5)). The Watts case established the principle that the

determination of what is medically justifiable must be based on an assessment of the individual circumstances of the patient (rather than, for example, based on reference to national waiting lists).

However, prior authorisation may be refused if:

- the patient would be exposed to an unacceptable risk, that outweighs the potential benefit from cross-border healthcare;
- the treatment would expose the general public to a safety hazard;
- the healthcare provider is suspected of not respecting safety and quality standards;
- the healthcare can be provided at home within a justifiable time limit (Article 8(6)).

The judgement on the last point must be based on an objective medical assessment of the patient's condition and take into account the history and probable course of their illness, the degree of pain and/or the nature of the disability.

3.5 ADMINISTRATIVE PROCEDURES (ARTICLE 9)

The Directive sets rules for administrative procedures in the *Member State of affiliation* (See glossary section 7), particularly regarding reimbursement and prior authorisation requests. Information related to these procedures must be easily available to the public (Article 9(2)).

In spite of that it is up to each Member State to define the general conditions and formalities for access to healthcare. For example, this means that if a Member State requires general practitioner (GP) referral for consulting a specialist, then it can also require GP referral for cross-border healthcare (although that GP consultation could take place in another Member State); but if GP referral is not needed at home then the Member State must not require referral for cross-border consultations. Member States should publish information about these conditions, which must be based primarily on medical considerations and should not impose any additional burdens on patients who wish to go abroad compared to patients being treated in the home country (Article 7(7), Recital 37).

3.5.1 HOW LONG WILL THE ADMINISTRATIVE PROCEDURE TAKE?

The directive does not say how long the procedure can take, but states that there must be "reasonable" time limits set for dealing with requests (Article 9(3)). The time limits must be publicly available. It is up to national authorities to define what constitutes a "reasonable" time to take a decision on prior authorisation.

If patient organisations feel that these time limits are not reasonable, they should challenge the national authorities.

3.5.2 WHAT ARE THE CRITERIA WHEN CONSIDERING REQUESTS?

When considering requests, Member States must take into account the patient's medical condition, the urgency of the case, and individual circumstances. Request should be dealt with objectively and impartially. Individual decisions must be properly reasoned and justified. Decisions must be subject

to review and should be able to be challenged in court. Member States should make provisions for interim measures in such cases (Article 9(2) and 9(4)) (See section 3.8 below).

3.6 INFORMATION TO PATIENTS (ARTICLES 4, 5 AND 6)

A key provision of the Directive is the creation of National Contact Points (NCPs) for information to patients and the public. The Member States will decide how many they will be and what form they will take. The directive says the NCPs must have facilities to provide the information and practical assistance to patients needed to make an informed decision.

Patients should look at the NCP of their own country as well as the one of that country where they are thinking of going to access healthcare services. Patients should also look at information provided by the healthcare providers – e.g. hospital or doctor – that they are thinking of using.

NCPs must provide, on request, the following information:

FOR PATIENTS CONSIDERING ACCESSING HEALTHCARE IN ANOTHER MEMBER STATE:

- The rights and entitlements of patients, including the terms and conditions for reimbursement;
- The administrative procedures for patients who wish to use cross-border healthcare;
- The procedures for appeal and redress if a patient considers that their rights have not been respected;
- Clear information about which rights patients have under the cross-border healthcare Directive, and which rights they have under other EU legislation (Regulation (EC)No. 883/2004). Sometimes one or the other regime may be more beneficial for the patient, and the NCP must inform which one is the better option;
- Contact details of the NCPs of other Member States.

FOR PATIENTS FROM ABROAD WHO CONSIDER USING HEALTHCARE IN THE MEMBER STATE:

- Information about healthcare providers in that country;
- Information on patients' rights in that country;
- Information on complaints procedures, mechanisms for seeking remedies, and what legal and administrative options exist to settle disputes;
- Information on the quality and safety standards that apply in the country, including provisions for supervision and assessment of healthcare providers ("fitness to practice") and which providers are subject to those standards and guidelines (e.g. some standards may only apply to public or only private healthcare);
- Information on the accessibility of hospitals for persons with disabilities;
- Information about cross-border prescriptions.

All information should be easily accessible, available in electronic format and in a format accessible to people with disabilities.

Healthcare providers providing services for cross-border patients should provide all the necessary information to patients to help individual patients to make an informed choice.

This includes information on:

- the treatment options and their availability;
- the quality and safety of the healthcare;
- clear invoices;
- information on prices.

They must also provide information about their authorisation or registration status and professional liability provisions (Article 4(2)). Healthcare providers are not obliged to provide more information to patients from other member states than they already provide to patients resident in the Member State.

