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COMMUNICATION FROM THE COMMISSION

**Follow-up to the high level reflection process on patient mobility and healthcare
developments in the European Union**

EXECUTIVE SUMMARY

Patients wish to benefit from high quality healthcare as close to home and as quickly as possible. Sometimes, however, this can be best achieved through healthcare provided in another Member State. The European Union provides freedoms for citizens to seek healthcare in other Member States, as confirmed by the European Court of Justice. Regarding reimbursement of health care costs when patients have sought medical treatment in another Member State, the Court of Justice has clarified the conditions under which they may be reimbursed¹. Accessing healthcare depends on having the right information regarding the quality, availability and appropriateness of different services, and to have clarity over the procedures to be followed. And when patients do seek healthcare in other Member States, it is essential to ensure that the well-being and safety of the patient is properly protected.

Patient mobility also has consequences for health services and medical care both in the country where the patient is insured and the country where care is provided. Beyond the consequences of patient mobility, health systems across Europe also already face common challenges as they adapt to constant developments in medical science, the ageing of the European population, and rising public expectations. Although these health systems are primarily the responsibility of the Member States, cooperation at European level has great potential to bring benefits both to individual patients and to health systems overall. A European strategy is therefore needed to ensure that citizens can exercise their rights to seek care in other Member States if they wish, and that European cooperation can help systems to work together to better meet the challenges they face.

For citizens, the first step must be to provide them with a clearer overview of the existing EU legal framework regarding access to healthcare and the reimbursement of the costs incurred in another Member State. Access to care for individuals of course is part of the responsibility of Member States for their health care and health insurance systems. Rights under Community law principally concern reimbursement for healthcare provided in another Member State. Based on the above-mentioned, well-established and constant jurisprudence of the Court of Justice, the Proposal for a Directive on Services in the Internal Market clarifies the authorisation regime for reimbursement of medical costs incurred in another Member State. This Proposal, together with the proposal for modernising and simplifying Regulation (EEC) N° 1408/71 on the application of social security schemes to employed persons and their families moving within the Community provides greater legal certainty as regards the conditions for the reimbursement of healthcare costs incurred in another Member State than the Member State of insurance of the patient. In the light of the above mentioned Court judgements,

- Any non-hospital care to which you are entitled in your own Member State you may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by your own system.
- Any hospital care to which you are entitled in your own Member State you may also seek in any other Member State provided you first have the authorisation of your own system. This authorisation must be given if your system cannot provide your care within a

¹ See in particular the Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363, Inizan judgement, Case C-56/01 of 23.10.03, not yet published; Leichtle judgement, Case 8/02 of 18.3.04, not yet published.

medically acceptable time limit considering your condition. Again, you will be reimbursed up to at least the level of reimbursement provided by your own system.

- If you wish to seek treatment abroad, your health authorities can provide you with information on how you can seek authorisation for care in another Member State, the reimbursement levels that will apply and how you can appeal against decisions if you wish to.

Furthermore, according to Regulation 1408/71, if you are staying temporarily in another Member State than your own - for travel, study, posting, or seeking employment - and if you happen to need healthcare, it will be delivered on the same basis as to people insured in that country. If you have to pay for this care, then you will be reimbursed in your home country, on the basis of the tariffs and fees in force in the Member State where the care was delivered. After June 1st, 2004, you can show this entitlement using the European health insurance card, which will replace the current paper forms, in particular form E111.

The Communication also sets out a range of ways in which European collaboration can bring concrete benefits to the effectiveness and efficiency of health services across Europe. This includes European collaboration to make better use of resources, covering issues such as developing a better understanding of the rights and duties of patients, sharing spare capacity between systems and cross-border care, mobility of health professionals, identifying and networking European centres of reference, and coordinating assessment of new health technologies. It also covers improving information and knowledge about health systems to provide a better basis for identifying best practice and ensuring universal access to high-quality services, and using the High Level Group on Health Services and Medical Care to help those responsible for health systems to work together at European level.

The new Member States face greater health problems than the rest of the Union but have less economic means to address them. Their health systems are therefore under particular pressure as they strive not just to improve the quality of life of their citizens, but by doing so also to contribute to the overall economic growth and sustainable development of those countries. Collaboration at European level can bring particular benefits to those systems, combined with setting a high priority for investment in health and health infrastructure in the new Member States.

The proposals set out in this communication are the Commission's response to the recommendations of the high level process of reflection on patient mobility and healthcare developments, which was established following the conclusions of the Health Council of June 2002. This forms part of a wider strategy. A separate communication on extending the 'open method of coordination' to healthcare and long-term care sets out proposals for European coordination to support national strategies to reform and develop health and long-term care. A further communication sets out an "e-Health action plan" within the framework of a European e-Health Area for using information and communication technologies to help improve access, quality and effectiveness for health services across the Union.

Achieving these ambitions will be a long-term and complex project, and may require further proposals in the future. It is nevertheless an essential endeavour. Over time, this strategy will repay dividends in better health and quality of life. It will contribute to better use of the resources invested in health systems across Europe. It will promote greater economic growth and more sustainable development for the Union as a whole. And, most tangibly for citizens, it will bring concrete benefits of European integration closer to people in their daily lives.

