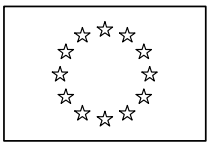

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COMMUNICATION FROM THE COMMISSION

A Community framework on the application of patients' rights in cross-border healthcare

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1. INTRODUCTION

The vast majority of EU patients receive healthcare in their own country and prefer to do so. But in certain circumstances patients may seek for some forms of healthcare to be provided abroad. Examples include highly specialised care, or in frontier areas where the nearest appropriate facility is on the other side of the border. In recent years, citizens have brought a series of cases to the European Court of Justice seeking to assert rights to reimbursement for healthcare provided in other Member States. In its judgements on these cases since 1998, the Court has consistently ruled that patients have the right to have reimbursement for healthcare received abroad that they would have received at home. It is necessary to clarify how the principles established on these specific cases should be applied in general. Community rules about how quality and safety of cross-border healthcare should be ensured more generally are therefore necessary. For this purpose, the Commission is planning to propose in 2008 a Communication and a Council Recommendation on Patient Safety and Quality of Health Services as well as a Council recommendation on health care associated infections.

Based on this case-law, this initiative aims at ensuring a clear and transparent framework for the provision of cross-border healthcare within the EU, for those occasions where the care patients seek is provided in another Member State than in their home country. When this happens, there should be no unjustified obstacles. The care should be safe and of good quality. The procedures for reimbursement of costs should be clear and transparent. While respecting principles of universality, access to quality care, equity and solidarity, the objectives of this framework will therefore be to:

– provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States;

– and ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

Member States are responsible for the organisation and delivery of health services and medical care. They are in particular responsible for determining which rules will apply to the reimbursement of patients and to the provision of health care. This proposal changes nothing in this respect. It is important to underline that this initiative does not alter the Member States' choice of the rules which will be applicable to a specific case. Instead, this framework is designed to facilitate European cooperation on healthcare, such as for European networks of centres of reference; sharing assessments of new health technologies; or using information and communication technology to provide more efficient healthcare ("e-health"). By doing so, this will provide additional support to the Member States in achieving their

overall objectives of universal access to high-quality healthcare on the basis of equity and solidarity, which will benefit all patients, whether they move countries or not.

These issues have been discussed on several occasions between the Commission and the responsible authorities of all Member States, representatives of the European Parliament as well as the health care community and the other stakeholders. Prior to bringing forward these proposals, the Commission also held a public consultation regarding Community action on health services, the results of which have provided a solid basis for developing and shaping this proposed framework[1] Both the Ministers in the Council and the European Parliament have also requested action on health services and their specific character has been confirmed by the exclusion of these services from the general services directive.

This proposal is based on Article 95 of the EC Treaty on the establishment and functioning of the internal market. It is also consistent with the provisions of Article 152 of the EC Treaty on public health and respects the responsibilities of the Member States for the organisation and delivery of health services and medical care as interpreted by the Court of Justice. The provisions of the Reform Treaty will not affect the legal basis.

2. PROPOSED FRAMEWORK

In order to achieve the objectives set out above, the Commission proposes the establishment of a Community framework for cross-border healthcare, as set out in the accompanying proposal for a directive. As well as setting out relevant legal definitions and general provisions, this is structured around three main areas:

– **common principles in all EU health systems**, as agreed in June 2006 by the Council, setting out which Member State shall be responsible for ensuring compliance with the common principles for healthcare and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards throughout the EU. Further cooperation amongst Member States will be promoted, in particular in upcoming Commission proposals for Communication and a Council Recommendation on Patient Safety and Quality of Health Services and for a Council recommendation on health care associated infections;

– **a specific framework for cross-border healthcare**: the directive will make clear the entitlements of patients to have healthcare in another Member State, including the limits that Member States can place on such healthcare abroad, and the level of financial coverage that is provided for cross-border healthcare, based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home;

[1] See Commission communication "Consultation regarding Community action on health services" SEC(2006)1195 of 26 September 2006; and the results of the consultation and the summary report, available at: http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm.

– **European cooperation on healthcare**: the directive establishes a framework for European cooperation in areas such as, European reference networks, health technology assessment, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be put effectively in practice and on a sustained basis.

2.1. A specific legal framework regarding reimbursement of cross-border healthcare

The directive will provide sufficient clarity about the rules to be applied for the reimbursement of healthcare provided in other Member States and how the rights of the patients will be implemented in practice in line with the case law of the Court of justice. The directive reflects the following principles:

– Any non-hospital care to which citizens are entitled in their own Member State, they may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system.

