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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

on telemedicine for the benefit of patients, healthcare systems and society

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1. INTRODUCTION

Telemedicine - the provision of healthcare services at a distance - can help improve the lives of European citizens, both patients and health professionals, while tackling the challenges to healthcare systems.

European citizens are getting older and are increasingly living with chronic diseases. Their health condition often requires enhanced medical attention. Medical support may not be available in remote areas and for certain specialities as easily or as frequently as their health condition would require.

Telemedicine can improve access to specialised care in areas suffering from a shortage of expertise, or in areas where access to healthcare is difficult. Telemonitoring can improve the quality of life of chronically ill patients and reduce hospital stays. Services such as teleradiology and teleconsultation can help to shorten waiting lists, optimise the use of resources and enable productivity gains.

The benefits go beyond improving patient care and healthcare system efficiency. Telemedicine can also make a significant contribution to the EU economy. This sector, where European industry - including thousands of small and medium-sized enterprises (SMEs) - is well placed, has been expanding rapidly in the past decade and is expected to continue to grow at a fast pace.

Despite the potential of telemedicine, its benefits and the technical maturity of the applications, the use of telemedicine services is still limited, and the market remains highly fragmented. Although Member States have expressed their commitment to wider deployment of telemedicine, most telemedicine initiatives are no more than one-off, small-scale projects that are not integrated into healthcare systems.

It is recognised that integrating these new types of services in healthcare systems is a challenging task. The aim of this Communication is to support and encourage Member States in this endeavour, by identifying and helping to address the main barriers hindering the wider use of telemedicine and by providing evidence to build trust and acceptance. The Communication defines a set of actions to be taken by Member States, the Commission and the broader stakeholders' community. It focuses in particular on:

- Building confidence in and acceptance of telemedicine services
- Bringing legal clarity
- Solving technical issues and facilitating market development

Regardless of the efforts in which the Commission and other stakeholders are willing to engage, it is the Member States' health authorities, primarily responsible for the organisation, financing and delivery of healthcare, that remain the principal actors with the ability to make telemedicine a reality in the life of European patients - in full respect of the subsidiarity principle.

The proposed actions build on the ongoing collaboration between Member States and the Commission as part of a number of Commission policy initiatives^{1,2}, in particular the recently adopted Renewed social agenda³. It is also in line with the resolution of the European Parliament⁴ acknowledging the importance of telemedicine. It builds on the extensive consultation conducted between September 2007 and June 2008, involving Member States and the main stakeholder groups: health professionals, patients and industry representatives. On privacy and data security issues the European Data Protection Supervisor has been consulted.

The European Commission, having recognised the potential of Information and Communication Technology (ICT) applications for Health (eHealth), and telemedicine in particular, has been funding research and development in this area for twenty years. In its Health Strategy⁵ and eHealth Action Plan⁶, the European Commission has further committed itself to supporting dynamic health systems and the beneficial use of new technologies. This commitment also led to external action through the European Commission's support to the use of telemedicine in developing countries.

2. TELEMEDICINE – DEFINITION AND EXAMPLES

Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.

Telemedicine encompasses a wide variety of services. Those most often mentioned in peer-reviews are teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology. Other potential services include call centres/online information centres for patients, remote consultation/e-visits or videoconferences between health professionals.

Health information portals, electronic health record systems⁷, electronic transmission of prescriptions or referrals (e-prescription, e-referrals) are not regarded as telemedicine services for the purpose of this Communication.

¹ COM(2005) 229 final, 1.06.2005

² COM(2007) 860 final, 21.12.2007

³ COM(2008) 412 final, 2.07.2008

⁴ European Parliament resolution 2006/2275(INI) of 23 May 2007

⁵ COM(2007) 630 final, 23.10.2007

⁶ COM(2004) 356 final, 30.4.2004

⁷ The issue of electronic health records has been addressed in a recent Commission Recommendation: C(2008) 3282 final, 2.07.2008

In the following section, telemonitoring and teleradiology services are outlined in more detail as together they encompass most of the challenges that are relevant to the implementation of telemedicine services in general.

2.1. Telemonitoring: a major opportunity for chronic disease management

Telemonitoring is a telemedicine service aimed at monitoring the health status of patients at a distance⁸. Data can be collected either automatically through personal health monitoring devices⁹ or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool). Data, once processed and shared with relevant health professionals, may be used to optimise the patient's monitoring and treatment protocols.

Telemonitoring is particularly useful in the case of individuals with chronic illnesses (such as diabetes or chronic heart failure – see also box below). Many of these patients - who are often elderly people - need regular monitoring because of the prolonged duration of their disease, the nature of their health condition and the drugs that they are using.

