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Telemedicine for the benefit of patients, healthcare systems and society

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EXECUTIVE SUMMARY

This staff working paper aims to provide additional information supporting the Commission communication “Telemedicine for the benefit of patients, healthcare systems and society”¹, which was adopted on 4 November 2008 and will be referred to hereafter as the “telemedicine communication”.

The telemedicine communication proposed a set of actions aimed at enabling wider deployment of telemedicine services, focusing on three main priorities: building confidence and acceptance of telemedicine services, bringing legal clarity, and facilitating market development.

The staff working paper expands on certain aspects of the communication, such as the outcome of the extensive consultation phase that was undertaken in preparation for the initiative, the policy context and the legal aspects. It also illustrates with concrete examples how wider deployment of telemedicine can affect individual patients, healthcare systems and society.

The general context which gave rise to the telemedicine communication and this staff working paper is that European healthcare systems are under increasing pressure from societal challenges and that the European economy is at a critical point in delivering growth and jobs to European citizens. Innovative approaches are needed to help address these major challenges.

Telemedicine, the delivery of healthcare services at a distance using Information and Communication Technologies (ICT), can help to address some of these challenges, providing benefits for individual patients, healthcare systems and society, including the European economy.

Member States have long realised the potential of telemedicine and are supportive of its beneficial deployment. However, despite this support and the considerable level of technical maturity of different technologies, the sector is not as well developed as could be expected. The telemedicine communication together with this staff working paper aim to help Member States make wider use of telemedicine and reap the benefits therefrom.

¹ Commission communication “Telemedicine for the benefit of patients, healthcare systems and society”, COM(2008) 689 final, 4.11.2008.

1. TELEMEDICINE AND ITS POTENTIAL TO CONTRIBUTE TO HEALTH AND SOCIETY

European healthcare systems are under increasing pressure from societal challenges, in particular as a result of the following issues: changing demographics combined with growing prevalence of chronic diseases, shortages in human resources in healthcare and increased demands from patients for more quality in provision of healthcare services. Within this challenging context, healthcare costs are increasing rapidly, posing fundamental questions on how to achieve sustainable and equitable healthcare systems in Europe.

There is evidence that, when combined with proper organisation, leadership and skills, telemedicine and innovative Information and Communication Technologies (ICT) can help to address some of the societal challenges to Europe's healthcare systems. Its benefits range over different levels, from individual patients **(a)**, through healthcare systems as a whole **(b)** to the wider European economy **(c)**. Member States have long realised the potential of telemedicine and are supportive of its beneficial deployment. Annex 1 provides additional information on the terms used in this paper.

(a) At the level of the **individual**, telemedicine can support improvements in a patient's health and quality of life, particularly for those with chronic diseases, by enabling safer monitoring at home and reducing the number of hospital visits. For example, a review of 14 random controlled trials involving 4 264 patients showed that remote monitoring programmes reduced rates of admission to hospital for chronic heart failure by 21% and all causes of mortality by 20%².

Example — Telemedicine supports patients on oral anticoagulation therapy (blood-thinning drugs) by enabling self-management³

A clinical study has shown that telemedicine can be effectively used to support patients in the self-management of oral anticoagulation therapy. The study was conducted by the Institute for Applied Telemedicine at the Bad Oeynhausen Heart and Diabetes Centre in Düsseldorf. It involved 1 300 patients and showed that one year of telemonitoring led to encouraging results including increased patient self-confidence.

This study showed how, for patients under long-term oral anticoagulation therapy, telemonitoring of blood coagulation measurements done at home and sent to their physicians allowed the patients to become active in their disease management. In this particular case telemedicine was used as a means to train patients effectively on how to cope with their disease and treatment, to get medical feedback when needed and eventually to monitor their health condition autonomously in a safer way.

Another key advantage of telemedicine is that patients can remain in their familiar environment and community networks, thus minimising the social disruption they may suffer in addition to the impairment of their health. For example, in Scotland it has been estimated that between 2006 and 2008 the Telecare Development Programme made it possible to

² Clark et al. Telemonitoring or structured telephone support programmes for patients with chronic heart failure; systematic review and meta-analysis, *BMJ* 2007;334, 942-5.

³ Ehealthurope 15 Sept. 2008: Telemedicine supports patients on warfarin. http://www.ehealthurope.net/News/4144/telemedicine_supports_patients_on_warfarin (accessed 20 Oct. 2008).

increase the number of persons able to maintain themselves at home through receipt of a telecare service by 3,800⁴.

(b) For healthcare systems, telemedicine can help to address the shortage of healthcare professionals, particularly in sparsely populated areas (e.g. by providing remote consultations in ophthalmology), and can improve the efficiency, quality and timeliness of healthcare service provision. Cutting waiting lists through teleradiology procedures (within or across national borders) and saving costs by enabling remote checks of implantable cardiac devices are some of the most commonly quoted examples. It has been calculated for instance that by enabling remote checks of cardiac rhythm management devices (commonly called *pacemakers*), the overall savings estimated per patient and per year ranged between €292 in France (a 30% saving)⁵ and €712 in Germany (a 61% saving)⁶.

Example — Teleradiology and cost-effectiveness: two illustrations

German study in neurosurgery⁷

A teleradiology study was carried out in Germany between 1995 and 2000 which included 1 024 neurosurgical cases. The aim was to determine the effectiveness and cost-efficiency of a teleradiology-supported triage mechanism for patients with brain injuries to decide whether to refer them to the neurosurgical centre.

Computed tomography (CT) and magnetic resonance imaging (MRI) scans from seven referral hospitals in southern Germany were read remotely. Retrospective analysis showed that in 67% of cases, admission and therefore transportation of the patients to the neurosurgical centre was not necessary for different reasons (e.g. no surgical intervention was required or no neurosurgical problems were present at all).

If each patient had been transferred, the potential costs for land transportation would have been between €340 and €374 per individual. The total cost of the image transfer system for all eight hospitals was €96 000. This was amortised after 282 teleconsultations, which occurred after 15 months of usage.

A simple teleradiology system in neurosurgery can thus enable rapid and reliable telephone consultations, mainly on patients with trauma, stroke and intracerebral haematoma, to be conducted at low cost.

⁴ “Telecare In Scotland: Embracing The Future, Benchmarking The Present.” Published by the Scottish Government, May, 2008, p. 8.

⁵ Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D, Clementy J, Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients. *Pacing Clin Electrophysiol.* 2005 Jan;28 Suppl 1:S255-9.

⁶ Eisner, C.H. Sommer, P. Piorkowski, C. Taborsky, M. Neuser, H. Bytesnik, J. Geller, J.C. Kottkamp, H. Wiesmeth, H. Hindricks, G. A Prospective Multicenter Comparison Trial of Home Monitoring against Regular Follow-up in MADIT II Patients: Additional Visits and Cost Impact. *Proceedings of the Computers in Cardiology Congress.* Valencia, 2006;33:241–244.

⁷ Kreutzer J et al. Teleradiology in neurosurgery: experience in 1024 cases. *J Telemed Telecare.*2008;14(2):67-70.

French cost-minimisation study on an inter-hospital teleradiology network⁸

A cost-minimisation study carried out on an inter-hospital teleradiology network in the Aquitaine area (France) established a comparison between the care procedures followed using the network and those which would have been implemented without the network. The outcome measures of effectiveness were the transfers, hospitalisations and consultations avoided or added. Fixed and variable costs were estimated.

Of the 664 transfers included in the study, 562 (85%) were made in an emergency and 102 (15%) were for elective (non-emergency) cases. In emergencies, 48% of transfers were avoided. In the case of elective teleconsultations, transfers were avoided for 37% of the patients and hospitalisation for 12%. Extra consultation occurred after remote consultation for 2% of the patients. Annual savings in the Aquitaine region were estimated at €102 779.

This study underlined the efficiency of an inter-hospital teleradiology network.

Savings may also be generated by shorter hospital stays and lower hospital admissions. For example, based on its preliminary results, the Scottish Telecare Development Programme is expected to generate core efficiency savings: *“over the period 2007-2010, at a minimum of: 46,500 hospital bed days saved by facilitating speedier hospital discharge; 225,000 care home bed days saved by delaying the requirement for people to enter care homes; 46,000 nights of sleepover care and 905,000 home check visits saved by substitution of remote monitoring arrangements. Collectively, these savings are valued at around £43 million - an anticipated benefit to programme funding cost ratio of 5:1.”*⁹

(c) Last but not least, telemedicine also has the potential to contribute to the growth of the **European economy**. Telemedicine is a global market that is expanding rapidly and is expected to continue enjoying high growth rates in the years ahead. European industry, which includes numerous SMEs in this sector, is in a good position to benefit from this expanding market.

