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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

**HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE**

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Brussels, 30 November 2004

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## HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

### EXECUTIVE SUMMARY

The report of the patient mobility reflection process represented a political milestone by recognising the potential value of European cooperation in helping Member States to achieve their health objectives. The High Level Group on health services and medical care was established as a means of taking forward the recommendations made by the reflection process. The report from the High Level Group sets out progress at this stage and orientations for future work in 2005 and thereafter, and this summary highlights some key points from the report.

The High Level Group has taken forward work through working groups involving interested Member States on particular topics, with regular reporting of their work to the full High Level Group. Work has been taken forward in the following areas:

- **cross-border healthcare purchasing and provision:** Future work should focus on a deeper analysis of the financial impact and sustainability of cross-border healthcare, developing a framework that could be used for cross-border healthcare purchasing, studying the reasons for mobility and the need for purchasing care abroad, providing information to patients on quality, safety and continuity of care as well as on patients' rights and responsibilities, considering liability issues in cross-border care, and gathering information to monitor cross-border healthcare purchasing and provision. The European Commission should also be invited to support a conference in 2005 to exchange knowledge and best practice, focusing on legal and financial aspects;
- **health professionals:** work should be taken forward through exchanging information on continuing professional development to ensure quality; ensuring that basic data on migration of health professionals is provided by all Member States; surveying the impact of migration out of Member States; and sharing information on recruitment practices in order to assess whether common principles could be developed;
- **centres of reference:** some principles have been developed regarding European centres of reference, including their role in tackling rare diseases or other conditions requiring specialised care and volumes of patients and some criteria that such centres should fulfil. Options and procedures for designating European centres of reference for limited periods of time at European level based on agreed lists of pathologies, technologies and techniques are also being developed. The High Level Group will

work towards a common approach which could then be implemented through pilot activities;

- **health technology assessment:** the usefulness of establishing a sustainable European health technology assessment network has been recognised. Such a network should address methods for developing common core information packages, methods to support transferability of assessments, methods for helping Member States to identify and prioritise topics and commissioning reports, tailoring common core information to national health policy processes and sharing methodologies, expertise and practice issues. This network could be established initially through the public health programme;
- **information and e-health:** e-health is the priority focus in this area, and its potential to add value to existing health services, improve quality and continuity of care and support citizen-oriented services - interoperability at national and European level is the cornerstone for achieving this. An overall health systems information strategy in a European context is needed, considering mobility of citizens and availability of Europe-wide e-health services. Future work will focus on developing such an information strategy and on outlining activities for the implementation of the e-Health Action Plan, looking at the information which should be available for patients, professionals and policy-makers; and looking at the appropriate structures for cooperation on information and e-health;
- **health impact assessment and health systems:** The European Union's impact on health takes place largely through policies other than those specifically related to public health. Work is required to ensure a coherent approach to evaluating the impact on health of other Community policies. However, there is no EU methodology to prospectively and systematically address the potential impacts of non-health policies on health systems. Work underway, including by other international organisations, should be drawn on to develop agreed instruments to measure impacts of non-health EU policies on health through impacts on health systems, which could then be tested for reliability and validity.
- **patient safety:** Health care interventions, although intended to benefit patients, may in some cases cause harm. An EU patient safety network or forum, working with other international organisations, could provide focus for efforts to improve the safety of care for patients in all EU Member States, through sharing information and expertise. If agreed, proposals for an EU patient safety network could be further developed during 2005.

The High Level Group has also contributed to other work relevant to health services and medical care, including the open method of coordination on healthcare and long-term care.

Subject to any comments, the High Level Group intends to work on this basis during 2005 and thereafter, taking into account comments and suggestions from the Council and keeping the Council informed and liaising with it on future work (including regular liaison with the Presidency). In order to ensure the broadest possible base of expertise, other stakeholders should be involved including civil society representatives and observers from the EFTA/EEA States, through mechanisms to be agreed by the High Level Group.

## HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

### REPORT FROM THE HIGH LEVEL GROUP TO THE EMPLOYMENT, SOCIAL AFFAIRS, HEALTH AND CONSUMER PROTECTION COUNCIL ON 6-7 DECEMBER 2004

#### 1. ESTABLISHMENT OF THE HIGH LEVEL GROUP

The report of the patient mobility reflection process<sup>1</sup> represented a political milestone by recognising the potential value of European cooperation in helping Member States to achieve their health objectives, from developing European cooperation on sharing resources to improving the integration of health objectives into all European policies and activities. A key recommendation of the patient mobility reflection process was to consider the development of a permanent mechanism to support European cooperation, and the Commission responded by establishing the High Level Group<sup>2</sup> on health services and medical care as a means of taking forward the recommendations made by the reflection process.

The High Level Group met in July, September, October and November of this year in order to set priorities and begin initial work. This report provides an opportunity to take stock of this first phase of work of the High Level Group and to provide any necessary guidance for work during 2005 and thereafter.