1. INTRODUCTION

Community law provides citizens with rights to seek healthcare in other Member States and be reimbursed. The European Court of Justice has clarified the conditions under which patients may be reimbursed for healthcare provided in another Member State than the Member State of affiliation of the patient². Community law also provides citizens to have entitlements to health care that they have acquired in one Member State to be recognised when they move to another. However, in practice it is often not straightforward for citizens to exercise these rights. Moreover, when they do, this has consequences for health services and medical care both of the country where they are insured and the country where care is provided. Beyond the consequences of patient mobility, health systems across Europe also already face common challenges as they adapt to constant developments in medical science, the ageing of the European population, and rising public expectations. Although these health services and medical care are primarily the responsibility of the Member States, cooperation at European level has great potential to bring benefits both to individual patients and to health systems overall.

A consensus has therefore developed that a framework at European level to facilitate cooperation and to shape developments is needed, but is lacking. This was reflected in the conclusions on patient mobility and healthcare developments in the European Union adopted at the Health Council of June 2002, which recognised that there would be value in the Commission pursuing in close cooperation with the Council and all the Member States – particularly health ministers and other key stakeholders – a high level process of reflection. The Commission therefore brought together health ministers from across the Union together with representatives of patients, professionals, providers and purchasers of healthcare and the European Parliament in a high level reflection process which agreed a wide-ranging report including nineteen specific recommendations³.

As the report emphasised, the organisation of health systems is the responsibility of the Member States. The report of the reflection process 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. However, whilst respecting the responsibilities of Member States in this area, there is nevertheless great potential for cooperation at European level to bring benefits to patients, to health professionals, and to those responsible for health systems overall.

The Commission therefore is responding to these challenges through an overall strategy set out in two complementary communications. This communication responds to the report of the reflection process on patient mobility and healthcare developments in the European Union

² See in particular the Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363, Inizan judgement, Case C-56/01 of 23.10.03, not yet published; Leichtle judgement, Case 8/02 of 18.3.04, not yet published.

³ For more information and the text of the report, see http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/patient_mobility_en.htm.

and the recommendations it made. A separate communication⁴ proposes extending the ‘open method of coordination’ to health care and long-term care, to support the efforts of Member States in developing high-quality, accessible and sustainable health and long-term care services. A further communication sets out an “e-Health action plan” within the framework of a European e-Health Area for using information and communication technologies to help improve access, quality and effectiveness for health services across the Union. In addition, in the light of the Court of Justice jurisprudence mentioned above, the Proposal for a Directive on Services in the Internal Market⁵ together with the proposals for modernising and simplifying Regulation (EEC) N° 1408/71⁶ on the application of social security schemes to employed persons and their families moving within the Community provides the legal framework for reimbursement of healthcare costs incurred in another Member State than the Member State of insurance of the patient. Together, these initiatives will enable patients to exercise their rights under Community law to healthcare in other Member States and to facilitate European cooperation on health systems whilst respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care. They will also supplement the implementation of sectoral initiatives such as the High Level Group on Innovation and Provision of Medicines⁷.

The structure of this communication broadly follows the structure of the patient mobility report:

- European cooperation to enable better use of resources
- information requirements for patients, professionals and policy-makers
- the European contribution to health objectives;
- and responding to enlargement through investment in health and health infrastructure.

A table summarising the Commission’s responses to the recommendations of the reflection process is also included at annex one.

2. EUROPEAN COOPERATION TO ENABLE BETTER USE OF RESOURCES

There are many existing examples of European cooperation that brings concrete benefits to patients, providers and those responsible for healthcare. Cross-border care can refer to patient mobility within border regions, for example in the Maas-Rhine Euregio between Belgium, the Netherlands and Germany. It can also refer to healthcare received in another Member State without any implication of proximity, such as the arrangements for referral between Malta and the UK for specialist diagnosis and treatment.

It is also clear from existing variations in techniques, resources and outcomes that there is enormous scope to improve the results obtained from existing resources by bringing

⁴ Commission Communication “Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of coordination”.

