



**AIM**

**ASSOCIATION INTERNATIONALE DE LA MUTUALITE**

Brussels, 17 June 2008

## **MEMORANDUM ON “TELEMEDICINE AND CHRONIC DISEASES”**

### **Purpose of the memorandum**

The aim of this memorandum is to give the viewpoint of AIM concerning telemedicine and chronic diseases, in the framework of the future Commission's communication on telemedicine and chronic diseases.

This memorandum is the summary of a workshop with different stakeholders and AIM members on 9 June 2008.

### **Context**

The society is facing a change in the health environment. The health demand of the population is increasing, chronic diseases are increasing and are by far the leading cause of mortality in the world representing, 60% of all deaths according to the WHO, and the need of long term care for the ageing people is rising. All these factors lead to an increase in health expenditure. Thus the longstanding challenge of all countries and the AIM members as well is how to give universal and affordable access to quality healthcare. To face this changing environment, the health system must change, as well as the health insurers. Telemedicine is one the tools “which can help to address these challenges and contribute to deliver better quality of care, to increase access to healthcare in remote areas and to overcome shortages of health professionals in given situations”, as well as “to empower patients in the management of their health condition”, as stated the European Commission.

### **Concerns**

AIM has the following remarks and recommendations regarding the deployment of telemedicine.

#### **1. Paradigm shift**

The technology is available, as telemedicine exists since more than 20 years and was developed and pushed the industry throughout this period. So that we need a paradigm shift:

***AIM calls on the users (health authorities, payers, providers, patients) to be in the driver seat, to really adapt the deployment of telemedicine to their needs.***

Some AIM members are still active in the field of telemedicine.

***AIM and their members wish to play an active role in the discussion and the debate at European level.***

#### **2. Technology**

The technical questions, like infrastructure and interoperability, are of course important, but out of the scope of the AIM members.

#### **3. Need of evidence**

The general list of benefits of telemedicine is known, but to really invest in telemedicine, the health insurers need to have evidence on the technology and on cost-benefit analysis.

***AIM deems that there is a need to give evidence based use of the telemedicine technology. To that purpose, appropriate tools of health technology assessment (HTA) should be developed. The European Commission should coordinate the development of European quality standardised tools.***

***Furthermore AIM estimates that there is a need to give evidence on cost benefit analysis, as well as to assess the return on investment of different telemedicine applications. Proposals of business cases/economic models for telemedicine applications are interesting tools.***

#### 4. Need of awareness and change in the organisation of the health system

- Like any new technology, there is a need to convince the providers and the patients of the benefits and the evidence of telemedicine, as soon as the evidence and the cost benefit analysis are available.

**AIM supports the need of strengthening the awareness of all potential users of telemedicine and at the same time of accompanying it by a change management.**

- As telemedicine changes the roles of the different providers, there is a need to redesign the organisation of the health system, adapt the health pathways and redefine the role of the providers, in order to better benefit of the technology and improve the efficiency and the quality of the system.

**AIM thinks that the stakeholders (health authorities, payer organisations, providers and patients) should discuss together the redesign of the health system organisation towards a more “integrated care” and rethink the role of different providers, according to the telemedicine applications.**

**AIM calls on the providers to develop the required tools to ensure a quality use of telemedicine by the providers, by developing:**

- **adequate training of the providers**
- **specific guidelines for telemedicine (like the guidelines proposed by CPME of in the US)**
- **a specific code of conduct (like the ethical principles proposed by CMPE)**
- **quality assurance in the process of telemedicine (total quality management, ISO certification, .)**

**To ensure the success of telemedicine on the side of the patient, an adequate training of the patient (and its family) is vital, as well as the support of the family to the patient is important.**

#### 5. Legal constraints:

There are some legal constraints well documented which need to be addressed in order to deploy the telemedicine applications, as soon as they are evidence-based and were submitted to cost-benefit analysis.