Telemonitoring supports patients and health professionals. Its use can allow symptoms and abnormal health parameters to be detected earlier than during a routine or emergency consultation, and corrective measures thus to be taken before more serious complications appear. It may also result in less frequent visits to healthcare facilities, thereby increasing the quality of life for patients.

Telemonitoring has been chosen as an example for its specific characteristics:

- It can contribute to re-organisation and re-deployment of healthcare resources, for instance by reducing hospital visits, thus contributing to the greater efficiency of healthcare systems.
- It has proven to increase quality of care for patients, in particular chronically ill patients. In the context of an ageing population and an increasing burden of chronic diseases, the benefits its wider deployment can provide are crucial.
- It requires a coherent approach and partnership involving patients, health professionals, healthcare providers, payers and the industry, to ensure sustainability of the services.

Investment from industry in the development of telemonitoring services has been significant, resulting in technically mature applications. Patients' compliance is high and some healthcare authorities have already acknowledged the need for these services. Yet, most telemonitoring services are still limited to the status of temporary projects without clear prospects for wider use and proper integration into healthcare systems. Commitment by healthcare providers and concerted action between all stakeholders are needed in order to ensure wider deployment of these types of services throughout the EU.

⁸ Paré G et al. . Systematic review of home telemonitoring for chronic diseases: the evidence base. J AM Med Inform Assoc. 2007;14:269-277.

⁹ Electronic devices, which might be portable, wearable or implantable collect data on specific health parameters

The example of chronic heart failure and the use of telemonitoring

Over six million people in Europe suffer from chronic heart failure. The burden on patients' quality of life and mortality and on healthcare systems' costs is considerable¹⁰.

Telemonitoring services for patients with chronic heart disease enable closer monitoring of their disease and contribute to treatment at the earliest possible stage. Dyspnoea (difficulty in breathing) and/or rapid increase in weight, which are key parameters to monitor on a daily basis, often signify aggravation of the disease. Early modification of treatment based on the monitoring data may stabilise the condition, make consultations unnecessary and avoid or shorten hospital stays.

Two review papers systematically analysed scientific publications issued respectively between 1966 and 1993¹¹ and between 1966 and 2006¹² on telemonitoring of chronic heart failure. The studies concluded, on the basis of available data, that telemonitoring might be an effective strategy for disease management, especially in high-risk heart failure patients. Both articles noted also that the evidence base for telemonitoring in heart failure is still very limited and that cost-effectiveness, scalability, safety and acceptability to patients need to be further assessed.

2.2. Teleradiology: a way to optimise management of scarce resources

Teleradiology is a telemedicine service which involves the electronic transmission of radiographic images from one geographical location to another for the purposes of interpretation and consultation¹³.

Teleradiology has developed alongside the gradual shift in medical imaging from film-based to digital-based technologies. Well structured professional organisations and early establishment of standards have supported this development.

Teleradiology can help healthcare facilities to cope with peak workloads, ensure round-the-clock services, reduce waiting lists for specific examinations and, above all, cut costs.

Teleradiology has been chosen as an example for its specific features:

- It is currently the telemedicine service in the most advanced stage of deployment.
- It is usually carried out as an outsourced service, on a commercial contract basis.
- The service can be offered in a national or cross-border mode involving other EU countries or third countries.

The most important challenge for teleradiology is to ensure that it develops in a manner that benefits patient care and ensures overall patient safety, and does not in any way reduce the quality of radiology services provided to the citizen. Therefore, urgent action needs to be taken to obtain legal clarity, including assurance of high quality in patient care.

¹⁰ McMurray et al. The burden of heart failure. Eur Heart J Suppl 4 (2002): D50-D58.

¹¹ Louis AA et al. A systematic review of telemonitoring for the management of heart failure. Eur J Heart Fail. 2003 Oct;5(5):583-90.

¹² Chaudhry SI et al. Telemonitoring for patients with chronic heart failure: a systematic review. J Card Fail. 2007 Feb;13(1):56-62.

¹³ European Society of Radiology, Nov. 2006.

3. TELEMEDICINE: MAKING IT HAPPEN!

In the eHealth High Level Conference Declaration of May 2008¹⁴, Member States' representatives acknowledged the urgency of ensuring wider deployment of telemedicine services and innovative ICT tools for chronic disease management.

The aim of this Communication is to support Members States in achieving large-scale and beneficial deployment of telemedicine services, by focusing on three strategic sets of actions:

- (1) Building confidence in and acceptance of telemedicine services
- (2) Bringing legal clarity
- (3) Solving technical issues and facilitating market development.

