Opinion of the European Economic and Social Committee on the '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'

COM(2008) 689 final

(2009/C 317/15)

Rapporteur: **Mr BOUIS**

On 4 November 2008 the Commission decided to consult the European Economic and Social Committee, under Article 262 of the Treaty establishing the European Community, on the

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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The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 26 June 2009. The rapporteur was Mr Bouis.

At its 455th plenary session, held on 15 and 16 July 2009 (meeting of 15 July), the European Economic and Social Committee adopted the following opinion by 160 votes, with three abstentions.

1. **Comments and recommendations**

1.1 The Committee welcomes the Commission communication which supports and encourages Member States in integrating telemedicine into their health policies.

1.2 The Committee endorses this move by the Commission aimed at building confidence in and acceptance of telemedicine, enhancing legal clarity in this area, solving technical issues and facilitating market development, while respecting the subsidiarity principle. Member States remain responsible for their own public health policy and for the deployment of telemedicine, as determined by their investment capacity.

1.3 In the Committee's view, more awareness should be raised among health authorities, professionals and patients, to whom consistent evidence of cost-effectiveness should be provided.

1.4 The Committee will keep an eye on research and development in this area as to whether it provides full assurances in respect of safety of use, simplified ergonomics and lower acquisition and usage costs. It notes the Commission's wish to support a large-scale pilot project on telemonitoring.

1.5 The Committee notes the difficulties in deploying telemedicine, despite the fact that under certain clearly defined conditions it can help improve the healthcare system for the benefit of patients, health professionals and social security bodies. It therefore thinks that its scope should be defined and that it should be given a sound legal basis.

1.6 The Committee would advocate sticking to simpler definitions of telemedicine procedures to ensure that confidentiality is guaranteed and the highest level of patient safety is sought.

1.7 The Committee welcomes the intention to establish a European platform in 2009 to support Member States in sharing information on national legal frameworks.

1.8 In the Committee's view, a medical act involving telemedicine – as a complementary technique – should comply with the rights and obligations attached to any medical act, and also take account of the obligations linked to its specific nature, such as providing information on the technical means of transmitting and securing data.

1.9 In the Committee's view, it is clear that broadband access [1] – of the same quality in all countries – and full connectivity are prerequisites to the development of telemedicine. Digital services in the regions, particularly in rural and outermost areas, must be bolstered to ensure equal public access to healthcare.

[1] OJ C 175, 28.7.2009, p. 8.

1.10 The Committee supports the Commission's intention to issue a policy strategy paper based on existing or emerging standards, aimed at ensuring the interoperability, quality and security of telemedicine systems.

1.11 The Committee would maintain that beyond the technical and organisational aspects, there is a need to develop exchanges on good clinical practice in the field of telemedicine.

1.12 The Committee welcomes the proposed three levels of action for the years ahead.

1.13 At Member State level, specific attention should be given to classifying the medical acts concerned and to their cost and levels of reimbursement.

1.14 As regards the countries that will be supported by the EU, piloting and assessment tools should be put in place in respect of the technical aspects and efficiency of telemedicine.

1.15 As for the actions to be undertaken by the Commission, the Committee would call on it to foster information and training programmes on the use of the new technologies, aimed at health professionals and the general public, to address the fears of users and build their confidence in these technologies.

1.16 The Committee regrets that specific attention is not given to the aspect of training health professionals. A structured programme of university-based and in-service training is crucial. Such training should not, however, produce *teledoctors*; rather, it should train all doctors in telemedicine.

1.17 The Committee urges the Commission and the Member States to fully comply with the recommendations in this communication and the proposed timetable of actions.

1.18 The Committee thinks that patient, consumer and health professional representative organisations should be involved in shaping the process of developing these new technologies. It deems it important to be involved in periodic progress assessments on the commitments made.

1.19 The Committee thinks that the deployment of telemedicine for the benefit of patients, healthcare systems and society should be seen in the context of the general development of health systems and policies.