3.7 SAFETY, QUALITY AND CONTINUITY OF CARE

The Directive includes specific provisions related to the safety and quality of healthcare. These provisions are not as strong as EPF would like, but nevertheless they are an important step forward particularly regarding transparency of national standards. Below we give the key points regarding quality and safety.

3.7.1 TRANSPARENCY OF NATIONAL SAFETY/QUALITY STANDARDS

The Directive states that cross-border healthcare has to be provided to patients in accordance with the safety and quality standards and guidelines that are in place in the Member State of treatment, and where applicable in accordance with EU legislation (Article 4(1)).

Member States must provide information to patients on their national standards and guidelines on quality and safety (Article 4(2)). They are also required to cooperate with each other in the area of safety and quality standards and guidelines (Article 10).

Furthermore, Member States must ensure that information regarding health professionals' right to practise is made available upon request to other Member States (Article 10(4)). The directive does not say explicitly that this information should be available to patients and the public, but as it is important for patient safety and informed patient choice, patients should make enquiries from the NCP of the member state of treatment to check the credentials of the health professional they are thinking of using.

3.7.2 CONTINUITY OF CARE

Patients who have received treatment in another Member State are entitled to a copy of the medical record. (Article 4(2)(f)) If a medical follow-up proves necessary after their return home, the home country must provide the same follow-up as for treatment received at home (Article 5(c),(d)).

Because the provisions of the directive are not specific, it is important that patients observe how well the continuity of care works in practice, and report their experiences to EPF.

3.7.3 WHAT IF SOMETHING GOES WRONG?

It is a responsibility of the Member States to ensure that there are complaints procedures and mechanisms in place for patients to seek remedies if they suffer harm arising from the healthcare they receive. Transparent information must be provided about these mechanisms and about the legal and administrative options available to patients to settle disputes (Article 4 (2)(c) and Article 5 (3)). Remedies would be in accordance with the legislation of the Member State of treatment.

It is therefore important for patients to contact the NCP of the Member State where they are considering getting treatment, and asking for information regarding healthcare-related harm.

However Recital 23 points out that the home Member State may apply the coverage of its domestic system to cross-border healthcare, if it so wishes. Therefore it is important also to check the from your NCP whether your country does this or not.

3.7.4 RECOGNITION OF PRESCRIPTIONS (ARTICLE 11)

Prescriptions issued abroad must as a rule be recognised. Implementing legislation[10] was adopted in December 2012 for the recognition of prescriptions and measures to enable health professionals to verify the authenticity of prescriptions issued in other Member States (Article 11).

A non-exhaustive list of information that should be included in a cross-border prescription is contained in the annex[11] of the implementing Directive. To avoid confusion, prescriptions should be made using the common name (INN)[12] rather than the brand name of the medicine (with the exception of biological medicines, for which both names must be included). The information on the prescriptions should make it easier for patients to understand the prescription and instructions for use. The Commission will regularly review the situation to check whether the new measures have been helpful to patients. The NCPs must provide patients with information on the list of information that should appear in cross-border prescriptions.

It is important to be aware that the Directive does not affect national pricing and reimbursement rules. (Article 11(1), recital 36).

3.8 PATIENTS WITH RARE DISEASES (ARTICLE 13)

Patients with rare diseases and their families are in a particularly vulnerable situation as for them, the decision to seek healthcare abroad is based on a global lack of expertise and/or the unavailability of treatment or even diagnosis in their own country.

In general, the directive says that the Commission will support Member States' cooperation to develop better capacity for the diagnosis and treatment of rare diseases. The main tool for this purpose will be European Reference Networks (see section 3.9 below). The Directive also says

[10] http://ec.europa.eu/health/cross_border_care/docs/impl_directive_presciptions_2012_en.pdf
[11] http://ec.europa.eu/health/cross_border_care/docs/impl_directive_presciptions_2012_en.pdf
[12] International non-proprietary name, the internationally agreed name of the substance (e.g. paracetamol) – not the brand name (e.g. Tylenol, Panadol).

Member States should exploit better the possibilities offered by Orphanet[13] and the existing Social Security Regulation for the referral of patients abroad in cases where diagnosis and treatment is not available in the home country.

If a patient is suspected to be affected by a rare disease and applies for prior authorisation, a clinical evaluation may be carried out. If no expert can be found in the home country, the Member State can request scientific advice (Article 8(4)).

These provisions of the Directive are rather vague, so it is important that patient organisations draw the attention of the national authorities to the specific problems faced by patients with rare diseases. The authorities should do everything they can to facilitate those patients' access to expert diagnosis and treatment.

We encourage patient organisations to report back to EPF regarding the specific problems faced by patients with rare diseases, and how well these are addressed by the cross-border healthcare directive in different Member States.