#### 2. ISSUES FOR THE HIGH LEVEL GROUP TO ADDRESS

The patient mobility reflection process made 19 recommendations across five areas:

- **European cooperation to enable better use of resources**, covering issues such as developing a better understanding of the rights and duties of patients; activities to facilitate the sharing of potential spare capacity and cross-border care; facilitating cooperation in border regions; European centres of reference; and the evaluation of medical technology;
- **Information for patients, professionals and providers**, covering issues including a strategic framework for information initiatives covering issues such as health policies, health systems, health surveillance, technological solutions, quality assurance, privacy, records management, freedom of information and data protection;
- **Access to and quality of care**, covering issues such as improving knowledge on access and quality issues and analysing the impact of European activities on access and quality;

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<sup>1</sup> See [http://europa.eu.int/comm/health/ph\\_overview/co\\_operation/mobility/patient\\_mobility\\_en.htm](http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/patient_mobility_en.htm).

<sup>2</sup> See Commission Communication COM(2004)301 of 20 April 2004 on the follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union.

- **Reconciling national objectives with European obligations**, covering issues such as improving legal certainty and developing a permanent mechanism to support European cooperation in the field of health care and to monitor the impact of the EU on health systems;
- **and health and the Union’s cohesion and structural funds**, looking at how to facilitate the inclusion of investment in health, health infrastructure development and skills development as priority areas for funding under Community financial instruments.

The task for the High Level Group is to implement these recommendations by developing concrete action bringing benefit to patients and helping to improve the effectiveness and efficiency of the health systems across the Union while respecting national responsibilities for health systems. This should be undertaken in close cooperation with other bodies working on relevant issues at European level, and ensuring a coherent approach with regard to other policy areas, in particular with the open method of coordination on healthcare and long-term care.

Current variations in techniques, resources and outcomes show that there is enormous scope to improve the results obtained from existing resources by sharing expertise and best practice. To take one example, the constant development of new medical technologies and techniques is one of the key drivers behind improved health, but is also the largest factor in the increases in expenditure of European health systems in recent decades. A network bringing together health technology assessment across the Union would reduce current duplication of effort in assessing new technologies and could strengthen the evidence base for healthcare decisions from which all Member States would benefit.

### **3. PROGRESS TO DATE**

Given the wide range of recommendations made by the patient mobility reflection process, the High Level Group decided to prioritise its first phase of work by focusing on six specific areas. Each topic is being taken forward by a working group led by one or more Member States:

#### **3.1. Cross-border healthcare purchasing and provision**

The Working Group on Cross-border Healthcare Purchasing and Provisions has met three times (September 22, October 13 and November 4) and 19 Member States<sup>3</sup> are actively participating. The working group is co-chaired by the Netherlands and Malta.

The group has based its work on the fact that the organisation and financing of health care services and social security systems are governed by national law. Hence Member States lay down the conditions governing affiliation to the social security system and the conditions governing entitlement to health care and social

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<sup>3</sup> BE, DE, DK, ES, FI, FR, HU, IE, IT, LT, LV, MT, NL, PL, SE, SK, SL, UK. (CZ did not participate in the group but responded to questionnaire)

security benefits, of course taking into account Community law (free movement provisions, prohibition of discrimination, public procurement rules).

There are a number of reasons for cross border healthcare, including:

- citizens temporary stay or long-term residence in other Member States,(e.g. for tourism, travel, work, or retirement), (1408/71)
- individuals, governments or institutions seeking clinical care abroad for reasons of access, expertise or other reasons that need to be explored.
- co-operation in border regions.

The working group recognises that cross border healthcare is not only an issue at an individual patient level and that the phenomenon has been institutionalised. Different routes for patient and professional mobility are being used and greater clarity is needed concerning the consequences of the different access-routes in theory and in practice. The working group has limited its work so far to cases where the sole purpose for the patient or provider is to receive or to provide medical treatment respectively. The working group formulated its mandate based on the issues set out in Commission Communication COM(2004)301.

The first part of the mandate is to explore further the possibility of reaching a common understanding on patient's rights, responsibilities, entitlements and duties, both individual and social, at European level. The second focus is 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. Within these two areas, the working group should also explore how legal certainty could be improved in practical terms following the Court of Justice Jurisprudence on the right of patients to benefit from medical treatment in another member state.

A questionnaire has been sent out to assess the perceived major challenges, obstacles and possibilities related to cross border healthcare. The contributions to this questionnaire led to the formulation of the following objectives for the working group on cross border healthcare purchasing and provision.

The working group recognises the need to provide easily accessible information for patients that could describe the specific provisions of healthcare in each Member State, such as how patients could seek treatment in other Member States and what conditions that would apply. Several Member States already provide such information, which should be complemented by information given and/or exchanged at European level on healthcare provision elsewhere in the EU. This information should help to improve clarity and legal certainty for patients by progressively addressing issues related to the quality, safety and continuity of care, as the information becomes available.