It should also be noted that wider deployment of telemedicine, in particular of telemonitoring solutions, has the potential to contribute to a paradigm shift in the way healthcare is delivered. ICT solutions can enable people to monitor their health status and conditions, and communicate the relevant data to their health professionals. Early adaptation of treatment based on monitoring data may stabilise a given health condition and avoid acute adverse events. Eventually, these innovations will help to shift from the current reactive and acute care-centred healthcare model to a more proactive, preventive and personalised one.

Example — The market potential for telemedicine

The global market for eHealth is estimated to have a potential value of €60 billion, of which Europe represents one third, i.e. €20 billion. eHealth can be considered the third largest health industry, after pharmaceuticals and medical devices. The European pharmaceutical market is

⁸ Daucourt V, Sicotte C, Pelletier-Fleury N, Petitjean ME, Chateil JF, Michel P. Cost-minimisation analysis of a wide-area teleradiology network in a French region. *Int J Qual Health Care*. 2006 Aug;18(4):287-93.

⁹ “Telecare in Scotland: Embracing the Future, Benchmarking the Present.” Published by the Scottish Government, May, 2008, p. 9.

valued at €205 billion based on retail prices¹⁰, while the figure for annual sales of the European medical technology sector is €64 billion — equal to 33% of the world market share¹¹.

The market potential for telemedicine in Europe is an important part of the overall eHealth sector, and there are various examples of optimistic estimates of market growth. In a recent report it was estimated that the telemedicine sector worldwide in 2007 was worth around \$5.8 billion, with the potential to grow by almost 20% annually over the next four years¹².

Supporting telemedicine will benefit eHealth market growth in general, since telemedicine services can be linked to numerous other services such as electronic health records and personal health systems. Finally, it can also be an additional incentive for Member States to accelerate the roll-out of broadband, which is a prerequisite for well-functioning telemedicine.

2. POLICY CONTEXT

Recognising the importance of this sector and the benefits it could provide, Member States, regional and local authorities, payers of healthcare services, industry and the European Commission have been supporting research in the field of telemedicine for over 20 years¹³. However, despite the considerable level of technical maturity of different technologies, the sector is not as well developed as could be expected.

Several recent Community policy initiatives provide the basis for the telemedicine communication.

The recently approved Commission communication “Renewed social agenda: Opportunities, access and solidarity in 21st century Europe”¹⁴ prioritises the need to foster “more and better jobs for individuals throughout their lives” as well as “helping citizens to enjoy longer, healthier lives in Europe’s ageing society”. The telemedicine communication sets out a strategy to meet these objectives using ICT and telemedicine in particular.

In 2004, the Commission adopted the communication “eHealth — making healthcare better for European citizens: An action plan for a European eHealth Area”¹⁵ (known as the *eHealth action plan*), which invited Member States to adopt pilot actions to accelerate the beneficial implementation of eHealth. An explicit deadline was agreed: “By the end of 2008, the majority of European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), ... telemonitoring and telecare”. The regular dialogue with Member States, held under the i2010 sub-group on eHealth, demonstrates that this objective is far from being met.

¹⁰ The Pharmaceutical Industry in Figures, report 2008 by the European Federation of Pharmaceutical Industries and Associations (EFPIA). <http://www.efpia.eu/content/default.asp?PageID=559&DocID=4883> (document accessed on the EFPIA website, consulted 31 Oct. 2008).

¹¹ Based on figures from Eucomed, the organisation representing the medical technology industry in Europe. <http://www.eucomed.org/abouttheindustry.aspx> (webpage accessed 31 Oct. 2008).

¹² BCC report. <http://www.bccresearch.com/report/HLC014C.html> (webpage accessed 31 Oct. 2008).

¹³ 5th, 6th and 7th Research and Development Framework Programmes.

¹⁴ COM(2008) 412 final, 2.7.2008.

¹⁵ COM(2004) 356 final, 30.4.2004.

The 2008 eHealth High Level Conference Declaration¹⁶ explicitly underlined the urgency of ensuring wider deployment of ICT solutions and in particular telemedicine services to meet the challenges healthcare systems are facing.

With the objective of supporting Member States in deploying interoperable Electronic Health Records Systems, the Commission has adopted a Recommendation on the subject¹⁷. This is an important supporting instrument which provides a set of guidelines and processes to be followed by individual Member States to ensure a minimum level of interoperability in EHR systems (see Annex 1(d)) and communication with fellow Member States.

In its White Paper “Together for health: a Strategic Approach for the EU 2008-2013”¹⁸, the Commission proposed a strategic approach to “support dynamic health systems and new technologies”.

Within the overall goals of the Lisbon Strategy, the strategic i2010 initiative — a European initiative for growth and employment — builds on ICT policies, regulation, research and innovation. The key priorities of this policy are promoting a supportive and competitive environment for electronic communications and media services, reinforcing research and innovation in ICT and ensuring that an inclusive information society has benefits for all. The recent mid-term review of the i2010 initiative¹⁹ identified eHealth as “a good example of how ICT innovation can serve overarching European policy goals”. Among the actions listed is the implementation of the Lead Market initiative in eHealth.

The report “Creating an Innovative Europe”²⁰ (known as the *Aho Report*) identified the eHealth market as a market with high societal and economic value, and major potential for growth. In response to the Aho Report, the Commission launched the communication “Lead Market Initiative for Europe”²¹, identifying barriers to be addressed to realise the potential that the market can offer. The roadmap²² associated with that communication underlined inter alia telemedicine, and in particular “ICT tools for chronic disease management”, as an area of eHealth in which action is needed and progress can be achieved.

Finally, since 2006, as part of the effort of the EU to strengthen health systems in developing countries and provide support for tackling such challenges as the critical shortage of health workers there, the European Commission has been supporting the creation of the Telemedicine Task Force. This taskforce brings together the African Union, the African Development Bank, WHO and the European Space Agency to identify opportunities for strengthening and further development of telemedicine services in Sub-Saharan Africa.

¹⁶ The Declaration was approved by the heads of delegations of the 27 EU Member States on 7 May 2008 in Portorož, http://ec.europa.eu/information_society/activities/health/policy/ehealth_conf/index_en.htm.

¹⁷ COM(2008) 3282 final, 2.7.2008.

¹⁸ COM(2007) 630 final, 23.10.2007.

¹⁹ Commission communication “Preparing Europe’s digital future: i2010 Mid-Term Review”, COM(2008) 119 final.

²⁰ Report of the Independent Expert Group on R&D and Innovation appointed following the Hampton Court Summit and chaired by Mr Esko Aho, January 2006.

²¹ COM(2007) 860 final, 21.12.2007.

²² “Accelerating the Development of the eHealth market in Europe”, eHealth task force report, European Communities, 2007.

In the context of the above policy initiatives, the telemedicine communication specifically targeting support for telemedicine deployment is consistent with the overall policy framework and is a natural follow-up to those initiatives.

3. CONSULTATION OF INTERESTED PARTIES

The telemedicine communication is based on the outcome of a consultation process that took place from September 2007 to June 2008 and involved Member States' representatives and key stakeholders. The consultation focused on the main challenges and opportunities presented by telemedicine, and the reasons why Europe has not yet achieved wider deployment of telemedicine solutions, and it aimed to assess whether specific actions are required to address the situation. The European Data Protection Supervisor was formally consulted and his recommendations were taken on board.

3.1. Organisation of the consultation process

Stakeholders consulted included various persons, entities and organisations involved in the development, implementation and deployment of telemedicine. All main stakeholder groups have had opportunities to participate in the consultation process and to provide input. They can be grouped broadly into three categories:

- Users (including health professionals, patients, payers²³ and their respective representative bodies);
- Member State representatives;
- Industry stakeholders (including their representative bodies).

It should be noted that across the three broad categories there is a fourth group of stakeholders referred to as "IT specialists". This category is horizontal and therefore the input provided will not be analysed separately, but as part of the three broad groups.

The following activities have been carried out as part of the consultation process:

3.1.1. Consultation with users (patients, health professionals and payers)

Various activities²⁴ were carried out to ensure that the input of users was well reflected in the proposed initiatives, namely:

- December 2007: TeleHealth 2007, Brussels. Conference on challenges and opportunities of teleHealth focusing on the users' perspective (150 registrations)²⁵. This conference was

²³ "Payers" should be understood as health insurance funds as well as national and/or regional authorities according to the way healthcare systems are organised in different Member States. They are listed separately from Member States' representatives, to reflect the way the consultation process was carried out. Member State representatives were regularly consulted via the i2010 subgroup on eHealth.

²⁴ An overview of the consultation activities is available at: http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm.

