europeanpatients'forum

EPF STATEMENT
on the Proposal for a Draft Directive
of the European Parliament and of the Council
on the application of Patients' Rights in Cross-Border Healthcare

25 November 2008

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients'voice at EU level, manifesting the solidarity, power and unity of the EU patients'movement. EPF currently represents 36 member organisations – which are chronic disease specific patients organisations operating at European level, and national coalitions of patients organisations. EPF reflects the voice of an estimated 150 million patients affected by various diseases in the European Union, and their families.
EPF facilitates the exchange of good practices and challenging of bad practice on patients' rights, equitable access to treatment and care, and health-related quality of life between patients organizations at European level and at Member States level. Developing knowledge on the needs and interests of patients, from a patient perspective, is only possible with the active involvement of patients and/or patients' representatives.

Introduction

EPF welcomes the European Commission's draft Directive to facilitate the application of European patients' rights in relation to cross-border healthcare, which is part of the Renewed Social Agenda Package. Our response[1] to the Commission's Consultation on Health Services[2] from January 2007 is to some degree reflected in the new proposal however there are some areas of concern.

Legal clarity

The Directive provides the legal clarity regarding patients' rights that was needed following several European Court of Justice (ECJ) rulings[3], initiated by patients

[1] *Response from the European Patients' Forum regarding the EC Consultation on Health Services,* http://www.eu-patient.eu/policy/attached_documents/EPF_Response_Health_Services_Consultation.pdf
[2] *Consultation regarding Community action on health services*, http://ec.europa.eu/health/ph_overview/co_operation/healthcare/community_framework_en.htm
[3] *European Commission - Employment, Social Affairs & Equal Opportunities - Coordination of Social Security Schemes - Costs incurred for healthcare abroad - Authorisation (E 112 form) - Case law* http://ec.europa.eu/employment_social/social_security_schemes/healthcare/e112/caselaw_en.htm

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themselves, which recognised patients' rights to reimbursement following treatment abroad. We welcome this, although the Directive does not go beyond the rulings of the ECJ and does not create other possibilities to receive healthcare abroad than those established by the ECJ.

Rights-based
The Directive is rights-based, focuses on core principles around quality, safety, and equity and provides for the tools to make it work for patients. It an important legal framework on which to build.

Value-driven
The Directive's objectives embed the values and operating principles shared by health systems throughout the EU and stated in the Council Conclusions on Common values and principles in the European Union Health Systems[4] (June 2006). These include: quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality.

In this sense, the Directive's overarching goal echoes **EPF's own vision** - of high quality, patient- centred, and equitable healthcare for all patients throughout the EU – and **EPF's core values** and guiding principles:

- patient–centred approach to healthcare;
- non-discrimination on the grounds of illness;
- holistic approach to healthcare (including social, economic, cultural, environmental and mental health aspects for patients, carers and their families);
- empowerment of patients, carers and their families;
- consultative approach and building consensus;
- independency and transparency;
- inclusiveness- reflecting the opinion of marginalised and under represented
- patients, carers and families;
- gender equity.

We consider therefore the rationale behind the Directive and the ambitions that underpin it are a progressive step forward and can be welcomed.

More specifically, EPF welcomes that the Directive introduces **<u>three key points that are very important</u>** for patients:

1. The Directive recognises **a new right for EU patients**: the right of insured persons to seek healthcare abroad (without prior authorisation) and to be reimbursed by the Member State of affiliation up to the level of costs of the healthcare that the patient would have received at home.

[4] *Council Conclusions on Common values and principles in the European Union Health Systems* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF

However, although the principles of universality and solidarity are mentioned in the Directive, EPF is concerned about access to healthcare for ALL patients, included undocumented persons, be it in the country of origin or in another Member States. This is an equity issue which should be further reflected upon and taken on board by Member States and Community legislation.

2. The Directive provides for the establishment of the **national contact points** in each Member State to inform patients of their rights related to cross-border healthcare, protection of personal data, procedures for complaints, means to redress in the event of harm, etc.

EPF welcomes this initiative and recommends that the national contact points are established in an efficient and transparent way and that information about their existence is appropriately disseminated across the country and regions, so that patients have an easy access to the information, in various formats.