The working group supports the possibility of developing a clear and transparent framework for healthcare purchasing, that could be used as a check list for governments, hospitals and institutions on issues such as contracting arrangements, comparison of treatments in terms of quality, safety, content and prices, experiences on incorporating capacity abroad into national systems, follow up of patients and exchange of relevant data. By providing information to the decision makers, this framework could facilitate the sharing of capacity within the existing health care

systems and help to take possible facilities in other Member States into account in domestic care planning and management.

In order to fulfil the objectives and given the wide range of issues that fall into the scope of the mandate, the working group decided that preliminary work should prioritise the following specific issues as a first phase:

*3.1.1. Financial impact and sustainability:*

The financial implication of cross border health care for patients, providers, institutions and governments vary depending on the method of financing of health care systems. The working group recommends a deeper analysis of the financial impact of cross border health care, taking into account the various access routes, the jurisprudence of the ECJ and the methods of financing of health care systems. This includes analysis of elements of price pressure in different parts of the system, budgetary control and the resource utilisation.

**Action point:** The Commission should during 2005 conduct further analysis of the financial impact of patient mobility for sending and receiving countries and the impact on financial sustainability of the involved health care systems, in close collaboration with all relevant stakeholders.

**Action point:** The working group will during 2005 develop a clear and transparent framework for healthcare purchasing.

**Action point:** The working group proposes that health ministers invite the European Commission to support a conference in 2005 aiming at exchanging knowledge about best practice related to cross border care with an initial focus on the legal and financial aspects as a priority.

*3.1.2. Reasons for mobility*

**Action point:** The working group invites the Commission to proceed further the work on the study on the motivation for patients to move across borders and to explore the need for institutions to purchase treatment abroad for their patients.

*3.1.3. Patients` rights and responsibilities:*

Greater information on patient rights and responsibilities in the Member States is needed before exploring the possibility of taking further steps at European level.

**Action point:** To collect information on the situation of the patient rights and responsibilities in the Member States, emphasising the effect on the ability of Member States to manage their healthcare systems.

*3.1.4. Give patients more certainty regarding legal liability*

**Action point:** In order to give more certainty to the patients, clarification should be sought on liability issues for patients receiving care in other Member States.

### 3.1.5. *Patient safety*

The proposal for an EU patient safety network merits further consideration when the overall situation across the EU is better understood (see section 3.7 below).

### 3.1.6. *Access to information*

**Action point:** To ensure easily available information to the patients, the group asks the European Commission to explore what information can be collected, including through the regulations on the coordination of social security, the information strand of the public health programme and the research framework programmes. This will be done in close liaison with the working groups on information and e-health, on health professionals and on centres of reference.

### 3.1.7. *Cooperation in border areas*

**Action point:** Identify what kind of actions regarding cooperation in border areas should remain addressed at bilateral level, and what kind of actions might benefit from coordinated European initiatives.

## 3.2. **Health professionals**

### 3.2.1. *Membership of Working Group*

UK, Hungary, Poland, the Netherlands, Italy, France and Estonia are members of the Group. The Group is chaired by the UK, and Hungary has now agreed to co-chair future meetings. The Group intends to invite the European Committees of doctors (CPME) and of nurses (PCN) to join in their deliberations.

### 3.2.2. *Issues addressed by the Group*

The Group is looking primarily at the potential impact of migration of health professionals around the European Union. It is looking at the relevance to patient mobility issues, and is concentrating on information about quality and safeguards to the safety of patients, and the impact on health systems and capacity in countries from which staff have moved. It has decided to concentrate, at least initially, on doctors and nurses.

### 3.2.3. *Importance and Added Value of the Work*

The concerns about the impact on the health systems of “donor” countries relate to the creation of severe shortages in specialties where mobility is easy/demand elsewhere is high, and the impact of that on wage levels and overall cost. There are also serious concerns about the information receiving countries have about the quality of staff education and training, and what is known about it, and about aggressive and unethical recruitment practices. These were concerns, but members acknowledged that the evidence base was lacking in order to assess their importance.



Countries that attract most staff are those which actively recruit. There are concerns about unethical practices, especially from private agencies. On the other hand, there is acknowledgement that individual workers are free to move within the EU, and it might be in their professional interest to do so. The active recruitment process may also mean they get better support when they migrate. There are also approaches to recruitment where something positive can be given back to the donor country.

The Group identified areas of work to address these issues, which added value, and did not duplicate other work – for example in the Committee of Senior Officials on Public Health (CSOPH), or other work connected with the Directives on Mutual Recognition, and the data collected in that context. Nor should this activity duplicate the work of the Presidencies on developing information channels on poor-performing professionals, though the High Level Group needs to be aware of what is going on.

So while the collection of statistics on the migration of health professionals is carried out in the CSOPH the group would emphasise the necessity for providing these data to the Internal Market Directorate-General. This could improve the present weak input from Member States. Furthermore discussions on sharing information on professional misconduct have been started by the Dutch Presidency in a Conference in Warsaw on 22/23 September 2004 and will be the main subject of a Conference in Amsterdam on 9/10 December 2004. The UK Presidency will probably follow-up on that. The participation of the Member States in this “Amsterdam process” is important.

