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Standardisation mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies

1 TITLE

Mandate to the European Standardisation Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth.

2 RATIONALE

2.1 Introduction

ICT for Health, also known as Health Informatics and as eHealth, describes the application of Information and Communication Technologies across the whole range of occupations that affect the health sector, from doctors to hospital managers, nurses, data processing specialists, health and welfare workers, social security administrators, public administrators, pharmacists and of course citizens.

ICT in the service of health provides tools for health authorities and professionals, as well as personal health systems for patients and citizens. Example components include health information networks, electronic health records, telemedicine and telecare services, personal wearable and portable communication systems, health portals, and many other ICT -based tools that assist disease prevention, diagnosis, health monitoring and lifestyle management.

The advance of eHealth applications and services and the wider level of implementation in the Member States oblige policy makers, industry, the medical profession and other stakeholders to carefully assess developments, taking into account the need to build seamless information networks across borders in regions and countries. eHealth has the potential to facilitate the applications of many defined health policies regarding citizens, care delivery, organisational or managerial needs.

Additionally, appropriate eHealth has the potential to provide the European citizen with improved access to better health systems and to empower citizens in managing their own health.

Through the coordinated flow of information related to health issues and at the managerial level, eHealth will contribute to an increased quality and efficiency of health services. eHealth also provides an opportunity for economic benefits; it will contribute to major cost savings in the delivery of high quality and effective health services.

eHealth has major business potential for industry; however, further market acceptance and trust in health services will depend on the interoperability of the services and applications and protection of data protection. Safe and secure interoperability is key to the faster adoption of ICT throughout the healthcare systems in Europe.

Interoperability is not limited to technical interoperability; many other aspects need to be taken into account such as semantic interoperability and linguistic criteria, cultural aspects and organisational issues.

In order to make eHealth services available and beneficial for EU health professionals and citizens, it must be guaranteed that these services are compatible and interoperable. The secure transport of personal health data between endpoints over both wired and wireless networks is an essential component of any operable health system.

There is general agreement that global standardisation, based on consensus between all the relevant stakeholders, is the prerequisite to achieve such interoperability. Standards are required that have been verified by consistent and coordinated interoperability testing.

2.2 The political environment

eHealth interoperability, within and among national, regional and global health systems became a major political priority as a result of the eEurope 2002 -2005 action plan.

The Communication COM (2004) 356: "eHealth - making health care better for European citizen: An action plan for a European eHealth area" subsequently defined the European Union's policy in the area. It identified a set of actions with the view of implementing interoperability objectives, focusing on increasing quality and safety of care, tackling patient mobility in Europe, and addressing industrial competitiveness in the eHealth area.

This eHealth action plan aims to enable the European Union to achieve the full potential of eHealth systems and services within a **European eHealth Area**. This concept was further pursued by the 2005-launched strategic framework *i2010 – European Information Society 2010*. This initiative sets as priorities the completion of a Single European Information Space, the promotion of innovation, and strong support for the inclusion of all European citizens – topics which are at the heart of eHealth interoperability.

At the **eHealth 2005 conference** in Tromsø, Norway, the Ministers and political representatives of the twenty-two Member States in attendance concluded: 'In a Europe in which our citizens are increasingly mobile – whether within the borders of their own Member State or among different countries – we need to raise awareness of the pressing need for a more **integrated and interoperable** European health information space. The Ministers

commit to taking up this challenge in a staged and structured approach over the next five -year period'. These crucial issues are also ones which were picked up in a major way at the eHealth 2006 in Malaga, Spain in May 2006 and were further explored at the World of Health IT conferences in Geneva, Switzerland in October 2006.

Similar sentiments were expressed by the Committee of the Regions in its comments on the eHealth action plan,¹ and in reports by the European Parliament.

Preliminary results of the eHealth ERA project also confirm the observation that interoperability issues are high on the agenda of most eHealth strategies and roadmaps of Member States.

The interoperability issue was taken up by the eHealth working group, now known as the i2010 subgroup on eHealth, and by the eHealth stakeholder group. The co-operation within these structures as well as the co-ordination with the relevant Commission services led to the production of the Report "Connected Health: Quality and safety for European citizens". The "Connected Health" report outlines priority issues which must be pursued in order to reach the health systems goals. They include improving patient safety, encouraging well-informed citizens and patients on health matters, and creating high-quality health systems and services while, at the same time, facing international competition in the eHealth sector. The report focuses on the overriding theme of comprehensive eHealth interoperability: eHealth solutions must be interoperable to facilitate and foster the collaboration of health professionals and health care organisations, and various stakeholders must co-operate and involve themselves in the issue so as to resolve the pending legal, organisational and policy barriers.