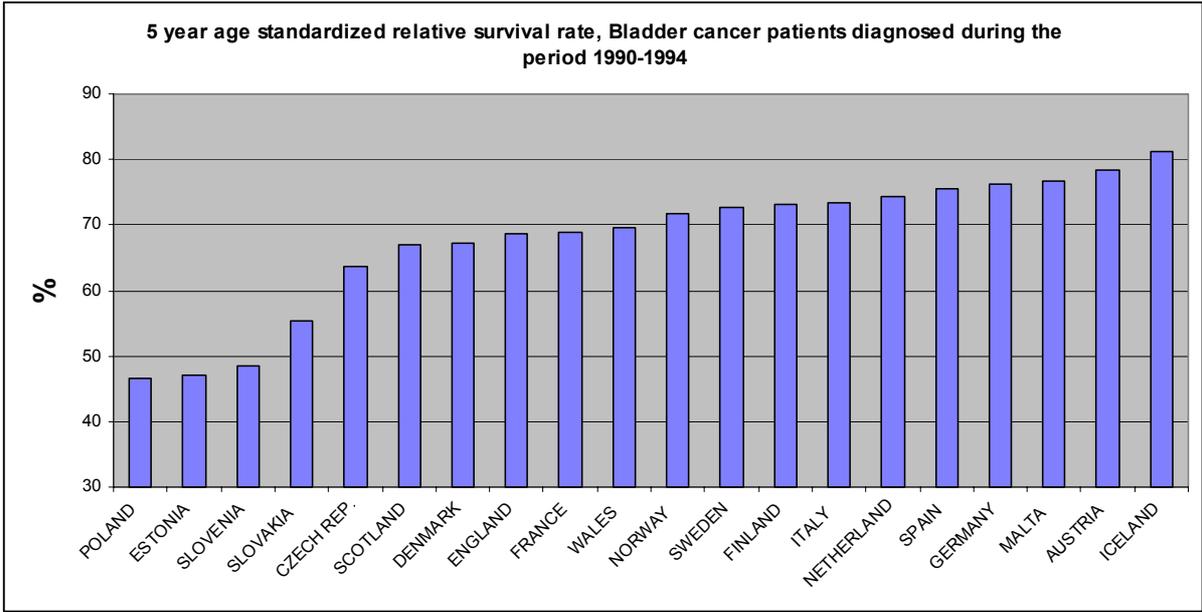
⁵ COM(2004) 2 final of 13.01.04

⁶ For further information, see http://europa.eu.int/comm/employment_social/soc-prot/schemes/index_en.htm.

⁷ Further details available at <http://pharmacos.eudra.org>.

healthcare across the Union towards the standard of the best. Take the example of bladder cancer; although survival rates are improving in general, there are substantial differences in survival among countries in Europe, with five-year survival rates ranging from highs of 78% in Austria to 47% in Poland and Estonia⁸ (see table).

Many of these specific areas also relate to the overall objectives of accessibility, quality and financial sustainability set out in the communication on extending the open method of coordination to healthcare and long-term care. As cooperation develops, the open method of coordination could provide a mechanism for structuring cooperation between Member States in particular areas, with specific objectives and regular reviews of progress toward them.



2.1. Rights and duties of patients

It is especially important when citizens need healthcare for them to be sure about what they can expect of health systems and providers of care, and what is expected of them. Statements or charters making these rights and duties clear already exist in many Member States. A step towards establishing clarity at European level was taken in the European Charter of Fundamental Rights, which states that “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.

The reflection process recommended exploring 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. The High Level Group on Health Services and Medical Care could take this forward, starting by identifying common elements across the EU. These might include providing timely and appropriate healthcare, providing patients with sufficient information for them to make informed choices about the different treatment options, respecting confidentiality of health data, respecting human dignity in health research, and compensation for harm from negligence in healthcare, and should also take into consideration the rights and duties of health professionals. There may be some areas of

⁸ EURO CARE 3 - survival of cancer patients in Europe; see <http://www.eurocare.it/>.

difference, but in time these discussions could aim to provide a consistent framework for patients' rights across Europe. This is an issue which could also be addressed through the open method of coordination, as set out in that communication.

For citizens, the first step must be a clearer statement of their existing rights to healthcare under Community law. Access to care for individuals is part of the responsibility of Member States for their health care and health insurance systems. Rights under Community law principally concern reimbursement for healthcare provided in another Member State, and are set out in the proposed directive on services in the internal market and the Regulation 1408/71 on coordination of statutory social security schemes⁹, both reflecting the case-law of the Court of Justice. This framework reflects the following general principles:

- Any non-hospital care to which you are entitled in your own Member State you may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by your own system.
- Any hospital care to which you are entitled in your own Member State you may also seek in any other Member State provided you first have the authorisation of your own system. This authorisation must be given if your system cannot provide your care within a medically acceptable time limit, considering your condition. Again, you will be reimbursed up to at least the level of reimbursement provided by your own system.
- If you wish to seek treatment abroad, your health authorities can provide you with information on how you can seek authorisation for care in another Member State, the reimbursement levels that will apply and how you can appeal against decisions if you wish to.

Furthermore, according to Regulation 1408/71, if you are staying temporarily in another Member State than your own – for travel, study, posting, or job search -, and if you happen to need healthcare, it will be delivered on the same basis as to people insured in that country. If you have to pay for this care, then you will be reimbursed in your home country, on the basis of the tariffs and fees in force in the Member State where the care was delivered. After June 1st, 2004, you can show this entitlement using the European health insurance card, which will replace the current paper forms, in particular form E111¹⁰.

The reflection process also invited 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.

The Commission has already taken, or will take action on several aspects to improve certainty over the impact of the rights of citizens under European law to seek healthcare in other Member States and be reimbursed. These include:

- providing better and clearer information about those rights and what they mean in practice, as described above;

⁹ Health care provided during a temporary stay has been addressed in a recent amendment providing alignment of rights

¹⁰ For more information on the deployment of the EHIC, see MEMO/04/75, accessible through the RAPID database at <http://europa.eu.int/rapid/start/cgi/guesten.ksh>.

- providing better legal certainty as regards the authorisation regime for reimbursement of health care costs incurred in another Member State, in the light of the jurisprudence of the Court through the Commission proposal for a Directive on services in the internal market (COM(2004)2);
- improving the decision-making process through extending the application of health impact assessment to assess the impact on health services, as described under the section on better understanding the European contribution to healthcare objectives;
- simplifying the existing rules on the coordination of social security systems through the modernisation and simplification of Regulation 1408/71;
- facilitating mobility of citizens through simplification of procedures and the deployment of the European health insurance card as from 1 June 2004;
- improving information about patient mobility and healthcare developments, as set out in the section on information;
- and facilitating cooperation at European level by establishing High Level Group on Health Services and Medical Care, as described under the section on the European contribution to health objectives.