²⁵ It should be noted that even if the intended focus of the conference was to obtain input from users (mainly health professionals, patients and regional/local healthcare providers), the audience came from different backgrounds, including industry, national and regional authorities.

preceded by a web-based survey addressed to participants. The results (52 responses, 17 from medical doctors, 35 from IT specialists) were used to define the main topics to be addressed in the agenda (organisational, legal and professional issues).

- February 2008: stakeholders’ workshop, Brussels. The workshop gathered a small number of stakeholders from all three categories. The objective was to examine in more detail the preliminary findings from the TeleHealth 2007 Conference and explore in detail the potential contribution of EU-level support for further deployment of telemedicine.
- February 2007-May 2008: several site visits were carried out by Commission staff to see telemedicine in action. For example, to Eurad Consult, a provider of diagnostic radiology reporting services in Mechelen, Belgium; European telemedicine Clinic, Barcelona, Spain; and Hôpital Européen Georges Pompidou, Paris, France.
- May 2008: EHTEL²⁶ meeting. This gathered representatives of competence centres and regional members of EHTEL. The Commission presented the main elements of the initiative, in the light of the outcome of the TeleHealth 2007 Conference, and of the report “Sustainable telemedicine: paradigms for future-proof healthcare” released by the Association in February 2008.²⁷
- May 2008: High Level Conference eHealth 2008, Portorož, Slovenia. Panel discussion on main aspects of the Commission initiative on telemedicine. Representatives of three subgroups of users and industry were included on the panel. Several comments from the 80-strong audience were from user representatives, national and regional authorities.
- May 2008: eHealth users’ stakeholders group consultation, including a delegation of the European Patient Forum²⁸ (a total of 24 participants, of whom 20 represented patient groups and four professionals). A briefing document outlining the main elements of the initiative was circulated in advance to all participants.
- June 2008: AIM²⁹ (payers/mutual societies) meeting with ten delegates and presentation from the Commission followed by discussion. Feed-back and follow-up to the group of 47 members from 42 States (mainly European) expected. A briefing document outlining the main elements of the initiative was circulated in advance to all participants and a written memorandum was provided by the Association as a follow-up³⁰.
- June 2008: CPME³¹ General Assembly, Health sub-committee. Meeting with delegates from all CPME Members. The Commission presented the main elements of the forthcoming Commission initiative and debate followed the discussion.

²⁶ European Health Telematic Association, Competence centres subgroup.

²⁷ Available at www.ehtel.org.

²⁸ The European Patient Forum is the umbrella group of pan-European patient groups active in the field of European public health and health advocacy – www.eu-patient.eu.

²⁹ The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. www.aim-mutual.org.

³⁰ AIM memorandum on “telemedicine and chronic diseases”:
http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm#_ftn4.

³¹ The Standing Committee of European Doctors (CPME) represents all medical doctors in the EU — approximately two million physicians. It is composed of the National Medical Associations of the European Union. It also unites associated members (those countries that are currently negotiating with

3.1.2. Consultation with Member State representatives

- September 2007: meeting of the i2010 subgroup on eHealth (Member State and EFTA representatives from Ministries of Health and/or technology/innovation constituencies). Preliminary debate with the subgroup on challenges and opportunities presented by telemedicine. The two co-chairs of the eHealth stakeholders group³² were invited to attend and received the relevant background information.
- December 2007: meeting of the i2010 subgroup on eHealth, preliminary round table on the level of deployment of telemedicine solutions in different Member States and debriefing on the main outcomes of the previous day's TeleHealth 2007 Conference. The two co-chairs of the eHealth stakeholders group were invited to attend and received the relevant background information.
- January 2008: questionnaire-based consultation of the i2010 subgroup members (Member State and EFTA representatives from Ministries of Health and/or technology/innovation constituencies) on challenges and opportunities of telemedicine from national points of view, including national developments and regulatory frameworks (15 respondents out of 27).
- February 2008: meeting of the i2010 subgroup on eHealth. Informed debate based on the outcome of the TeleHealth 2007 Conference in December as outlined in the conference report³³; the outcome of the stakeholders' workshop in February; and the results of the questionnaire. The two co-chairs of the eHealth stakeholders group were invited to attend and received the relevant background information.
- May 2008: meeting of the i2010 subgroup on eHealth: update on the status of the initiative, presentations of the main issues to be addressed and possible ways forward.

3.1.3. Consultation with industry stakeholders

- December 2007: TeleHealth 2007 Conference, Brussels²⁵.
- April 2008: European Parliament high-level consultation workshop with industry on "Innovative ICT tools and telemedicine services: challenges and opportunities", European Parliament, Brussels, with 30 high-level industry representatives. Invited speakers were: a representative from a national organisation providing telemedicine services to patients³⁴, a representative from a European organisation of health professionals³⁵ and a guest from a

the EU), associated organisations (specialised European medical associations) and observers. www.cpme.be.

³² The Commission (DG Information Society and Media) has set up and facilitates an "eHealth stakeholders group". This is divided into two subgroups: one representing industry, the other users. More details available at:

http://ec.europa.eu/information_society/activities/health/policy/stakeholders_group/index_en.htm.

³³ Report was put on line and called on stakeholders and interested parties for input and feedback. The report is available at: http://ec.europa.eu/information_society/events/telehealth_2007/docs/2007th-conf-rep_final.pdf.

³⁴ ŽIVOT 90, Czech Republic. www.zivot90.cz.

³⁵ President of the Radiology Section, European Union Medical Specialists. www.uems.net.

payer representative association³⁶. The event was hosted and co-chaired by Milan Cabrnock, MEP.

- April 2008: Medetel³⁷ Conference, presentation by the Commission on the initiative to a 200-strong plenary; focused panel workshop with the eHealth industry stakeholders group (composed of Continua Health Alliance³⁸, EHTEL, IHE³⁹ and COCIR⁴⁰) to discuss the needs for telemedicine.
- April 2008: Commission presented and discussed the main elements of the initiative at the Continua Health Alliance Summit³⁸.
- May 2008: eHealth industry stakeholders group⁴¹, panel discussion at high-level conference eHealth 2008, Portorož, Slovenia. Focus was on business models and sustainability of eHealth services, with specific reference to the telemedicine communication and innovative ICT tools for chronic disease management.
- June 2008: meeting between the European Commission and the Eucomed⁴² telemedicine task force. Results of scientific reviews on telemedicine were presented as well as Eucomed's position regarding the Commission telemedicine policy initiative.

3.2. Outcome of the consultation process

3.2.1. Outcome of users' consultation

The consultation raised a number of issues that are described below.

Patients' organisations

The consultation showed the low awareness of patients' organisation representatives as regards the opportunities telemedicine could provide (such as patient empowerment or improved care and quality of life). For example, in one of the specific consultation

³⁶ AIM, see footnote 20.

³⁷ Medetel is an annual conference held in Luxembourg, providing an international educational and networking forum for eHealth, telemedicine and health ICT experts.

³⁸ The Continua Health Alliance is a group of technology, medical device and health and fitness industry leaders collaborating to improve the quality of personal healthcare. Continua represents 156 companies and national organisations active in the personal health field. www.continuaalliance.org.

³⁹ IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. www.ihe.net.

⁴⁰ COCIR is the voice of the European radiological, electromedical and healthcare IT industry. It is a non-profit trade association, founded in 1959, representing the medical technology industry in Europe. www.cocir.org.

⁴¹ The Commission (DG Information Society and Media) has set up and facilitates an eHealth stakeholders group. This is divided into two subgroups: one representing industry, the other users. More details available at:

http://ec.europa.eu/information_society/activities/health/policy/stakeholders_group/index_en.htm.

⁴² Eucomed represents 4 500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Eucomed members include national trade and pan-European product associations and internationally active manufacturers of all types of medical technology.

workshops⁴³, only four of the 20 representatives were aware of telemedicine's potential. It was also interesting to note that after the workshop, with one exception (Eurordis⁴⁴), all other participants said they would raise the issue within their constituency since they now saw important opportunities. The patients' organisations active in Alzheimer's disease and related dementia, ageing-related conditions, multiple sclerosis, macular degeneration and cancer expressed particular interest. All but one welcomed the initiative from the Commission, in particular as a good way to raise awareness of the major opportunities telemedicine can provide.

Patients' organisations pointed out that to enhance trust in telemedicine applications, systematic collection and dissemination of solid evidence (in a patient-friendly and understandable way) should be made available to patients and their representative associations. Involvement of patients in the design and development of telemedicine solutions was considered an essential criterion to enhance confidence in these types of applications.

Patients' organisations agreed that their most relevant concern is linked to the protection of personal data, particularly related to health, and procedures for obtaining informed consent.

