

# CROSS-BORDER HEALTHCARE

## EPF Summary Position Statement

### 25 November 2010

EPF broadly welcomes the draft recommendation for second reading prepared by the Rapporteur and adopted in Committee on 27 October. The draft recommendation is encouraging, and EPF applauds the Parliament for upholding the shared overarching values of universality, access to good quality care, equity and solidarity, and for plainly placing the focus of the Directive on the needs and preferences of patients.

There are some areas where the draft recommendation could be refined, to ensure it really works for patients and avoids creating new or exacerbating existing health inequalities, and that it includes sufficiently strong provisions to support future technological developments, for example in eHealth and telemedicine.

Below we set out EPF's comments regarding the key points of the Directive prior to the Council consideration of the proposal scheduled for 6 December 2010, and the plenary vote in the European Parliament scheduled for 18 January 2011.

---

#### 1. Prior authorisation and reimbursement

The provisions in the Council text were too vague and left too much open to interpretation. Patients need above all legal clarity as to their rights and responsibilities in order to make an informed choice. EPF welcomes the draft recommendation of Mrs Grossetete as it is much clearer about the types of healthcare that may be subject to prior authorisation, the reasons for refusal, and the application process. It also allows Member States the necessary flexibility regarding reimbursements, and specifies the patient's individual needs will be the deciding factor in assessing prior authorisation applications.

- Member States must apply the principle of *non-discrimination* regarding access to cross-border care to patients from other Member States. Any *restrictions* on the provision of cross-border care must be justified and publicised, and must not pose an obstacle to the free movement of patients.
- Member States may require *prior authorisation* for cross-border healthcare to avoid seriously undermining the financial balance of their social security systems or their capacity to provide a balanced medical service in their territory. However, the basis of prior authorisation is defined to include only certain types of healthcare that requires planning (involving overnight hospitalisation or use of highly specialised/cost-intensive infrastructure/equipment), or that involves particular safety risks. The types of healthcare which will require prior authorisation must be set out in a defined list that must be made public.
- The reasons for Member States to *refuse prior authorisation* are strictly limited: if the patient is not entitled to the healthcare, if there is an unacceptable safety risk for the patient or a substantial safety risk to the general population, or if the healthcare provider is not properly authorised or licensed. It cannot be refused solely on the grounds that there are national waiting lists for hospital case based on "predetermined general clinical priorities".
- The *application systems* for prior authorisation must be accessible, transparent and fair, with clear rules for application and refusals that are made public in advance. Citizens will have options for appeal and second opinion.

- Decisions on prior authorisation should be made within “reasonable time limits”, publicised in advance by Member States. The individual patient’s medical condition and circumstances, such as degree of pain and disability, and the urgency of the case, but also the patient’s ability to carry out a professional activity should be a factor in the decision.
- Member States *must reimburse* cross-border healthcare if it is “the same or equally effective for the patient” – thus not necessarily the exact same treatment that would be available in the MS Affiliation. Any refusal of reimbursement must be based on a medical justification.
- Member States may also, if they wish, *cover extra costs*, for example rehabilitation of transport. Extra costs that are due to a *disability* should be reimbursed according to national legislation. In this context EPF considers that clear information should be provided as to which disability-related costs will be reimbursed.

---

## 2. Up-front payment and direct transfer of costs

EPF’s starting point is that access to healthcare should be based on “needs, not means” – which is the view taken also by the Rapporteur. It is essential that patients who need to access cross-border healthcare can do so on an equitable basis, regardless of their social or economic position.

EPF is pleased that the Rapporteur has taken this message clearly on board and proposed solutions. However, it is necessary to identify mechanisms for direct transfers of the costs of cross-border healthcare, in order to ensure that the financial burden is not placed on individual patients and their families. EPF feels that the provisions of the draft recommendation are an improvement on the Council position, but require some fine-tuning in order to avoid exacerbating existing health inequalities.

- The draft recommendation includes a provision for a system of “*voluntary prior notification*”: upon obtaining prior authorisation, patients will receive written confirmation of the maximum costs that will be covered, which they will take to the healthcare provider. The costs will then be transferred directly. However, Member States are not obliged to set up such a system.
- Member States are asked to organise “*in all cases where and when appropriate*”, transfers of funds directly between the competent institutions. This would not result in additional costs for Member States as they would be able to utilise the same practices that are already being used for the coordination of social security payments under Regulation (EC) No. 883/2004. If this is not possible, then it must be ensured that patients receive the reimbursement without delay.
- EPF is concerned that an amendment asking the Commission to conduct a study on a future system for handling cross-border payments (EP First Reading position Art.9(7)) has been dropped, as we believe *European-level coordination* would add significant value here, and ensure that all Member States would eventually be able to adopt a system that works for Member States and patients alike.