These different sets of actions are partially interlinked. Building acceptance among health professionals, for instance, is closely related to the existence of a coherent legal framework for carrying out specific telemedicine services, such as teleradiology.

3.1. Building confidence in and acceptance of telemedicine services

There is limited evidence of the effectiveness and cost-effectiveness of telemedicine services on a large scale. Awareness, confidence and acceptance by health authorities, professionals and patients still need to be strengthened.

- (a) *Scientific evidence of effectiveness and cost-efficiency in a large-scale setting*

Various studies have demonstrated benefits on a small scale for patients and healthcare systems. Commonly accepted methodologies for assessing effectiveness, such as those used to assess pharmaceutical products, must be further developed.

It can be difficult to put a precise monetary value on the factors that are contributing to gains in effectiveness and cost savings, such as: fewer adverse health events; fewer prescriptions; more time spent at work or better quality of life of patients. Savings on health costs may occur in a sector other than the sector where the investments have been made. For instance, investment in telemonitoring for chronic heart failure patients in the primary care sector may result in savings in hospitals through fewer or shorter hospital stays. The benefits of action, as well as the full consequences of inaction, can sometimes only be observed over long periods of time and in a broad context.

To obtain sustained, large-scale telemedicine programmes, it will be essential for the cost of these services to be reimbursed. However, the readiness of health authorities' to reimburse certain types of these services, in particular telemonitoring, will very much depend on the outcomes of effectiveness and cost-effectiveness studies.

¹⁴ www.ehealth2008.si/

Actions

- The Commission will support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness. This will be based on the work of experts in the field, Commission-supported studies, large-scale pilot schemes and relevant research projects.

Telemedicine industry players, in particular SMEs, do not have the financial capacity to engage alone in large-scale telemonitoring trials as do pharmaceutical companies. Stronger intervention by the public sector, fully respecting the Community law on state aid and public procurement, seems to be necessary. Public-private partnerships can also be an instrument for the deployment of large-scale telemonitoring projects.

Actions

- In 2010, the Commission, via its Competitiveness and Innovation Programme, will support a large-scale telemonitoring pilot project. This will include a network of procurers and payers of healthcare services.

(b) *Confidence and acceptance of telemedicine solutions by health professionals, patients and health authorities*

Healthcare systems focus on meeting the needs of patients. Achieving telemedicine's potential, therefore, depends on patients being convinced of its ability to satisfy their healthcare needs. Acceptance by patients depends crucially on acceptance by the health professionals treating them, given the high degree of trust the former place in the latter.

An important factor for ensuring the confidence and acceptance of health professionals is enhanced dissemination of the evidence base regarding the effectiveness of telemedicine services, their safety features and user-friendliness.

For both health professionals and patients, adequate needs assessment and training actions will play an important role in ensuring that the necessary skills and familiarity with the tools are present, as well as a fair understanding of the context of interaction in which they are operated.

Member States are responsible for the organisation, provision and funding of national healthcare. The leadership of their health authorities in achieving wider deployment of telemedicine is essential. Collecting evidence and sharing good practice on implementation of telemedicine services and reimbursement schemes are therefore critical in order to secure the necessary acceptance and commitment on the part of the health authorities.

The wider deployment of telemedicine, and telemonitoring in particular, raises new ethical concerns, in particular because of the way in which the patient-doctor relationship is affected. Health professionals and patient organisations have signalled their intention to work on European-wide guidelines to address these issues. The Commission will welcome any initiative in this area driven by users' needs and aimed at enhancing trust and acceptance of telemedicine among patients and health professionals in the best interests of safety and care.

Privacy and security related aspects are also major components of building trust and confidence in telemedicine systems. The respect of rights and fundamental freedoms, like the

fundamental rights to private life and to the protection of personal data, must be guaranteed during the collection and processing of personal data, in particular when relating to health. As any other transmission of personal health-related data, telemedicine can pose a risk to data protection right (in the sense that disclosure of a medical condition or diagnosis could adversely affect an individual's personal and professional life). Data privacy aspects should be systematically assessed whenever telemedicine services are provided. In all cases it is essential that the Member States' and Community provisions on the protection of personal data are complied with.

Actions

- The Commission will continue to contribute to European collaboration between health professionals and patients in key areas with the potential for greater application of telemedicine, in order to make specific recommendations on how to improve confidence in and acceptance of telemedicine, also taking into account ethical and privacy related aspects.
- Member States are urged to assess their needs and priorities in telemedicine by the end of 2009. These priorities should form part of the national health strategies to be presented and discussed at the 2010 eHealth Ministerial Conference.
- The Commission will support the collection of good practice on deployment of telemedicine services in the different Member States.