3.9 EUROPEAN REFERENCE NETWORKS, HEALTH TECHNOLOGY ASSESSMENT AND eHEALTH

The directive encourages European cooperation in several key areas in addition to safety and quality of care.

3.9.1 EUROPEAN REFERENCE NETWORKS (ARTICLE 12)

European Reference Networks (ERNs) already exist for some rare diseases[14]. The Directive gives them a legal basis and clear objectives, and encourages Member States to facilitate the development of such networks. In principle, ERNs could be applied not only to rare diseases but to any disease where diagnosis and treatment needs to be improved. ERNs bring together specialised centres of expertise across Member States to work together and pool their resources and knowledge. Their objectives are defined in the directive (Article 12(2)):

- to realise the potential of European cooperation for patients and healthcare systems in highly specialised healthcare;
- to pool knowledge on prevention;
- to improve diagnosis and delivery of high-quality, accessible and cost-effective healthcare for all patients with "a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare" (primarily rare diseases but also conceivably others);
- to reinforce research, epidemiological surveillance and training of health professionals;
- to encourage sharing of expertise and information for improving diagnosis and treatment of rare diseases;
- to encourage development of quality and safety benchmarks and help spread best practices; and

[13] Orphanet is the reference portal for information on rare diseases and orphan drugs, for all audiences. More information: http://www.orpha.net/consor/cgi-bin/Education.php?lng=EN

[14] http://ec.europa.eu/health/rare_diseases/european_reference_networks/index_en.htm

- to help Member States with small numbers of patients in particular conditions, or lack of expertise/technology to provide specialised services of high quality.

In 2013, the Commission launched a public consultation on the implementation of ERN and in particular on the criteria that ERN and healthcare providers that wish to become part of an ERN should fulfil (Article 12(4)). The results of the public consultation were published in June 2013.[15]

The Directive does not mention patient organisations' involvement in ERN. However, the "Quality Criteria for Centres of Expertise for Rare Diseases in Member States" developed in 2011 by the European Union Committee of Experts in Rare Diseases (EUCERD) state that a centre of excellence should have links and collaboration with patient associations.[16] Furthermore, the Council Recommendation on rare diseases[17] (2009) calls on Member States to consult patient representatives on policy development, facilitate patients' access to updated information, and promote patient organisation activities.

3.9.2 EHEALTH (ARTICLE 14)

The Directive establishes a voluntary network for cooperation between the national authorities responsible for eHealth in Member States. The eHealth network was established through a Commission implementing decision[18] in December 2011 and at the time of writing comprises representatives of all 28 Member States and Norway.[19]

Objectives and functioning

The network is given broad objectives to work towards enhancing the continuity, safety and high quality of healthcare. It should for example draw up guidelines on the data to include in patient summaries for continuity and safety of care across borders, and the use of medical information for public health and research. (Article 14(2))

In contrast with the HTA network, the Directive does not set rules of governance for the eHealth network, and stakeholder participation is not explicitly mentioned.

3.9.3 HEALTH TECHNOLOGY ASSESSMENT (ARTICLE 15)

The Directive established a voluntary network for cooperation between the bodies and authorities in Member States responsible for health technology assessment (HTA). The HTA network was established through a Commission implementing decision[20] in June 2013. It was due to meet for the first time in October 2013. The members of this network will be national authorities or bodies responsible for HTA, which will be designated by the participating Member States. At the time of writing, information on the designation of representatives from the Member States was not yet published.

[15] For more information and the report see http://ec.europa.eu/health/cross_border_care/consultations/cons_implementation_ern_en.htm
[16] Available at http://www.eucerd.eu/
[17] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF
[18] http://ec.europa.eu/health/ehealth/docs/decision_ehealth_network_en.pdf
[19] More information available at http://ec.europa.eu/health/ehealth/policy/network/index_en.htm
[20] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:175:0071:0072:EN:PDF

STAKEHOLDER INVOLVEMENT AND TRANSPARENCY

The Directive states that the HTA network should be based on principles of good governance, including transparency, objectivity, and "appropriate stakeholder consultation" (Article 15(1)). Moreover, the network rules of procedure facilitate stakeholder consultation. Working groups may be set up to examine specific questions. Member States may designate experts to participate in the network meetings, and the network may invite European and international organisations to attend its meetings as observers. The Directive provides for aid from the European Union so that the network may achieve its objectives. Aid can be granted, among other things, to facilitate the consultation of stakeholders on the work of the network (Article 15(3)).