---

## 3. Rare diseases

The compromise solution proposed in the draft recommendation is not entirely satisfactory for patients. Families affected by rare diseases are already in a vulnerable position, which should not be exacerbated further. The provisions of the draft recommendation go some way towards alleviating their position *in principle*, but in practice they leave rather much open to interpretation by the Member States.

- While EPF welcomes the recognition that patients with rare diseases have the right to receive cross-border healthcare and be reimbursed for it, *even if the healthcare in question is not among the benefits in their country*, this is made subject to prior authorisation. EPF considers that if patients with rare diseases must be subject to prior authorisation, it is essential that a medical assessment be made by a *specialist familiar with the condition* in order to avoid unjustified negative decisions and lengthy appeal procedures for families.
- EPF welcomes and supports the provisions regarding *European Reference Networks*, which are given clear objectives such as developing EU-level cooperation and sharing best practices in specialised areas; pooling of knowledge; promoting access and improvements in diagnosis and good quality healthcare for conditions needing specialist expertise; helping Member States with few patients or lack of technology/expertise to provide a full range of high-quality specialised services; and developing quality and safety benchmarks.
- EPF further welcomes the provision that the Networks should have links and cooperation with patient organisations, and it is appropriate that the Networks should receive part of their funding from the European Commission.

---

#### 4. Safety and quality of healthcare

EPF welcomes the stronger safety and quality provisions of the draft recommendation, including the following:

- *Member States* providing cross-border healthcare must take into account the principles of universality, access to good quality care, equity and solidarity. They must *define clear quality standards* for healthcare provided on their territory and *ensure compliance* with existing EU and national legislation/standards on safety and quality. Patients must not be “encouraged against their will” to receive treatment outside of their Member State of affiliation, for example on costs basis.
- Transparent complaints procedures, and mechanisms for seeking remedies in case of harm arising from the healthcare, must be in place. Patients will receive a copy of their medical record as well as advice relating to the continuity of care.
- The same safety and quality standards will apply to *eHealth and telemedicine services*. Moreover, regulatory requirements for health professionals engaged in eHealth will be introduced, similar to non-electronic healthcare.

---

#### 5. eHealth and ePrescriptions

EPF has argued strongly for the importance of including eHealth and telemedicine in the Directive. The draft recommendation returns to the stronger eHealth provisions of the first reading, though the provisions seem more explicitly directed towards cross-border healthcare. EPF considers the eHealth provisions should be robust as they form not only an essential patient safety support in the cross-border context, but also a fundamental cornerstone to secure future innovations that will contribute to the sustainability of European health systems.

- The Commission will be asked to adopt “specific measures necessary” for achieving *interoperability* of ICT systems in health. However, it is left up to MS when they want to introduce such systems. The measures must conform to data protection laws in each MS, and “reflect developments in health technologies and medical science, including telemedicine and telepsychiatry”. They will focus on *standards and terminologies*.

- The Commission will be asked to draw up a *non-exhaustive list of data to be included in electronic health records*, methods for use of medical information for public health and research, and identification and authentication measures for transferability of data while protecting personal data.
- The Commission will be asked to adopt a *single EU cross-border prescription template* and guidelines supporting the interoperability of prescriptions, as well as measures for the correct identification of medicines/devices prescribed in one MS and dispensed in another; for the comprehensibility of information to patients concerning prescriptions; and for ensuring that the prescribing and dispensing parties can communicate if necessary to ensure complete understanding of the prescription, whilst maintaining confidentiality of patient data.
- *Recognition of prescriptions from other Member States* will be mandatory, subject to the national legislation in force in the Member State of affiliation. Member States may restrict this only if there are legitimate doubts about its “authenticity, content or comprehensibility”. For drugs or devices that are not normally available in the Member State of affiliation, the Member State may decide whether to authorise exceptionally, or to provide an alternative that will have the same therapeutic effect.
- The mutual recognition provision will not affect national rules governing prescribing and dispensing, substitution, reimbursement, or the ethical duty of pharmacists that may result in refusal to dispense.

---

## 6. Health Technology Assessment (HTA)

EPF welcomes the provisions overall on HTA which have been strengthened by the Parliament compared to the Council’s position.