The Commission also invites Member States to act to raise awareness of these initiatives and to improve legal certainty concerning the right of patients within their system to benefit from medical treatment in another Member State. It is up to each Member State to determine the rules governing rights or duties of healthcare cover under their social security system. It is also up to each Member State to determine the conditions on which benefits provided by their sickness insurance scheme are granted. EC rules on free movement require only that these conditions be neither discriminatory nor an obstacle to freedom of movement of persons, of services and of establishment. Member States could therefore review their systems to see if they wish to clarify the benefits they provide and the conditions for access to them. For example, Member States could improve legal certainty within their own systems by making any conditions for access to healthcare explicit and transparent. The Commission is ready to support such efforts, for example by exchanging information through the High Level Group on Health Services and Medical Care and possibly by developing guidance at European level.

The initiatives described above will go a long way to address the concerns over legal certainty raised by the reflection process. The responsibility of Member States for health services and medical care is also clearly recognised in the EC Treaty, as well as in how they are interpreted and implemented by the European institutions. Other options remain available for the future, including further legal clarification at European level, but these should be considered in the light of the measures already described in this Communication and further developments in this sector

The Commission will develop materials to provide more information based on these principles and detailed provisions for citizens across the Union, together with relevant contact points for different systems in the Member States. Existing citizens' information offices such as the European Consumer Centres and Euro Info Centres could also help to raise awareness of these rights, and we will work to ensure that citizens can receive concrete advice on resolving any difficulties they encounter when exercising their rights in practice.

2.2. Sharing spare capacity and trans-national care

As the report of the reflection process sets out, cooperation between healthcare systems can bring benefits for patients and for better functioning of systems overall, for example in border regions or where there are capacity constraints. Many such projects already exist, and have developed a wide range of solutions to the practical difficulties of cross-border cooperation. However, because these projects have largely grown up out of local initiatives, there is limited pooling of knowledge at European level on the lessons learnt.

The reflection process recommended evaluating existing cross-border health projects, in particular Euregio projects, and developing networking between projects in order to share best practice. The Commission plans to support a project under the public health programme¹¹ to evaluate Euregio health projects and to assess the most successful regions in terms of cooperation on health care. This study plans to collect information through interviews with the best existing cross-border health projects and will disseminate results through workshops, a conference and a website. The Commission will also look at how to support networking between these projects and will make any appropriate proposals.

The reflection process also invited 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. The first step should be to gather information on any existing arrangements for healthcare purchasing, including any formal agreements between purchasers and providers in different EU countries that provide mechanisms to enable patients to have healthcare in other Member States. We will invite Member States to provide information on such arrangements through the High Level Group on Health Services and Medical Care, and will consider with the Member States how best to proceed once the information is available, perhaps including a common objective on this topic as part of the open method of coordination on healthcare and long-term care.

2.3. Health professionals

Mobility in the field of health is not only about patients; health professionals also move between countries. This is facilitated by European rules on the recognition of professional qualifications. These rules are currently being simplified on the basis of the proposal for a Directive on the recognition of professional qualifications (COM(2002) 119), which aims to ensure clear, simple and transparent recognition procedures through consolidation of the current legislation in this field, in particular regarding automatic recognition for some health professions. It also introduces some new elements for other health professions, such as a possibility for automatic recognition on the basis of professional platforms. The reflection process encouraged 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. The Commission will continue to take forward this work with the other institutions involved in order to adopt the Directive as soon as possible.

One particular issue being addressed in these discussions is the notification of professional malpractice procedures, in order to identify the most appropriate method to ensure adequate

¹¹ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271 of 9.10.2002.

confidential exchange of information relevant to the free movement of health and other professionals. Preparatory work has already been undertaken through a project called “Sysex” in Belgium, which provides citizens with information on rules and procedures for professional recognition, allows on-line applications for recognition, and enables confidential information exchange between the responsible authorities. The Commission and the Member States are considering whether it is feasible to extend this project across the EU.

More generally, information on the number of health professionals, their specialisations, and their distribution is important for planning and providing health services. The reflection process invited Member and acceding States and the Commission to develop and reinforce the system of gathering accurate data about the mobility of health professionals and encouraged Member and acceding States to collect and share comparable workforce data regarding health professionals, in collaboration with the Commission and relevant international organisations. This data should be gathered through the existing committees on recognition of professional qualifications, but in practice the statistics provided by the Member States through these committees for the health professions are far from complete. The Commission calls on national health authorities to provide these committees with up-to-date and complete statistics on the movement of health professionals for the purposes of both cross-frontier provision and permanent establishment in another Member State.

Gathering this information is especially important given the existing shortages of health professionals in some Member States. These shortages will be compounded in the coming years by the ageing of the health workforce. Between 1995 and 2000, the number of physicians under the age of 45 across Europe dropped by 20%, whilst the number aged over 45 went up by over 50%. For nurses as well, average ages are rising; in five Member States nearly half of nurses are aged over 45. If these trends continue, shortages will become critical across the whole Union in the coming decades. Facilitating mobility can go some way toward ensuring that health professionals go where they are most needed. But if the overall numbers and specialisations of health professionals are not adequate, this still represents a serious risk for health systems across the Union, with the impact being felt hardest in the poorest Member States. In this context, it will be difficult for any one country to invest in training health professionals without knowing that other countries will do likewise. A concerted European strategy covering issues such as monitoring, training, recruitment and working conditions of health professionals could ensure that Member States would see a return on their investment in health professionals and that the Union as a whole will be able to meet its objectives of providing high-quality healthcare. The Commission invites the Member States to consider this issue, in collaboration with the health professions.