Health professionals

The umbrella organisation representing medical doctors (CPME, see footnote 31) expressed concerns about the consequences that wider deployment of telemedicine applications could have on the doctor-patient relationship. The risk of undermining such relationships was considered to require specific attention. On the other hand, in the context of the TeleHealth 2007 Conference, health professionals using telemedicine argued that these new types of services provide additional useful tools to offer to their patients and thus potentially strengthen the relationship.

The importance of addressing ethical issues linked to telemedicine was pointed out as a priority and as a pre-requisite for wider deployment of telemedicine. CPME committed itself to work with the Commission in this area.

While CPME expressed concerns on the reliability and accuracy of the technical solutions, as well as on their security, health professionals active in radiology⁴⁵ did not consider technical issues to be of major concern.

Healthcare professionals active in the radiology area (see footnote 45), welcome telemedicine services. They called for action to ensure that teleradiologists could access relevant patient health data (electronic health record and/or patient summary⁴⁶) to deliver best services. Radiology is not "only" looking at an image. Knowing the clinical context of the patient is as important as the image. The importance of the relevant safeguards to ensure protection of personal data was also underlined.

⁴³ May 2008: eHealth users' stakeholders group consultation, including a delegation of the European Patient Forum.

⁴⁴ Eurordis represents patients with rare diseases. Considering the specificity of the field in which the association has to operate, the concern expressed as to whether the issue should be a priority for them is not surprising. www.eurordis.org.

⁴⁵ Radiology Section, European Union Medical Specialists (www.uems.net) and providers of teleradiology services visited during the study visit (see section 1.2).

⁴⁶ See 2.1 Definitions.

Enhancing legal certainty, with special reference to liability of providers of telemedicine services, is considered to be an issue to be urgently addressed.

The lack of a “business model” which allows health professionals to be reimbursed for telemedicine services was also cited as a factor discouraging them from embracing telemedicine solutions and thus requiring action.

The importance of assessing the effectiveness of telemedicine solutions in providing high-quality care using validated scientific methodologies was considered a key area to be addressed.

Payers

Representatives of payers, mainly health insurance companies, considered it essential to identify and promote an adequate “**sustainability**” **model**, i.e. a model of telemedicine which is affordable and sustainable for healthcare systems in view of the budgetary constraints and challenges they face. The successful examples of sustainable models presented at the TeleHealth 2007 Conference⁴⁷ underlined the importance of creating the relevant political awareness of the benefits and opportunities offered by telemedicine and at the same time the need systematically to assess telemedicine applications, especially in relation to their effectiveness and cost-effectiveness. The consultation confirmed that only when all these elements are adequately addressed can payers (being regional and/or national authorities and/or private health insurers⁴⁸) be persuaded to pay for the services, thereby enabling an adequate sustainability model to be implemented and wider uptake ensured.

For payers to be able to reimburse telemedicine services, small but essential organisational steps will have to be implemented. For example: the need to give each telemedicine service a specific billing code, corresponding to the provision of the health service which could then result in reimbursement. Only two Member States have apparently included telemedicine services in their nomenclature allowing for potential reimbursement.

3.2.2. Outcome of Member State representatives’ consultation

National authorities are aware of the opportunities telemedicine solutions could offer to individuals, healthcare systems, society and the overall economy. In several Member States, eHealth and telemedicine are considered a priority. Member States have reemphasised their commitment towards telemedicine in the 2007 Portorož declaration⁴⁹, which states that “the Member States and the European Commission commit to support together the deployment of high-capacity infrastructure and infostructure for health and social care information networks and services such as telemedicine (teleradiology, teleconsultation, telemonitoring, telecare), ePrescription and eReferral.”

The lack of incentives (including financial incentives) for health professionals to embrace telemedicine services was considered one of the top three barriers preventing wider

⁴⁷ Simonetta Scalvini, IRCCS Foundation Salvatore Maugeri, Italy; Alain Franco, University Hospital Grenoble, France.

⁴⁸ This will differ between Member States according to how healthcare systems are organised.

⁴⁹ http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=4094.

deployment of telemedicine. The other barriers identified were legal uncertainty and the need to implement technical standards to ensure interoperability of the solutions⁵⁰.

Clarifications on the impact of Community legislation on telemedicine (e.g. applicability of the *e-Commerce Directive* (Directive 2000/31/EC) and the related *Transparency Directive* (Directive 98/34/EC on telemedicine services provision) would contribute to enhancing overall legal certainty (see 4.2). The relevance of the proposal for a Directive on patients' rights and the cross-border provision of telemedicine services, recently adopted by the Commission and currently under discussion in the European Parliament and the Council, was also considered to be an important consideration.

Member States emphasised the importance of building trust and confidence in telemedicine applications among users. The adequacy of the training of health professionals for this purpose was referred to as an area to be considered.

Only 6 Member States (out of the 15 respondents) declared that they have a specific legal framework in place for telemedicine, with another four stating that they have a horizontal legal framework covering some aspects of telemedicine services.

3.2.3. *Outcome of industry stakeholders' consultation*

Industry pointed out that one of the main issues preventing wider deployment of telemedicine is the lack of active engagement of health professionals in finding solutions. The absence of financing and sustainability schemes for these services in the vast majority of Member States was identified as a major obstacle. Training of health professionals was also considered an issue requiring attention.

The importance of raising awareness of the benefits and effectiveness of certain types of telemedicine solutions was one of the recommendations industry made during the consultation.

Industry representatives called for a policy initiative to bring together Member States to exchange practices, to encourage them to assess their regulatory framework with a view to enabling wider deployment of telemedicine and to facilitate sharing of feasibility and evaluation studies.

It was considered important to promote the development of a methodological framework to assess the effectiveness and cost-effectiveness of telemedicine applications. The Commission was generally seen to be in a good position to provide guidance and support in this type of work.

Continua³⁸, an alliance of companies working in the area of personal health devices, noted that, in order to achieve wider deployment of telemedicine, companies are working to address some of the outstanding issues linked to interoperability of monitoring devices (devices which monitor health parameters such as blood pressure and/or heart rhythm via sensors).

The Commission was invited to continue promoting the wider use of broadband, a prerequisite for the deployment of telemedicine. Uptake still varies among Member States and

⁵⁰ Result of the "Questionnaire to i2010 subgroup members", January 2008.

is particularly low in rural and remote areas²⁰ where telemedicine services would be of most benefit due to lower medical coverage.

The consultation demonstrated genuine support among stakeholders for a possible Commission initiative in this area. Consensus was reached on the challenges to wider deployment of telemedicine and on the main areas where action is needed and feasible. However, the priorities given to specific actions differed among the diverse stakeholders.

4. CHALLENGES TO ENABLE WIDER DEPLOYMENT OF TELEMEDICINE

As a result of the extensive consultation exercise, several issues were identified as barriers to the wider deployment of telemedicine. These can be grouped into three categories:

4.1. Confidence in and acceptance of telemedicine services

Telemedicine changes traditional working methods and brings new ways of practising medicine and delivering care. New roles for health professionals, new skills and new actors (e.g. telemedicine call centres) appear in the process of healthcare delivery. Understanding and implementing these changes in an acceptable and coherent manner is essential to enable wider deployment.

Awareness of the benefits of telemedicine among users (patients, health professionals and payers) and acceptance of the technology by health professionals are crucial elements for the success of telemedicine. Only the buy-in of users will allow the required changes in medical practice to take place.

The consultation revealed limited confidence and trust in the effectiveness of telemedicine solutions among professionals. From the evidence gathered during the consultation exercise and the corresponding background research, this is due to a combination of factors:

- Users are often involved too late in the development of telemedicine solutions and might therefore feel little ownership.
- Methodologies used for testing and validating the effectiveness of telemedicine applications are often based on small-scale pilots and do not follow the “traditional” scientifically validated methodologies, undermining the credibility of the results for the medical community and payers.
- Professionals are rarely trained to use these new technologies and some see them as an unnecessary intrusion into the way they are used to practising medicine.

Another important concern raised relates to the fundamental right to the protection of personal data⁵¹. Telemedicine by its nature generates and/or transmits personal health data. The processing of health-related personal data is particularly sensitive: unauthorised disclosure of a medical condition or diagnosis could negatively impact on an individual’s personal and

⁵¹ The fundamental right to the protection of personal data is recognised in Article 8 of the European Convention on Human Rights (“ECHR”, CETS No 005, adopted on 4 November 1950 and available at: www.coe.int) and in the general principles of Community law, as well as in Article 8 of the EU Charter of Fundamental Rights (“the Charter”, OJ C 364, 18.12.2000, p. 1; Lisbon Treaty version: OJ C 303, 14.12.2007, p. 1).

professional life. Maintaining health data in an electronic format increases the risk that patients' information could be accidentally disclosed to or accessed by unauthorised parties⁵².

