Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare'

COM(2008) 414 final — 2008/0142 (COD)

(2009/C 175/22)

On 23 July 2008 the Council decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

COM(2008) 414 final — 2008/0142 (COD).

The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 4 November 2008. The rapporteur was Mr BOUIS.

At its 449th plenary session, held on 3 and 4 December 2008 (meeting of 4 December 2008), the European Economic and Social Committee adopted the following opinion by 80 votes to three.

1. **Comments and recommendations**

1.1 Having addressed problems relating to health and patients' rights in a number of opinions, the EESC is now examining this proposal for a Directive, especially since as well as presenting a response to the rulings of the European Court of Justice, the text concerns the rights of patients and steps to structure the coordination of European health policies in the Member States.

1.2 The text re-affirms that health systems fall under the remit of the Member States and leaves unchanged practices for reimbursing treatments provided. However, the provisions proposed will necessarily have an impact in the long term on health systems which are based on solidarity and financial sustainability. The EESC therefore raises questions about the specific application arrangements regarding the subsidiarity principle in health policy and makes some observations and recommendations.

1.3 The Committee is concerned about the risk of widening differences in care among various groups in society and would like the Directive to mention that care must be provided on the basis of the equal worth of all human beings and that people with the greatest need and/or the lowest level of social security cover must also be given priority access to care.

1.4 The basic right of each user to enjoy the necessary guarantees of quality and safety creates obligations with regard to standardisation, certification and evaluation of material and human capacity, and organisation of healthcare.

1.5 Access to cross-border healthcare services requires that healthcare organisations in the different countries complement and counterbalance each other in terms of their capacity with respect to technical services and human resources, medical equipment and the responsibilities of service providers. This presupposes a European policy to support healthcare facilities and the training of healthcare professionals. Particular attention should be paid to certain medical risks linked to increased patient mobility.

1.6 In the EESC's view, the text should not propose to make patient mobility common practice but should put forward a framework in which this right can be exercised, without neglecting the need for quality healthcare as close to the patient as possible. The mechanisms introduced should not be disproportionate to the scope of cross-border healthcare.

1.7 The EESC is concerned about the distinction made in the Directive between hospital and non-hospital care, a distinction that is based more on financial factors than on the reality of healthcare organisation in each country. It therefore recommends, in accordance with the subsidiarity principle and Article 86(2) of the Treaty, that each Member State provide its own definition of hospital and non-hospital care.

1.8 The access to healthcare in another Member State offered to each citizen must be without discrimination as defined in Article 13 of the Treaty and must respect patients' rights as set out by the EESC [1], based in particular on a European medical file and health booklet that have been properly updated and to which medical professionals and patients themselves have access.

1.9 An effective information policy is even more vital in relation to cross-border healthcare because it is the only way of honouring the principle of equality of access to care and enabling the user to make free and informed choices. This policy must be developed under the responsibility of the Member States.

1.10 Information also concerns grievance procedures in the case of harm and arrangements for dealing with legal disputes. It would thus be useful to introduce a single information point, and provision must be made for cases to be brought before the courts in the patients' place of residence. The EESC also recommends that the compulsory liability insurance system should be extended to include all healthcare professionals.

1.11 In order to limit inequalities in access to healthcare, where systems of retrospective reimbursement are concerned particular attention must be paid to reimbursement times and to differences in therapeutic practices and methods of delivering medicines or appliances between the country of treatment and the country of affiliation.

1.12 The reimbursement system must also take into account the risk of inequality and even legal disputes because sickness insurance systems are not homogeneous, but have particular national characteristics: direct settlement, co-payment, tiered fees, referring doctor, coding of treatments, etc.

1.13 All systems for providing information must not only ensure that messages sent meet security and quality requirements, but even more importantly must enable individuals to choose freely and make it easier to reconcile economic competitiveness, cohesion, social justice and collective solidarity.

1.14 National contact points must have links with the various workers', family and user organisations and work in close cooperation with sickness insurance schemes so that they transmit this information. They must also develop information and training activities for medical practitioners, paramedical staff and social workers in relation to options for cross-border healthcare.

1.15 Particular attention must be paid to ensuring continuity of care, patient follow-up, adjustment of medical devices and taking of medicines. To this end, healthcare professionals and systems must coordinate their activities with regard to medical specialties and patients' long-term treatment protocols.

1.16 The introduction of European reference networks must go hand in hand with development of fully interoperable information technologies that allow all patients to benefit, no matter where they live. Exchanging expertise should help to improve quality in the healthcare systems of the Member States to the advantage of all stakeholders — organisations, healthcare professionals and patients.