– Any hospital care to which they are entitled in their own Member State they may also seek in any other Member State. The directive allows Member States to provide for a system of prior authorisation for reimbursement of costs for hospital care provided in another Member State, if Member States can provide evidence that the outflow of patients resulting from implementation of this Directive has such an impact that it seriously undermines or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector. The costs of such hospital care provided in another Member State should also be reimbursed by the Member State of affiliation at least up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation.

In any event, the Member States of the patient may impose the same conditions that apply domestically, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care.

This 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. For instance, the conditions upon which plastic surgery is reimbursed in the Member State of origin of a patient will continue to apply when this patient will seek reimbursement for a treatment provided in another Member State The same applies for instance for hydro or balneo-therapy as well as spa cure. In addition, the proposal does not prevent the Member States from extending their benefits in kind schemes to healthcare provided in other Member States a possibility already implemented by several Member States.

The proposed directive will also clarify some relevant terms as well as the criteria for the procedures to be followed for cross-border care to ensure that these are objectively justified, necessary and proportionate. It will also require appropriate mechanisms to be put in place to provide information and assistance to patients through national contact points.

By providing a clear legal framework regarding rights to reimbursement for cross-border healthcare, the proposal will reduce the inequalities inherent in the current uncertainty regarding the general application of the principles established by the case-law. Citizens will be sure about when they will and will not be reimbursed for care received in another Member State, and on what basis, and will have clear processes for any decisions or appeals. Member States may also take further steps to address such inequalities, such as through advancing costs, or making arrangements to reimburse healthcare providers directly rather than requiring patients to advance money.

Alongside the proposed directive, the existing framework for coordination of social security schemes would remain in place with all the general principles on which the regulations on coordination of social security schemes are based, including putting the patient receiving healthcare in another Member State on equal footing with the residents of that Member State, and the existing European Health Insurance Card. In terms of patients seeking planned cross-border healthcare, this regulation ensures that if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds. Whenever the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be granted and the benefits provided in accordance with that Regulation. This is explicitly recognised by the proposed directive. The Regulation (EC) No 1408/71 will therefore continue to provide the general tool and the "safety net" to ensure that any patient who cannot have access to healthcare in their own country within a reasonable time will be authorised to have that healthcare in another Member State.

2.2. Guaranteeing quality and safety for cross-border healthcare

Whenever healthcare is provided, it is vital for patients to ensure:

– clear information that enables people to make informed choices about their healthcare;

– mechanisms for ensuring the quality and safety of the healthcare that is provided;

– continuity of care between different treating professionals and organisations;

– and mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

However, there are no clear rules at Community level about how these requirements should be met for cross-border healthcare, or who is responsible for ensuring that they are. This is the case no matter how the care is paid for – whether it is paid for publicly or privately, whether it is undertaken through the regulation on coordination of social security systems or whether it is in application of the additional free movement rights described above. Without such clarity, there is a risk of confusion leading to difficulties in ensuring quality and safety of healthcare in cross-border cases.

The proposed directive would therefore set out what the common principles in all EU health systems are, taking as a basis the Council conclusions on "Common values

and principles in European Union Health Systems" in June 2006, and the principle that it should be for the authorities of the Member State on whose territory the healthcare is provided to ensure compliance with such common principles. The directive would make clear that responsibilities of the authorities of that Member State would include ensuring that healthcare is provided according to clear standards of quality and safety defined by the Member State in advance, that healthcare providers make available relevant information to enable informed choices by patients, that patients have a means of making complaints and obtaining redress if they suffer harm from the healthcare they receive, and that both access to and privacy of medical records is guaranteed.

Member States remain responsible for setting the standards that apply to healthcare provided in their country. But by making clear which is the Member State that is responsible in any given situation, the directive will ensure that the quality and safety of healthcare is guaranteed throughout the Union.

2.3. Future practical European cooperation on healthcare

There are situations where European cooperation can add value to the actions of the Member States because of the scale or nature of the healthcare concerned. The framework established by the directive will help to realise the potential of this European added-value. It makes provision for developing future practical cooperation at European level in three areas in particular.

2.3.1. European reference networks

European networks of centres of reference ("European reference networks") would bring together on a voluntary basis specialised centres in different Member States. These could help to provide healthcare to patients who have conditions requiring a particular concentration of resources or expertise in order to provide high quality and cost-effective care. This can often be achieved by using such networks to bring relevant expertise to the patient, although in some instances patients will need to go to centres in other countries.

European reference networks could also be focal points for medical training and research, information dissemination and evaluation. Collaboration in this area has great potential to bring benefits to patients through easier access to highly specialised care, and to health systems by enabling the most efficient use of resources, for example by pooling resources to tackle rare conditions.

