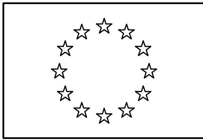

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

HIGH LEVEL PROCESS OF REFLECTION ON PATIENT MOBILITY AND HEALTHCARE DEVELOPMENTS IN THE EUROPEAN UNION

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HIGH LEVEL PROCESS OF REFLECTION ON PATIENT MOBILITY AND HEALTHCARE DEVELOPMENTS IN THE EUROPEAN UNION

INTRODUCTION

The high level process of reflection on patient mobility and healthcare developments in the European Union was convened by the Commission following the conclusions of the Health Council on 26 June 2002. As health systems and health policies across the EU become more interconnected than ever in the past, it is intended to provide a forum for developing a shared European vision in this area whilst respecting national responsibility for health systems. Section 4 of the report goes into more detail on what national responsibility for health systems includes, covering issues such as how the health system is financed; internal allocation of resources, setting of overall priorities for health expenditure and the right to determine the scope of public funded care; prioritisation of individual's access to the system (if being paid for by the national scheme) with regard to clinical need, management strategies within set budgets; and issues of quality, effectiveness and efficiency of health care such as clinical guidelines.

Although according to Article 152 of the Treaty Community action in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care, other developments (such as those relating to the internal market) have an impact on health systems. Important issues have already been identified, notably by the High Level Committee on Health in its report of 17 December 2001 on the internal market and health services[1], and at the meeting of EU health ministers in Malaga on 8 February 2002. In addition, the Commission services produced a synthesis report in July 2003 on the application at national level of the Court jurisprudence on the issue of reimbursement for medical services incurred in another Member State[2]. As set out in the Council conclusions, there is added value in examining certain health issues from a perspective that goes beyond national borders. There is a need to strengthen cooperation in order to promote opportunities for access to health care of high quality while maintaining the financial sustainability of healthcare systems in the European Union. The imminent enlargement of the European Union makes this even more important, since the diversity in health care systems across an enlarged Europe will provide greater impetus for mobility of both health care professionals and patients. This could create particular challenges for acceding countries in safeguarding accessibility, quality and sustainability of healthcare systems.

The EU has a great potential for improving the lives of its citizens. It has brought clear benefits in the field of public health both in tackling the determinants of ill-health and threats to health, and will go further through the public health programme[3]. Regulation 1408/71 on the coordination of social security systems provides for access to healthcare

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[1] See http://europa.eu.int/comm/health/ph_overview/Documents/key06_en.pdf.

[2] SEC (2003) 900 of 28 July 2003.

[3] See http://europa.eu.int/comm/health/ph_programme/programme_en.htm.

for people moving within the EU, and has been updated to reflect changing circumstances. The social protection committee provided for by Article 144 TEC[4] promotes cooperation on social protection policies, including healthcare. The European framework programmes for research and technological development help to improve knowledge about health and healthcare. Article 152 TEC requires a high level of human health protection to be ensured in the definition and implementation of all Community policies and actions. The draft Constitutional Treaty includes an aim for the Union as being to promote the well-being of its peoples, as well as the objectives of promoting social justice and protection.

Enhanced cooperation in the field of health and medical care will be able to better meet our citizens' expectations and provide patients with improved access to care and a wider choice of health providers. It also facilitates citizens' freedom of movement to travel, study, work or live elsewhere. It is in the interests of all citizens that these advances are achieved in a way that upholds the fundamental principles characterising all EU countries' health systems: universality, equity, solidarity and financial sustainability. In order to ensure high quality care and patient safety it is also necessary to have appropriately trained and skilled health professionals distributed throughout the Union and to facilitate their mobility.

To this end, the Council and the representatives of the Member States meeting in the Council recognised that there would be value in the Commission pursuing a high level process of reflection, in close cooperation with the Council and all the Member States, particularly with health ministers and other key stakeholders. Ministers from Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the United Kingdom took part in the process, as well as representatives of the International Mutual Association (AIM), the Standing Committee of the Hospitals of the EU (HOPE), the European Health Management Association (EHMA), the European Patients Forum (EPF), the European Social Insurance Partners (ESIP), the Standing Committee of European Doctors (CPME), and the European Parliament. The high level reflection process met during on 3 February, 7 July with a concluding meeting 8 December, supported by additional meetings of personal representatives of the members of the reflection process throughout. In order to identify and incorporate specific enlargement-related aspects, ministers of health of acceding states were invited to the final meeting, supported by the involvement of their representatives in the concluding phase of the reflection process.