- EPF welcomes the provision that the Network and its members must adopt *principles of good governance*: transparency, objectivity, independence of expertise, fairness of procedures, and broad stakeholder participation from all relevant groups. The names of individuals participating in its activities will be made public, together with their declarations of interest.
- The HTA Network has *clear objectives in line with the recommendations of the Pharmaceutical Forum’s Relative Effectiveness working group*: to support cooperation between national HTA bodies; find sustainable ways to balance the objectives of access, reward for innovation and management of healthcare budgets; support MS in the provision of scientific information on relative efficacy, and “short- and long-term effectiveness when applicable” of health technologies and facilitate the sharing of such information; analyse the nature and type of information that can be exchanged; avoid duplications of assessments made by EU regulatory bodies.
- The *Commission will coordinate* the Network, though it must respect MS competence in the area of HTA. The member bodies will be designated by MS, but the Commission must only accept members into the Network which fulfil the conditions of good governance.

---

## 7. Information to patients

The overall aim of the draft recommendation is to ensure that patients are able to make an informed choice regarding cross-border healthcare. EPF welcomes this, particularly the provision for involvement of stakeholders in ensuring that information to patients is clear, accessible and relevant. EPF recommends that as much information as possible should be made available to the public in advance, for example through a dedicated Internet portal, rather than being available on request only.

- Member States will be required to set up one or more *National Contact Points* to provide clear and accessible information to patients. Information about the existence of the Contact Points will be disseminated throughout the EU.
- The Contact Points must be *established in an independent, efficient and transparent way*, and encompass independent patient organisations, sickness funds and healthcare providers. The Contact Points will form a network of cooperation with each other, the Member States and the Commission. EPF welcomes the principle of stakeholder involvement, but is concerned that the term “*independent patient organisations*” does not specify how that independence would be assessed, and by whom. It is entirely appropriate that individual experts involved in policy processes should be subject to a transparency requirement, such as under the Health Technology Assessment. Collective qualification, however, is more problematic and if defined too narrowly could have the unintended consequence of excluding groups of stakeholders from having a voice in the democratic process. As a model of good practice, EPF proposes the criteria used by the European Medicines Agency in its work with patients’ and consumers’ organisations.
- The information provided must *enable patients to make informed choices* about cross-border healthcare. Patients will *receive upon request* information on: the standards and guidelines in place in the Member State of treatment, including for healthcare providers; which healthcare providers are subject to those standards and guidelines; clear information on costs; accessibility for persons with disabilities; and the healthcare provider's authorisation or registration status and number. The rights of patients under the cross-border Directive and the rights under Regulation (EC)No.883/2004 (coordination of social security systems) will be clearly distinguished.
- National Contact Points will also provide information on the protection of personal data, patients' rights, complaints procedures and mechanisms for seeking remedies, and the options available for settling of disputes. They will provide information on addressing problems such as *disputes*, and *assistance* for people with complex needs. The information must be provided in the official language(s) of the Member State, and may be provided in other additional languages.
- Member States must consult stakeholders, including patient organisations, to ensure the information provided is clear and accessible.
- *Healthcare providers* will be required to provide all the necessary information to enable patients to make an informed choice – including treatment options, availability, prices, insurance and liability cover.
- Patients who have received cross-border healthcare are entitled to a *written or electronic medical record* of the treatment, and of any *medical advice for the continuity of care*. This is without prejudice to the national legislations of Member States.

---

## 2. Cooperation at EU level and between MS

Cooperation between Member States and with the Commission is essential for the successful implementation of cross-border healthcare. EPF urges Member States to support these provisions and to establish strong cooperation with each other and the Commission.

- Member States are required to *render mutual assistance* as necessary for the implementation of the Directive, particularly regarding exchange of information between National Contact Points and the *standards and guidelines on quality and safety*.

- Member States are also required to *facilitate cooperation in cross-border health provision at regional and local levels*, and through ICT “and other forms of cross-border cooperation”.
- EPF welcomes the provision for the Commission to encourage Member States, particularly neighbouring countries, to *conclude agreements among themselves and to develop joint action programmes*, and to encourage Member States to create “areas where patients will have improved access to health care, particularly in cross-border areas”.
- However, we are disappointed that an amendment regarding the designation of “trial areas” in certain border regions to test innovative cross-border initiatives has been removed. (First reading, Article 18). We believe this would be more supportive to the future development of eHealth and interoperability in particular.
- MS must ensure that *registers of health professionals* are available to relevant authorities of other MS. They must “immediately and proactively” inform other MS about any disciplinary or criminal findings against health professionals, “where they impact upon their registration or right to provide services”. This is an important provision for patient safety.