The Commission is already funding pilot projects to test the concept of European reference networks developed by the High Level Group on health services and medical care[2] The aim of these pilot projects, developed especially in the area of rare diseases, is to identify best practice for establishing European reference networks, to identify outstanding legal or practical obstacles that the networks are facing and to develop general conclusions and recommendations that could be used beyond the area of rare diseases. A clear framework for European reference networks can be established under the proposed directive on the basis of the results of these projects.

[2] See http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm.

In addition, under the cross-border strand of the Territorial Cohesion Objective of Cohesion Policy a wide range of projects that facilitate the access of patients to cross-border health services are financially supported. The Commission will also be actively involved in one of the projects funded under the URBACT II programme. This project has the title 'Building Healthy Communities'.

2.3.2. Health Technology Assessment

Constant innovations in medical science and health technologies bring benefits in better healthcare. However, they also create a continuing challenge for health systems to ensure that they are properly evaluated and used in the most cost-effective manner possible. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology, in order to ensure this. This is a clear area of European added-value, where cooperation at Community level can help to reduce overlap and duplication of efforts and hence promote the effective and efficient use of resources.

The Commission is supporting a pilot European network on health technology assessment called "EUnetHTA". The overall aim of EUnetHTA is to establish an effective and sustainable European network for health technology assessment that informs policy decisions. EUnetHTA connects public HTA agencies, research institutions and health ministries to enable effective exchange of information and support to policy decisions by the Member States. The EUnetHTA project is being co-financed by the European Commission and contributions from network members. As with European reference networks, a clear framework for taking forward these activities can be established under the directive on the basis of the results of this pilot.

2.3.3. E-health

Information and communication technologies have enormous potential to improve the quality, safety and efficiency of healthcare. The European Commission is supporting work in this area in accordance with the E-Health Action Plan[3], and many examples of e-health projects already exist. These cover areas such as remote provision of specialist support from large hospitals to smaller local facilities; remote reading of diagnostic images; monitoring of chronic diseases to enable people with chronic conditions to remain active, rather than requiring hospitalisation; or ensuring coordination between different healthcare providers to provide integrated packages of care to individual patients.

However, safe and efficient provision of e-health services requires shared formats and standards that can be used between different systems and different countries, and these are currently lacking. The directive will therefore allow for such formats and standards to be put in place, enabling informal cooperation and individual projects to be continued and generalised on a more solid and sustainable basis. The proposal does not oblige any introduction of e-Health systems or services but aims at ensuring interoperability once the choice of introducing such systems is done by Member States.

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3 COM(2004)356 of 30 April 2004.

3. THE IMPACT OF THE FRAMEWORK

3.1. How large is cross-border healthcare?

The Commission estimates that around 1% of public healthcare budgets is spent on cross-border healthcare, equating to around €10 billion for the Community as a whole. This share can be higher in some cases:

– in border regions

– for smaller Member States

– for rare diseases

– in areas attracting large amounts of tourists;

though even in these case, cross-border healthcare remains limited to a few percent of overall volumes.

This relatively small scale of cross-border healthcare is unsurprising, as people prefer to have healthcare as close to home as possible. The Commission surveys[4] show that healthcare needs of the vast majority of patients throughout the EU are met through the care provided by their domestic system – over 90% across the EU as a whole. So although this framework is of great importance for the individuals concerned, the overall volume of cross-border healthcare will not have a major impact on health systems as a whole.

3.2. What will the impact of this proposal be for citizens?

Even though the directive is based on rights already established by the Court of Justice interpreting the Treaty, the directive brings added-value in the sense that it will provide clarity about these additional rights conferred to patients when they seek the healthcare, to which they are entitled from providers in other Member States and how they are reimbursed. And whenever cross-border healthcare is provided, patients can have confidence about the quality and the safety of that healthcare. For those who cannot get the healthcare to which they are entitled to within a reasonable time in their own country, the existing social security regulations ensure that they can go to another Member State[5]. This system remains unaffected. This proposal therefore provides an additional option for cross-border healthcare, responding to the cases brought by citizens themselves and having resulted in the jurisprudence of the Court. It is important to underline that the rights stemming from this jurisprudence do not substitute any rights existing under the national frameworks or Regulation (EC) No 1408/71 but they represent additional rights that citizens can choose to exercise. They thus provide better access for all to different healthcare within the EU. It should be noted, as already mentioned, that certain Member States have already chosen, under certain conditions, to extend the benefits in kind schemes to the patients seeking cross-border healthcare. The provisions of the proposal will also help

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4 See the estimates of unmet medical need provided by the European Statistics on Income and Living Conditions (EU-SILC).