All members of the reflection process have participated on a personal basis, and these conclusions are without prejudice to any positions adopted in other discussions or forums. In particular, the European Commission has acted as facilitator for the high level reflection process, but the views expressed are not necessarily those of the European Commission. All those addressed by the recommendations of the reflection process will have to consider how best to respond; for its part, the Commission plans to issue a Communication in response to the reflection process in March 2004.

[4] Treaty establishing the European Community.

This report is structured around five themes:

- European cooperation to enable better use of resources;
- information requirements for patients, professionals and policy-makers;
- access to and quality of care;
- reconciling national health policy with European obligations
- and health-related issues and the Union's cohesion and structural funds.

1. EUROPEAN COOPERATION

The members of this working group considering European cooperation to enable better use of resources were France, Sweden, Denmark, Austria, ESIP, and HOPE. The conference organised by HOPE with the support of the European Commission on "Free movement and cross-border cooperation in Europe: the role of hospitals" on 18-20 June 2003 in Luxembourg and associated work has also contributed material relevant to this topic. On the basis of the work of this group, the reflection process has identified the following issues and recommendations.

Rights and duties of patients.

Patients have a number of rights, entitlements and expectations when accessing healthcare. Patients' rights are also partially recognised in the Charter of Fundamental Rights; Article 35 says "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices". Greater clarity at European level about these issues would be useful, covering questions such as general information about healthcare, personal information, protection of personal data, compensation, and informed consent. Issues concerning rights and obligations of professionals with regard to patients could also be clarified, and obligations of patients such as providing complete and accurate information.

Recommendation:

– to explore further the possibility of reaching a common understanding on patients' rights, entitlements and duties, both individual and social, at European level, starting by bringing together existing information on these issues and how they are addressed within the Member and acceding States.

Sharing spare capacity and trans-national care

Cooperation between healthcare systems may bring benefits in some situations, such as in border regions or where there are limitations due to capacity constraints. 'Cross-border care' is a general term which covers both cooperation in border regions and more generally care received in another Member State, without any implication of proximity. Cooperation between systems faces potential difficulties linked to different legal frameworks, liability issues, planning constraints of different systems, and reimbursement mechanisms, which should be addressed. Acquiring healthcare in other Member States may have effects both in the country of provision and in the country of the beneficiary.

Recommendations:

– to invite the Commission to facilitate information sharing at European level on possible available healthcare, existing supply of care, entitlements and procedures, costs, prices, adverse incidents, patient records, nomenclature of conditions, treatments and products, and continuity and quality of care across the Union, as part of the overall framework for information discussed in the section on information below. Action could include support to networking and developing databases.

– to evaluate existing cross-border health projects, in particular Euregio projects, and to develop networking between projects in order to share best practice.

– to invite the Commission to explore whether it is possible to draw up a clear and transparent framework for healthcare purchasing which competent bodies in Member States could use when entering into agreements with each other, and to make any appropriate proposals.

– to encourage ongoing work by the Commission, Council and Parliament to ensure clear, simple and transparent recognition procedures incorporating a high degree of automatic recognition as with the current sectoral rules in order to facilitate and develop mobility of health professionals.

European centres of reference

European centres of reference could provide healthcare services for conditions requiring a particular concentration of resources or expertise in order to provide high quality and cost-effective care, especially for rare diseases. Centres of reference could also contribute to medical training and research, information dissemination and evaluation. Any system of European centres of reference should be flexible, objective and transparent, with clear criteria, scientific and professional involvement, should ensure that centres are distributed across the enlarged European Union, and should leave choices open about the use of any centre of reference to the authorities responsible for the care concerned.

Recommendation:

– to invite the Commission, in collaboration with the Member and acceding States, to carry out a mapping exercise relating to centres of reference taking into account the principles set out above, and to explore how to foster networking and cooperation on these issues, including the organisation, designation and development of centres.

Health technology assessment

Health technology assessment (HTA) can assist policy-makers to make informed decisions by providing evidence on medical, social, economic and ethical issues concerning healthcare policy and practice. The present fragmentation of health technology assessment across the Union leads to the duplication of effort, while many high priority technologies are not assessed at all. Exchanges of information could be enhanced through more systematic European collaboration.