Article 7 of the implementing decision states that information on the activities of the network must be published on the European Commission's website.[21]

OBJECTIVES AND CRITERIA OF THE HTA NETWORK

The Directive provides objectives and criteria for the HTA network. Its objectives are:

(a) to support cooperation between national bodies responsible for HTA;

(b) support Member States in the provision of information on the relative efficiency and short- and long-term effectiveness of health technologies,[22] and enable effective exchange of information between the national bodies;

(c) support the analysis of the nature and type of information that can be exchanged between Member States; and

(d) avoid duplication of assessments by Member States (Article 15(2)).

COOPERATION BETWEEN THE HTA NETWORK, EUNETHTA AND THE EUROPEAN MEDICINES AGENCY

The second Joint Action EUnetHTA[23] will be supporting the HTA Network in technical and scientific issues. The European Medicines Agency (EMA) and EUnetHTA announced their closer collaboration in the area of scientific advice in June 2013, which will be formalised in a three-year joint work plan.[24]

[21] More information will be available at http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

[22] A health technology can be any intervention to improve health, including drugs, medical devices, equipment and procedures relating to healthcare. Healthcare includes prevention, diagnosis and treatment.

[23] http://www.eunethta.eu/activities/EUnetHTA Joint Action 2 (2012-15)/eunethta-joint-action-2-2012-2015

[24] EMA press release is available here; more information and minutes of joint meetings are available here.

4 Opportunities for patient organisation involvement

Patient organisations can encourage patient centred implementation of the directive in their own countries. Below we suggest some areas where you may wish to get involved:

- **Engage with your National Contact Point** and provide feedback on the relevance and comprehensibility of the information it provides;
- Advocate to your national government to set up a **system for direct payments and/or prior notification;**
- Advocate to your national authorities to **reimburse travel costs and the full cost of treatment** where appropriate; help your authorities to identify cases where this is particularly needed;
- Give **feedback on the complaints procedures and mechanisms** and whether they meet the needs of patients;
- Engage with the bodies in your country responsible for **eHealth and HTA**
- Provide feedback to the Commission regarding the possibilities that exist in your country for **referral abroad** in cases of (suspected) rare diseases
- Provide **information on your website** regarding cross-border healthcare (see also Links section, below)
- Provide **feedback regularly to EPF** on different aspects including your national laws, administrative procedures, waiting times, reimbursement, prior authorisation, complaints and redress mechanisms, and cross-border prescriptions
- Keep **monitoring** the functioning of the Directive in preparation for the 2015 progress report!

5 List of national contact points

A comprehensive Internet listing of all Member States' national contact points is maintained by the European Commission. This information will change as more countries set up their national contact points. For this reason EPF is not compiling a separate table.

Please check this webpage regularly to see the status of your country's NCP:
http://europa.eu/youreurope/citizens/health/contact/index_en.htm

6 Links to further information

Please note that these information resources are not formally endorsed by EPF.

Information on the cross-border healthcare directive:

- Full text of Directive 2011/24/EU
- The European Commission's question & answer document in 22 languages
- European Commission leaflet "know before you go"
- European Commission video
- "Your Europe" portal – health contains practical information on:
    - Unplanned healthcare during temporary stays, holidays, etc.
    - Planned healthcare
    - Prescriptions
    - Healthcare when living in another EU country

DG Health and Consumers – cross-border healthcare page contains information on EU policy

Social security coordination:

- European health insurance card
- EU social security coordination – rules and citizens' rights

7 Glossary

Member State of affiliation: This is the Member State where the person is insured or entitled to sickness benefits.

Member State of treatment: This is the Member State where healthcare is provided to the patients, and in the case of care provided by telemedicine the Member State where the healthcare provider is established.

National Contact Points: Bodies (at least 1 per Member State) who will be responsible for providing information to patients and practical assistance for cross border healthcare (see point 3.1.)

Prior authorisation: It is a system that can be established by the Member State of affiliation in certain limited cases (see point 3.3) whereby the patients has to request an authorisation for the reimbursement of cross border healthcare. The Member State of affiliation can refuse to grant it for justified and limited reasons.

Transposition: The directive sets out general rules and objectives but leave Member States the choice as to how to attain them. This process is carried out by national governments and parliament and may involve local authorities. Member States will provide to the European Commission tables to

show the link between the provisions in the directive and national dispositions. They have until October 2013 to adopt the necessary dispositions into their national law.

8 List of useful acronyms

DG SANCO: Directorate General for Health & Consumers - European Commission

EC: European Commission

EP: European Parliament

ECJ: European Court of Justice

EHIC: European Health Insurance Card

EMA: European Medicines Agency

ERN: European Reference Networks

GP: General Practitioner

HTA: Health Technology Assessment

MS: Member States

NCP: National Contact Point