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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26 September 2006

COMMUNICATION FROM THE COMMISSION

Consultation regarding Community action on health services

1. INTRODUCTION

High-quality health services are a priority issue for European citizens¹. Rights to healthcare are also recognised in the Charter of Fundamental Rights of the EU². The European Court of Justice has made clear that Treaty provisions on free movement apply to health services, regardless of how they are organised or financed at national level. However, many healthcare stakeholders have asked for greater clarity over what Community law means in general terms for health services. The Commission's proposal for a directive on services in the internal market³ at the start of 2004 included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach, however, was not considered appropriate by Parliament and Council, which invited the Commission to develop specific proposals in this area.

The Commission therefore undertook in its 2007 Annual Policy Strategy to develop a Community framework for safe, high quality and efficient health services, by reinforcing cooperation between Member States and providing certainty over the application of Community law to health services and healthcare⁴. This reflects the Commission's commitment as part of the Citizens' Agenda to more effective means of ensuring citizens' rights of access to health care across Europe⁵. It also reflects the aims of the White Paper on services of general interest⁶ to develop a systematic approach in order to identify and recognise the specific characteristics of social and health services of general interest and to clarify the framework in which they operate, complementing the recent Communication on social services of general interest⁷.

Moreover, in its 2005 Report on Patient Mobility and Healthcare Developments in the EU, the Parliament called for the Commission to act on a wide range of issues related to patient mobility and wider cooperation between health systems. At the 'Health' Council of 1 June 2006 ministers adopted a "Statement of common values and principles in EU health systems"⁸ which underlined the importance of "*protecting the values and principles that underpin health systems in the EU*" and called for action:

"..ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and enshrining these values and principles in a legal framework in order to ensure legal certainty".

Community action on health services does not mean harmonising national health or social security systems. The benefits that different health and social security systems provide and their organisation remain the responsibility of the Member States, in accordance with the principle of subsidiarity. Nor does Community action mean stepping back from what already exists. Any Community action must respect the principles already established by the Court in

¹ See Eurobarometer 63 at http://ec.europa.eu/public_opinion/archives/eb/eb63/eb63_en.htm.

² See Article 35 on health care.

³ COM(2004) 2, 13.1.2004.

⁴ COM(2006) 122 of 14 March 2006.

⁵ See COM(2006) 211 of 10 May 2006, in particular page 5.

⁶ COM(2004) 374 of 12 May 2004.

⁷ COM(2006) 177 of 26 April 2006 "Implementing the Community Lisbon programme: Social services of general interest in the European Union"

⁸ Council Conclusions on Common values and principles in EU Health Systems, 2733rd Employment, Social Policy, Health and Consumer Affairs Council meeting, Luxembourg, 1-2 June 2006.

this area, as well as other existing Community provisions and the basic principles underpinning European health systems, including equity, solidarity and universality.

The Commission considers that Community action should be founded on two pillars:

- **legal certainty**, which citizens as well as national and local health actors currently feel the lack of. There is a need to address the wider application of European Court of Justice rulings regarding Treaty provisions on free movement of patients, professionals and health services. This focuses in particular on cross-border care, but cross-border care has consequences for all health services, whether provided across borders or not;
- **and support for Member States** in areas where European action can add value to their national action on health services. This should enable those responsible for health systems (including social security institutions) to have a clear framework of Community law within which to operate and take advantage of cooperation between health systems where helpful in providing safe, high-quality and efficient health services.

The purpose of this Communication is to consult on the issues to address through Community action on health services, and the appropriate tools to be used for different topics. Responses to this consultation, focused around the nine specific questions indicated, are invited by 31 January 2007.

2. THE NEED FOR COMMUNITY ACTION ON HEALTH SERVICES

2.1. The need for legal certainty

Discussions on using internal market rules to access healthcare provided in other Member States only really began in 1998 after judgements of the European Court of Justice. Until then, the Community mechanism enabling patients to receive treatment abroad (other than patients paying for such treatment themselves) was considered to be only the regulations on coordination of social security schemes, specifically Regulations (EC) 1408/71 and 574/729. These entitle persons for whom a medical treatment becomes necessary during a stay in the territory of another Member State to the same benefits as patients insured in the host Member State, using the European Health Insurance Card. They also ensure assumption of costs for planned treatment in other Member States, subject to prior authorisation, and deal with the settlement of financial claims between receiving and sending Member States. This framework remains in place.

