

# Consultation on eHealth Lead Market Initiative

## PLEASE ANSWER THE FOLLOWING QUESTIONS

**Please send your response via email to [eHealth@ec.europa.eu](mailto:eHealth@ec.europa.eu), or if unable to email please fax to 00 32 (0)2 296 0181, preferably by Wednesday 25 April 2007**

### Introduction

The Aho Report on "Creating an Innovative Europe" recognised the importance of information and communication technologies (ICT) in tackling specific challenges which the healthcare sector faces, thus identifying eHealth as a "lead market" with considerable potential and the necessity for specific and timely attention. In its follow-up to the Aho Report, "Putting knowledge into practice: A broad-based innovation strategy for the EU", the Commission proposed to launch a new "lead market initiative", coordinated by DG ENTR, aiming at facilitating the creation and marketing of new innovative products and services in promising areas, with contributions from public authorities to accelerate and drive market growth.

A "lead market" can be defined as a market:

1. for innovative products and services with high growth potential (R&D & innovation intensive, based on increasing public and private customer need/demand)
2. where EU industry can develop competitive advantage to lead in international markets (EU knowledge and industrial basis to capitalise on investments in promising new technologies)
3. that require action by the public authorities (as a regulator lifting obstacles, as a customer driving developments, as a facilitator)

Consequently we are asking for input that provides:

1. evidence of emerging market segments
2. evidence of industry commitment
3. evidence of expected influence of public action

### Questions:

- 1. What are the emerging eHealth market segments? (see elaboration of growing demand for eHealth + draft definition of eHealth market segments below)**
- 2. What are European industry and technology strengths for the eHealth Market? What are the industry commitments? (see short description below)**
- 3. What do you consider to be the main obstacles to the development and growth of the eHealth Market? What do you consider to be the top 3 challenges for EU-wide deployment of eHealth services and solutions? How can the growth of the development of the eHealth market be accelerated?**

**What could/should the public authorities (regional, national, EU) do to weaken/remove these obstacles?**

**(see text below on obstacles and possible solutions)**

**Please feel free to share any other comments or views regarding the texts below and the development of the eHealth Market. Concrete figures on market assessment would be appreciated.**



## **The growing demand for innovative eHealth products and services**

The Health domain employs almost 10% of Europe's workforce, and represents 9% of Europe's economy. In the Health domain, the eHealth industry is one of the largest growing sectors with a double digit annual growth and an estimated size of 20 Billion Euro in 2006, forecast to become 50 Billion Euro by 2010.

Europe's population is ageing rapidly. The number of people over 65 will rise by nearly 40% between 2010 and 2030 and the number of people over 80 will have doubled by 2050. Progress in eHealth is helping us contain health costs while providing higher quality health services. An older, increasingly wealthy Europe is bound to increase demand for innovative eHealth systems and tools.

In fact, there is mounting pressure for increased growth and efficiency in health sector in general and in eHealth in particular, given:

1. increasing demand, pressure and strain on the social security and health systems (in a context of public budget constraints and pressure to maintain/reduce the tax burden on companies and individuals)
2. social need for higher availability of a healthy work force (in a context of slow demographic growth and longer work lives, and aiming at meeting high employment, social cohesion and participation objectives)

At the same time, health (and eHealth in particular) can also potentially contribute:

1. to regional equity and competitiveness (as an anchor, relevant for both local and tourist populations)
2. to economic growth, being arguably a high-innovation, high-technology industry, with a growing market and potential high multiplier effects.

eHealth can deliver significant benefits to the entire community, through improvements in access to care, quality of care, citizen-centred health systems and the efficiency and productivity of the health sector. Furthermore it contributes to citizen-centred health systems (citizens are being empowered by technology and policy to participate more in the management of their health and to make their voice heard by all policy-makers) and to the efficiency and sustainability of the health sector.

The potential of eHealth to contribute to health systems' improvement - and improving healthy life years - should not be forgotten, especially under the context of stricter budgeting constraints.

Besides strong links with patient safety and fraud and tampering control, for instance, further development and deployment of eHealth solutions may additionally contribute to wider targets concerning innovation, market enlargement and international competitiveness.

## **Draft Definition of eHealth Market Segments**

The eHealth Market comprises broadly the following (overlapping) major categories and subcategories:

1. Regional/National Health Information Networks and Distributed Electronic Health Record Systems including
  - a. Administrative and Clinical Information Systems for GP's and hospitals (including electronic health records, decision support systems, laboratory and radiology information systems)
  - b. (On-line) services such as e-prescription, e-referrals, e-booking, messaging/reminders, etc
  - c. Public health databases, registries, networks and portals
2. Telemedicine systems and services (e.g. telecare, teleconsultation and telemonitoring) including
  - a. Personal Health systems (e.g. mobile, wearable, portable monitoring devices)
  - b. Home care & Chronic disease management services
  - c. Other telecare services
3. Specialised tools for health professionals and researchers
  - a. Advanced robotics and imaging environments for diagnosis and surgery
  - b. Modelling and simulation tools for pre-operative planning, drug development
  - c. HealthGrid, educational tools and access to knowledge services
4. Support systems
  - a. Logistics (supply chain management, scheduling, accounting)
  - b. Other (Electronic Data Interchange applications, health professionals directories, etc)



eHealth can thus be said to cover the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients or health professionals; it can also include health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for monitoring and supporting patients.