The paper recommends the necessary steps to reach the goals for the benefit of Europe, its citizen and societies, thereby supporting the long-term objectives of the Lisbon strategy. The recommendations cover political, social and regulatory issues; appropriate processes and structures to achieve eHealth interoperability; standardisation; semantic interoperability; certification and authentication processes.

3 STANDARDISATION FOR eHEALTH

The Communication COM (2004) 356 -: "eHealth - making health care better for European citizen: An action plan for a European eHealth area" as well as the recent report "Connected Health: Quality and Safety for European Citizens" report both refer to the important role of standardisation in achieving the objectives set out in the area of interoperability of eHealth applications.

Further to a Commission invitation in the context of the eEurope standardisation action plan (2002-2005) CEN has published the final version of the CEN/ISSS eHealth Focus Group report. The report provides an analysis of the current standardisation environment for eHealth, at European and international levels. It identifies the specific standardisation needs to respond to recent developments in eHealth policies while covering the eHealth scope defined in the context of the eEurope action plan. Subsequently the CEN/ISSS report defines a set of 14 Recommendations for a future standardisation work programme.

Recommendation 1 in the CEN/ISSS report sets out the need for establishing a stakeholders' platform that identifies and agrees on policy priorities for ICT standardisation. It subsequently promotes further a coherent implementation of the resulting eHealth standards.

The other 13 Recommendations cover various aspects of eHealth such as: safety of health informatics, mobility of the patient, e-prescribing, security issues, and availability and implementation of standards.

Recommendation 1 has been implemented, at least with respect to the electronic health record, through the creation of the i2010 subgroup on eHealth in combination with the eHealth stakeholders' group. Both have confirmed the priority for achieving adequate interoperability for eHealth solutions. Their conclusions lay out several actions in view of achieving an adequate level of eHealth interoperability. Furthermore, within the overall eHealth interoperability domain, patient and health practitioner identifiers, the patient summary, as well as an emergency data set, have been identified as the most critical priorities to be covered by standardisation activities.

The result of such a co-ordinated eHealth standardisation process will be a set of standards and guidelines on eHealth interoperability. This will require a plan to migrate from the currently scattered, set of loosely connected standards to the "next generation". There the results of the state of the art work currently being undertaken by the Standard Development Organisations, various consortia and in R&D projects can be fully explained and exploited in an implementable and interoperable way. The result would be a set of standards that would be much more effectively implemented in the Member States and at the level of the European Union, notably to facilitate compliance with cross-border mobility and legal requirements as laid down in Communication COM (2004) 356.

Furthermore, the standardisation activities should aim to bridge between different parts of the healthcare work thereby allowing different sectors to communicate. For example those working to protect public health that work by monitoring the safety of medicines need to receive reports of suspect adverse reactions to medicines from healthcare professionals. By building "reporting forms" into prescribing and dispensing software, and ensuring that terminologies are interchangeable, healthcare professionals and public health professionals will be able to communicate directly. This will provide significant resource savings and better protect public health through faster and more thorough reporting of adverse reactions to medicines.

The policy context for eHealth fully recognises the potential of standardisation to contribute efficiently to a better level of interoperability. Both technical and semantic interoperability would both benefit especially from a consensus between those stakeholders involved through the EU standardisation process.

To promote the implementation of standards in support of interoperability, the European Standardisation Organisations should consider the compliance verification and conformance testing aspects, including the potential role of certification. Further standardisation work should include test specifications in support of verification of compliance for defined uses.

It is also proposed that large -scale pilots that test and validate eHealth interoperability in a practical and applied manner will be supported as a result of funding from the Information and Communication Technologies Policy Support Programme within the Competitiveness and Innovation Framework Programme 2007 -2013.

4 R&D PROJECTS

Past, current and future R& D projects, studies and other initiatives in the interoperability area (including those funded by the EU) can have a considerable impact on the standardisation area. They may impact the need for standards, the subject of standardisation , the standards development process as well as the implementation and validation of standards. Some such projects co- funded by the EU, are listed in Annex 1.