Therefore, enabling wider deployment of any type of telemedicine services in the Member States can only be conceived in a framework that ensures a high level of protection of personal data. The legal framework is built around the Community provisions on the protection of personal data, in particular Directive 95/46/EC⁵³ (known as the *Data Protection Directive*) and Directive 2002/58/EC (known as the *Directive on privacy and electronic communications*⁵⁴), as well as the national laws implementing these directives.

Article 8 of Directive 95/46/EC prohibits processing of sensitive health data as a general principle. Limited exceptions to this principle are laid down in the same Directive, in particular if processing is required for specified medical and healthcare purposes.

Article 29 of Directive 95/46/EC established a working party on the protection of individuals with regard to the processing of personal data. Its role is to relay expert opinion from Member State level to the Commission on questions of data protection, to promote the uniform application of the general principles of the Directive in all Member States and to advise and make recommendations on issues related to data protection.

Data protection concerns not only telemedicine as such, but also the systems that might interoperate with telemedicine systems. For instance, if telemonitoring data is fed into electronic health record systems, data security and privacy needs to be assured at all levels of the process.

Telemedicine is creating a new environment for patients, health professionals as well as informal carers. To understand better the social and ethical implications, more in-depth analysis is needed, for instance through studies focusing specifically on the impact of telemedicine on the patient-doctor relationship and on other relevant ethical aspects.

During the consultation it was pointed out that telemedicine, especially when referring to "patients to health professionals" applications (cf. Annex 1(a)), will often entail the virtual presence of a health professional in a patient's home through a video link. This situation represents a challenge to physical space privacy and therefore vigilance is required when considering the patient's rights in this respect. Ethical guidance in this area may prove to be particularly useful.

The consultation also made it clear that an important issue in ensuring acceptance of telemedicine by health professionals has to do with funding and reimbursement. The main problem here is the lack of incentives (including financial incentives) and the impossibility of "charging" for telemedicine services. According to the information made available to date,

⁵² For the principles applicable to the processing of health data in electronic form see, in particular, Article 29 Working Party Working Document 131 on the processing of personal data relating to health in electronic health records (EHR), adopted on 15 February 2007. http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf.

⁵³ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995, p. 31.

⁵⁴ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector, OJ L 201, 31.7.2002, p. 37.

telemedicine services are currently reimbursed in only one Member State (another one is examining the possibility). The consultation pointed out that if these services are not reimbursed by national health systems and no successful business model is identified, wider deployment will be very difficult to achieve.

Finally, acceptance by patients and patients' organisations is another area to be addressed. Key issues are: limited awareness of the benefits telemedicine, in particular homecare solutions, can provide to quality of life and health outcomes and the legitimate concerns expressed regarding the protection of personal data. Making adequate training and education on telemedicine available to patients is another crucial point, especially for patients who may not be very "e-literate".

4.2. Legal clarity

Typical examples of the legal obstacles that wider deployment of telemedicine is facing are the need for physicians to be registered in all EU countries where they are providing services via telemedicine (e.g. interpretation of radiographs received via teleradiology), or the legal requirement for all medical acts to be carried out in the physical and simultaneous presence of the health professional and patient. As a matter of fact, by not recognising telemedicine services specifically (the definition of healthcare services often does not include the concept of "at a distance"), most Member States discourage its wider use.

During the consultation phase, the right of establishment for health professionals exercising telemedicine, accreditation and authorisation schemes to provide telemedicine services, and issues surrounding liability, recognition of professional qualifications or protection of health-related personal data were among the areas which prompted most concerns, at both EU and national level.

From the standpoint of Community law, telemedicine is both a health service and an information society service within the meaning of Article 49 of the EC Treaty. The European Court of Justice⁵⁵ 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 movement. A recipient of a healthcare service may therefore freely seek and receive medical treatment from another Member State, regardless of how the service is delivered, i.e. also by telemedicine. In principle, the fact that telemedicine is a service delivered by electronic means does not constitute a reason for treating telemedicine as a special type of health service.

Another key driver for the clarity of legislation is to ensure that telemedicine does not in any way reduce the quality of the services provided to the public. At EU level, a range of actions have already been taken. Specific aspects of the provision of health services are governed by the existing secondary legislation, which builds on the basic principle enshrined in Article 49 of the EC Treaty and the above-mentioned ECJ case law.

⁵⁵ See for example Case C-385/99 *Müller and Van Riet* [2003] ECR I-4509; Case C-157/99 *Smits and Peerbooms* [2001] ECR I-5473; Case C-372/04 *Watts* [2006] ECR I-4325; Case C-159/90 *Society for the Protection of Unborn Children Ireland* [1991] ECR I-4685; Joined Cases 286/82 and 26/83 *Luisi and Carbone* [1984] ECR 377.

The legislation which covers some aspects of telemedicine includes Directive 2000/31/EC⁵⁶ (known as the *e-Commerce Directive*), Directive 2005/36/EC⁵⁷, Council Regulation No 1408/71 on coordination of social security schemes, Directive 98/34/EC⁵⁸ (known as the *Transparency Directive*), as amended by Directive 98/48/EC⁵⁹, the *Data Protection Directive*⁵³ and the *Directive on privacy and electronic communications*⁵⁴ previously mentioned.

Directive 2000/31/EC (known as the *e-Commerce Directive*)

This Directive lays down rules for the provision of information society services. The definition of an information society service is enshrined in the *Transparency Directive*, as amended by Directive 98/48/EC. An information society service is defined as any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services. Whenever telemedicine meets those requirements, it must be considered as an information society service⁶⁰. In spite of the increasing role played by online services, the concept of “information society services” in the field of healthcare, and in particular in the area of telemedicine, has not been particularly explored by Member States⁶¹. The consultation suggested that this could be due to a lack of awareness of the applicability of the *e-Commerce Directive* to the healthcare sector, and specifically the right of Member States to adopt national regulations on telemedicine under Directive 98/34/EC, as amended by Directive 98/48/EC.

The *e-Commerce Directive* sets out 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 exempt from the country of origin principle: the service might need to comply with the rules of the recipient’s (i.e. the patient’s) country.

Directive 2005/36/EC on the recognition of professional qualifications

This Directive establishes the rules for the mutual recognition between Member States of a set of regulated professions (including medical doctors and a number of medical specialities). In the case of telemedicine, where cross-border healthcare services may be offered, criteria for the recognition of health professionals are important. Yet the Directive does not cover the

⁵⁶ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, OJ L 178, 17.7.2000, p. 1.

⁵⁷ Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications, OJ L 255, 30.9.2005, p. 22.

⁵⁸ OJ L 204, 21.7.1998.

⁵⁹ OJ L 217, 5.8.1998.

⁶⁰ For more information about the definition and scope of information society services, see, in particular, “Vade-mecum to Directive 98/48/EC which introduces a mechanism for the transparency of regulations on information society services”. Doc. C-42/98-EV (def.) http://ec.europa.eu/enterprise/tris/vade9848/index_en.pdf.

⁶¹ To date only one Member State (Hungary) has notified a draft technical regulation related to the deployment of information society services in healthcare under Directive 98/34/EC.

situation where the health professional and the patient are not simultaneously present, which is the case most of the time for telemedicine.

Directive 95/46/EC (known as the *Data Protection Directive*)

This Directive specifies a number of requirements relating to confidentiality and security which telemedicine and all other interactive on-line services have to meet in order to lawfully operate within the internal market. When deploying telemedicine in the internal market, the regulator and/or provider must strictly follow the national framework implementing the above-mentioned Directive, which had to be transposed in a harmonized way to allow free exchange and access to person identifiable data across the internal borders of the European Union and the EEA balancing the protection of individual rights and public good as appropriate. The Directive stipulates that processing of personal data related to health is particularly sensitive and therefore contains the requirements, exceptions and safeguards to lawfully process such sensitive data.

Security and privacy enhancing technologies (PETs)⁶², embedded in the very design and implementation of telemedicine systems, can help actively to ensure personal data protection when using these technologies.

Other legislation relevant to telemedicine

The *Transparency Directive* (98/34/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 services⁶³, including telemedicine, before they are adopted in national law.

Telemedicine is also recognised in the proposal for a Directive on the application of patients' rights in cross-border healthcare⁶⁴. This addresses patients' cross-border mobility, including their ability to access services across borders. Article 2 stipulates that "This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private". The proposal is without prejudice to the Directives mentioned above, notably the *e-Commerce Directive* and Directive 2005/36/EC. Thus, the existing legal framework applies and the current proposal will be applicable only insofar as the measures are not already covered by those Directives⁶⁵.

