Patients' Rights in Cross-Border Healthcare
EPF's position on the vote on the
Draft Recommendation for Second Reading (27 October 2010)
Brussels, 22 October 2010

The European Patients' Forum, through its 44 member organisations, represents the interests and rights of some 150 million patients across the European Union. EPF welcomes the Draft Recommendation prepared by Mrs Françoise Grossetête MEP, which is based on the principles of universality, access to good quality care, equity and solidarity, and provides the clarity that patients need.

We appreciate the difficulty in developing a compromise solution acceptable to all parties, particularly given the current financial concerns of many Member States. Nevertheless, we urge the Parliament to take a long-term view and ensure that any compromise solution is based on what is best for patients. The Directive will form the basis of much future policy and research, and is an important statement of intent of the EU's commitment to high quality, equitable healthcare for its citizens.

Amendments tabled to the Draft Recommendation

We would like to highlight the areas that we consider are of crucial importance for European patients, and ask that you take note of these when voting on the Draft Recommendation and its amendments.

1. Safety and quality standards, harm arising from healthcare

Article 4

EPF supports the Rapporteur's position regarding safety and quality, which are among the fundamental values and shared principles of European health systems. The added value provided by cooperation at European level is also in line with the many current and future initiatives for enhanced European collaboration[1] in the area of safety and quality. **Continuity of care** is an important element in quality and safety, and should be safeguarded. Regarding **harm arising from healthcare**, it is important that complaints procedures and mechanisms to seek remedies are put in place, and that these are transparent and accessible to the patients. Therefore **we agree with the spirit of amendments 148** and **149** that the Council's position could be further refined.

EPF supports amendments 33, 39, 111, 134.

[1] e.g. EU-funded patient safety projects under the 2nd Health Programme and the Research Framework Programmes, including EUNetPas, SIMPATIE, Marquis, and HANDOVER; the proposed Joint Action on Safety and Quality; the implementation of the Council Recommendation on Patient Safety; and the upcoming Communication on Quality of Healthcare.

European Patients' Forum, Rue Belliard 65, B-1040 Brussels
Phone : +32 (2) 280 23 34 Fax: +32 (2) 231 14 47
Email: info@eu-patient.eu Web: www.eu-patient.eu

2. National Contact Points for information

Article 6

EPF supports overall the Rapporteur's position regarding information to be provided to patients by national contact points and healthcare providers, and that this should be available to patients with disabilities. However, information about cross-border healthcare should be made available to the public through an appropriate channel, rather than just provided upon individual request. The involvement of patients' organisations is key to **ensure that the information provided meets the real needs of the patients, is provided in a format that is user-friendly and accessible, and is disseminated effectively** to its target audiences. The existing ***Core Quality Principles***[2] agreed in the Pharmaceutical Forum are recommended to be used as a basis for all information provided to patients.

EPF supports amendments 34, 40, 42, 43, 125, 147, 159, 160, 161, 162 and 163.

3. Reimbursement

Article 7

EPF supports the Rapporteur's position regarding flexibility for Member States to reimburse *more than* strictly the cost of the healthcare itself, should they so choose. This recognises the fact that treatments are not the same in each Member State, but they may be equivalent or equally effective; and that Member States may wish to include other related elements such as physiotherapy or recuperation in the reimbursement, if it has clear health benefits – e.g. avoiding rehospitalisation.

EPF supports amendments 12, 48 and 115.

Regarding **reasons for refusing reimbursement** (cf. amendments 166, 167), EPF considers that such reasons **must be clearly limited, and information about such reasons must be made publicly available, in order to allow patients to make an informed decision.** The aim of the Directive is to create legal clarity for patients about their rights and entitlements regarding cross-border healthcare. Given that prior authorisation applies if one of the conditions under Article 8 – paragraph 2 apply to the cross-border healthcare, in our view the only valid reasons for refusing reimbursement "after the fact" should be strictly limited to the same reasons as refusing prior authorisation. Information about these reasons must be made publicly available in advance, and a system for appeal should be in place.

4. Rare diseases and European Reference Networks

Article 7 and Article 12

We would like to emphasise again that patients with rare diseases and their families are in a particularly vulnerable situation. For them, the decision to seek healthcare abroad is based on a global lack of expertise and/or unavailability of treatment in their country. EPF maintains that patients with rare diseases should have the right to access cross-border healthcare without prior authorisation, and to receive reimbursement for such care, whether or not it is among the benefits provided in their Member State of affiliation, as provided for notably in the Rapporteur's amendments 47 and 64.

However, in the interests of a compromise solution, it may be acceptable to make this subject to prior authorisation, *provided that* the authorisation can be obtained within an acceptable time-frame (amendment 193), and that the assessment is done by a recognised medical expert having

[2] http://ec.europa.eu/pharmaforum/docs/itp_quality_en.pdf

knowledge of the specific case (amendment 186). If a prior authorisation cannot be obtained under these criteria, then the patient should have the right to access the healthcare without authorisation and be reimbursed. Reimbursement should be based on the *actual costs*, not on the level of reimbursement in the MS of affiliation, where the healthcare is either not provided or is of inadequate quality (the reason for seeking healthcare abroad in the first place).

We urge the Parliament and the Council to seek a solution that will ensure that patients with rare diseases will have access to the treatment they need – wherever it is available – without incurring an "extra" financial penalty.

EPF supports amendments 16, 20, 47, 64, 116, 166, 167, 168, 186, 189, 193.

Regarding **European Reference Networks**, EPF supports the Rapporteur's comprehensive provisions for European Reference Networks and their criteria, which are logically based on the criteria of the Rare Diseases Task Force (2006).