While recognising the lack of wider consensus represented by R&D projects, the European Standardisation Organisations are encouraged to use the overall methodologies being developed in the COPRAS IST project to ensure that where appropriate projects can contribute their outputs coherently towards standardisation, avoiding duplication and validating established, new and emerging standards.⁸

5 PURPOSE OF THE MANDATE

5.1 Description of the mandated work

The goal of phase 1 (planning and analysis) of the programme should be to:

- list existing relevant standards and technical reports with short descriptions,
- list relevant needed tasks for achieving the result, it is important that the most needed standards are planned for adoption earlier,

The goal of phase 2 (execution) should be to agree on implementable standards, technical reports, guidelines, methods etc. In the work the European Standardisation Organisations shall use quality and project management principles to ensure that content and context within and between the standards are consistent.

In phase 1, the European Standardisation Organisations are to further develop the relevant recommendations set by both - but not limited to - the CEN/ISSS Focus Group report on eHealth standardisation and the work carried out by DG INFSO and the i2010 Sub -Group on eHealth into a detailed work programme.

In addition the European Standardisation Organisations are to consider the impact of information appliances (especially those commodity, perhaps unregulated, items for personal use) in the provision of health care and to describe functional boundaries between the eHealth domain and other domains (such as finance, logistics and eGovernment). The work should also take due account of ETSI Special Report SR 002 564 , and to provide the necessary interoperable standards to ensure that eHealth -related data can be transferred correctly and securely, including in a home network environment and/or in a chronic disease management network for older adults . The Report details which of the existing standards

may be usefully implemented for eHealth applications, and which ones may have to be prepared or updated. Relevant aspects address in particular transmission aspects, technical interoperability, security, authentication, authorisation, data privacy and usability.

The development of testing and verification methods, the drafting of testing standards, as well as the demonstration of interoperability between eHealth services is also key. The experience in this area exists within the European Standardisation Organisations (in particular within ETSI with the Protocol and Testing Competence Centre, and the ETSI Plugtest service).

The programme will list identified work items, the priority level for each of the tasks, a summary description, the expected deliverables, the lead responsibility, timetables, and approaches for public relations, publicity and marketing.

The deliverables should include standards and technical reports such as implementation guidelines, methods for conformance testing. The work programme should include (where in scope), items to address the recommendations of the eHealth Focus Group following on from validation procedures

One or more open meetings shall be organised with representatives from relevant governmental, healthcare provider, industry, user and domain expert stakeholders to consolidate the draft work programme and to reach broad acceptance for it.

In order to provide optimal technological foundations, infrastructure, safety and regulatory integration in Europe and within global markets the European Standardisation Organisations CEN, CENELEC and ETSI are strongly encouraged to collaborate together and with international standards organisations, (notably International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU)) as well as with European and international Standards Development Organisations and their liaisons including relevant standards consortia and organisations (such as IEEE, DICOM, HL7, OASIS, W3C, GSI and WHO). In addition, it is recommended that they seek to work with Information and Communication Technologies (ICT) companies, healthcare authorities, healthcare providers, professional healthcare associations, including large corporations and small and medium sized enterprises, in order to create a basis for development of interoperability guidelines.

Similarly, it is recommended that they seek to work in support of those organisations mandated by their government to work on the specifications for the deployment of interoperable services. This is of utmost importance that the standardisation organisations further develops co-operation between experts in the standardisation field and involve experts on providing healthcare services, e.g. medical professionals in order to achieve the long-term goal of interoperable health care systems not limited by borders. Furthermore it is of importance that the standardisation development work is in coherence with the Government Agencies' priorities on the health care area, e.g. National health care information structure plans and guidance.

This co-operation between different parties is a prerequisite for interoperable health care services, delivered in accordance with a predefined quality level and will also assure safety issues for the patients and healthcare professionals.

Another important field that also must be taken into account is how standards will be used in research and developmental purposes.

The resulting final work programme will be submitted to the Commission services which will consult the 98/34 Committee prior to the launch of phase 2 covered by this mandate.

During phase 2 of the standardisation work covered by this mandate CEN, CENELEC, and ETSI (as appropriate and recommended in the agreed work programme) shall develop the European standardisation initiatives as listed in the work programme. The European Standardisation Organisations shall use work structures (such as workshops, and technical committees) appropriate to the work programme.