3.2. Bringing legal clarity

Although telemedicine may be an interesting option for many healthcare facilities, the lack of legal clarity has been repeatedly mentioned in the stakeholders' consultation as an obstacle to its wider use.

The paramount objective in providing legal clarity in this area is to guarantee that telemedicine develops in such a manner that it benefits patient care while ensuring privacy and the highest standards of patient safety.

The lack of legal clarity – in particular with regard to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, jurisdiction – is a major challenge for telemedicine and, in particular, for teleradiology. Cross border provision of telemedicine services also require legal clarification with regard to privacy.

Only a few Member States have clear legal frameworks enabling telemedicine. In some Member States, for a medical act to be legally recognized as such, the physical presence of the patient and the health professional in the same place, is required; this is a clear obstacle to the use of telemedicine. Moreover, there are often limitations in law or administrative practice on reimbursement of telemedicine services.

Respecting the principle of subsidiarity, these issues (of regulation of health services and professions and of reimbursement) are primarily of Member State responsibility, and thus require action at their level. However, given the complexity of these issues and their inter-relationship with aspects of Community law, Member States can be supported by action at Community level, such as sharing of good practices in order to improve legal and administrative frameworks.

Actions

- In 2009, the Commission will establish a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations.
- In 2009, the Commission, in cooperation with Member States, will publish an analysis of the Community legal framework applicable to telemedicine services.
- By the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should be addressed.

The box below provides an overview of the main existing EU legislation applicable to telemedicine services.

Applicability of EU legislation to telemedicine services

Telemedicine is both a health service and an information society service¹⁵. As such, it falls under the EC Treaty (Article 49) and existing EU secondary legislation, in particular Directive 2000/31/EC, referred to hereinafter as the “e-Commerce Directive”.

The European Court of Justice has stated that neither the special nature of health services nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement¹⁶. This includes the freedom for recipients of the healthcare service to seek and receive medical treatment from another Member State, regardless of how the service is delivered, i.e. also by telemedicine.

Directive 98/34/EC as amended by Directive 98/48/EC establishes a procedure which imposes an obligation on Member States to notify the Commission and each other of all draft technical regulations concerning products and Information Society Services¹⁷, including telemedicine, before they are adopted in national law.

The e-Commerce Directive defines rules for the provision of Information Society Services both within and between Member States. It also applies to telemedicine. For business-to-business (professional-to-professional) telemedicine services, such as teleradiology, the country of origin principle applies: the service offered by the professional must comply with the rules of the Member State of establishment. In the case of business-to-consumer activities (which might be relevant to telemonitoring services) the contractual obligations are exempted from the country of origin principle: the service might need to comply with the rules of the recipient’s country.

Definition of medical acts is a matter for the Member States. As a general principle, the classification of specific telemedicine services as medical acts should ensure that these meet the same level of requirements as equivalent non-telemedicine services (e.g. teleradiology vs.

¹⁵ As defined by Directive 98/34/EC.

¹⁶ See notably *Müller and Van Riet* (case C-385/99) [2003]; *Smits and Peerbooms* (case C-157/99) [2001]; *Watts* (case C-372/04) [2006].

¹⁷ Provided that they are not covered by one the exceptions laid down by Directive 98/34/EC as amended by Directive 98/48/EC.

radiology)). This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services and it avoids discrimination between providers of the same service which would be incompatible with the e-Commerce Directive.

Directive 95/46/EC, on the processing of personal data and the protection of privacy, specifies a number of additional requirements relating to confidentiality and security which telemedicine and all other interactive on-line services have to meet in order to safeguard individuals' rights.

Directive 2002/58/EC, concerning the processing of personal data and the protection of privacy in the electronic communications sector, lays down specific requirements on providers of electronic communications services over public communications networks to ensure confidentiality of communications and security of their networks.

Directive 2005/36/EC establishes the criteria for a set of regulated professions according to which qualifications obtained in one Member State are recognised by another. The recognition of professional qualifications by the host Member State allows the beneficiary to gain access in that Member State to the same profession as that for which he is qualified in the home Member State and to pursue it in the host Member State under the same conditions as its nationals.

Telemedicine is also recognised in the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare¹⁸, which addresses patients' cross border mobility including their ability to access to services across borders. This proposal is without prejudice to the abovementioned Directives, notably the e-Commerce Directive and Directive 2005/36/EC. If adopted, the Directive would require the Commission to take measures ensuring the interoperability of means for the provision of e-health services, including telemedicine (Article 16)¹⁹.