#### *3.2.4. Work undertaken*

The Group has done some preliminary scoping of the situation in the countries who are members of the Group. No additional work has yet been commissioned (but see below). However the Group was made aware of the fact that the tender issued by the Health and Consumer Protection Directorate-General on the “Analysis of health staff shortages and human resources on health planning tools” will yield important information about the impact of professional mobility.

#### *3.2.5. Any contributions expected*

As well as to the activities mentioned above, it is noted that the Council of Europe is preparing a report on professional mobility which the Group could take into account.

#### *3.2.6. Outline plans for future work*

The Group considered that the following work programme through 2005 would produce practical outcomes of added value

#### *Quality*

There is a need to improve knowledge about how countries approach continuing professional development, as the mutual recognition process does not really capture lifelong learning, which is crucial to quality. **Action: to exchange information in the sub-group on arrangements/requirements**

**for continuing professional development, and consider if an inventory on this should be drawn up.** If so further consideration would need to be given to how this would be supported and maintained.

#### *Evidence*

Many member states still do not return basic data on migration of health professionals within the EU and EEA required by the Internal Market Directorate-General in connection with their work on the directives on the mutual recognition of professional qualifications. **Action: Member States should do this in order to improve the data base. The information would then be put together within the framework of the CSOPH.**

Better information is needed about the impact of migration on the health services of the countries losing the staff. Particularly to identify which specialties are worst affected. **Action: conduct a short study of a small sample of old and new member states (taken from the members of the sub-group) to obtain this information, and consider how to monitor this situation in the future.**

#### *Recruitment*

The Group does not see the need for an EU Code of Practice on recruitment, but there was a strong feeling that exchanging information and sharing principles of ethical recruitment would be very welcome. **Action: Group to share information on recruitment practices/ethical code, and assess whether common principles could be shared.**

### **3.3. Centres of reference**

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, and could also be focal points for medical training and research, information dissemination and evaluation. Chaired by France, and with the involvement of the Czech Republic, Denmark, Germany, Greece, Ireland Italy, Luxembourg, Hungary, Malta, Austria, Poland, Portugal, Slovenia, Slovakia and Sweden, this working group has been looking at how to how to foster networking and cooperation on these issues, including the organisation, designation and development of centres.

Developing European collaboration on centres of reference has major potential to bring benefits by:

- improving access for EU citizens to treatment requiring a particular concentration/pooling of resources (structures, equipments, financial, knowledge) or expertise, in particular for rare diseases and to offer patients the highest possible chance of success;
- maximising cost-effective use of resources by concentrating them where appropriate;
- helping to share knowledge and provide training for health professionals;

- acting as benchmarks to help develop and spread best practice throughout Europe;
- and helping small countries with a insufficient number of patients to provide a full range of highly specialised services of the highest quality.

The detailed views of the working group are set out in a synthesis document (HLG/COR/2004/7) drawing on contributions from members of the working group on how to implement these principles in practice. A lot of work still needs to be carried out before it is possible to propose a precise model for establishing European centres of reference. Nevertheless, the synthesis document sets out some principles, focusing in particular on the definition and criteria for European centres of reference, including:

- **role:** European centres of reference should tackle rare diseases or other conditions requiring specialised care and volumes of patients, serving also as research and knowledge centres updating and contributing to the latest scientific results, and treating patients from other Member States. The definition of European centres of reference should also reflect the need for services and expertise to be appropriately distributed across the enlarged European Union;
- **criteria:** as well as focusing on an appropriate subject, centres of reference should fulfil criteria including having a minimum volume of relevant activity, appropriate capacities to treat patients from other Member States, provide patient-centred care and multidisciplinary teams, evidence of good outcomes, a high level of expertise and experience, efficient quality management procedures and quality indicators, and ensure availability of subsequent treatment facilities where necessary;
- **labelling:** the labelling of a centre of reference should only be for a limited number of centres for a limited time (five years); not all national centres of reference need to be European centres of reference;
- **areas to cover:** agreement at European level on the pathologies, technologies and techniques to be covered by European centres of reference would be needed, drawing on national experience and existing lists, and with regular review to remove and add areas;
- **process for selection of centres:** following a decision on the criteria and framework for assessment of such centres, one option would be to establish a selection committee made up from leading experts of the Member States and the Commission;
- **form of centres:** the definition of European centres of reference should be flexible enough to allow centres of reference to take different forms, including the possibility of networks or mobile teams;
- **networking:** there could be more than one European centre of reference working in the same field, but all such centres should be networked.

Other issues addressed include dissemination of information to patients and professionals, links to national centres of reference, and possible legal options for supporting cooperation on European centres of reference.