## **European industry and technology strengths for the eHealth Market**

eHealth is a sector that strongly and directly benefits from research and technological development but also one that triggers them. eHealth can be an example of 'business driving technology', making Europe a more competitive economy and reducing barriers to introduction of new technologies.

eHealth offers therefore a wide range of new business opportunities to be tapped and European industry is well placed to seize these opportunities. In addition to the three major large European companies (Siemens, Philips, and Agfa) that are world leaders in this field, more than 5,000 other European companies, most of which are SMEs, are operating in various sub sectors of eHealth.

## **Main Obstacles**

### *a) Risk- / Innovation- / Reform-averse health authorities*

Information and communication technologies (ICT) are largely under-exploited in the EU as a whole, but in the public sector in particular.

Improved public procurement practices can help foster market uptake of innovative products and services, while raising the quality of public services in markets where the public sector is a significant purchaser.

Striving towards a "European eHealth Area" by coordinating actions and promoting synergies between policies and stakeholders will contribute to a larger internal market for eHealth applications, therefore allowing for a better entrepreneurial environment and for scale economies to be found, promoting international competitiveness, namely vis-à-vis the US.

It can also be mentioned that, being part of a market under strong public surveillance, the potential role of public drive and procurement should not be discarded.

### *b) Market fragmentation*

One of the major hurdles for the further and quicker development of the sector in Europe is market fragmentation and lack of system interoperability (technical and semantic). The added value offered by a European eHealth market could be fully exploited only if the various products and/or services can be integrated and connected, i.e., can "talk to each other". Today, however, the interoperability of those systems, and the market transparency to identify good quality products, are not the strongest facets of this market.

To address this gap, the EC therefore focuses its activities on eHealth **interoperability<sup>1</sup>, labelling and certification** of eHealth systems and services<sup>2</sup> within the framework of the eHealth Action Plan 2005 -2009 (COMM (2004) 356 final).

### *c) A legal and regulatory framework that is not conducive to innovation*

Legal, medical and ethical issues of confidentiality, ownership and access to data arising from the use of eHealth tools, in particular in relation to exchange of electronic health records in cross-border settings, must be addressed.

Legal certainty is a pre-requisite for businesses to invest in innovation and for buyers and users to take up new products and services.

The EU has a clear responsibility in providing such certainty. A great deal has been done by the EU in protecting consumers in relation to data privacy, liability issues, and in the quality and certification of products and services.

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<sup>1</sup> Draft eHealth Commission staff working paper "Connected eHealth: Quality and safety for European citizens" [http://ec.europa.eu/information\\_society/activities/health/policy\\_action\\_plan/interoperability/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy_action_plan/interoperability/index_en.htm)

<sup>2</sup> European Quality Labelling and certification of Electronic Health Records system. [www.eurorec.org](http://www.eurorec.org)



However eHealth is an area which raises specific concerns. These relate, among others, to the scope and purpose of data collection, conditions for access to data, patient agreement, traceability, storage, transferability, etc.

To address this critical issue, the EC launched early in 2006 a study entitled "Legally e-Health". Its principal objective is to clarify those legal issues specific to eHealth, in particular in relation to data privacy and security, liability and competition. The study has already reached the stage where it has examined in detail the contents of the Data Protection Directive in potential relation to eHealth. The EC services will examine carefully the findings of this study, which are due in spring 2007, in order to assess whether additional regulatory provisions are necessary or whether current provisions are sufficient to ensure legal certainty. This will be done within the context of a parallel move on the part of DG SANCO to explore the possibilities for a framework initiative, specific to health and healthcare, which will cover issues relating to the legal certainty of EU cross-border healthcare provision. DG SANCO's ongoing 'Open Consultation Regarding Community action on health services' will also provide valuable learnings.

### **Obstacles to eHealth Market Development that could be target for EU actions**

- a) Fear of risk-taking and innovation by the health authorities, insufficient protection, lack of trust and uptake between the different stakeholders (authorities, industry, users, payers)
  - o ... Need to expand footprint of services and devices to include more illnesses and diseases. More economies of scale leads to market growth
  - o ... Being part of a market under strong public surveillance, the potential role of public drive and procurement should not be discarded
  - o Proposed Solutions/Actions: Supporting large scale pilots and sharing the risk, building synergy and best practices, creating evidence and disseminating knowledge, coordinating multi-stakeholder discussions and organising events
- b) Lack of interoperability between systems, companies guarding IP, 'Lock-in' of certain company's systems.
  - o Proposed Solutions/Actions: Facilitating the synergy between industry, authorities and users for the provision and acceptance of interoperability guidelines and standards, encouragement of Open Source Software, perceived risk.
- c) Legal and regulatory obstacles
  - Data protection regulation
    - o Which legislation to apply? Needs to be adjusted to involve patients, forcing better sharing of data, negotiating "whole sale" deals with national data protection agencies
    - o How to find a common ground to deal with related confidentiality and ethical issues?
    - o What EU-wide communication policy to resort to so as to increase trust?
    - o How should data meant for Public Health surveillance be dealt with? What is the role of patient agreement?
  - Liability Legislation needs to be reframed
    - o Clarify who is liable and how. PHS products subject to Consumer goods legislation, based on security and certainty, contract-law based, individual contracts for each product clearly hampers market growth.
    - o Which is the competent (national) court in case of liability claims? Country of patient, country to which the tele-service has been sent to?
  - Accreditation, Conformity, Qualification of services, registries of professionals
    - o Proposed solutions: Rearrangement of medical environment and clarification of registration procedures.
  - Reimbursement through health insurance - e.g. patient who received a "tele-treatment" (from a foreign practitioner) is refused reimbursement or coverage from/in own health insurance
    - o EU: Tax law, social security law and labour law: different assignation rules