1.17 Aggregating the statistical data collected by the Member States should make it possible to evaluate the application of the Directive, but also to produce indicators that can be used to understand the strengths and weakness of healthcare systems, as well as people's needs and preferences. This evaluation should also be submitted to the EESC, which is committed, for its part, to conducting a follow-up and, if necessary, adopting further own-initiative opinions.

1.18 Applying real patient rights in relation to cross-border healthcare requires a certain adjustment time to allow a radical change in practices and a change in the attitudes and training of healthcare professionals to take place. It means incorporating into national legislation the principles of a European charter of reciprocal rights and duties of the various actors in the sphere of public health.

1.19 It is obvious to the EESC that the approach adopted has not been able to fully reconcile the issue of subsidiarity in health care and the need for a consistent modus operandi for cross border treatment. This leaves open the possibility of varying interpretation, a source of legal difficulties for both patients and health providers.

2. **Gist of the communication**

2.1 *Legal and political context*

2.1.1 In the light of ECJ case law, the Commission was asked in 2003 to examine ways of improving legal certainty in relation to cross-border healthcare.

2.1.2 The 2004 Directive on services in the internal market contained relevant provisions. The European Parliament and the Council rejected these because they considered that they did not take sufficient account of the particular features of healthcare policies, which vary considerably between countries, and of their technical complexities and financing issues. Public opinion is also very sensitive on this issue.

[1] EESC own-initiative opinion on *Patients' rights*, rapporteur Mr Bouis, OJ C 10 of 15.1.2008.

The Commission therefore decided to present a communication and a Directive in 2008 with a view to establishing a clear and transparent framework for provision of cross-border healthcare in the Union, namely healthcare services received abroad, where a patient moves to a healthcare provider in another Member State for treatment ('patient mobility'). The Commission puts forward a definition of hospital and non-hospital care to this effect.

2.2 *Proposed framework*

2.2.1 The proposal presented is based on Article 95 of the Treaty, which concerns the functioning of the internal market, Article 152 on public health, and the general principles of the Charter of Fundamental Rights as set out in the reform treaty.

2.2.2 In order to achieve the objectives, the relevant legal definitions and general provisions are structured around three main areas: the common principles in all EU health systems, a specific framework for cross-border healthcare, and European cooperation in the sphere of healthcare. The Directive sets out the principles that apply to reimbursing the costs of healthcare in another Member State, as well as the terms under which patient rights are to be exercised in practice, drawing a distinction between hospital and non-hospital costs.

2.2.3 This proposal does not modify the existing framework for coordination of social security schemes.

2.2.4 The Directive sets out the procedures to be followed and also provides for the introduction of appropriate mechanisms for informing and helping patients via national contact points. Any patient who cannot find healthcare within a reasonable time in their own country will be authorised to receive it in another Member State.

2.2.5 The Directive promotes more European cooperation through the setting-up of European reference networks, evaluation of healthcare technologies, and development of online information and communication technologies.

3. **General comments**

3.1 The EESC has addressed problems relating to health and patients' rights in a number of opinions and notes the European Commission's wish to consider the issue of cross-border healthcare.

3.2 The EESC feels that the intention should not be to make patient mobility common practice but rather to put forward a framework in which this right can be exercised. The mechanisms introduced should not be disproportionate — in terms of their scale or cost — to the scope of cross-border healthcare activity.

3.3 This text reflects the values of the European Union and of the Tallinn Charter ([2]), which are intended to ensure high-quality healthcare provision throughout Europe and their accessibility to everyone.

3.4 The proposal for a Directive in its present form tends to ignore the complexity, variety and divergence of the health systems of the 27 Member States. The Directive will almost certainly not be interpreted in the same way by the different healthcare systems in the respective Member States. The EESC therefore has questions to raise about the specific methods of application and wishes hospital and non-hospital care to be clearly defined so as to increase legal certainty for patients and health services.

3.4.1 The text re-affirms that health systems fall under the remit of the Member States and seems to fully respect their competence for organising health systems, delivery of medical care and reimbursement of services provided. However, the provisions proposed will have an impact in the longer term on health systems, their financial sustainability and the extent of the rights associated with them.

3.4.2 In view of the considerable differences in healthcare services provided and their cost, the reimbursement system poses a risk of inequality and even legal disputes because sickness insurance schemes are not homogeneous, but have particular national characteristics. The EESC fears that the Directive may provide an opportunity to open the healthcare market up to competition and in practice, following the introduction of the services directive, undermine the quality of healthcare in Europe overall.