5.2 Modus operandi and co-ordination aspects

CEN, CENELEC and ETSI are to establish suitable collaborative arrangements to organise the response to this mandate, and strive for adequate involvement of stakeholders. These arrangements should take due account of Recommendation 12 of the Focus Group report, which proposes that the European Standardisation Organisations shall establish an appropriate and co-ordinated mechanism, possibly under the ICT Standards Board's auspices.

The programme resulting from Phase 1 should be a single document agreed by all three European Standardisation Organisations, and coordinated under the above mechanism. The Phase 1 Report shall set out the proposed arrangements for collaboration between the European standards development organisations, with their global counterparts ISO, IEC and ITU-T, other Standards Development Organisations and with industry standards consortia over Phase 2.

6 EXECUTION OF THE MANDATE

6.1 Arrangements for the execution of the mandate

CEN, CENELEC and ETSI shall jointly present to the Commission within 3 months of the date of acceptance of this mandate, a report setting out the arrangements they have made for the execution of the mandate. Particular attention shall be given to the involvement of all relevant parties. It should be noted that this is not limited to industry groups, and to the international working arrangement that are set up to identify and adopt internationally agreed standards but must also include health care professionals as well as professionals from the governmental agencies responsible for providing a qualitatively accepted health care (including safety and efficiency).

6.2 Work programme

Within 12 months of acceptance of this mandate, CEN, CENELEC and ETSI shall jointly present to the Commission the Phase 1 work programme. The work programme shall be submitted for consultation from the Member States.

6.3 Standstill

The notification to the European Standards Organizations of the acceptance of the proposed work programme by the Commission starts, where deliverables are European Standards, the period of standstill required under Directive 98/34, for those items where standstill has not already been imposed.

6.4 Progress reports

CEN, CENELEC and ETSI shall present annual progress reports to the Commission services.

6.5 Evaluation

Three years after the commencement of the work in Phase 2, an evaluation report shall be presented by CEN, CENELEC and ETSI to the Commission on the results achieved in terms of market impact. The terms of reference of the report shall be agreed between the three European standardisation bodies and the Commission services.

6.6 Results

CEN, CENELEC and ETSI will present to the Commission services the standards listed in the programme in accordance with the Mandate.

Annex : Projects and studies in the eHealth interoperability area

1) EU research projects and support or coordination actions: ongoing - ending 2006/7:

1. ARTEMIS (IST 002103, A Semantic Web Service -based P2P Infrastructure for the Interoperability of Medical Information) is a STREP funded by the 6th FP RTD. Artemis is developing a semantic web service -based P2P Infrastructure for the Interoperability of Medical Information Systems. Artemis project enables the Healthcare Institutes to exchange Electronic Healthcare Records in interoperable manner through semantically enriched web services and semantic mediation.

2. Semantic Mining (IST 507505, Semantic Interoperability and Data Mining in Biomedicine)¹⁰ is a Network of Excellence Project, funded by the 6th FP RTD. The goal of the Semantic Mining network is the development of generic methods and tools supporting the critical tasks of the field; data mining, knowledge discovery, knowledge representation, abstraction and indexing of information, semantic -based information retrieval in a complex and high-dimensional information space, and knowledge -based adaptive systems for provision of decision support for dissemination of evidence based medicine.

3. INFOBIOMED (IST 507585, Structuring European Biomedical Informatics to Support Individualised Healthcare)¹¹ is a Network of Excellence Project, funded by IST programme. The INFOBIOMED network aims to set a durable structure for the described collaborative approach at a European level, mobilising the critical mass of resources necessary for enabling the collaborative approach that supports the consolidation of BMI as a crucial scientific discipline for future healthcare. One of the main objectives of the INFOBIOMED is to enable systematic progress in clinical and genetic data interoperability and integration .

4. DICOEMS (IST 507760, A diagnosis collaborative environment for medical relevant situations) is a STREP Project, funded by IST programme. DICOEMS is developing an integrated environment for cooperation of actors of the medical sector (doctors, nurses and other paramedical staff) to assist them to perform proper, i.e., quick and accurate decision making, in critical situations, where data is collected from care providers on the incident field.

5. DOC@HAND (IST 508015, Knowledge Sharing and Decision Support for Healthcare Professionals)¹² is a STREP Project, funded by IST programme. The aim of Doc@Hand is to support Healthcare professionals in this changing environment, by providing a set of IT tools that help reducing the time and associated costs to collect the information and knowledge required, and more crucially, in making the best use of it for a more informed decision making (diagnoses, therapies, protocols).