Referral of patients and funding has also been discussed, including the need for some specific gate-keeping or referral mechanism within each Member State, and agreement that the costs of patients being treated in other Member States should be paid for by the country of origin. On this point, the existing mechanisms for coordination of social security systems based on Article 42 of the Treaty establishing the European Community could provide a practical mechanism for referring patients, and this should be explored further in cooperation with the Administrative Commission on the Social Security of Migrant Workers. The Commission is also supporting the work of this group through a call for tender to provide information and analysis on centres of reference, which should provide initial reports during 2005 and final results during 2006.

The working group intends to continue to further refine its proposals on this basis in order to work towards a common approach on the organisation, designation and development of European centres of reference which could then be implemented through pilot activities, taking into account ongoing activities at national level and data to be collected through the mapping exercise to be taken forward by the Commission.

### **3.4. Health technology assessment**

The Working Group on Health Technology Assessment met twice (on 22 September and 13 October) to make progress on establishing a network on health technology assessment as requested by the Council in 2003. The Working Group is chaired by Finland involving sixteen Member States<sup>4</sup>.

#### *3.4.1. Reasons for establishing a European HTA Network*

Health technology assessment (HTA) aims at informing decision-makers by using the best scientific evidence on the medical, social, economic, and ethical implications of investment in health care. Technology is broadly defined to include medical devices, surgical procedures, pharmaceuticals, rehabilitation and disease prevention measures.

When new technologies emerge they need to be properly assessed to ensure high level patient safety, protect public health and promote optimal use of resources. Health technology assessment is a valuable tool in this context.

Health technology assessments are currently being done in many EU Member States even on same topics and thus there is obvious overlap in activities. For example, more than ten countries have produced their own HTA reports on breast cancer screening. Similar research questions are often brought forward in different Member States at the same time. This calls for European wide collaboration.

National settings differ in cultural, economical, social and ethical aspects. This has naturally resulted in each national HTA agency making its own assessments, combining systematic reviews with data relevant to its own

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<sup>4</sup> The Member States who are members of this working group are BE, DK, DE, EE, IE, CY, LV, LT, LU, MT, NL, PT, SI, SK, SV, UK.

country. The resulting HTA report is context-specific. It has so far been difficult to distinguish between the "core evidence" transferable to other settings and the nationally specific data.

Against this background, HTA has become a political priority and there is an urgent need for establishing a sustainable European network on HTA. The Working Group on Health Technology Assessment has considered in practical terms how a sustainable HTA network between health ministries and organisations involved in HTA should be established.

The key aim of the network would be to connect public national HTA agencies and health ministries, enabling an effective exchange of information and support to policy decisions by Member States. The network should therefore first and foremost help to provide reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies.

In addition to collecting such core sets of evidence, the network would provide tools for tailoring this information to fit in various settings by listing relevant organisational, economic, and ethical issues to be addressed nationally. Thus the network would also be able to provide content support for emerging HTA agencies.

The membership of the HTA Network should be open for all EU Member States, which would nominate focal points (contact institutions or persons) for the network. National HTA agencies currently exist in 12 EU Member States (Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Latvia, Netherlands, Spain, Sweden and the United Kingdom). Ireland and Slovakia are currently planning to establish a national HTA agency. The organisation of the network should be carried out by a Steering Group consisting of one representative per participating Member State.

#### *3.4.2. Key tasks of the European HTA network*

The network collaboration would aim at designing and testing:

- 1) methods for the development of "common core information" packages on HTA topics, including core evidence of diagnostic and therapeutic effectiveness (benefits and harms), core economic information and a list of key socio-economic and organisational issues to be addressed nationally;
- 2) methods to support transferability of HTA information between various European settings using a common framework;
- 3) tools for helping Member States to identify and prioritise topics for European HTAs;
- 4) methods for commissioning reports of common core information on appropriate topics;
- 5) quality management procedures for the production of common core information or joint assessments;

- 6) tools for tailoring the common core information to national health policy processes;
- 7) tools for information support in the establishment of new agencies through benchmarking and training;
- 8) tools for sharing methodologies, expertise and practical issues;

The HTA network rests on the principle that *evidence does not make decisions, people do*. Sound clinical, epidemiological, organisational and economic evidence is a necessary tool in health policy decisions, combined with local, regional and national considerations on resources, societal values, ethics and priorities. The network should enable this kind of action more effectively at the EU level.

Collaboration with important international organisations such as INAHTA, HTAi, Euroscan, Guidelines International Network, Cochrane Collaboration, OECD, WHO, and the Council of Europe would facilitate the functions of the network. Relationships with patient organisations and NGOs should also be encouraged through the network. The role of industry should be considered carefully as it is a major player in the field of HTA as well.

The network would be established in two consecutive phases. In the first three-year phase, the network would be launched by funding from the EU Public Health Programme. During the second phase of the network a financially sustainable solution for running the network should be considered by the Commission and the Member States.

During the third active year of the network, its processes and outcomes should be evaluated to provide a basis for deciding about its future and whether or not it is appropriate to proceed. The deliverables should be evaluated in terms of improved capability in HTA in all participating Member States, organised flow of relevant HTA results/data between the participating Member States and a creation of shared database of quality assured HTAs.