We also recommend that patients organisations are involved in cooperating with national contact points and competent national authorities in the process of providing and disseminating information to patients. They should also be involved by the Commission when drafting and adopting guidelines on information to patients, which should reflect the quality principles on information to patients adopted recently by the High Level Pharmaceutical Forum.

3. The Directive facilitates the development of **European reference networks of healthcare providers** – to boost cooperation on highly specialised healthcare and promote access to healthcare for patients with a medical condition requiring a particular concentration of resources and expertise.

EPF considers these reference networks are fundamental for patients with rare or specific diseases and fully supports the sharing of knowledge and training of health professionals in highly specialised services.

Continuity of care

We believe that appropriate mechanisms should be created to ensure a continuity of care for patients when they are back home after having travelled to receive highly specialised care. The proposal for the increased use of "e-health" should be fully explored to this effect. We would further argue that, as far as possible, it should be medical experience and know-how that travel rather than the patient.

There are some further key elements of concern regarding specific aspects of the Directive, that in our view undermine the fundamental vision behind a Directive focusing on patients' rights in cross-border healthcare.

Up-front payment

From the patients' perspective, it is **not acceptable** for patients to be asked to pay up-front for treatment (in their country of affiliation or abroad). This will widen the

social inequalities even further and the vast majority of the population will not be able to benefit from this new right if the up-front payment provision is maintained.

In EPF's view, Member States and the Commission should work together to put in place some mechanisms to pay healthcare providers directly and thus avoid the need for patients to advance funds themselves.

Prior-authorisation

The Directive removes the general prior authorisation obligation for hospital care, while keeping the possibility for Member States to re-introduce it provided they show evidence that - as a result of cross-border healthcare - their health system is at risk.

EPF recommends that, if Member States opt for introducing prior authorisation, this should be based on fair, clear and transparent criteria. The resulting system should be functional and speedy and should not lead to untenable waiting times for patients (undue delay).

EPF considers that prior authorisation *can* offer patients a degree of certainty about the right to full reimbursement and healthcare. Such mechanisms of cooperation between some Member States with regard to prior authorisation already exist and function well. This should be further explored and encouraged, with the condition that an unworkable administrative burden is not created.

Higher quality of healthcare at home

The Directive does not change the right of Member States to define the benefits that they choose to provide. "If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, this directive does not create any new entitlement for patients to have such treatment abroad and be reimbursed."

Although Member States are responsible for the organisation and provision of healthcare services and it is up to them to decide on the standards for healthcare in their country, EPF strongly recommends that more Community action is taken to <u>further encourage and support cooperation among Member States</u> to share experiences and information (about good practices, available treatments, research outcomes, etc) and thus contribute to an improved quality and safety of healthcare throughout the EU.

Stakeholders' involvement in health technology assessment

The Directive provides that Member States shall facilitate development and functioning of a network connecting national authorities or bodies responsible for health technology assessment.

EPF recommends that stakeholders, including patients, should be involved in this network. We believe that co-operation at EU level for such a European network could help to reduce the costs of by eliminating duplication of efforts in different Member States. It also would remove the technology assessment from political influence and concentrate on the evidence and hopefully allowing patients to have faster access of new treatments under specific conditions.

Conclusions

EPF welcomes the Directive and the fact that it provides, for the very first time, the right of patients to seek healthcare abroad, in accordance with the principles of universality, access to good quality care, equity and solidarity. We also welcome the emphasis on Member States, while being responsible for the organisation and delivery of healthcare, to define clear quality and safety standards on their territory.

EPF supports the Directive, while acknowledging at the same time that it needs further fine-tuning**. We are passionate about ensuring that the critical issues raised above are taken into consideration**. We highlight also the fundamental importance of involving patients' organisations in the eventual transposition, evaluation and review of the Directive.

Finally, EPF commits to be a strong and constructive partner in discussions on the Directive during its legislative pathway and implementation. Through our patients constituency we commit ourselves to making the Directive more visible at Member States level and to raise awareness of the use of EU instruments and actions for health.