2. **Gist of the communication**

2.1 *Background*

2.1.1 Telemedicine [2], i.e. the provision of healthcare services at a distance, can help improve the lives of patients and health professionals, whilst also tackling the challenges faced by healthcare systems (ageing populations, increasing prevalence of chronic diseases, older people remaining at home, patients in remote areas or with limited mobility, medical demography, disparities in the geographical distribution of healthcare, etc.)

2.1.2 Beyond improving patient care and healthcare system efficiency, telemedicine can also make a contribution to the EU economy given that this is a dynamic sector (in which SMEs are prevalent). However, the use of telemedicine is still limited and the market remains fragmented.

2.2 *The communication's approach*

2.2.1 The communication supports and encourages Member States in integrating telemedicine into their health policies, by identifying and helping to address the barriers hindering its use as well as by providing evidence aimed at raising interest in such services so as to win the acceptance of the medical community and patients.

2.2.2 Bearing in mind that the Member States are primarily responsible for the organisation, financing and delivery of healthcare and that they alone have the ability to make telemedicine a reality, while respecting the subsidiarity principle, the Commission has defined a set of actions to be taken by the Member States, the Commission itself and the relevant stakeholders.

3. **General comments**

3.1 While the Committee notes the scope of the Commission communication, it would highlight the benefit of computerising medical files, and point out that this issue ties in closely with the development of telemedicine.

3.2 The Committee supports the development of telemedicine as a way of meeting the overriding objective of universal equal access to quality healthcare. It notes its likely impact on the healthcare system and the practices of health professionals and feels that more care should be taken to guard against the risk of healthcare becoming a commercial commodity.

[2] Telemedicine encompasses a variety of services including teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring and teleophthalmology, with the exception of telesurgery. However, for the purpose of the communication, health information portals, electronic health record systems and electronic transmission of prescriptions or referrals are not regarded as telemedicine services.

3.2.1 The development of telemedicine is a lever for standardising the collegial practices of medical practitioners and the organisation of healthcare via networks, as well as a means of improving the quality and accessibility of healthcare. Nevertheless, these changes should be anticipated and accompanied by consideration of the organisation, prioritisation and delegation of tasks and of establishing protocols for telemedicine practices.

3.3 The Committee welcomes the **three levels of action** proposed, while making the following comments.

3.3.1 Building confidence in and acceptance of telemedicine services

3.3.1.1 In the Committee's view, more awareness should be raised among health authorities, professionals and patients and their respective organisations by creating forums for discussion and by highlighting evidence of the effectiveness of telemedicine. Evidence of cost-effectiveness is needed here. It should be borne in mind that developing sustained use of telemedicine hinges on the level of reimbursement of the cost of these services and the remaining cost to be borne by patients.

3.3.1.2 The Committee points out that SMEs in this sector do not have the financial wherewithal for research and development. Thus public sector intervention and public-private partnerships constitute a suitable instrument for the large-scale deployment of telemonitoring projects. As regards telemedicine equipment, the Committee will keep an eye on its technical development with a view to ensuring that it guarantees safety, simplified ergonomics and lower acquisition and usage costs. This technical development should not be the sole preserve of manufacturers.

3.3.1.3 The Committee emphasises that the deployment of telemedicine, and telemonitoring in particular, raises new ethical concerns because it affects the patient-doctor relationship. In order to win acceptance of these techniques, which cannot replace human contact, it considers it crucial that the relationship between healthcare provider and patient is clearly defined for patients seeking human warmth, as well as clear, precise and reassuring explanations.

3.3.1.4 The Committee considers it essential to democratise the use of the relevant technical tools to allow patients to keep control of their own lives and choices.

3.3.1.5 Moreover, medical personnel dealing with patients by phone or PC should have received training in psychology, with a view to humanising the remote relationship and mitigating the fact that the physical presence that until now has underpinned the doctor-patient bond is absent.

3.3.1.6 The Committee notes with interest the Commission's intention to support, via its Competitiveness and Innovation Programme, a large-scale telemonitoring pilot project, involving payers of healthcare services. It underlines the fact that it is up to Member States to assess their needs and priorities in telemedicine by the end of 2009.