2.4. European centres of reference

As set out by the reflection process, European centres of reference could provide healthcare services to patients who have conditions requiring a particular concentration of resources or expertise in order to provide high quality and cost-effective care, in particular for rare diseases. Centres of reference could also be focal points for 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 health professional involvement, and should take into account the need for services and expertise to be appropriately distributed across the enlarged European Union.

The reflection process invited 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. The Commission will take this recommendation forward through a call for tender under the public health programme. On the basis of the results of this project we will consider any specific proposals on these issues at European level, including any new cooperation structures and methods for identifying centres of reference across Europe. Collaboration in this area has great potential to bring benefits to patients through easier access to highly specialised care, and to health systems by making the most efficient possible use of resources, for example by pooling resources to tackle rare conditions.

2.5. Health technology assessment

Developments in health technology have been a key element in the massive improvement of human health in modern times. Health technology in this sense includes health-related devices and products as well as techniques. Progress in health technology has not only allowed us to develop more effective therapies than before, but also to widen the scope of health intervention in order to treat previously untreatable conditions.

Partly because of this, developments in health technology are the largest factor behind the increases in expenditure of European health systems in recent decades. We all wish to benefit from the most effective healthcare available. However, the most expensive or the most recent treatment is not necessarily the most effective. New developments in health technology need to be properly evaluated and compared with other options in order to provide a solid evidence base for healthcare decisions. Health technology assessment can be used to assess the safety, effectiveness and wider implications of different health technologies. As yet, this kind of evaluation is not sufficiently undertaken, and existing work across the Union is fragmented. An example is the pharmaceutical sector where though assessments of clinical and cost effectiveness of medicines are becoming a regular feature of most national healthcare pricing and reimbursement schemes, they operate in a variety of different ways. Cooperation at European level can bring added value by sharing information, avoiding duplication and coordinating activities to achieve maximum results. Some work has already begun in the pharmaceutical sector through the Transparency Committee established under Directive 89/105/EEC.

The reflection process invited 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. We can build on collaboration and projects already supported under the public health programmes to harmonise methodology for assessments and to explore the role of health technology assessment in the future systems of health care in the Member States. The Commission plans to establish a coordinating mechanism to link together the different projects, organisations and agencies which already exist and to pool results and information in a usable and effective way, and will bring forward separate specific proposals, including for a study. The cost-effectiveness of health technologies may also be the subject of specific objectives within the open method of coordination proposed for health and long-term care. These initiatives will help to ensure that patients throughout Europe benefit from care reflecting the latest advances in medical technology, and also that health systems can ensure that they are using their limited resources in the most effective and efficient way.

3. INFORMATION

3.1. Health systems information strategy

Information about health systems is vital. It underpins the ability of citizens to use health systems; of professionals to diagnose, treat or refer; and of health authorities to plan and manage systems as a whole. At a European level, information is the basis of identifying best practice and comparing standards. Many aspects of the strategy outlined in this communication depend on appropriate information. Yet one of the effects of the primarily national focus on health systems is that information is lacking at the European level.

A strategy is required for developing information on health systems for the future. The reflection process invited 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; the responsibilities of the different actors concerned; and taking account of relevant work by the WHO and the OECD. The report also identified a range of areas where more information is required, from information related to the detailed provision of healthcare to setting up a framework for systematic data collection on the volume and nature of patient movement, including data on tourism-related flows and long-term stay.

Work is already underway to improve information on patient mobility and mobility of health professionals at European level. This is being taken forward in the health systems working party that has been set up under the first strand of the public health programme. This expert group will meet twice annually and will advise the Commission on how to meet information needs in the field of health systems, including dissemination of results. This can build on work begun by the health monitoring programme through twelve projects in the field of health systems information covering hospital data, primary care, pharmaceuticals, efforts in prevention and health promotion, health care professionals and an umbrella project providing descriptive information on health care provision actors and activities. The work of the health systems working party is closely coordinated with the Community statistical programme¹² and in particular with the core group on health care statistics, and also with the ongoing work in OECD and WHO. The framework programmes for research and technological development¹³ can also contribute; for example, one forthcoming project will address performance assessment of health care institutions to assess and compare different quality strategies.

The information strand of the public health programme is also developing the concept of a European Public Health Portal. The portal will serve as a single point of access to thematically arranged health information produced with Community funding. Specifically, it will give access to Community health indicators on six themes (mortality and morbidity, injuries and accidents, lifestyles, health and environment, mental health and health systems) and analysis on the basis of the indicators and policy recommendations. In addition, the Commission, the European Medicines Evaluation Agency and the Member States are implementing an informatics strategy for the pharmaceutical sector which contains a proposal for establishing a EuroPharm database containing a harmonised set of information on all licensed medicines in the EU. This will also form part of a broader strategy to improve the

¹² See Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics.

¹³ Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the Sixth Framework Programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006), OJ L 232/1 of 29.08.2002.

quality of existing consumer information on medicines. These initiatives will provide a solid basis for developing a coherent European information strategy for health systems as a whole.

3.2. Motivation for and scope of cross-border care

The reflection process specifically identified the need for more information on the motivation for and the scope of cross border care, inviting 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. The Commission plans to address this through a specific study under the public health programme, as well as through a research project “Europe for Patients” examining the benefits and challenges of enhanced patient mobility in Europe.