Finally, a key condition for wider deployment of telemedicine is the recognition of telemedicine as a properly evaluated and legally valid medical act in order to ensure universal acceptance and allow for reimbursement. According to the principle of subsidiarity, the classification of telemedicine as a valid medical act should be carried out at national level by Member States in cooperation with professional bodies. It should be based on general principles relating to standard (i.e. "non-telemedicine") medical acts applicable according to the national legislation of the Member State. This principle ensures that adequately regulated

⁶² See Commission communication "Promoting Data Protection by Privacy Enhancing Technologies (PETs)", COM(2007) 228 final, 2.5.2007.

⁶³ Provided they are not covered by one of the exceptions laid down by Directive 98/34/EC as amended by Directive 98/48/EC.

⁶⁴ COM(2008) 414 final, 2.7.2008 (http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf), accessed 31 Oct. 2008.

⁶⁵ As stipulated in the explanatory memorandum and also Articles 3, 5 and 11 of the proposal.

health services are not replaced by less regulated telemedicine services and it avoids discrimination between suppliers of the same service which would be incompatible with the *e-Commerce Directive* (Article 4).

Clarification of the existing Community legal framework with regard to concrete examples in telemedicine is planned in a specific action under the telemedicine communication (see also Annex 2) to be carried out in 2009.

Regulatory modes for telemedicine

Based on the available information and experience, the most common ways in which Member States can regulate telemedicine are:

- *To adopt national technical regulations on telemedicine. If these acts contain a rule on information society services, in accordance with Directive 98/34/EC, as amended by Directive 98/48/EC, they will have to be notified to the Commission under Directive 98/34/EC. This procedure aims to avoid the creation of new obstacles to the internal market and to ensure the freedom to provide such services on the basis of the principle of mutual recognition.*
- *To sign bilateral or multilateral agreements on telemedicine with other Member States. Such agreements should be at government level and should cover issues related to telemedicine (licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement and jurisdiction).*
- *To allow bilateral or multilateral commercial agreements between providers, most often private individuals and legal entities. In this case, the determination of rights and obligations in telemedicine is left to the contracting parties. This may often lead to confusion and asymmetric models of deployment of telemedicine. Contracts should likewise address the issues of licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement and jurisdiction.*

All the rules adopted via the above routes must comply with Community legislation.

4.3. Technical issues and facilitating market deployment

Issues linked to infrastructure, such as access to broadband and the ability for the provider to enable full connectivity across the European territory from urban, highly-populated areas to remote, rural, scarcely-populated areas, still represent a major challenge. The security of the network, the reliability and accuracy of certain types of telemedicine applications (for instance, using GSM lines to measure certain vital signs) were pointed out as additional challenges. On the other hand, for other types of telemedicine solutions, for instance the remote monitoring of cardiovascular implantable electronic devices⁶⁶, reliability and accuracy of the measurements are considered to be sufficient⁶⁷.

⁶⁶ These include mainly pacemakers, but also implantable defibrillators and cardiac resynchronisation devices.

⁶⁷ Wilkoff BL et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm*. 2008 Jun;5(6):907-25.

In the emergent market of telemedicine and personal health systems, European SMEs play a vital role due to their agility and innovation potential benefiting from the existing measures. However, further support to extend the present "window of opportunity" will be needed, for SMEs to continue innovating in the transition towards a less fragmented European market place.

Although industry (see footnotes 38 and 39) is working in a coordinated manner in this area, interoperability is not yet fully achieved, especially with regard to the ability of personal devices measuring vital signs to interact and feed information into electronic health records systems.

Reliability and dependability of measurements and devices is another crucial technical issue. This is particularly relevant to personal health monitoring devices, which involve measurements of health parameters in the absence of health professionals. All current gold standards on what is reliable and can be acted on are based on measurements in controlled (healthcare facility) environments. As the conditions under which measurements are taken in the home environment of an individual are not "clinically controlled", this particular point needs to be tackled.

Finally, issues linked to terminology and semantics, as well as technical solutions to enable authentication of professionals and/or patients (i.e. patients' cards and/or professionals' cards to ensure secure service provision) also require more targeted action.

5. THE EUROPEAN COMMISSION'S ROLE IN THE PROCESS

The overall rationale for the Commission to act on the specific topic of telemedicine is, on the one hand, to ensure a high level of human health protection by improving public health, and preventing human illness and disease, as stipulated in Article 152 of the EC Treaty, and, on the other, to support the development of a sustainable and innovative internal market that will foster competition and support investment, growth and jobs in Europe in line with Article 29 of the Treaty.

Clearly, the responsibility for organising and delivering health services and medical care lies with Member States. However, under Article 152 of the EC Treaty, there exists the concrete opportunity for Community action to help Member States coordinate among themselves and to encourage cooperation — which could take place, for example, in the area of telemedicine — for the benefits of the health of the population of all Member States.

During the consultation exercise, Member States underlined the urgency of acting in this area. National healthcare systems are at a critical point in ensuring their future sustainability and are looking into different options to meet their challenges. Most Member States agree that eHealth in general, and telemedicine services in particular, would provide useful tools to meet some of these challenges.

Several Member States have already successfully implemented telemedicine services on smaller scales. Some do not have the expertise and capacity to do so as soon as they would wish. Others are waiting for guidance and the experience of others before proceeding. The Commission can not only provide a platform for sharing best practice, expertise and lessons learned from the various pilot projects supported by national and EU programmes, but also

offer guidance in developing technical and legal frameworks in order to ensure cross-border interoperability and legal certainty.

For example, it will be essential to address the issue of liability and the extent to which it is already covered by existing Community and/or national rules. The clarification of existing provisions on informed consent linked to the transmission of personal health data and the way it should be implemented for telemedicine solutions and the importance of safeguarding the fundamental right to privacy are crucial areas to be addressed.

Support and coordination from the Commission at this stage would ensure consistency between upcoming national rules and thus provide a clearer framework for telemedicine, especially in relation to cross-border care issues. It would avoid future problems in interpretation and implementation of Community instruments relevant to these services.

A Europe-wide policy initiative in this area would support convergence towards common solutions, avoid further market fragmentation and prevent a situation where Member States move in different individual, organisational and technical directions, missing the opportunity to build a common base for interoperable telemedicine applications.

Action is needed to address the legitimate concerns voiced by some stakeholders on the possible risks that may arise if telemedicine develops in an inadequately regulated environment, particularly in relation to quality of care.

The Commission's role in the area of trust-building and improved user acceptance would be important, as indicated by the consultation exercise. The Commission is in a position to gather the expertise and lessons learned from Member States and disseminate it widely to stakeholders. Moreover, the Commission will continue to support research and dialogue on the ethical aspects of telemedicine including the potential impact of telemedicine on the patient-doctor relationship.

The Commission is committed to the objectives set out in the communication on a Lead Market Initiative for Europe and was requested by the Competitiveness Council in June 2008 to report regularly on the progress made. Deploying the potential of the eHealth market and taking action in the area of telemedicine and innovative ICT tools for chronic disease management has been identified as a way forward. The telemedicine communication is a concrete response to previous commitments and a tangible move towards progress in this area.

This initiative builds on some 20 years of investment in research and development that has been supported by the Commission and has aimed to enable the coordination required to enhance eHealth, and more specifically, telemedicine deployment.

Calling for support for further technological development in ICT (e.g. on the telemedicine aspects of personalised health) has a legal basis in Articles 163 to 172 of the EC Treaty. These Articles relate to research and development.

From a market standpoint, other aspects of the telemedicine communication can be based on Article 157 of the EC Treaty, which aims to contribute to creating the necessary conditions for the competitiveness of the Community's industry.

Other Community initiatives referred to in Chapter 2 also support action by the Commission in this area.

6. ACTIONS PROPOSED BY THE COMMISSION IN THE TELEMEDICINE COMMUNICATION

The general objective of the Commission communication is to enable wider deployment and use of telemedicine applications in the European Union. The focus of the communication is on actions which appear to be most urgent, and in which the Commission could provide the maximum added value. Annex 2 provides a summary table of the challenges and the corresponding actions.

The consultation and analysis of the sector undertaken by Commission staff identified additional issues not addressed by specific actions, but nevertheless relevant to the desired objective. These issues are listed in Annex 3.

7. MONITORING AND EVALUATION

Monitoring actual implementation of the actions proposed in the communication will be an important part of the work.

Several policy monitoring tools are currently in place and can be adapted to the purpose of this exercise.