3.3.1.7 The Committee also endorses the funding of programmes such as *Ambient Assisted Living* (AAL) ([3]), implemented under Article 169 of the EC Treaty, and encourages Member States to participate in such programmes.

3.3.2 Enhancing legal clarity

3.3.2.1 The Committee notes that the deployment of telemedicine is proving difficult. This is despite the fact that – under certain clearly defined conditions – it can help improve the healthcare system for the benefit of patients, healthcare professionals and social security bodies: it constitutes an effective means of optimising the quality of healthcare due to the speed of interaction and because it helps make more efficient use of medical time. The Committee thinks that its scope should be defined and that it should be given a satisfactory legal basis.

3.3.2.2 The Committee would advocate sticking to simplified definitions of telemedicine procedures such as:

— **teleconsultation**: medical act undertaken in contact with the patient who interacts remotely with the doctor. The diagnosis may result in a prescription for treatment or medication;

— **teleexpertise**: diagnosis and/or therapy, carried out in the absence of the patient. This involves an exchange between several medical practitioners who make their diagnosis on the basis of data in the patient's medical file;

— **teleassistance**: medical act whereby one doctor provides assistance to another health professional who is in the process of performing a medical or surgical act. This term is also used in relation to assisting ambulance staff in emergency situations.

In respect of these medical acts, it is crucial to enhance legal clarity and ensure that data protection systems are bolstered and that the highest level of patient safety is ensured as regards the collection, storage and use of the relevant data.

3.3.2.3 The Committee has noted that the definition of medical acts and their implications in legal and judicial terms, as well as in respect of reimbursement, varies across the Member States. In the light of this, it points out that patients are free to seek a consultation and medical treatment in a different Member State than their own, regardless of the manner in which the service is delivered ([4]), i.e. including via telemedicine.

3.3.2.4 The Committee reiterates its call for the establishment of complaints procedures in the case of harm and clear arrangements for dealing with legal disputes, including at trans-national level, which should lead to the widespread take-up of a compulsory liability insurance system for all health professionals.

([3]) OJ C 224, 20.8.2008.
([4]) OJ C 175, 28.7.2009, p. 116.

3.3.2.5 The Committee welcomes the Commission's intention to establish a European platform in 2009 to support Member States in sharing information on national legal frameworks and on any changes in respect of telemedicine.

3.3.2.6 The Committee believes that telemedicine cannot and should not replace conventional medicine. It is a complementary technique, limited by the absence of clinical examinations. It is subject to compliance with the same rights and obligations attached to any medical act. Furthermore, particular attention should be given to the following aspects:

— the status of the health practitioner should be clearly indicated;

— the patient must benefit from the latest medical knowledge, regardless of his/her age, financial situation and pathology;

— the patient must be informed of the purpose and scope of the medical act and the means used;

— the patient must be able to give his/her free consent;

— medical confidentiality must be ensured;

— consecutive prescription must be recognised;

— questions asked and answers given by health professionals must be understandable by the patient;

— resulting documents must be secure and recorded in the medical file;

— continuity of care must be ensured;

— the medical act must be of at least equivalent quality to a traditional act;

— the absence of clinical examination should not be compensated by a proliferation of x-ray examinations or biological tests; and

— strict confidentiality must be ensured as regards the technical means of transmitting data and the way in which they are processed by medical and paramedical staff.

More specifically, telemedicine must also include the provision of information on the technical means used to transmit the data concerned.

3.3.3 Solving technical issues and facilitating market development

3.3.3.1 In the Committee's view, broadband access ([5]) – required for ensuring maximum security – and full connectivity are a prerequisite for the development of telemedicine. Health professionals and patients need a guarantee that the technology used is secure and easy to use if they are to have confidence in telemedicine.

3.3.3.1.1 Digital services in the regions, particularly rural and outermost areas, must be consolidated, as telemedicine requires an efficient framework, especially as communities in such areas are particularly concerned.

3.3.3.1.2 Should health professionals lack broadband access, their response time would be unacceptable and they would be unable to transmit large files; poor quality information can create serious medical risks.