3.3. Solving technical issues and facilitating market development

Although some telemedicine services have existed for a long time and most of the ICT has been in place for a while, there are still areas where technical issues need to be addressed.

Broadband access and the ability of providers to enable full connectivity is a prerequisite for the deployment of telemedicine. With broadband for all, telemedicine can eventually become a public good, accessible to all. Connectivity with all geographical areas in the EU, including rural and ultra-peripheral regions, is a precondition for telemedicine deployment and for universal access of all individuals to healthcare. The EU's cohesion policy supports both the broadband accessibility and the development of content, services and applications for citizens²⁰.

Interoperability and standardisation in telemonitoring are crucial to allow widespread use of the technologies, to enable them to benefit from the single market²¹ and to contribute to its completion. Use of existing standards and adoption of new standards and standardised approaches to achieve interoperability should be supported by standards development

¹⁸ COM (2008) 414 final, 2.7.2008

¹⁹ As stipulated in the proposal in its articles 3,5 and 11

²⁰ Regulation (EC) No 1080/2006 of 5 July 2006

²¹ Health Information Network Europe (HINE), 2006 - European eHealth forecast (report)

organisations, with the active participation of industry. Coordinated community action is necessary, and indeed has been explicitly called for in the proposal for a Directive on patients' rights in cross-border healthcare.

Trust and confidence in new and innovative technologies and ICT-based services within the health sector need to be built through rigorous testing, agreed standards and a widely accepted certification process. This applies particularly to telemonitoring devices. To avoid market fragmentation, concerted action is needed at EU level to agree on a common set of specifications for these telemedicine systems and services. Such concerted action could bring together the necessary expertise and knowledge to ensure that good quality and safe and secure telemedicine services, which are not covered by existing legislation, are available throughout the EU.

Actions

- By the end of 2010, the Commission invites industry and international standardisation bodies to issue a proposal on the interoperability of telemonitoring systems, including both existing and new standards.
- By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level.

4. CONCLUSIONS

The societal and economic benefits from wider use of telemedicine are potentially huge. Yet, at the present moment, they are far from being fully appreciated or achieved.

Now is the time for telemedicine to enhance patients' lives and to offer new tools to health professionals. Telemedicine can help addressing the major challenges to healthcare systems and offer major opportunities for the European industry.

The Commission will give its full support to ideas and initiatives to turn this goal into a reality and is ready to work with Member States and all stakeholders to achieve this objective. It proposes a concrete set of actions for this specific area. Other issues not specifically targeted in this communication, such as the availability of broadband for all and consistent attention to the implementation of measures aimed at ensuring respect for the right to protection of personal data, are also instrumental in the full beneficial deployment of telemedicine.

However, the onus for making this initiative a success rests mainly with Member States. It is they who bear the responsibility for the organisation, provision and funding of their healthcare systems. Telemedicine will only realise its full potential if Member States engage actively in integrating it into their health systems.

ANNEX

THREE LEVELS OF ACTIONS FOR THE YEARS AHEAD

Actions at the level of Member States

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| (1) | Member States are urged to assess their needs and priorities in telemedicine by the end of 2009. These priorities should form part of the national health strategies to be presented and discussed at the 2010 eHealth Ministerial Conference. |
| (2) | By the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should be addressed. |

Member States' actions to be supported at EU level

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| (3) | In 2009, the Commission will establish a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations. |
| (4) | In 2009, the Commission, in cooperation with Member States, will publish an analysis of the Community legal framework applicable to telemedicine services. |
| (5) | By the end of 2010, the Commission invites industry and international standardisation bodies to issue a proposal on the interoperability of telemonitoring systems, including both existing and new standards. |
| (6) | By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level. |

Actions to be undertaken by the Commission

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| (7) | In 2010, the Commission, via its Competitiveness and Innovation Programme, will support a large-scale telemonitoring pilot project. This will include a network of procurers and payers of healthcare services. |
| (8) | The Commission will support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness. This will be based on the work of experts in the field, Commission-supported studies, large-scale pilot schemes and relevant research projects. |
| (9) | The Commission will continue to contribute to European collaboration between health professionals and patients in key areas with the potential for greater application of telemedicine, in order to make specific recommendations on how to improve confidence in and acceptance of telemedicine, also taking into account ethical and privacy related aspects. |

(10) The Commission will support the collection of good practice on deployment of telemedicine services in the different Member States.