The eHealth ERA database⁶⁸ is a tool which makes it possible to monitor Member States' progress in the deployment of eHealth technologies (telemedicine being one of them) in their respective health systems.

Specific standard criteria should be used in the surveys to allow comparison between Member States and over different periods. These criteria would be chosen to measure progress in the three specific objectives identified (building confidence, bringing legal clarity and solving technical issues). The surveys could be carried out with internal Commission resources, as part of the eHealth policy activities of DG Information Society and Media (ICT for health Unit) or using as an instrument one of the studies planned to start in 2009, which has as its main objective to monitor progress in Member States on deployment of eHealth⁶⁹. The study is to last for 18 months and its tender specification already provides for examining progress on the use of telemedicine, teleradiology, telecare and other eHealth services.

The regular meetings of the i2010 subgroup on eHealth⁷⁰ would also be a useful instrument to monitor progress with the activities and actions Member States will be taking in this area.

Finally, it is suggested that every year a specific session on telemedicine should be included in the programme of the Annual High Level Conference on eHealth⁷¹. This will be an effective and powerful instrument to monitor progress, keep awareness high and concentrate the attention of the eHealth community on the actions to be undertaken, and assess the effectiveness of the actions proposed by the Commission in the communication.

⁶⁸ <http://www.ehealth-era.org/database/database.html> (accessed 31 Oct. 2008).

⁶⁹ "Monitoring eHealth strategies: lessons learned, trends and good practices" SMART 2008/0063 — OJ 2008/S 107-142554.

⁷⁰ The i2010 subgroup on eHealth is made up of ministerial representatives of the 27 Member States who have responsibility for national eHealth policy.

⁷¹ The eHealth Conference is an annual ministerial/high-level conference, which gathers together key actors in eHealth.

ANNEXES

Annex 1: Definitions

For the purposes of the communication and this staff working paper the following definitions are applied:

- (a) **Telemedicine** means the delivery of healthcare services at a distance using information and communication technologies. Telemedicine is the provision of a healthcare service to a patient in situations where the patient and the health professional (or two health professionals cooperating on a specific patient) are not in the same location. It involves secure transmission of medical data and information, such as biological/physiological measurements, alerts, images, audio, video, or any other type of data needed for prevention, diagnosis, treatment and follow-up monitoring of patients.

There are two main groups of telemedicine applications:

- applications linking a patient with a health professional. For example, different types of teleconsultation such as (home) telemonitoring for chronic disease management, telecardiology or teleophthalmology. In this case, the telemedicine applications comprise systems that acquire and process data (e.g. wearable, portable health monitoring systems with advanced biosensors) and securely communicate with health professionals;
 - applications linking two health professionals (such as tele-second opinion, teleradiology or telepathology). The telemedicine system in this category mainly includes the secure communication and specialised clinical system to display and process clinical information supporting decision making by health professionals.
- (b) **Patient** means any natural person who receives or wishes to receive healthcare in a Member State.
- (c) **Health professional** means any professional exercising activities in the healthcare sector within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications.
- (d) **Electronic health record** means a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes.
- (e) **Patient summary, emergency data set, medication record** should be understood as possible subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event.

- (f) *Electronic health record system* means a system for recording, retrieving and handling information in electronic health records.

Annex 2: List of challenges and actions as proposed in the telemedicine communication

Building confidence in and acceptance of telemedicine services	<i>Provide scientific evidence of effectiveness and cost-efficiency in a large-scale setting</i>	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.
		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.
	<i>Secure confidence in and acceptance of telemedicine solutions by health professionals, patients and health authorities</i>	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.
Providing legal clarity	<i>Address the lack of legal clarity — with special reference to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement and jurisdiction</i>	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.
Resolving technical issues and	<i>Address the need for interoperability and standardisation to allow</i>	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.

facilitating market development	<i>widespread use of telemedicine technologies and enable them to benefit from the single market</i>	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.
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Annex 3: Additional actions suggested during the consultation

The communication highlights the most important actions to be carried out to support telemedicine, while fully respecting the competences and responsibilities of the Member States and the Commission.

The following additional actions were proposed during the consultation phase and supplement the core actions developed in the communication or are already covered by other EC initiatives, such as the Lead Market Initiative for Europe²¹ or the *eHealth action plan*¹⁵.

- Target users, in particular health professionals, via their conferences and training events, to present results of studies outlining the benefits provided by telemedicine solutions for health outcomes.
- Require EC co-funded research projects, when publishing results, to target also clinical medical journals rather than predominantly medical informatics journals.
- Require EC co-funded projects to involve patients and patients' organisations in the design and validation of telemedicine solutions.
- Encourage Member States and payers to exchange practices in assessing cost-effectiveness of telemedicine applications, by using existing Community mechanisms already in place (such as the EU Health Technology Assessment Network).
- Encourage Member States and payers to explore and exchange practices on sustainability and funding mechanisms for telemedicine services including incentives and long-term benefits.
- Cooperate with user representatives, in particular health professionals and patient representatives, to develop and disseminate guidelines addressing ethical issues relevant to telemedicine.
- Encourage Member States, higher education institutions and professional bodies to explore the opportunity of including telemedicine in the training of health professionals.
- Promote the development of the necessary infrastructure for telemedicine (in particular broadband access) in remote and insufficiently connected areas.
- Call on Member States and stakeholders to ensure that data protection safeguards are embedded in telemedicine systems, including through the widest possible use of Privacy Enhancing Technologies (PETs) in their design and implementation.

Annex 4: Non-exhaustive list of relevant articles, studies and reports

Ahern DK, Kreslake JM, Phalen JM. What is ehealth (6): Perspectives on the evolution of ehealth research. *Journal of Medical Internet Research* 2006 Jan–Mar; 8(1).

Armstrong IJ, Haston, WS. Medical decision support for remote general practitioners using telemedicine. *Journal of Telemedicine and Telecare* 1997; 3: 27–34.

Barlow J. Building an evidence base for successful telecare implementation. CSIP Factsheet November 2006.

Bashshur RL, Reardon TG, Shannon GW. Telemedicine: A new health care delivery system. *Annual Review of Public Health* 2000; 21: 613–37.

Bergmo TS. A cost-minimization analysis of a realtime teledermatology service in northern Norway. *Journal of Telemedicine and Telecare* 2000; 6: 273–277.

CPME (Standing Committee of European doctors). The practice of telemedicine in Europe: analysis, problems and CPME recommendations (CPME 2002/027).2002.

Clark RA, Inglis SC, McAlister FA, Cleland JG, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure; systematic review and meta-analysis, *BMJ* 2007;334, 942-5.

Daucourt V, Sicotte C, Pelletier-Fleury N, Petitjean ME, Chateil JF, Michel P. Cost-minimization analysis of a wide-area teleradiology network in a French region. *International Journal for Quality in Health Care* 2006; 18(4): 287–293.

Debnath D. Activity analysis of telemedicine in the UK. *Journal of Postgraduate Medicine* 2004; 80: 335-338.

EHTEL. Sustainable telemedicine: paradigms for future-proof healthcare. Netherlands: EHTEL report, Feb. 2008.

Elsner CH, Sommer P, Piorkowski C, Taborsky M, Neuser H, Bytesnik J, Geller JC, Kottkamp H, Wiesmeth H, Hindricks G. A Prospective Multicenter Comparison Trial of Home Monitoring against Regular Follow-up in MADIT II Patients: Additional Visits and Cost Impact. *Proceedings Computers in Cardiology, Valencia, 2006*; 33:241-244.

European Space Agency, World Health Organization, International Telecommunication Union. Towards Interoperable eHealth for Europe. *Telemedicine Alliance Strategy. Report. 2005.*

Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D, Clementy J Potential cost savings by telemedicine-assisted long-term care of implantable cardioverter defibrillator recipients. *Pacing Clin Electrophysiol.* 2005 Jan;28 Suppl 1:S255-9.

Health Canada. Evaluating telehealth ‘solutions’: A review and synthesis of the telehealth evaluation literature. Canada: March 2000.

Heidbüchel H, Lioen P, Foulon S, Huybrechts W, Ector J, Willems R, Ector H. Potential role of remote monitoring for scheduled and unscheduled evaluations of patients with an implantable defibrillator. *Europace* 2008;10:351-357.

Hersh W, Hickam D, Severance S, Dana T, Krages K, Helfand M. Diagnosis, access and outcomes: Update of a systematic review of telemedicine services. 2006; 12 (Suppl. 2): S2: 3-31.

Hersh WR, Helfand M, Wallace J, Kraemer D, Patterson P, Shapiro S, Greenlick M. Clinical outcomes resulting from telemedicine interventions: a systematic review. *BMC Medical Informatics and Decision Making* 2001; 1: 5.