3.4.3 The efficiency and proper use of healthcare services in a cross-border context require that healthcare organisations in the different countries complement and counterbalance each other in terms of their capacity with respect to technical services and human resources, medical equipment, and determining the responsibilities of service providers.

3.4.4 In all cases, whenever cross-border healthcare is provided, patients have the right to expect guarantees of the quality and safety of such care. This fundamental right raises the question of alignment between certification procedures, evaluation of professional practice, capacity of medical equipment, and compensation arrangements in the case of harm.

3.4.5 In the context of cross-border healthcare, high-quality treatment and trust in the care provided in a host country require that a number of conditions be met, in order to ensure continuity of care. These would include:

— widespread use of a health booklet kept by each individual patient from birth;

([2]) Charter signed in Tallinn on 27 June 2008 by the Ministers for Health of the WHO European Region.

— existence of a properly updated European medical file to which healthcare professionals and patients have access;

— a common formulation for reimbursement protocols;

— coordinated prescribing practices, including generalised use of generic names rather than trade names, notwithstanding the fact that medicines are subject to international trade rules;

— standards and certification for medical implants, appliances and devices;

— introduction of a European validation or even certification procedure for medical and paramedical hospital equipment;

— a Community procedure for marketing authorisations for medicines.

All these requirements mean that new technologies with interoperable IT systems will have to be developed.

3.4.6 Such changes in the way the system is organised and in professional practice will also require a change in the attitudes and training of healthcare professionals, as well as revision of the legal definition of the competences, role and responsibilities of healthcare authorities in each country, which will entail a necessary period of adjustment.

3.4.7 The possibility of cross-border healthcare offered to each patient must be an extension of equal access to the whole range of healthcare services and professionals, without discrimination on grounds of gender, race or ethnicity, religion or beliefs, handicap, age, or sexual orientation. Among other things, this will require an effective information policy covering two dimensions:

3.4.7.1 firstly, information on the supply of healthcare, which every citizen must have in order to decide to use cross-border healthcare and which is published under the responsibility of healthcare authorities, who will also have to ensure that this information is accessible to certain vulnerable groups, e.g. people who are socially isolated or financially insecure;

3.4.7.2 secondly, information which must be provided on the patient's medical condition, possible treatments — including benefits and risks — and the type of systems or professionals delivering the healthcare.

3.4.7.3 Since this information will be provided through an interaction with a healthcare professional, that person must themselves be up to date on what options exist in Europe. It is therefore essential to establish the link between healthcare providers and national contact points, and funding will have to be found for this. In addition, the language barrier must be overcome.

3.4.8 The information must be complete and relevant so as to enable the patient to make free and enlightened choices rather than being prey to customer poaching and commercialisation practices.

3.4.9 This obligation to provide information is the only way to realise the principle of equality of access to care as set out in the Directive, whatever the need for cross-border healthcare is.

4. **Specific comments**

4.1 *Article 3*

4.1.1 The EESC notes that the proposal for a Directive should apply without prejudice to Community provisions referred to, in particular Regulations 1408/71 and 883/2004.

4.2 *Article 4(d)*

4.2.1 The EESC considers the list of healthcare professionals to be incomplete and would like paramedical practitioners, such as speech therapists and orthoptists, to be added.

4.3 *Article 5*

4.3.1 The EESC draws particular attention to this article, noting that the challenge will be to guarantee that the healthcare provided meets people's needs and wishes by granting them rights, while also imposing responsibilities, in order to promote well-being by reconciling economic competitiveness, cohesion, social justice and collective solidarity. The EESC will pay careful attention to ascertaining that quality and safety standards are not defined in such a way as to undermine the diversity of national healthcare systems (Article 152(5) TEC).

4.3.2 The EESC emphasises the importance of healthcare systems for citizens, especially the most disadvantaged among them, as well as the impact on economic growth of better access to healthcare, and it stresses that any investment allowing access to healthcare services will be much more effective if it is coordinated.

4.4 *Article 6*

4.4.1 The EESC believes that great care must be taken to ensure in relation to systems of retrospective reimbursement that therapeutic practices, and methods of delivering medicines or appliances, are determined by the country of treatment rather than the country of affiliation, which is responsible for fixing the criteria for reimbursement. This means that equivalence lists must be laid down both for reimbursement rates and for obligations relating to continuity of care.

4.4.2 The EESC is concerned about the additional costs that will have to be borne by the patient in the event of unanticipated non-reimbursement. To ensure continuity in the long term it will be necessary to envisage a system whereby the country of affiliation pays the costs of such treatment, which could have a significant impact on financing systems.