3.3.3.2 The Committee supports the Commission's intention to issue a policy strategy paper in cooperation with Member States on ensuring the interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level. In the Committee's view, given that these technologies are constantly evolving, only regular assessment of the reliability of the equipment is likely to instil confidence.

3.4 The Committee believes that while the deployment of these technologies represents an opportunity for the economy overall, its impact on the fragile funding of health systems should be assessed; moreover, EU aid for research and development would be useful. It feels that the programme *ICT for ageing* ([6]) should in future cover the specific features of telemedicine.

4. **Specific comments**

4.1 Given that telemedicine should not be considered merely in terms of the development of e-commerce – as it remains a fully-fledged medical act – the Committee welcomes the proposed **three levels of action** for the years ahead.

([5]) OJ C 175, 28.7.2009, p. 8.

([6]) Under FP7 (7th Framework programme).

4.1.1 At **Member State** level, the Committee points out that attention should be given to classifying the medical acts concerned and to reimbursement. Indeed, not all health insurance systems have included telemedicine as a medical act and are cautious as regards the conditions for its prescription.

4.1.1.1 Clearly, given the cost of investment, public health institutions and/or bodies responsible for health policy must seek possible means of sourcing and securing funding, via the platform for exchange between all the relevant stakeholders. Nevertheless, the Committee is concerned about the risk of patients' health insurance contributions rising considerably on the pretext of this development.

4.1.2 As regards the **Member States that are to be supported** by the EU, the Committee points out that given the varying regulations, practices and usage across these countries, an analysis of the Community legal framework that may be applied to telemedicine services should be published in 2009.

4.1.2.1 Beyond this analysis, the Committee would call for piloting and assessment tools to be set up with EU help. It would also be useful to identify strategic coherent objectives to achieve the visibility required by policymakers. This visibility requires a medical and economic assessment adapted to the challenges of demographics and of developing healthcare systems for the benefit of patients.

4.1.3 As for the actions to be undertaken by the **Commission**, the Committee would call on it to foster educational programmes aimed at familiarising patients with telemedicine practices and the new tools involved, in order to address the fears of users and the related issues of confidence. This is particularly important given that such patients are often older people.

4.1.3.1 The Committee regrets that the Commission does not devote specific attention to the aspect of training healthcare professionals for the purpose of familiarising them with the new conditions under which they will practise their profession. To achieve continuity and coordination of care, the new tools of doctor-patient dialogue also need to be mastered.

4.1.3.1.1 The Committee maintains that in the field of telemedicine, as in many others, training tailored to each category of health professional should be considered a major tool for change. There is a crucial need for a structured programme of university-based and in-service training aimed at optimising the use of telemedicine to enhance the quality of healthcare. A sustained public information campaign will also be required.

4.1.3.1.2 The Committee also notes that the interactive and inter-professional nature of the use of these new technologies constitutes in itself a teaching aid conducive to self-learning as part of a developing partnership.

4.1.4 The Committee considers it vital that telemedicine be considered a fully-fledged medical practice, rather than a fashion or a substitute, with regard to technological research, the development of equipment and software, the economic aspect of supplying equipment and of reimbursement, and acceptance of and confidence in telemedicine. Harmonisation and approval should be provided for to facilitate contacts between health professionals and the involvement of patients, by creating a convivial environment.

5. **Conclusions**

5.1 Telemedicine constitutes a cultural change and as such requires suitable communication. New professions may be spawned by this development.

5.2 The Committee thinks that the deployment of telemedicine should be seen in the context of the development of health systems and policies.

5.3 Health system users are set to become increasingly responsible for their own health. Patient and health-sector professional representative bodies will therefore need to be involved in shaping the process of developing and funding these new technologies.

5.4 It is important for the Committee to be involved in periodic progress assessments on the commitments made: beyond the operational development of telemedicine and the resources provided, this is a matter of equal access to healthcare.

Brussels, 15 July 2009.

The President
of the European Economic and Social Committee
Mario SEPI