

Terms of Reference for the CEN/ISSS eHealth Standardization Focus Group

1 Task description

The CEN/ISSS e-Health Focus Group is formed to prepare an overview report on current and future standardization issues in the e-Health domain.

2 Objectives

- To consider, with all the relevant stakeholders, priorities and objectives for eHealth standardization and interoperability and how the CEN system and others can contribute;
- To overview the existing achievements and current programme of work of CEN/TC251, starting from the report presented to the Commission in June 2001, and to consider its current achievements and Business Plan;
- To overview other current and proposed e-Health related and relevant standardization activities, in formal standardization and industry consortia, and in particular interface with the recommendations of the e-Health Standardization Co-ordination Group recently formed by an ITU-T initiative, and which includes CEN/TC 251, ISO/TC 215, ITU, DICOM and HL7;
- To consider the standards implications of the Ministerial Declaration of 22 May 2003, following the Commission/Presidency eHealth 2003 Conference (**Annex A**);
- To take due account of requirements of eEurope Health Online key actions;
- To take due account of other policy and legal requirements in the European context, including initiatives at national and regional level;
- To prepare a draft report, containing proposals and priorities for future standardization work, and present this to a Commission-organized Open Meeting;
- To finalise the report in the light of public comments and the Open Meeting discussions.

3 Scope

The activities of the CEN/ISSS eHealth Focus Group should cover the concept of eHealth as defined in the context of eEurope¹ – the application of information and communications technologies (ICT) across the whole range of functions and services which, one way or another, affect the health of citizens and patients, specifically:

- Delivery of care to patients by healthcare professionals;

¹ http://www.europa.eu.int/information_society/eeurope/2005/all_about/ehealth/text_en.htm

- Health-related information;
- Electronic trading of healthcare goods.

4 Membership

The Focus Group will be open to all interested parties through public web announcement.

Participants in existing relevant European standards shall be invited to join the Focus Group, as will the CENELEC Central Secretariat and ETSI Secretariat and other interested members of the ICT Standards Board.

Representatives of the health sector including Governments, industry, insurance companies, health professionals and patient associations shall be invited to attend, as will the European Health Telematics Association (EHTEL), EUROREC and the CEN Sector Forum for the medical sector (CHeF).

The European Commission DGs ENTR, EMPL, INFOSOC, SANCO and the EFTA Secretariat shall be invited as Observers.

5 Working methods

The CEN/ISSS eHealth Standardization Focus Group shall be formally responsible to the CEN/ISSS Forum, which shall endorse the Terms of Reference and the final Report.

The Chair will be nominated by the Group and endorsed by the Forum. The Secretariat shall be provided by a CEN Member.

A Steering Committee will be formed to ensure that the Focus Group is effectively managed and the results representative. It will comprise five people and be coordinated by the Focus Group Chair.

The Group will work on a voluntary basis. Physical meetings may be held as required, but full electronic working facilities shall also be provided.

The Group shall organize the drafting of the report, and may select and manage a document Editor, for which initial Terms of Reference will be prepared and endorsed at the Kick-Off meeting. The Group will work by consensus; otherwise it may choose its own operational methods. It shall provide progress reports to the CEN/ISSS Forum and ICT Standards Board.

The selection and appointment of one paid editor shall be made under CEN/ISSS rules.

The Group will be disbanded on completion of its final report.

6 Expected deliverable(s)

Report, containing proposals and priorities for e-Health standardization activities in connection with the eEurope 2005 Action Plan.

7 Outline work plan, including duration and target dates (Provisional)

1. Approval of Group and outline approval of Terms of Reference by CEN/ISSS Forum, 7 October 2003
2. Web announcement, 14 October 2003
3. Kick-Off meeting: discussion of ToRs for the Focus Group and nominations of Chair candidates, appointment Secretariat, 17 December 2003
4. Appointment of Chair and Steering Committee, launch of Call for Editor, January 2004
5. Availability of initial proposal(s) for discussion, end April 2004
6. Open Conference on e-Health standardization (proposed), May 2004
7. Availability of Interim Report, June 2004
8. Availability of Final Report for approval by CEN/ISSS Forum, Sept 2004

Appendix 1 to Terms of Reference

Ministerial Declaration Brussels, 22 May 2003

Ministers of EU Member States, Acceding and Associated countries, as well as EFTA countries met on 22nd May 2003 in the framework of the eHealth 2003 conference organised jointly by the European Commission and the Greek Presidency of the Council.

eHealth refers to the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers.

On this occasion, Ministers expressed their commitment to the development of national and regional eHealth implementation plans as an integral part of eEurope 2005. Ministers declared their willingness to work together towards best practices in the use of Information and Communication Technologies (ICT) as tools for enhancing health promotion and health protection, as well as quality, accessibility and efficiency in all aspects of health care delivery.