3.3. Data protection

The reflection process also raised specific concerns about data protection and sharing of confidential data between Member States and at EU level, inviting the Commission to address this issue. These issues are covered by Directive 95/46/EC¹⁴ on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The objective of this Directive is to harmonise data protection legislation in the Member States in order to facilitate the free movement of personal data within the Union while protecting the fundamental rights and freedoms of natural persons. The Directive contains a general prohibition on processing sensitive data, including data concerning health, but with a limited number of exceptions. In particular, the general prohibition on processing sensitive data may be lifted if the subject of the data gives their explicit consent, provided that the laws of the Member State concerned allow individuals to give such consent. Health data may also be processed in situations where this is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional who is subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

This provides a framework for handling personal data and health data in cross-border care. However, awareness of these provisions may not be sufficient in the health sector. If they are not applied, this may mean that the privacy of citizens is not properly respected – or conversely, that relevant information for their care does not follow patients when they seek care elsewhere within the Union. The Commission will work with the Member States and with the national data protection authorities to raise awareness of these provisions as they apply to healthcare and to address any outstanding issues if needed.

3.4. E-health

Use of information technology offers great potential for patients, professionals and for health systems overall. Health-related information is already one of the most searched-for topic on the internet, as citizens look to be better informed about their health and decisions affecting it. Some health-related services are also available using information technology, both to patients and to professionals. The Commission is taking forward actions to promote e-health, in

¹⁴ OJ L 281 of 23/11/1995.

particular through the public health programme and as part of the e-Health action plan. Issues of interoperability and compatibility among health-related information systems are of particular importance in this regard. The reflection process invited the Commission to consider establishing European principles concerning the competence and the responsibilities of all those involved in e-health service provision.

Directive 2000/31/EC¹⁵ on electronic commerce contributes to the legal certainty and clarity needed for information society service providers to be able to offer their services throughout the Union. Of course, activities which cannot be provided on-line, such as medical advice requiring a physical examination of the patient are not information society services and remain subject to the rules of the Member State where the service is provided. In any event, requirements for the protection of public health established in Community law apply whether the health services concerned are provided on-line or off-line; likewise, Member States may also take action to restrict the provision of services from another Member State where this is necessary to protect public health, subject to the conditions established in the directive on electronic commerce.

Nevertheless, beyond this general framework there is scope to improve clarity over legal and ethical issues related to e-health. The Commission has already presented, a Communication in 2002 defining quality criteria for health related websites¹⁶. This focused primarily on the reliability of health related websites, and presented a set of commonly agreed quality criteria which website operators should apply in addition to relevant Community law. The Commission plans to consider these issues further as part of the eEurope 2005 action plan and the specific actions on eHealth¹⁷.

4. EUROPEAN CONTRIBUTION TO HEALTH OBJECTIVES

Ensuring a high level of health and well-being for citizens throughout Europe is a value shared by the whole Union. Some European action is directly focused on health, such as the public health programme or legislation to ensure the safety of blood and blood products. Other actions have different primary aims but also integrate health protection requirements in their definition and implementation, as required by the Treaty establishing the European Community (Article 152, paragraph 1).

Member States themselves also of course act to achieve this shared commitment to health and well-being for their citizens, in which their health systems are crucial. The health systems of the Member States also share fundamental principles: universal access on the basis of need, high-quality health provision, and financial sustainability on the basis of solidarity. European rules and actions have an increasing role to play in meeting health objectives, and these principles are proposed as common objectives for open coordination on health care and long-term care. At the heart of the reflection process was the need to develop a better understanding of the contribution of the Union to ensuring a high level of health and well-being for citizens throughout Europe, and for the political authorities responsible for health and health systems to have a stronger role in shaping that European contribution.

¹⁵ OJ L 178 of 17/07/2000.

¹⁶ Communication “eEurope 2002: Quality Criteria for Health related Websites”, (COM (2002) 667 final, adopted on 29.11.2002).

¹⁷ Commission Communication “e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area”.

4.1. Improving integration of health objectives into all European policies and activities

The European contribution to high levels of health protection for European citizens needs to be better analysed and understood. The reflection process invited 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, in particular with regard to access routes arising from European rules. The Commission will work with Member States to gather this information through the High Level Group on Health Services and Medical Care and taking account of data assembled under the information strategy described above.

More generally, the reflection process invited 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, and to review evidence related to the issues raised by the interaction of Community rules and national health policy objectives. The reflection process also invited the Commission to provide a review of evidence relevant to the issues raised by the interaction of Community rules and national health policy objectives.

At European level, the Commission is already working to ensure that assessing the impact of European initiatives on health objectives is integrated into overall impact assessments of new initiatives. The Treaty provisions on health require a high level of human health protection to be ensured in the definition and implementation of all Community policies and activities. As well as the impact on the overall health of citizens, this assessment should also take account of the impact on health systems and their objectives. The public health programme is supporting work to refine methods of health impact assessment, including specific case studies on Community policies, legislation and actions; mapping the use of health impact assessment in the Member States; and evaluating the way health has been taken up by other impact assessment methodologies and in particular ‘integrated’ assessment tools. The Commission will build on this work to ensure that the impact of future proposals on health and healthcare is taken into account in their overall integrated assessment.

4.2. Establishing a mechanism to support cooperation on health services and medical care

It is clear that there is a need to facilitate European cooperation on health services and medical care whilst respecting the responsibilities of the Member States in this area. This must closely involve the Member States in order to ensure that national, regional and local levels are fully involved in and aware of the European context to their work. The reflection process invited 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.