- The national law on health care should normally cover telemedicine, but as telemedicine has particular aspects,  
**AIM calls on to check if national law on health care legislation cover telemedicine and to adapt it necessary.**
- The specific accreditation and licensing of telemedicine providers is fixed nationally.  
**But concerning cross border telemedicine, AIM asks the European Commission to think about the need of a cross border accreditation and authorisation for telemedicine, in order to ensure quality and avoid illegal use of telemedicine.**
- About the protection of the confidentiality (data and privacy), the security and the need of informed consent of the patient, national existing laws apply in the field of telemedicine.  
**The question of the informed consent raises the question of the need of an implicit or explicit informed consent.**  
**As far as the cross border telemedicine applications is concerned, see below the EU legislation.**
- Every provider need a liability insurance to cover malpractice, as well as the manufacturing company of medical devices used in telemedicine.  
**The concerned provider needs to check if the liability insurance cover telemedicine.**  
**Concerning the cross border activities, see also below the EU legislation.**
- **Concerning the telemedicine equipment, which is theoretically covered by the national regulation on medical devices, AIM asks the European Commission to think about the need of developing European quality standards on telemedicine equipment.**
- Finally, some EU legislation concern telemedicine, like *inter alia*:
  - Free movement of goods, services, labour and capital set in the EU Treaty
  - Telemedicine is considered as a provision of a service (according to article 49 of the EU Treaty)
  - European Directive on certain legal aspects of information society services in the Internal Market: The Electronic Commerce Directive (00/31/EC) and the Electronic Commerce (EC Directive) Regulations 2002 (SI 2002 No. 2013).
  - European Data Protection Directive 95/46/EC:

- Free transfer of personal/medical data between EU member states
- EU-wide recognition of medical diploma's (2004)  
Medical doctors can practice in any other member state
- Directive 1999/93/EC on a Community framework for electronic signature

***AIM asks the European Commission to review all the existing legislation relevant to Telemedicine, to check if it is adequate or needs updates or if there is a need of new legislative measures or guidelines to cover all the aspects of telemedicine.***

## 6. Reimbursement

The reimbursement question should be adapted to the telemedicine specificity, considering the different cases of telemedicine applications, consultation (diagnosis/treatment) or tele-monitoring, and the different forms like the one described by ETHEL:

- D2D: doctor to doctor (teleradiology, telepathology, teleconsultation)
- D2P (doctor to patient: telemonitoring, telehomecare, emergency, care of 'travelling' patients, internet based patient consultation)
- D2D2P.

Questions like the need of the presence of a doctor should also be adjusted.

***The reimbursement questions have to be fixed through a national nomenclature and rules for reimbursement, taking into account the different telemedicine cases.***

The question of fraud and abuse should also be tackled like other medical practices.

## 7. Others remarks and recommendations

- Concerning the problem of financing of the investment and the sustainability of telemedicine applications, the development of business models are the best way to deal with.

***AIM supports the initiative of the European Commission to study the business models of innovative e-health applications in particular in the field of telemedicine applied for chronic diseases.***

- About the **advertising for telemedicine**, the national regulation on advertising on medical services and medical devices should apply.
- The question of the **emails and the doctor-patient the relationship** should be regulated by specific national guidelines, as well as the reimbursement of the emails should be regulated within the national nomenclature and rules for reimbursement.
- Regarding **e-prescription**, a registered system of e-signature is a requested condition to recognise the e-signature and recognise the doctor.  
As far as the cross-border e-prescription is concerned, insofar as the doctor is recognisable and the drug is recognised through its labelling in INN (international non proprietary names), the question of reimbursement is regulated by the Community legislation co-ordinating the national provisions of social security (Regulation (EEC) No 1408/71, Regulation (EC) No 883/2004), implementing Regulation (EEC) No 574/72).
- As the experiences and the pilot projects on telemedicine are numerous in the EU,  
**AIM supports the need of a "European supporting framework for sustainable telemedicine" proposed by ETHEL**, with the aim to build an interdisciplinary service framework, a reference system of definitions and nomenclature, an inventory of best practices and a help desk.

## **About AIM**

The 'Association Internationale de la Mutualité' (International Association of Mutual benefit societies) (AIM), created in 1950, brings together 45 national federations of autonomous health insurance and social protection bodies in 28 countries, all operating according to the principles of solidarity and not-for-profit orientation. They provide coverage against sickness and other social welfare risks to more than 170 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; finally, autonomous management and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

*AIM endeavours to voice concerns and ideas raised within the sphere of non-profit health insurance institutions in the EU. AIM positions, requiring validation through its own statutory decision-making process, do not commit its individual member organisations. Therefore, AIM involvement does not detract from its member organisations taking dissentient views.*