In conclusion, the Working Group on Health Technology Assessment proposes that the European Commission support a pilot project to set up a European HTA Network under an appropriate financing mechanism such as EU Public Health Programme.

### **3.5. Information and e-health (including data protection)**

The working group has a broad mandate to examine information needs for citizens / patients, health professionals and authorities, which arise in the context of increasing cooperation between health systems and by movement of citizens or professionals. eHealth services can provide important possibilities to support mobility.

Mobility policies in Europe make health services relevant to the international market. Furthermore, eHealth services in principle can be offered world-wide via secure Internet-like networks. In this context, it shall be possible, for example, for a doctor to use a patient's electronic health record, if given secure access to it -

perhaps using his / her electronic health card or an electronic passport. This, however may only be realised under conditions of interoperability.

The working group noted that a lack of standards and other issues of interoperability as well as concerns regarding security and privacy are hampering the development of European-wide eHealth services. There is a need for appropriate measures at the highest level to overcome the existing barriers.

European cooperation in eHealth brings added value to national health systems, improves quality of care and citizen oriented services.

The WG will address the need for an overall health systems information strategy in a European context. In addition to this, the working group shall review ongoing activities of relevance and comprise a continuous review mechanism for the eHealth action plan implementation process, taking into account national roadmaps and priorities.

*Interoperability - both at national and at European level - is the corner stone to support patient centred care and mobility of citizens.* The WG has set as first priority to focus on eHealth for the initial phase.

#### *3.5.1. Issues addressed by the working group*

This working group<sup>5</sup> has looked at the following issues.

First, developing an overall **health systems information strategy in a European context**, considering mobility of citizens and availability of Europe-wide or cross-border eHealth services, including the following issues:

- Information for citizens / patients,
- Information for health administrations / authorities,
- Information for healthcare professionals, considering new working methods, training and educational aspects,
- Data “following” the patient to optimize reimbursement processes, provision, treatment and care,

taking into account acceptance of new eHealth services by citizens and security / data protection issues.

Second, **reviewing current work** to identify issues, priorities and potential support mechanisms to establish eHealth services supporting citizens` mobility and define suitable indicators to compare health systems services and to monitor the impact of the EU on health systems.

Third, defining a continuous **review process** of the EC Communication on eHealth (COM(2004)356 final)) “e-Health – making healthcare better for European citizens: **An action plan for a European e-Health Area**” to

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<sup>5</sup> Chaired by Germany, with the participation of AT, CY, CZ, EE, EL, ES, FR, HU, IE, IT, NL, SE, SI.

**implement it**, update it, add flexibility, anchor it on concrete national and cross-border activities, and define further actions especially in support of patient mobility. In connection to this, priority shall be given to appropriate measures, at the highest level, to facilitate agreement on the use of standards for interoperability, building trust in the confidentiality of such services and resolving all other issues of interoperability.

Fourth, **establishing well structured European-wide cooperation** between Member States, EC and stakeholders for the implementation of interoperable eHealth services and necessary electronic secure infrastructures as a permanent mechanism.

The working group has discussed and commented on the Communication on eHealth (COM(2004)356 final). It is of high priority to define further activities for its implementation, including resources, and organizational structures.

### *3.5.2. Contributions expected and relation to other activities*

As a first activity, the WG will identify on going relevant activities and will establish appropriate links in order to import information and results of significance. Examples of such initiatives are the European Health Telematics Association (EHTEL)- , the eTEN project Netc@rds (a pilot for a European Health Insurance Card), other relevant upcoming projects in the eTEN or 6./7. Framework Programme and the announced report of the eHealth Standardization Focus Group, which is hosted by CEN/ISSS and funded by the Commission. Furthermore, coordination of work with organizations receiving and analyzing statistical data on the health systems is needed to avoid duplication of work.

As set out in COM(2004) 301, work is already underway to improve information on patient mobility and mobility of health professionals at European level. This is being taken forward in particular through the health systems working party that has been set up under the first strand of the public health programme.

### *3.5.3. Plans for work in the future*

Priority is given to outline such activities for the implementation of the eHealth Action Plan that need cooperation between the Member States and support by the EC.

The working group will therefore propose an overall health systems information strategy and will outline a work plan for 2005 and the following years, taking into account all other issues such as dealing with the targets of the Public Health Programme. All activities should be based on an overall information strategy and on political targets

Further work in this area should also look at the information which should be available for patients, professionals and policy-makers. Besides this, data for comparison of eHealth services to measure effects of European integration should be defined. Concrete activities – to be coordinated by the WG - will follow.



A challenge will be to set up an appropriate organizational structure and secure the needed financial resources for an effective cooperation of the Member States and the European Commission in pursuit of the above objectives. At the same time, healthcare authorities (supported by the Commission and cooperating with relevant stakeholders) have to take the lead in facilitating the realisation of European-wide or cross-border eHealth services within the framework of a commonly accepted eHealth Action Plan. The High Level Group can play a politically-oriented coordination role in this process.