However, in 1998 the Court established new principles through its rulings in two cases¹⁰ regarding direct application of the Treaty articles on free movement to the reimbursement of health services provided to patients abroad (otherwise known as ‘patient mobility’ – see section 2.2 below). In its rulings, the Court made clear that when health services are provided for remuneration, they must be regarded as services within the meaning of Treaty and thus relevant provisions on free movement of services apply. The Court also ruled that as a result measures making reimbursement of costs incurred in another Member State subject to prior authorisation are barriers to freedom to provide services, although such barriers may be justified by overriding reasons of general interest.

⁹ OJ L 149, 5.7.1971, p.2, and OJ L 74, 27.3.1972, p. 1, as since amended.

¹⁰ Case C-158/96 Kohll [1998] ECR I-1931 and Case C-120/95 Decker [1998] ECR I-1831.

On the basis of these and subsequent cases¹¹, the Court's rulings have developed the following principles:

- Any non-hospital care to which a person is 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 provided they first have the authorisation of their own system. This authorisation must be given if their system cannot provide them care within a medically acceptable time limit considering their condition. They will be reimbursed up to at least the level of reimbursement provided by their own system.

Two clarifications were provided by the *Watts* judgement on 16 May 2006¹². First, some Member States with systems based on integrated public funding and provision of health services had argued that the Treaty provisions on the freedom to provide services did not apply to them; the *Watts* judgement confirmed that they do. Second, some Member States have argued that the requirement in Article 152, paragraph five of the Treaty to “*fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care*” prevented binding obligations under Community law regarding health systems. In the judgement, the Court stated that this provision does not exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation (EC) 1408/71, to make adjustments to their national systems of social security.

The Court's rulings on these individual cases are clear in themselves, and no pre-condition may be required for the exercise of the rights of patients recognised by the Court. However, it is necessary to improve clarity to ensure a more general and effective application of freedoms to receive and provide health services, to address issues such as:

- whether there are shared values and principles for health services on which citizens can rely throughout the EU and what practical issues need to be clarified for citizens who wish to seek healthcare in other Member States;
- what flexibility Member States have to regulate and plan their own systems without creating unjustified barriers to free movement;
- how to reconcile greater choice in exercising individual entitlements with financial sustainability of health systems overall;
- how to ensure a proper financial compensation mechanism for cross-border healthcare provided by ‘receiving’ health systems;
- how patients or professionals can identify, compare or choose between providers in other countries;

¹¹ For example, Case C-368/98 *Vanbraekel* [2001] ECR I-5363; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473; Case C-56/01 *Inizan* [2003] ECR I-12403; Case C-8/02 *Leichtle* [2004] ECR I-2641; Case C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4503.

¹² Case C-372/04 *Watts*, judgement of 16 May 2006, not yet published.

- and the link between health services and related services such as social services and long-term care.

These issues are the focus of this Communication.

2.2. Different kinds of cross-border healthcare

Patient mobility is only one of the four possible types of cross-border healthcare, all of which are covered by this consultation. These are:

- Cross-border provision of services (delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;
- Use of services abroad (ie: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility'. As stated above, the European Health Insurance Card is intended to cover care that becomes necessary whilst in temporarily another Member State for other reasons;
- Permanent presence of a service provider (ie: establishment of a healthcare provider in another Member State), such as local clinics of larger providers; and,
- Temporary presence of persons (ie: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

2.3. Relevance of Community action to overall health system objectives

European action on health services will necessarily also contribute to the wider challenges facing health systems, beyond the specific case of cross-border healthcare itself. The cost of healthcare systems to public funds has risen significantly faster than inflation in recent years, and is projected to rise by one to two percent of GDP in most Member States between now and 2050 as a direct result of ageing populations¹³. However, these projections of future costs are very sensitive to changes in costs of providing a given package of care. The key to sustainability for healthcare systems is therefore controlling costs and improving efficiency, alongside prevention and health promotion measures to maximise the number of years of life spent in good health (as measured by the Healthy Life Years indicator). Ensuring future sustainability of healthcare and social security systems will therefore require efforts to improve efficiency and effectiveness whilst respecting the shared European objectives of universal access to high-quality healthcare on a financially sustainable basis, founded on the principles of equity, equality and solidarity.