Recommendation:

– to invite the Commission to consider how a sustainable network and co-ordination function for health technology assessment could be organised and funded, and to make any appropriate proposals.

2. INFORMATION

The members of the working group considering issues relating to information for patients, professionals and providers were Finland, Spain, Ireland, CPME and EPF. On the basis of the work of this group, the reflection process has identified the following issues and recommendations.

EU framework for information

Increased mobility of people means that professionals and citizens need to have access to information on health-related decisions and on health services, both with regard to their own systems and others. Policy-makers and service providers also need information to be able to guarantee sustainable development of health services. A strategic framework is required that brings coherence, complementarity and transparency to information initiatives at EU level and which is responsive to the spectrum of issues and concerns of all stakeholders. The framework should address general issues such as health policies, health systems, health surveillance, quality assurance, access to information and data protection. It will also need to tackle specific points such as appropriate technological solutions and standards, records management, liability rules, guidelines for best practice licensing and recruitment of health professionals (including ethical issues) and notification of professional malpractice procedures.

Enlargement of the Community will create further challenges to collecting data both for citizens and decision-makers at EU level. Data standards will need to ensure that data is comparable, and appropriate technology can ensure that it is available where it is needed. The main basis for the creation of a strategy concerning information governance at EU level is the public health programme 2003-2008, which has the improvement of information as one of its principal objectives. An information strategy will also need to take account of other relevant work at international level, including by the World Health Organisation (WHO) and the Organisation for Economic Cooperation and Development (OECD). Many aspects relating to information have also been the subject of discussion and specific recommendations in the other three themes on European cooperation, access and quality, and reconciling national policies with European obligations, and their information aspects should be taken into account in the overall approach outlined below.

Recommendations:

– to invite the Commission to develop a framework for health information at EU level building on the results of the public health programme, including identifying different information needs from the perspective of policy-makers, patients and professionals; how that information can be provided and the responsibilities of the different actors concerned, and taking account of relevant work by the WHO and the OECD.

– to invite the Commission to address issues concerning data protection and sharing of confidential data between Member States and at EU level.

- to invite the Commission to consider establishing European principles concerning the competence and the responsibilities of all those involved in e-health service provision.

3. ACCESS AND QUALITY

The members of the working group considering access to and quality of care were Germany, Italy, Greece, the UK, Portugal, EHMA and AIM. Contributions to the group included a literature review on cross-border care commissioned from EHMA and material from the conference on "Access and Quality in Health Care in the EU – improving patient experience and outcomes", 4-6 May 2003, at the University of Patras (under the Greek Presidency with the support of the European Commission).

There is a wide diversity of health systems across Europe. Access and quality also both have different aspects. Access includes physical accessibility, financial accessibility and access to information, and covers the following areas in particular:

- the share of the population covered under the publicly funded scheme;
- the range of services available under the publicly funded scheme;
- access to voluntary health insurance;
- the time it takes to get a service;
- the availability of good quality services;
- availability of innovative treatments;
- the price of health care services and level of cost-sharing;
- the choices people have (such as referral arrangements or contracted providers);
- socio-economic variations; and,
- information about services/professionals, including their mobility.

Quality includes conditions for market entry, procedural conditions and evaluation of individual professional practice, and covers the following areas in particular:

- national standards based on evidence of effectiveness of care;
- organisational mechanisms to ensure safe, high-quality care;
- monitoring and evaluation mechanisms;
- patient safety;
- and patient experience.

A wide range of European and other international activities have an impact on access and quality. For example, in matters related to social protection policies, including healthcare, the advisory Social Protection Committee promotes cooperation between Member States and with the Commission. However, there is still a need to improve mechanisms for taking a coherent look from a health perspective at how all these activities help to further access and quality in healthcare.

On the basis of the work of this group, the reflection process has identified the following issues and recommendations.

Improving knowledge on access and quality issues

More information is needed about the volume, nature, mechanisms, motivations and results of cross-border healthcare. This should tackle specific questions, including numbers of people, difficulties encountered with cross-border healthcare, outcomes and satisfaction, existing mechanisms (at national level, direct agreements between countries or Community-level mechanisms), and the impact on provision of care to citizens remaining within the system of their own country, building on existing data to make progress as quickly as possible. Collecting information on specific challenges facing acceding states is also important.