EPF supports amendments 28, 80, 81, 82, 83, 127, 209.

5. Prior authorisation and refusal, upfront payment

Article 8 and Article 9

Prior authorisation and reimbursement are among the key issues of the legislative proposal from the patients' perspective. Patients need absolute clarity about the types of healthcare that may be subject to prior authorisation, and we are pleased that this is recognised by MEPs.

EPF supports the position of the Rapporteur regarding the conditions and requirements for prior authorisation. We do recognise the need of Member States to have a safeguard clause protecting the financial balance of their social security systems, which is provided by the **Rapporteur in** amendment 56.

EPF's position regarding reasons for refusal of prior authorisation or reimbursement is that this should be a **defined list**. Should changes be made in the interests of reaching a compromise with Council, EPF recommends a provision that **a precise list of reasons for refusal** should be developed in consultation with stakeholders, notably patients' organisations.

EPF supports amendments 55, *56*, 59, 60, 61, 63, 65, 176, 177, 182, 184, 187.

We reiterate that **up-front payment is a key "deal-breaker" for patients**. It is not acceptable, from an equity perspective, for patients to have to pay the costs of cross-border healthcare upfront. By far the majority of patients wish to receive healthcare close to home, and those who seek cross-border healthcare do this because they *need* it – not because they want to travel. A return to up-front payment as proposed by the Council would mean that only wealthy patients could benefit from the rights provided by the Directive, while the vast majority of the population could not. It would only serve to widen the already existing health and socio-economic inequalities between and within Member States.

EPF supports the approach taken by the Rapporteur based on principles of equity and equality of opportunity for all citizens: "access to healthcare based on needs, not means". Our members overwhelmingly support a **system of voluntary prior authorisation, where the costs are transferred directly between Member States.** EPF strongly supports the Rapporteur's proposal to establish a future **'clearing-house' system** to manage cross-border payments. We are confident that Member States can develop such a system that functions in a smooth and timely manner.

EPF supports amendments 48, 53, 62, 63, 67, 68, 175, 192, 194.

6. E-health

Article 13

EPF supports the Rapporteur's position on eHealth. eHealth, particularly Electronic Medical Records, form an **essential support to patient safety and continuity of care** in cross-border healthcare. Furthermore, it is crucial that the same professional medical quality and safety standards apply to eHealth as for non-electronic healthcare (point a) and that appropriate regulatory requirements apply to health professionals involved in eHealth (point b). The movement of healthcare professionals across borders also increases the need for effective data flows to ensure patient safety.

The Directive must also be forward-looking and take account of current and possible future technological developments. The development of interoperable ICT systems across Europe is a key factor in enabling the development of eHealth and telemedicine applications. eHealth in turn is predicted to play a key role in **ensuring the future financial sustainability of national health systems as well as the provision of good quality, safe healthcare**, being one of Europe's six Lead Market Initiatives[3] and a key contributing area to the objectives of the EU2020 Strategy for smart, sustainable and inclusive growth, adopted by the Council on 17 June 2010.

The Directive plays a **key role in providing a legal basis for EU-level developments in eHealth**. EU-wide projects such as *CALLIOPE* and *epSOS*, and activities such as the *eHealth Joint Action and Thematic Network*, are all intended to improve the interoperability of patient data sets within Member State IT systems, and also across borders. A strong Article 13 is essential for these projects, and for future work and research in this area.[4]

EPF supports amendments 86, 110, 128.

7. Health Technology Assessment

Article 14

EPF believes it is essential to involve patients' organisations as partners in any policy or service development, to ensure that healthcare services are genuinely patient-centred and address patients' real-life needs effectively. **We support the Rapporteur's position** regarding a strong Health Technology Assessment (HTA) network with involvement of stakeholders and clear objectives and criteria for good governance. This is a key provision, in view of the **growing contribution of Health Technology Assessment to the sustainability of health systems across the European Union and the importance of knowledge sharing and transparency in this arena.** It also reflects well the outcomes of recent EPF events with its members regarding the role of patients in HTA processes to harness effectively their expertise and experience in assessing a product or service.

EPF supports amendments 87, 88, 90, 91, 131, 132.

8. Other

Article 11 – e-prescriptions

EPF supports the provisions for greater interoperability of e-prescriptions, and **EPF supports amendments 76, 202, 203.**

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[3] http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/ehealth/index_en.htm

[4] Only this year, the EU has launched 27 e-health projects under the 7th Research Framework Programme, in key areas like ICT for personal health systems, ICT for patient safety, and international cooperation on virtual physiological human (VPH). (Source : *EHI Europe*, 17.06.2010)

Article 10 – information about health professionals

EPF supports the Rapporteurs proposals regarding the register of health professionals and information about disciplinary/criminal findings against health professionals. This is an important patient safety factor. Member States' regulatory bodies should be encouraged to cooperate in the exchange of such information, and this should also be made publicly available for the patients and public. **EPF supports amendments 72, 73.**

Article 10 – cross-border areas and pilot regions

EPF supports the development of pilot programmes and test regions, especially border regions in neighbouring countries, for concluding mutual agreements and developing joint action programmes. This is important not only to develop and test cross-border healthcare solutions, but also to facilitate the development of eHealth and telemedicine solutions as referred to under Article 13. **EPF supports amendments 71, 74 and 198.**

The European Patients' Forum (EPF) is a not-for-profit, independent organisation and umbrella representative body for patient organisations throughout Europe. We advocate for patient-centred, equitable healthcare, and the accessibility and high quality of that healthcare. EPF currently represents 44 patient organisations – chronic disease-specific patient organisations working at EU level, and national patients' platforms. EPF reflects the voice of an estimated 150 million patients affected by various diseases in the EU.