4.4.3 The EESC is concerned to avoid two classes of medicine, from the point of view both of patients and of Member States, and therefore considers it necessary to clarify the issues of cost calculation systems in the country of treatment and of payment terms. The EESC emphasises that care must be taken to ensure that accounting arrangements cater for existing practices and are appropriate to the institutions involved.

4.5 *Article 6*

4.5.1 The EESC is particularly concerned about the distinction made in the Directive between hospital and non-hospital costs, noting that this is based more on financial factors than on the reality of healthcare organisation in each country.

4.5.2 While the Commission is proposing that a supplementary list be issued, the EESC recommends — in accordance with the subsidiarity principle and Article 86(2) of the Treaty — that the Member States should be responsible, except in the case of manifest abuse, for providing their own definition of hospital care. The necessary changes would then be made to Article 8(1) and (2).

4.6 *Article 9*

4.6.1 The EESC believes that prior authorisation systems may be valuable if they involve a process of assessment and providing information to the patient based on a dialogue that can be set up between the patient and his or her funding organisation. Such systems can also guarantee funding of specific services such as reimbursement of travel costs.

4.6.2 The EESC considers that any refusal of authorisation should be duly justified and explained to the patient, regardless of whether the criteria for prior authorisation were published in advance.

4.7 *Article 10*

4.7.1 It is important from the EESC's perspective that systems be introduced for informing patients so as to enable them to make a choice about cross-border healthcare. This information must include the requirements and limits of the service provided, as well reimbursement arrangements and the excess to be paid by the patient.

4.7.2 The EESC recommends that the compulsory liability insurance system ([3]) be extended to include all healthcare professionals and that information be provided on grievance procedures in the case of harm caused by medical accident, with or without negligence (therapeutic risk).

4.7.3 The EESC considers it appropriate to apply the principle of a single point of contact for procedures and lodging complaints, and that any legal dispute should be dealt with by the courts in the patient's place of residence.

4.7.4 The EESC believes that it would be useful to develop online information services and sites as a way of providing information to patients. However, information sources and systems cannot be limited to this medium, since a large number of people have little or no access to the internet. There would be a risk of promoting a two-speed health system in which only the more advantaged or better-informed social classes could enjoy access to cross-border healthcare.

4.8 *Article 12*

4.8.1 National contact points must have links with the various workers', family and healthcare user organisations, be designed in close cooperation with the health insurance schemes and the providers' self-regulation bodies, and function as the appropriate bodies for transmitting this information. Contact points must also develop information and training activities for medical practitioners, paramedical staff and social workers so that they are aware of the options available for cross-border healthcare, with each Member State being responsible for setting up its own national contact point.

4.9 *Article 14*

4.9.1 The EESC draws attention to this article, which guarantees continuity of care in terms of patients' use of medication, but it would like to see this rigorously applied in view of the potential risks of over-consumption or even trafficking.

4.10 *Article 15*

4.10.1 This article partly assuages the EESC's concern about disparities in the quality of healthcare services provided in the Member States. The introduction of European reference networks must still go hand in hand with development of information and communication technologies that allow all patients to benefit, no matter where they live.

([3]) Third-party insurance.

4.10.2 The following should be added to the objectives of the European networks:

— in Article 15(2)(a): 'appraisal and registration of therapeutic practices';

— In Article 15(2)(d): 'recognition of qualifications and monitoring of codes of ethics'.

4.10.3 In addition, although a procedure is envisaged for joining these networks, the EESC highlights the importance of evaluation, or even introducing a certification procedure.

4.10.4 In the list of specific criteria and conditions that the networks must fulfil, the EESC would like the following to be added:

— in Article 15(3)(a)(ix): 'Such collaboration is particularly essential in terms of involving users in defining a reasonable waiting period for treatment.'

— Article 15(3)(a)(x): 'promoting recognition and application of a common charter of patient rights guaranteeing the effective application of those rights both in the country of origin and in relation to cross-border healthcare'.

4.11 *Article 18*

4.11.1 Aggregating the statistical data collected by the Member States should make it possible to assess application of the Directive. It would also be good if this resulted in indicators being produced that can be used to understand in more detail the strengths and weakness of healthcare systems and to identify the needs and preferences of patients.

4.12 *Article 20*

4.12.1 The arrangements for prior authorisation should be made explicit and forwarded to the Commission as data for analysis.

4.12.2 The report should also be submitted to the EESC.

Brussels, 4 December 2008.

The President of the European Economic and Social Committee
Mario SEPI

The Secretary-General of the European Economic and Social Committee
Martin WESTLAKE