The practical utility of European cooperation has been shown through increasing cross-border cooperation on health services across most of the internal borders of the Union. The nearest hospital for citizens in border regions may be in a neighbouring Member State. For smaller Member States, it may not always be efficient or safe to provide specialised diagnosis or care where there is insufficient volume of patients to maintain the specialist skills of health

¹³ The impact of ageing on public expenditure: projections for the EU25 Member States on pensions, health care, long-term care, education and unemployment transfers (2004-2050), European Economy Special Report 1/2006, produced by DG ECFIN.

professionals or to justify investment in the necessary equipment. The lessons from existing cooperation should be taken into account in future Community action.

Cooperation is not only about patients moving between countries, but also about mobility of health professionals, as well as more complex structures such as networking centres of reference or transferring expertise. Information and communication technologies (eHealth) can support mobility and continuity of care, and even enable cross-border healthcare without either patient or professional leaving their own country. However, cross-border healthcare has often encountered problems due to incompatible rules between the countries concerned and the lack of a transparent legal framework and European structure for cooperation¹⁴. Moreover, although Directive 95/46/EC¹⁵ on the protection of individuals with regard to the processing of personal data and on the free movement of such data includes specific provisions on health data, awareness of these provisions may not be sufficient in the health sector.

The ‘open method of coordination’ for healthcare and long-term care is developing information exchange, peer review and comparison, and the High Level Group on health services and medical care¹⁶ is developing practical cooperation on issues such as health technology assessment. European competition policy also helps to ensure a level playing field for economic actors providing and financing healthcare, and can contribute to the development and improvement of efficient services. EU research framework programmes help to improve efficiency and effectiveness of all European health systems. The action plan for a European e-health area¹⁷ is helping to put in place secure eHealth infrastructure, systems and services, and the structural funds support investment in health infrastructure more generally. Nevertheless, much more remains to be done to realise the potential for European cooperation.

2.4. Nature and impact of cross-border healthcare

Careful analysis of the economic, social and health impacts of cross-border healthcare for citizens as well as for health and social security systems overall will be required. This should include the impact on ‘receiving’ countries (including appropriate compensation for cross-border healthcare) and smaller Member States in particular, as well as the potential benefits and economies of scale from European cooperation.

Patients generally prefer to be treated near their homes wherever possible, and the current volume of patient mobility is relatively low, estimated at around 1% of overall public expenditure on healthcare. But this figure is very approximate, as most health systems in Europe do not provide the necessary data for an accurate picture. It is clear that many more

¹⁴ See “Patient Mobility in the European Union – learning from experience”, edited by Magdalene Rosenmöller, Martin Mckee and Rita Baeten, published by the World Health Organisation 2006 on behalf of the Europe 4 Patients project and the European Observatory on Health Systems and Policies, (ISBN 92 890 2287 6) and supported by the Sixth Community Framework Programme for Research and Technological Development.

¹⁵ OJ L 281 of 23/11/1995.

¹⁶ The High Level Group is made up of senior Member State representatives (with other stakeholders contributing on relevant subjects) and was established to take forward the recommendations of the High Level Reflection Process on patient mobility and healthcare developments in the EU, as set out in COM(2004) 301 of 20 April 2004.

¹⁷ COM(2004) 356 e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area

patients are interested in cross-border healthcare in principle¹⁸. But the lack of information about healthcare possibilities in other Member States and the lack of a transparent framework act as a deterrent to seeking care abroad, even where it is appropriate to do so.

Question 1: what is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

3. AREAS OF POSSIBLE COMMUNITY ACTION

3.1. Legal certainty

Clarity is needed in order to facilitate the general application of Treaty provisions on free movement to health services following the legal developments set out above, for citizens as well as for health systems overall. The following four sections set out possible groups of issues to be addressed and consultation questions for each.