Recommendations:

– to invite the Commission to explore how to set up a framework for systematic data collection across the enlarged Union on the volume and nature of patient movement, both within and outside the systems established by Regulation 1408/71 and including data on tourism-related flows and long-term stay.

– to invite the Commission to carry out a study to establish the motivation for patients to move across borders, the specialities affected, the nature of bilateral agreements, the information requirements of patients and clinicians and the patient experience, with particular regard to enlargement.

– to invite Member and acceding States to provide their views on how the different access routes for healthcare in other Member States operate in their country and their impact, and to invite the Commission and the Member States to consider any appropriate options for responding.

– to invite Member and acceding States and the Commission to develop and reinforce the system of gathering accurate data about the mobility of health professionals and to encourage Member and acceding States to collect and share comparable workforce data regarding health professionals, in collaboration with the Commission and relevant international organisations.

Analysing the impact of European activities on access and quality

Potential European collaboration should be assessed in terms of its impact both on cross-border healthcare and on domestic healthcare. There are a wide range of European activities with an impact on access and quality, including coordination of social security systems (such as the Regulation 1408/71 scheme), support for cross-border projects, the Social Protection Committee's work on healthcare and long-term care for the elderly, the public health programme, the framework research programmes, rules on professional qualifications, e-Europe, regional policy and structural funds, and the European health insurance card, as well as other international work (in particular by the WHO and the OECD).

Recommendation:

– to invite the Commission to prepare an analysis of Community activities to see how these can better contribute to access and quality in healthcare, taking account of relevant activities in other international organisations.

4. RECONCILING NATIONAL OBJECTIVES WITH EUROPEAN OBLIGATIONS

The members of the working group on reconciling national objectives with European obligations were Belgium, the Netherlands, Finland, the UK, France, EPF, HOPE, EHMA, and ESIP. This group elaborated a questionnaire on "National health care systems in an integrated Europe" with questions relating to the basic aims of national health care systems; the specific impact of internal market rules on the management and steering capacity of health care systems; issues related to cross border care; and mechanisms for improving legal certainty. Responses have been provided by representatives from Belgium, the Netherlands, Finland, the UK, France, HOPE, ESIP, Sweden, CPME, AIM, Germany and Ireland. On the basis of the work of this group, the reflection process has identified the following issues and recommendations.

The organisation and financing of healthcare and social protection systems is the responsibility of Member States. However, Member States must exercise their responsibilities in this area in accordance with Community law. From an economic point of view, there are substantial differences between services within the health care sector and services within a commercial market, for example because of the key role played by health professionals in determining the services required by the patient. Moreover, in most cases, patients do not pay directly for medical services which are paid for by social security systems or health insurance. A market for healthcare delivery is inevitably imperfect and increasingly complex, with major information asymmetries.

Governments across the Union have played an active role in the organisation of healthcare in order to put in place systems based on the principles of universality, solidarity and equity. In a series of judgements[5] on whether health systems were required to pay the costs of treatment provided in another Member State, the Court of Justice recognised the right of patients to reimbursement for healthcare provided in other Member States under certain circumstances. At the same time, the Court of Justice recognised the need for Member States to be able to plan health services to ensure access to a balanced range of high-quality hospital treatment, to avoid the risk of seriously undermining the financial balance of the social security system, and to control costs in order to prevent as far as possible any wastage of financial, technical and human resources. Member States should continue to exercise their responsibility for setting policies in a range of areas in order to organise and finance their health and social security systems, while respecting Community law. These responsibilities include:

- how the health and social security system is financed (e.g. tax, social insurance etc) and overall organisation of the system including how prices are fixed;

- internal allocations of resources (including human resources), through central or devolved mechanisms;

- setting overall priorities for health expenditure, and the right of determining the scope of publicly funded care;

- prioritisation of individuals' access to the system (if being paid for by the national scheme) with regard to clinical need;

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[5] In particular, Kohll and Decker (1998), Smits-Peerbooms and Vanbraekel (2001) and Müller-Fauré/van Riet (2002).

- management strategies within set budgets, for instance the use of evidence-based medicine - with allowance for national diversity in health policies and treatment patterns;
- and issues of quality, effectiveness and efficiency of health care such as clinical guidelines.

In all these areas exchanges of best practice would be valuable for all Member States. An appropriate place could also be given to private non-profit organisations providing services that strike a balance between those public organisations and private-sector profit-making organisations.