In accordance with Article 152, paragraph 2, the Community shall encourage cooperation between the Member States in the areas referred to in that article and, if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and activities in particular with regard to improving public health, preventing human illness and disease, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

Further to these provisions, and building on the success of the reflection process, the Commission has decided to establish a “High Level Group on Health Services and Medical Care”, based on the following principles:

- **role:** high level group to support European cooperation between the Member States on health services and medical care, in order to help patients to have the high-quality health care they seek and to help health systems to improve their effectiveness and efficiency.
- **activities:** to promote cooperation between the Member States and take forward the recommendations of the reflection process through activities such as developing a better understanding of the rights and duties of patients, sharing spare capacity between systems and cooperating on cross border care, identifying and networking European centres of reference, and coordinating assessment of new health technologies.
- **membership:** senior representatives of Member States, normally at the level of Directors-General, and the Commission, calling on external experts as necessary;
- **legal basis:** established by a Commission decision and implementing the provisions of paragraph 2 of Article 152 on public health of the Treaty establishing the European Community, to support the cooperation and coordination between the Member States provided for in that paragraph in the area of health services and medical care.
- **links with other bodies:** The group will work closely with other relevant bodies at European and international level, in particular the Social Protection Committee and the Economic Policy Committee.
- **involvement of other stakeholders:** Civil society stakeholders from the health sector should also be involved on a regular basis, in particular through the European Union Health Forum. Representatives of regional and local authorities with responsibility for healthcare should also be able to contribute, as in most Member States the responsibility for providing health services is at regional or local level.

Health services and medical care are primarily the responsibility of the Member States and should remain so. However, it is clear from the conclusions of the reflection process that there is great potential for cooperation at European level to help patients to have high-quality health care and to help health systems to improve their effectiveness and efficiency. Respecting national responsibility for health systems does not mean doing nothing at European level. Rather, this committee can ensure that there are structures in place to facilitate cooperation where useful and ensure that where Europe does have an impact on health or health systems, it does so in a positive way and that those responsible for achieving health objectives can shape those developments.

5. RESPONDING TO ENLARGEMENT THROUGH INVESTMENT IN HEALTH AND HEALTH INFRASTRUCTURE

Every Member State of the Union faces challenges in meeting its health objectives. These challenges are particularly acute for the new Member States. Not just the quality of life of their citizens, but the overall economic growth and sustainable development of these countries depends on investing in health and health systems. This investment must be a priority both for the countries concerned and for the Union. However, enlargement will also help the new Member States to better cope with their problems since it sustains the economic development

of the relevant countries. Moreover, already the market opening has shown positive influences on the development of the state of health due to the access to better or higher quality products which is likely to continue and further improve after accession.

The state of health in the new Member States varies, but life expectancy in all is significantly lower than in the current Union; men's health is particularly poor. Prevalence of major western diseases is higher than in the current Union, such as cardiovascular disease and cancer – especially lung cancer. Risk factors are also greater than in the current Union, for example with higher rates of smoking and alcohol consumption, and low levels of physical exercise. Health systems across the acceding States have been reformed with a focus on decentralisation, reform of insurance and funding systems, and more efficient use of resources. But the overall level of resources invested in healthcare is still much lower than in the current Union – around 4.5% on average of Gross Domestic Product (GDP), compared to 8.5% GDP for the current Union.

Poor health status compounded by under-investment in health and health systems will be a major brake on development, if it is not addressed. Health is a productive factor in a competitive economy. The cost every time a worker is absent is not just the direct cost of their sickness payments, but also the cost of their replacement by other workers and lower productivity for their employer as a whole. For workplace accidents alone, this cost is estimated to represent 1-3% of GNP a year. At a macro level, health is crucial to raising the activity level of the population. Chronic illness affects about 15% of the working age population in the European Union. This represents a burden not just for sufferers but for those who care for them; about 15 million people in the current EU need the assistance of a third person to fulfil the basic functions of normal life.

On the positive side, increased longevity and better overall health increases the potential return to people from investing in their own education and training. It also gives people the confidence and capabilities to remain active longer. Early investment in health reduces subsequent costs for the economy as a whole. The future economic growth and sustainable development of the entire Union therefore depends on investment in health - investment that will be doubly important for the new Member States to reduce the gap with the rest of the Union.

The reflection process invited 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. In fact, the Union already supports investment in health in the existing Member States, where this has been identified as a priority by the countries and regions concerned, including:

- in the “Health” operational programme in Portugal, € 475m is being invested in order to promote health and prevent illness, improve access to healthcare, and develop partnership in the health sector;
- in the “Ceuta” programme in Spain (overall budget € 105.5m), the “urban and local development” strand will support technological renovation and improvement of health centres and hospitals.
- in the regional programmes for Epirus and continental Greece (overall budget € 1,553m), infrastructure and urban improvement programmes include support for health-related activities.

Taking forward this recommendation therefore depends on the regions and countries concerned identifying investment in health and health infrastructure as a priority for European support. The Commission will work with the Member States through the High Level Group on Health Services and Medical Care and through the appropriate structures for the financial instruments concerned to ensure that health is given the necessary weight in the development of overall plans. The need for additional European investment in health infrastructure will also be addressed as part of developing the new financial perspectives for the Union from 2006.