Ministers welcomed the eHealth Conference initiative of the Greek Presidency working in close collaboration with both the public health and information society directorates of the European Commission.

Promoting quality of and enhancing efficiency in health care through eHealth applications

The ministers recognised that efficient national planning and evaluation of health policy, as well as cost effective delivery of health care, require speedy, accurate and comprehensive exchange of data.

Ministers noted that the accessibility to appropriate health information can be enhanced through the use of secure shared eHealth applications, such as those described in the objectives of the eEurope 2005 Action Plan¹, and agreed in the Council's Resolution² of 18 February 2003 on the implementation of the eEurope 2005 Action Plan.

Ministers reiterated their commitment to the developing of an information system for the early warning, detection and surveillance of health threats, both on communicable diseases and on non-communicable diseases.

The ministers acknowledged that eHealth applications can enhance efficiency and bring added value to health care by avoiding duplicate or unnecessary diagnostic or therapeutic interventions, by supporting the continuity of care, by improving communication between healthcare establishments and by widening access to health knowledge and evidence-based medicine.

Ministers welcomed the initiative on the European Health Insurance Card announced

¹ COM (2002) 263

² OJ: C 048, 28/02/2003, p.2-9

at the Barcelona Council³ and endorsed by the Seville Council as part of the eEurope 2005 Action Plan. Ministers encouraged the Commission to explore further initiatives in developing European Electronic Health Cards also taking into account the recent Communication from the Commission (COM (2003)73)³ on the European Health Insurance Card.

Facilitating citizen involvement through access to high quality information

The ministers shared the view that citizens' needs must be at the centre of attention in the development of high quality health related information services. Ministers noted the potential for citizen empowerment through widespread availability of high quality appropriate health information on the internet. Ministers welcomed the Commission Communication on Quality Criteria for Health related Websites⁴ and encouraged the Commission to explore the possibilities of EU level Quality Seals⁵.

The ministers expressed concern about the possible exclusion of sectors in society that do not enjoy easy access to the internet. Ministers acknowledged the need to widen the provision of public access points to the internet to facilitate wide citizen accessibility to appropriate health related information. Ministers noted that such access points and publicly supported health related websites should comply with guidelines on Web Accessibility⁶.

Implementing and sharing best practices of eHealth

Ministers agreed to share experiences on the utilisation, efficiency and impact of eHealth applications, and to assist the Commission in further dissemination of information on best eHealth practices.

Ministers supported concerted actions to address particularly the development of standards enabling interoperability of diverse systems and services and to especially explore the possibilities of open source applications for achieving this objective.

Ministers took note of the best practices in the utilisation of eHealth technologies identified and presented at the conference and agreed to explore further how best to use them within their countries, across Europe and internationally. Ministers invited the Commission to further refine and develop assessment methodologies for eHealth ICT applications.

Looking to the future

The ministers recognised that full exploitation of eHealth goes beyond local information systems and Internet based provision of information to integrated or linked eHealth systems, that serve the needs of citizens, patients, healthcare professionals, health service providers as well as policy makers.

³ Communication from the Commission concerning the introduction of a European health insurance card, COM (2003)73 final, 17 February 2003

⁴ COM (2002) 667 final

⁵ Decision N° 1786/2002/EC of the European Parliament and the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) - Commission

⁶ Communication from the Commission concerning eEurope 2002: Accessibility of Public Web Sites and their Content COM (2001) 529, 25 September 2001

Ministers welcomed the Commission's initiative to explore the possibilities to promote co-ordination at a European level, in order to meet the targets and objectives laid down in the eEurope 2005 Action Plan and the Programme of Community Action in the Field of Public Health (2003-2008), and liaising with other Community initiatives as appropriate.

Ministers encouraged Member States, Acceding and Associated countries as well as EFTA countries, to take, as appropriate, effective legislative, executive, administrative and other measures, to promote the adoption and use of eHealth applications.

Ministers noted that the full exploitation of the benefits of eHealth technologies requires continued commitment to the development and use of a robust, secure and interoperable infrastructure, as well as to wide availability and use of broadband communications to maximise the efficiency of eHealth systems and applications. Ministers acknowledged the importance of continued commitment to the implementation of eHealth applications, as agreed to by the Heads of State through the eEurope 2002 Action Plan and noted that benchmarking of such implementation will be carried out under the eEurope 2005 Action Plan.

Ministers encouraged the continued investment in research and technological development⁷, ensuring steady advancement of European eHealth technology applications that meet European demands for confidentiality⁸, data security and interoperability.

Ministers noted the successful collaboration on issues related to eHealth with the World Health Organisation, the Council of Europe and the OECD and encouraged its further continuation.

Ministers welcomed the initiative of the Irish Government to take stock of further eHealth developments at the second eHealth Conference in 2004.

⁷ Comm (2002) 499 more research for Europe towards 3% of GDP

⁸ 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.31-50)