3.1.1. Minimum information and clarification requirements to enable cross-border healthcare

This could include clarifying procedures and conditions to obtain cross-border healthcare, such as clarification regarding the condition referred to by the Court that authorisation for care abroad must be granted if such care cannot be provided domestically without ‘undue delay’ (though this should focus more on processes for consideration than setting any specific period). It could also include mechanisms through which patients could contest decisions regarding cross-border care (perhaps such as requirements to designate and notify fair appeals procedures and timetables).

Moreover, being entitled to healthcare in other countries is not sufficient unless patients or professionals have adequate information to make informed choices about treatments and providers in other Member States. Transferring health-related data between different health systems should also be ensured, building on work already underway related to developing interoperability standards for electronic medical records or developing a European Health Card providing access to key health data for citizens.

Question 2: what specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

3.1.2. Identifying the competent authorities and their responsibilities

A key concern raised about the application of internal market rules is clarity over which Member States’ authority is responsible for supervising health services for each of the different kinds of health service provision described in section 2.2 above. For example, which authority is responsible for ensuring the quality and safety of health services provided to people from other Member States, and whose complaints

¹⁸ See further results of the 'Europe for patients' project www.europe4patients.org.

and compensation system should apply for each different type of cross-border health services.

Specific issues to address include continuity of care when a patient is transferred to another Member State to undergo a specific medical intervention and then returned to their own Member State after that intervention, or when care is provided by health professionals moving temporarily to another country.

Question 3: which issues (eg: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

3.1.3. *Responsibility for harm caused by healthcare and compensation arising from cross-border healthcare*

Although healthcare is clearly intended to benefit patients, sometimes patients suffer harm through errors or omissions in healthcare. An ancillary but important issue is therefore to be clear about who is responsible for ensuring patient safety in cross-border healthcare, how patients will be compensated when they suffer harm, and if there are errors, whose liability rules apply and how those errors will be followed up.

Ensuring this may require effective reporting and learning systems integrated within health systems. When harm is caused, there should be a clear mechanism for appropriate compensation and follow-up to avoid repetition of errors.

Question 4: who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

3.1.4. *Ensuring a balanced healthcare accessible to all*

Although the overall volume of patient mobility is relatively low, the proportion of patient mobility can be higher in some circumstances¹⁹, such as:

- in border regions or popular tourist destinations, where more than half of patients can sometimes be from abroad;
- for care outside hospitals, such as dental care. In some of the recently joined Member States, patients from abroad can be a third of the total in some dental clinics, for example.

Greater clarity is needed over the possibilities given to the Member State of treatment (i.e. the “receiving country”) to ensure that treating patients from other Member States will not prevent the provision of a balanced healthcare service open to all or undermine the overall sustainability of the health system of the Member State (for example, in terms of organisation and delivery of services).

Question 5: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services

¹⁹ See “Patient Mobility in the European Union – learning from experience”, as cited above

accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

3.1.5. *Other issues*

There should also be clarity over ethical issues, and the ability of Member States to take different decisions about what care they consider appropriate to provide, for example (eg: fertility treatment).

Free movement of health professionals is already largely addressed Community legislation²⁰, although there may be further issues to address in the specific context of health services for either the temporary movement of health professionals or the establishment of healthcare providers in other Member States.

Question 6: are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

Question 7: are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

3.2. **Support to Member States**

In the patient mobility reflection process²¹, health ministers and other stakeholders also identified areas where the economies of scale of coordinated action between all Member States can bring added value to national health systems. Some progress has already been made in taking these forward through the High Level Group on health services and medical care²², and the Seventh Community Framework Programme for Research will support collaborative research on health services. However, a more formal framework at the EU level is needed to ensure that these actions will be implemented effectively and on a sustained basis.

3.2.1. *European networks of centres of reference*

Some types of health services require a particular concentration of resources or expertise, for example for rare diseases. Establishing European networking for such centres of reference would help to provide high-quality and cost-effective care, and would thus bring benefits to both patients and healthcare systems as well as helping to promote the highest possible quality of care.

²⁰ See in particular Directive 2005/36/EC on the recognition of professional qualifications, OJ L 255, pp 22-143 of 30.9.2005.