### **3.6. Health impact assessment and health systems**

The main aim of this working group has been to examine the links between and the different aspects of Health Impact Assessment and Health Systems. The working group was composed of representatives from Portugal (chair), Belgium, Finland, Lithuania and the Netherlands. The group agreed that impacts of EU non-health policies on public health and health systems needs to be tackled as a high priority in the EU.

The European Union's impact on health takes place largely through policy areas other than those specifically related to public health. A coherent approach to evaluate the impact on health of all Community policies is therefore required. The rationale behind addressing and assessing impacts on health in other policy areas is found in the Treaty establishing the European Community. *Article 3 (p)* states that ... 'For the purposes set out in Article 2, the activities of the Community shall include, as provided in the Treaty and in accordance with the timetable set out therein: a contribution to the attainment of a high level of health protection'. Moreover, *Article 152* stipulates that 'A high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities'. Therefore, there is a strong obligation consider possible health implications of measures and actions concerning policies not directly concerning health.

Though 'health status' and 'health systems' are intrinsically linked, it is important to point out that the actual measurement of impacts of policy proposals on health status (Health Impact Assessment) and health systems (Health Systems Impact Assessment) require two different methodologies; mainly due to the fact that the two have different outcomes of interest. The former looks at potential direct effects on health status of the population and its distribution among specific population groups. The latter, examines systemic impacts on organisations (health systems) which in turn may affect the way health care is organised and delivered, and thus, would have impacts on the health status of the population through influencing the ability of health systems to achieve their objectives of improving health.

However, although methodologically different, both aspects should be an integral part of the Health Impact Assessment procedure. Several such instruments do indicate the need to look at the potential effects on health systems, unfortunately without any further assistance as how to actually conduct such an assessment.

With the intention of improving the quality and coherence of the policy development process, the Commission has recently streamlined different impact

assessments into an integrated assessment tool<sup>6</sup>, organized around social, environmental and economic impacts. Public health impacts as well as impacts on health systems are specifically mentioned in the social section of impacts. This impact assessment procedure is applied to all major initiatives, i.e. those presented in the Annual Policy Strategy or later in the Work Programme of the Commission. The new method builds on existing practices and experiences from sectorial tools and the result is a common set of basic questions, minimum analytical standards and common reporting format.

The Commission has been working with other services and experts to improve the understanding about the impact of EU non-health policies and actions on health status, how these impacts can be determined and measured, and how they can be taken into account in policy development<sup>7</sup>. Furthermore, the High Level Committee on Health (HLCH) has worked in a special ad hoc group with an aim to set out a more coherent way for the HLCH to work with Health Impact Assessment in general and Health in Other Policies, in particular<sup>8</sup>. The HLCH has also discussed and collected information about the numerous instruments available for conducting Health Impact Assessment at regional, national and EU level. This work on the impact of non-health EU policies on health status will continue, but is outside the scope of the High Level Group, which focuses in particular on health services and medical care.

Unfortunately, there is no methodology available to prospectively and systematically address the potential impacts on health systems as an effect of EU non-health policies. This is a crucial issue which needs to be addressed if the EU is to develop a coherent policy which considers both the improvement of quality life of the European citizen and the sustainability of the national health systems. Such an instrument would take its starting point around the three broad principles of accessibility of care, high quality and financial sustainability.

Drawing on the expertise of World Health Organisation (*WHO*) in general and the *WHO European Observatory on Health Systems and Policies* in particular as well as the *OECD* would facilitate the development of a framework for estimating impacts of EU non-health policies on health systems. The OECD started the “Health Project” in 2001 which addresses some of the key challenges policy makers face in improving the performance of their countries’ health systems. Moreover, several European Commission funded projects (supported by Eurostat) are investigating different aspects of health systems that could prove useful for the continuation of this working group. For example, two projects are of particular interest: “Development of a methodology for collection and analysis of data on efficiency and effectiveness in health care provision”, and “Defining a minimum data set and related indicators for use with the system of health accounts in the European Union”. In order to get a more in-depth understanding of the issue, it may be

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<sup>6</sup> Communication from the Commission on Impact Assessment COM (2002) 276 final of 5.06.2002

<sup>7</sup> Impact of EU policies and actions ([www.europa.eu.int/comm/health](http://www.europa.eu.int/comm/health))

<sup>8</sup> Report from the HLCH ad hoc group concerning the HLCH’s role in “Health in All Policies”, 21 April 2004

necessary to apply, in addition to traditional data analysis, methods that emphasise legal issues, equity questions and national policy processes.

The next logical steps in this work would be for the Commission to set up an expert group to develop the tools for measurement of impacts of non-health EU policies on health systems. The work could be conducted in collaboration with relevant international organisations. The instrument will be useful in the Commission's Impact Assessment Procedure, specifically for the subsection on impacts on Health Systems. Moreover, the instrument may prove useful in supporting the other working groups of the High Level Group on health care and medical services. As soon as a pilot version of such an instrument has been developed it could be tested on an appropriate EU policy proposal for reliability and validity. After this trial a future network could be considered in order to ensure that experiences are shared between Member States.