5 Using the E112 forms – see http://ec.europa.eu/employment_social/social_security_schemes/healthcare/e112/conditions_en.htm.

creating added-value from broader and more efficient EU-wide cooperation on healthcare. Additional benefits for the patient can be drawn from the proposal. The creation of European reference networks while on a voluntary basis will enhance the expertise in new therapeutic fields and will help making these therapies more easily available to patients irrespective of their home country. The improved co-operation on management of new health technologies will provide additional tools to the Member States in order to evaluate those technologies, and make their choices more efficient and more sustainable. Through better monitoring of data and pooling of statistical tools the proposed directive will also improve the monitoring of the provision of cross-border healthcare, with the direct effect on inducing a better knowledge on epidemiological patterns.

3.3. What will the impact of this proposal be for health professionals?

This proposal is aimed at ensuring a clear framework for safe, high-quality and efficient healthcare throughout the Union. Health professionals will therefore benefit from a clear set of rules about the quality and safety standards applicable when they treat patients from other Member States or when they provide services in other Member States.

However, this directive will not affect the existing provisions of Community law. In particular, it will not affect provisions regarding the recognition of professional qualifications or create additional barriers to such recognition; nor will it affect the rights of health professionals to establish themselves in other Member States. Moreover, it will make clear that regardless of the status of a healthcare professional, the rules applicable to healthcare are those of the country of treatment (meaning the country where the care is provided).

3.4. What will the impact of this proposal be on the Member States and public budgets?

In the long term, the added value of European cooperation on issues such as European networks of centres of reference; sharing assessments of new health technologies; and using information and communication technology to provide more efficient healthcare ("e-health") will help to improve the quality and efficiency of all healthcare, both for those patients who move and those who do not.

In the short term, our impact assessment shows that the additional costs of treatment arising from these proposals are not likely to be such as to undermine the sustainability or planning of health systems overall. This is because citizens are only entitled to be reimbursed for healthcare that they were entitled to at home, so Member States only have to pay for healthcare that they would have had to pay for in any case. The impact assessment estimated that the additional costs of treatment would be a small fraction of one percent of overall health expenditures, and far outweighed by the benefits. And if in the short term an unpredictable surge of cross-border healthcare were to cause a major problem - in planning local facilities, for example - the proposal allows Member States to put in place limits necessary to safeguard their overall system), respecting the caselaw of the Court of Justice. In such a case, a Member State can introduce prior authorisation for patients seeking cross-border hospital care under the conditions set out by the Directive which reflect the case law by the Court.

3.5. What will be the impact on the overall organisation of health systems?

Some stakeholders have raised concerns about the potential of cross-border healthcare to alter the possibilities of Member States to control access to healthcare. Cross-border healthcare can provide a route for quicker access to care. It can also help in ensuring efficient overall organisation of health systems. Healthcare provision requires a critical mass of patients in order to enable and maintain high-quality services and of course to justify investments which can be for certain new therapies heavy and not available in certain Member States. If providing cross-border care can help to generate such a critical mass, it can also help to support more developed healthcare which will also benefit domestic patients.

In any event, providing care to patients from other countries must not undermine the primary purpose of the health systems of the Member States, which is to provide healthcare to their own residents. The proposed directive makes clear that using this framework for cross-border care does not entitle people from abroad to be treated more quickly than domestic patients. Where there are waiting lists for a particular kind of treatment, patients from other Member States should be integrated on the same basis, and should wait as long as a domestic patient with a similar health need. Moreover, healthcare providers are not obliged to accept patients from abroad for planned treatment if this would endanger the maintenance of treatment capacity or medical competence in the receiving Member State. But where the country has capacity to treat patients more quickly than at home without increasing waiting times for others, and the patients concerned are willing to incur the inconvenience of travelling to another country to have that treatment, then this means more efficient care for everyone.

4. CONCLUSION

The shared objectives of health systems throughout the European Union reflect some of the most fundamental values of European citizens. The underlying principles of universality, equity, good quality and solidarity must be respected. The organisation and delivery of health services and medical care is and will remain under the competences of the Member States, competences which must be exercised in the respect of the Treaty. In addition, the European Union can bring significant added-value through enhanced cooperation to the benefit both of those patients who move and those who do not. By doing so, the EU will be also helping to meet some of the most central priorities of its citizens, and will be providing a tangible example of the benefits of European integration into their daily lives. It has to be remembered that all the case-law of the Court of Justice in this matter are based on referrals initiated by single citizens trying to exercise individual rights stemming from the EC Treaty itself.

The main objective of the proposed legal framework is thus to clarify the Court of Justice principles stating that the patients have the right to be reimbursed for healthcare received in another Member State up to the level that they would have been for healthcare received in their own Member State. This right is the direct application of the EC Treaty and the legal framework proposed by the Commission aims at facilitating its practical application.

Much of this Community support is therefore about cooperation and mutual learning. Nevertheless, the key first step is to establish a clear legal framework within which such European cooperation can take place. That is the aim of this initiative.