6. CONCLUSION

The health ministers and other stakeholders involved in the high level reflection process on patient mobility and healthcare developments in the European Union identified a wide range of issues where progress is needed. The report of the reflection process also represents a milestone by recognising the potential value of European cooperation in helping Member States to achieve their health objectives.

Developing the European response to these issues through the initiatives set out in this communication, the communication on extending the open method of coordination to health and long-term care and the communication on the European e-Health Area (and its associated action plan on e-Health) will be a long-term project requiring significant resources. Further proposals beyond those set out at this stage may also be needed. However, over time this effort will repay dividends in better health and quality of life; in better use of the resources invested in health systems across Europe; in greater economic growth and more sustainable development for the enlarged Union as a whole; and in bringing concrete benefits of European integration closer to citizens in their daily lives.

ANNEX 1

SUMMARY OF THE RECOMMENDATIONS OF THE REFLECTION PROCESS AND THE COMMISSION'S RESPONSES

RECOMMENDATIONS	COMMISSION RESPONSES
Rights and duties of patients	
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.	To be taken forward through the High Level Group on Health Services and Medical Care, starting by bringing together existing information as recommended by the reflection process.
Sharing spare capacity and trans-national care	
To evaluate existing cross-border health projects, in particular Euregio projects, and to develop networking between projects in order to share best practice.	The Commission is supporting work to evaluate Euregio projects under the public health programme, and will look how to support networking between these projects.
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.	The Commission will invite Member States to provide information on any existing arrangements for healthcare purchasing through the High Level Group on Health Services and Medical Care, and will consider with the Member States how to proceed once that information is available.
Health professionals	
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.	The Commission calls on the Member States to provide up-to-date and complete statistics on the movement of health professionals through the structures governing recognition of professional qualifications. The Commission will also continue work to ensure clear, simple and transparent recognition procedures together with the Council and Parliament.

<p>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 sectorial rules in order to facilitate and develop mobility of health professionals.</p>	<p>The Commission will also continue preparatory work with the Member States to ensure adequate confidential exchange of information relevant to the free movement of health and other professionals.</p> <p>The Commission invites Member States to consider issues related to current and future shortages of health professionals in the Union.</p>
<p>European centres of reference</p>	
<p>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.</p>	<p>The Commission will take this forward through work under the public health programme, and will consider any further proposals on that basis.</p>
<p>Health technology assessment</p>	
<p>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.</p>	<p>The Commission proposes addressing this through specific proposals, including a specific study with a view to developing a collaboration mechanism as part of cooperation on health services, and will bring forward separate proposals if appropriate.</p>
<p>Health systems information strategy</p>	
<p>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.</p> <p>To invite the Commission to facilitate information sharing at European level on possible available healthcare, existing</p>	<p>The Commission will take this forward through the information strand of the public health programme, in particular through the working party on health systems and with dissemination through the planned public health portal. This work will be carried out in close collaboration with other relevant bodies at European and international level.</p>

<p>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.</p> <p>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.</p>	
<p>Motivation for and scope of cross-border care</p>	
<p>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.</p>	<p>The Commission proposes to address this through a specific study under the public health programme, and it will also be addressed by the research project “Europe for Patients”.</p>
<p>Data protection</p>	
<p>To invite the Commission to address issues concerning data protection and sharing of confidential data between Member States and at EU level.</p>	<p>This communication provides a short description of how data protection rules take account of the specific nature of health data. The Commission will work with the Member States through the High Level Group on Health Services and Medical Care to raise awareness of these provisions and to address any outstanding issues.</p>
<p>E-health</p>	
<p>To invite the Commission to consider establishing European principles concerning the competence and the responsibilities of all those involved in e-health service provision.</p>	<p>The Commission will consider these issues in more detail as part of its overall action plan for e-health, as set out in the Communication on “e-Health – making healthcare better for European citizens: an action plan for a European e-Health area”.</p>

Improving integration of health objectives into all European policies and activities	
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.	The Commission will work with the Member States to gather this information through the High Level Group on Health Services and Medical Care, taking account of the data assembled under the information strategy described above.
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. 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.	The Commission will build on existing projects regarding health impact assessment to ensure that the impact of future Commission proposals on health and healthcare is taken into account in their overall impact assessment.
Establishing a mechanism to support cooperation on health services and medical care	
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.	The Commission has established a High Level Group on Health Services and Medical Care.
Developing a shared European vision for health systems	
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	The Commission is proposing to extend the open method of coordination to health care and long-term care in a separate communication. The Commission has or will take action on several aspects to improve legal certainty in this area, including providing better information about rights to seek healthcare in other Member States and to be reimbursed; clarifying the application of existing jurisprudence through the directive on services in the internal market;

	<p>improving assessment of the health impact of European proposals; simplifying the rules on coordination of social security systems and improving their usability with the European health insurance card; improving knowledge about patient mobility and healthcare developments; and facilitating cooperation at European level by establishing a High Level Group on Health Services and Medical Care.</p> <p>The Commission also invites Member States to act to improve legal certainty within their systems, and is ready to support such initiatives, for example by exchanging information or possibly by developing guidance at European level.</p>
Responding to enlargement through investment in health and health infrastructure	
<p>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</p>	<p>The Commission will work with the Member States through the High Level Group on Health Services and Medical Care and through the appropriate structures for the financial instruments concerned to ensure that health is given the necessary weight in the development of overall plans. The need for European investment in health infrastructure should also be addressed as part of developing the new financial perspectives for the Union from 2006.</p>