Hunt D, Haynes R, Hanna S & Smith K. Effects of computer-based clinical decision support systems on physician performance and patient outcomes: A systematic review. *Journal of the American Medical Association* 1998; 280: 1339-1346.

Israel CW, Cicek-Hartvig S, Foresti M, Seidl K, et al. Telemonitoring for Restriction of In-House ICD Follow-up to 12-Month Intervals: First Results of the HOT Registry; Abstract.

Johansen I, Breivik E. Is teleradiology service in primary health care cost-effective? *Tidsskr Nor Laegeforen*. 2004 Oct 7;124(19):2490-2.

Johnston B, Wheeler L, Deuser J, Sousa KH. Outcomes of the Kaiser Permanente telehome health research project. *Archives of Family Medicine* 2000; 9: 4045.

Kerr C, Murray E, Stevenson F, Gore C, Nazareth, I. Internet interventions for long-term conditions: Patient and caregiver quality criteria. *Journal of Medical Internet Research* 2006 Jul-Sep; 8(3): e13.

Koo C, Razavi M, Roelke M, Greer S, Rome M, Nichols A, Oza A. Efficiency in using the housecall plus remote Monitoring system for ICD Follow-Up. *Europace* 2007.

Kreutzer J et al. Teleradiology in neurosurgery: experience in 1024 cases. *J Telemed Telecare*.2008;14(2):67-70.

Kumar S, Marescaux J, eds. *Telesurgery*. Australia: Springer, January 2008.

Lamothe L, Fortin JP, Labbe F, Gagnon MP, Messikh D. Impacts of telehomecare on patients, providers, and organizations. *Telemedicine and e-Health* 2006; 12(3): 363-369.

Latifi R, ed. *Current principles and practices of telemedicine and e-health*. In: *Studies in Health Technology and Informatics*. Netherlands, 2008.

Louis AA, Turner T, Gretton M, Baksh A, Cleland JG. A systematic review of telemonitoring for the management of heart failure. *Eur J Heart Fail*. 2003 Oct;5(5):583-90.

Luck J, Parkerton P, Hagigi F. What is the business case for improving care for patients with complex conditions? *Journal of general internal medicine* 2007; (Suppl 3): 396-402.

Lunati M, Gasparini M, Santini M, Landolina M, Perego GB, Pappone C, Marzegalli M, Argiolas C, Murthy A, Valsecchi S; InSync ICD Italian Registry Investigators. Follow-up of

CRT-ICD: implications for the use of remote follow-up systems. Data from the InSync ICD Italian Registry. *Pacing Clin Electrophysiol.* 2008;31:38-46.

Marietti C. Year of Changes: The 2008 outlook for physician groups points to more work, lower reimbursements and evolving service models. *Healthcare Informatics* 2007; 24(12): 50.

McIntosh E, Cairns J. A framework for the economic evaluation of telemedicine. *Journal of Telemedicine and Telecare* 1997; 3: 132–139.

Melzer SM, Poole SR. Computerized pediatric telephone triage and advice programs at children's hospitals. *Archives of Pediatrics & Adolescent Medicine* 1999; 153: 858-863.

Munro J, Nicholl J, O’Cathain A, Knowles E. Impact of NHS Direct on demand for immediate care: observational study. *British Medical Journal* 2000; 321: 150-153.

O’Brien M. Remote Telemonitoring. A Preliminary Review of Current Evidence. Draft. European Centre for Connected Health. 30 June 2008.

Oakley AM, Kerr P, Duffill M, Rademaker M, Fleischl P, Bradford N, Mills C. Patient cost–benefits of realtime teledermatology — a comparison of data from Northern Ireland and New Zealand. *Journal of Telemedicine and Telecare* 2000; 6: 97–101.

Oh H, Rizo C, Enkin M, Jadad A. What is ehealth (3): A systematic review of published definitions. *J Med Internet Res.* 2005 Feb 24;7(1):e1.

P. Brugada. What evidence do we have to replace in-hospital implantable cardioverter defibrillator follow-up? *Clin Res Cardiol* 2006;95:Suppl 3, III/3 - III/9.

Pagliari C, Sloan D, Gregor P, Sullivan F, Detmer D, Kahan JP, Oortwijn W, MacGillivray S. What is ehealth (4): A scoping exercise to map the field. *Journal of Medical Internet Research* 2005 Jan–Mar; 7(1): e9.

Paré G, Jaana M, Sicotte C. Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base. *J Am Med Inform Assoc.* 2007;14:269-277.

Pejman Azarmina. Real-time Home Telecare: A Systematic Review. (MSc thesis, University of Surrey School of Management 2005).

Perings C, Korte T, Trappe HJ. IEGM-online based evaluation of implantable cardioverter defibrillator therapy appropriateness. *Clin Res Cardiol* 2006;95:Suppl 3, III22-III28.

Perings SM, Bläse I, Marx R, Plehn G, Müller C, Trappe H-J, Perings C. Register zur verzahnten Nachsorge von ICD-Patienten durch Home Monitoring: Erfahrungen mit den ersten Patienten im 1-Jahres-Follow-up. *J KARDIOL* 2008;15:(1-2).

Pinnock H, McKenzie L, Price D, Sheikh A. Cost-effectiveness of telephone or surgery asthma reviews: Economic analysis of a randomised controlled trial. *British Journal of General Practice* 2005; 55: 119-124.

Res JC, Theuns DA, Jordaens L. The role of remote monitoring in the reduction of inappropriate implantable cardioverter defibrillator therapies. *Clin Res Cardiol* 2006;95:Suppl 3:III17-III21.

Ricci RP, Morichelli L, Santini M. Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization. *Europace* 2008;10:164–170.

Roine R, Ohinmaa A, Hailey D. Assessing telemedicine: a systematic review of the literature. *Canadian Medical Association Journal* 2001; 165(6): 765-71.

Senges-Becker JC, Klostermann M, Becker R, Bauer A, Siegler KE, Katus HA, Schoels W. What is the “optimal” follow-up schedule for ICD patients? *Europace* 2005;7:319-326.

Shea S. Health delivery system changes required when integrating telemedicine into existing treatment flows of information and patients. *Journal of Telemedicine and Telecare* 2006; 12 (Suppl. 2): S2:85–90.

Shore JH, Brooks E, Savin DM, Manson SM, Libby AM. An economic evaluation of telehealth data collection with rural populations. *Psychiatric Services* 2007; 58(6).

Strehle EM, Shabde N. One hundred years of telemedicine: does this new technology have a place in paediatrics? *Archives of Disease in Childhood* 2006; 91: 956-959.

van Eck JW, van Hemel NM, de Voogt WG, Meeder JG, Spierenburg HA, Crommentuyn H, Keijzer R, Grobbee DE, Moons KG; FOLLOWPACE investigators. Routine follow-up after pacemaker implantation: frequency, pacemaker programming and professionals in charge. *Europace* 2008;10:832-7.

Vitacca M, Assoni G, Pizzocaro P, Guerra A, Marchina L, Scalvini S, Glisenti F, Spanevello A, Bianchi L, Barbano L, Giordano A, Balbi B. A pilot study of nurse-led, home monitoring for patients with chronic respiratory failure and with mechanical ventilation assistance. *Journal of Telemedicine and Telecare* 2006; 12: 337–342.

Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, Hayes DL, Howlett JG, Kautzner J, Love CJ, Morgan JM, Priori SG, Reynolds DW, Schoenfeld MH, Vardas PE; Heart Rhythm Society; European Heart Rhythm Association; American College of Cardiology; American Heart Association; European Society of Cardiology; Heart Failure Association of ESC; Heart Failure Society of America. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm* 2008;5:907-25.

Williams T, May C, Esmail A. Limitations of patient satisfaction studies in telehealthcare: A systematic review of the literature. *Telemedicine Journal and e-Health* 2001; 7(4): 293-316.

Woo J. Development of elderly care services in Hong Kong: challenges and creative solutions. *Clinical Medicine* 2007; 7: 548–50.

Wootton R, Bloomer SE, Corbett R, Eedy DJ, Hicks N, Lotery HE, Mathews C, Paisley J, Steele K, Loane MA. Multicentre randomised control trial comparing real time teledermatology with conventional outpatient dermatological care: Societal cost-benefit analysis. *British Medical Journal* 2000 May 6;320(7244):1252-6.

Wootton R. Clinical review: Telemedicine. *British Medical Journal* 2001; 323: 557–60.

Wu RC, Delgado D, Costigan J, MacIver J, Ross H. Pilot study of an internet patient-physician communication tool for heart failure disease management. *Journal of Medical Internet Research* 2005 Jan–Mar; 7(1).