### **3.7. Patient safety**

In addition to the six working groups, another area raised within the High Level Group has been that of patient safety. Ensuring the safety of patients has become a high visibility issue for those delivering health care - not just in any single country, but worldwide. Indeed, as people begin to move more freely across borders, they will begin to expect and demand that the care they receive in any country meets increasingly consistent high standards of safety and quality. The United Kingdom circulated a paper (HLG/2004/13) outlining the seriousness of this issue and setting out proposals for taking work forward. This was welcomed by the High Level Group, with Spain, Italy, Ireland, France and Austria in particular interested in taking part in work on this subject. Comments on the paper were also provided by Cyprus.

Health care interventions are intended to benefit patients, but may in some cases cause harm. The complex combination of processes, technologies and human interactions that constitutes the modern health care delivery system can bring significant benefits. However, delivering care also involves an inevitable risk of adverse events that can - and too often do - happen. Research from around the developed world consistently suggests that a considerable percentage - perhaps some 10% - of hospital admissions may involve some kind of patient safety incident. Studies estimate that perhaps half of these errors may be avoidable.

Action to reduce risks to patients can cover any aspect of care - around the organisational factors, the systems and environments that can contribute to errors or to the prevalence of health care acquired infections, or by addressing more specific risks associated with certain treatments, medicines or devices.

Effective reduction of avoidable risks to patients calls for a concerted international effort. In May 2002 the World Health Assembly passed resolution WHA55.18, which urged countries to pay the greatest possible attention to patient safety and requested the Director-General of WHO to carry out a series of actions to promote patient safety. The resolution has ensured that the drive for safer health care is now becoming a worldwide endeavour, bringing significant benefits to patients in countries rich and poor, developed and developing, in all corners of the globe.

Following on from this resolution, the WHO World Alliance for Patient Safety will be launched on 27 October in Washington, presided over by Dr Lee Jong-Wook,

with keynote speeches by Secretary Thompson, Sir Liam Donaldson and others. The fundamental purpose of the Alliance will be to facilitate the development of patient safety policy and practice in all countries. The Alliance will bring together work in systemic and technical issues.

Specific European nations - including UK, Sweden, Denmark, Switzerland, Netherlands, Ireland and the Czech Republic - have established their own patient safety programmes and systems for reporting and learning from patient safety incidents. More generally, in Spring 2005, a Council of Europe Expert Committee will produce recommendations for European action to improve patient safety.

The paper circulated by the United Kingdom invited the High Level Group to consider whether an EU patient safety network or forum would have value, and what form it could take. Such a forum could provide focus for efforts to improve the quality and safety of care for patients in all EU Member States, through:

- sharing information, approaches and experience from individual nations' own patient safety programmes to the benefit of others;
- working with the WHO Alliance to share solutions to known avoidable risks between countries and facilitate the adaptation of solutions to meet the needs of different health care economies - bearing in mind that any such risk is unlikely to be unique to any single nation; and progress and influence the broader global effort to improve the safety of health care systems;
- and considering how work in the EU could draw on the Council of Europe's forthcoming patient safety recommendations.

If this approach is agreed, proposals for an EU patient safety network could be developed during 2005.

### **3.8. Contribution from the High Level Group to other work relevant to health services and medical care**

The High Level Group also provides a means for its members to contribute to other initiatives that are relevant for health services and medical care, whilst respecting the responsibilities of other bodies and institutions. One example is the open method of coordination on healthcare and long-term care, where the High Level Group has already provided comments on the draft Opinion of the Social Protection Committee on applying the open method of coordination to healthcare and long-term care, and will be able to make further input in future as the open method of coordination develops in this area. Another example is dialogue with other Commission services – the directors-general for the internal market and for regional policy have both come to exchange views with the High Level Group to help improve mutual understanding for the future.

It is crucial that the work of the High Level Group takes account of the remit and activities of other groups, including the Council working party on public health.

### **3.9. Other issues**

Other issues that could be taken up in the future but not pursued during this first phase of work include:

- developing a common understanding of the specific characteristics of health systems, as a basis for ensuring that the specificities of health systems are properly taken into account;
- and exchanging information on the needs for investment in health and health infrastructure including examples of current projects in order to generate a better understanding of possible initiatives for national and regional authorities to draw on in setting priorities.

#### **4. ORIENTATIONS FOR FUTURE WORK**

The High Level Group has made a good start in developing concrete, practical cooperation between Member States. The work underway marks the first steps in implementing the recommendations of the patient mobility reflection process and thus to bring tangible results from European cooperation to patients and to health systems as a whole.

Developing this cooperation will require several years of work and significant investment of time and resources, both within the Member States and at European level. It is therefore important to ensure that this work reflects the political priorities and orientations of health ministers from the start, and this report provides an opportunity to ensure that this is the case. The Council will of course also be kept informed of the progress of the High Level Group during 2005 and thereafter in order to provide any necessary political guidance.

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