Forms of additional health protection play an important role in several Member States in ensuring access to healthcare. The European legal framework for insurance is based on an approach of Community-wide competition between insurers whose solvency is guaranteed by the competent authorities of the home Member State. However, there are uncertainties regarding Member States' possibilities to promote non-life (health) insurance based on solidarity principles.

It is not clearly defined in the Treaty how the national competence in regulating the healthcare services interacts with internal market rules. However, the Court of Justice has issued several rulings on the application of internal market rules to the issue of reimbursement of health services provided in another Member State, taking account of the characteristics of the health sector. Further action may be needed to preserve public health and social considerations in the health sector.

Different options for improving legal certainty regarding the application of European rules to health care systems include:

- Changing the Treaty;
- Secondary legislation;
- European co-operation, including communications from the Commission;
- Improving the decision-making process, including assessing the impact of proposals on health;
- Initiatives by Member States and bilateral cooperation.

As the inter-governmental conference process has not formally been completed at the time of this report, it has not been possible to make a full assessment of these options. Health Ministers, with the Commission, will wish to look at them more fully in the light of the final text of the new Treaty. Options for secondary legislation could include further updating provisions on the coordination of social security systems, general provisions on the free movement of patients or specific clarifications on the application of Community law to health services.

A permanent mechanism at EU level could support European cooperation in the field of health care and monitor the impact of the EU on health care systems. This could comprise health representatives at high level from Member States and the Commission and involve relevant stakeholders to provide oversight of access and quality issues affecting patient and professional mobility, to facilitate policy dialogue and enhanced

cooperation in the area of health care and to provide a means for collaborating on issues such as best practice, whilst taking account of existing structures and the work of other organisations active in this area (including the WHO and the OECD).

Recommendations:

- to invite the Commission to provide a review of evidence relevant to the issues raised by the interaction of Community rules and national health policy objectives.
- to invite the Commission in consultation with the Member States to explore how legal certainty could be improved following the Court of Justice jurisprudence concerning the right of patients to benefit from medical treatment in another Member State and to bring forward any appropriate proposals.
- to invite the Commission to consider the development of a permanent mechanism at EU level to support European cooperation in the field of health care and to monitor the impact of the EU on health systems, and to bring forward any appropriate proposals.

5. HEALTH-RELATED ISSUES AND THE UNION'S COHESION AND STRUCTURAL FUNDS

Increased patient mobility raises a number of issues and concerns in acceding states in respect of health infrastructure development and health status improvement as well as skills development in certain cases. Current application and funding conditions do not place health high on the list of priority areas to be supported from the cohesion and structural funds. It is essential to put health high on the agenda with regard to the application and financing criteria under these Community financial instruments. Increased possibilities to successfully apply for financing from Community financial instruments for investment in health (improving the health status of the population, decreasing the disease burden), for health infrastructure development (including, as part of general infrastructure development programmes, support to up-grading infrastructure in potential centres of reference with existing high-level skills and capacities; or to implement the information technology development necessary for verifying entitlement to health services when applying social security co-ordination) could contribute to promoting opportunities for access to high quality care while helping to maintain financial sustainability of healthcare systems in new Member States.

Recommendation:

- to invite the Commission, Member and acceding States to consider how to facilitate the inclusion of investment in health, health infrastructure development and skills development as priority areas for funding under existing Community financial instruments, in particular in objective one areas.

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ANNEX 2 – REFERENCE DOCUMENTS

These documents are available from the European Commission website – see http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/patient_mobility_en.htm.

Synthesis document from working group one on European cooperation to enable better use of resources.

Synthesis document from working group two on information for patients, professionals and providers.

Synthesis document from working group three on access to and quality of care.

Synthesis document from working group four on reconciling national objectives with European obligations.

Report by the High Level Committee on Health of 17 December 2001 on the internal market and health services.

Contribution by DG Employment and Social Affairs "Council Regulation (EC) No 1408/71 — a sound basis for mobility for both patients and social security institutions"

Synthesis report from the Commission services on the application at national level of the Court jurisprudence on the issue of reimbursement for medical services incurred in another Member State (SEC (2003) 900 of 28 July 2003).

HOPE report on hospital cooperation in border regions in Europe, June 2003.

EHMA literature search on quality issues on cross-border care, April 2003.

European Health Forum recommendations on health and enlargement, and on mobility of health professionals.

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