²¹ For more information and the text of the report of the High Level Process of Reflection on patient mobility and healthcare developments in the European Union, see http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/patient_mobility_en.htm.

²² See http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm.

3.2.2. *Realising the potential of health innovation*

A key challenge for health services is the management of innovation, and ensuring that treatment is provided on the basis of the best scientific evidence. Collaborating on providing common criteria with a view to establish such an evidence base at European level will help to spread best practice, avoid duplication of resources and develop common core information packages and techniques that can then be used by Member States, to help them make best use of new technologies, therapies and techniques.

3.2.3. *A shared evidence base for policy-making*

Current mechanisms to ensure efficiency and effectiveness of health services need strengthening. Where we have been able to compare outcomes across Europe (for instance for cancer)²³, this has shown wide variations in techniques and outcomes. Improving the availability and comparability of healthcare data and indicators can provide the basis for improving healthcare for all throughout Europe. Some operational mechanism (such as an observatory) may be needed to carry out monitoring and cooperation at European level.

3.2.4. *Health systems impact assessment*

Impact on health systems is already a specific item within the Commission's integrated impact assessment guidelines. A clear methodology for assessing the impact of Community proposals for health systems is being developed through the High Level Group. Implementing this will help the Commission to ensure appropriate regulation respecting the objectives of healthcare systems.

Question 8: in what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

4. TOOLS AND INSTRUMENTS FOR COMMUNITY ACTION

4.1. Options for instruments

There are a wide range of possible tools for action at Community level on health services. Legal certainty would be best ensured by a binding legal instrument. This could be a regulation or a directive (which could for example be based on Article 95), although the appropriate form should be considered taking into account the results of this consultation. A modernised system of coordination of social security systems is also being put in place replacing Regulations 1408/71 and 574/72²⁴.

A Commission interpretation of case-law (e.g. an interpretative Communication) could provide additional clarification. Indeed, the Commission has already issued a Communication

²³ For example, although survival rates for bladder cancer are improving in general, there are substantial differences among countries, with five-year survival rates ranging from 78% in Austria to 47% in Poland and Estonia (in EURO CARE 3 - survival of cancer patients in Europe; see <http://www.eurocare.it/>). The conclusions of the EU Summit of June 2006 also referred to the need to improve the treatment of rare diseases at EU level.

²⁴ See COM(2006) 16 final of 31 January 2006.

on patient mobility and healthcare developments in the EU²⁵ in 2004, which included broad principles on how Community law applies in this area. However, although this was welcomed, this has clearly not proved a sufficient response to the specific issues that arise.

There are also other non-legislative options, including practical cooperation through the High Level Group on health services and medical care. The open method of coordination is being used to provide a common framework to support Member States in the reform and development of health care and long-term care borne by the social protection system²⁶. These can be valuable in taking forward the practical agenda of cooperation between Member States, although they would not be able to provide legal certainty.

Any or all of these different types of instruments could be combined in an overall package of Community action. However, ensuring legal certainty seems likely to require at least some elements being dealt with through legislative action. Other issues could be addressed through softer mechanisms such as recommendations, communications or guidelines. Support for practical cooperation between health systems (e.g.: enhanced networking or centres of reference) is also likely to need strengthening, to ensure that there are practical structures in place to enable cooperation to work in practice.

Given the constant reform of health services, some mechanism for keeping these instruments and rules up to date would also be needed.

Question 9: what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

5. NEXT STEPS

Responses to this consultation, focused around the nine specific questions identified in the text above, should be sent to the Commission by 31 January 2007, by email to health-services-consultation@ec.europa.eu, or by post to:

European Commission

Health and Consumer Protection Directorate-General

Health services consultation

B232 8/102

B-1049 Brussels

Belgium

All contributions received will be published, unless specifically indicated otherwise. Following this consultation, the Commission intends to bring forward appropriate proposals in 2007.

²⁵ COM(2004) 301 of 20 April 2004 on the follow-up to the High Level Process of Reflection on patient mobility and healthcare developments in the European Union.

²⁶ See COM(2004) 304 of 20 April 2004.