6. Netc@rds The NETC@RDS Project aims to improve the access of mobile European citizens to the national health care systems using advanced smart card technology. It also addresses the recommendations from the European Commission to evaluate technical solutions for European Health Insurance Card electronication and for additional services such as health costs clearing/billing processing. It is currently in its' second (out of four) project phase where

the target is to establish and evaluate a number of large scale “e -EHIC advanced demonstrators”. Among other things the project will establish and demonstrate practical technical interoperability for use of different national cards at the 10 NETC@RDS pilot sites (regions in Austria, Finland, France, Germany, Greece, Italy Czech Republic, Slovak Republic, Slovenia and Hungary).

7. Interoperability Initiative for a European e -health area (i2-Health): eTEN (Trans-European telecommunications networks): Building upon the activities in Member States, the results of European RTD, and learning from international efforts, i2 -Health project will initiate a process for accelerating the deployment of interoperable e -health infrastructures and applications for trans -European use. It will

- identify interoperability and connectivity issues and priorities, barriers and gaps, and solution approaches,

- focus on fundamental interoperability issues (like identification of actors, organisations, adequate measures to achieve interoperability, integration tests and certification)
- analyse key topics relating to e-prescription and messaging
- develop a roadmap and concrete projects involving all relevant actors – guided by an open discussion process amongst Member State Health Authorities.

8. Telemedicine Alliance (TMA) Bridge:

The second phase of the TMA project, TMA -Bridge project focuses on building the bridge between the vision of citizen -centred healthcare and its realisation, and is aimed at promoting the creation of a European eHealth Area, favouring the mobility aspects in the European Union. To do so the projects tackled the barriers to the achievement of a real mobility space for EU citizens, and facilitate citizen -centred healthcare services. Emphasis is on all echelons of interoperability required for the cooperation of different health systems, such as technical, organisational, social and political. A very pertinent final report has been recently published.

9. Biopattern :This Network of excellence aim to develop a pan -European, coherent and intelligent analysis of a citizen’s bioprofile; to make the analysis of this bioprofile remotely accessible to patients and clinicians; and to exploit bioprofile to combat major diseases such as cancer and brain diseases.

10 see <http://www.itri.brighton.ac.uk/projects/semanticmining/>

11 <http://www.infobiomed.org>

12 <http://services.txt.it/docathand>

2) New FP6 research projects:

1. e-Health ERA

The goal of this coordination action, which was started on April 1, 2005, is to coordinate planning of national innovation -oriented e-health RTD as the basis for a common road -map and joint RTD activities, thereby establishing an effective ERA in this key IST field and

important European market. Reducing the serious fragmentation of current planning can be expected to have a strategic impact on regional, national and trans-European e-health infrastructures, improve the quality of medical outcomes and hence the quality of life of citizens in Europe.

2. Q-REC

The main objective of Q-REC is to create an efficient, credible and sustainable mechanism for the certification of EHR systems in Europe by addressing mainly- EHR Systems Quality Labelling and Certification Development, thereby:

- producing a State of the Art Report on EHR-Certification Schemas as already implemented in at least three European countries;
- performing a Pan-European Requirements Assay;
- proposing a Labelling Terminology and Functional Profiles for EHRs to be certified;
- comparing and harmonising the EHR-Certification Procedures at a European level;
- drafting Model Certification Guidelines and Procedures;
- planning the Validation of the Guidelines.

3. RIDE

RIDE is a roadmap project for interoperability of eHealth systems leading to recommendations for actions and to preparatory actions at the European level.

This roadmap will prepare the ground for future actions as envisioned in the action plan of the eHealth Communication COM 356 by coordinating various efforts on eHealth interoperability in member states and the associated states.

4. SEMANTIC HEALTH

To efficiently implement e-health to meet the rising needs of mobile citizens, patients and providers, its fragmented interoperability initiatives must come together and coordinate with the increasing need to link clinical data to information from basic biological sciences and evidence of best clinical practice.

5. SHARE

Starting from the conclusions of the HealthGrid White Paper, this proposal aims at identifying the important milestones to achieve the wide deployment and adoption of Healthgrids in Europe.

3) Studies

A limited number of studies focusing on the exchange of good practices in eHealth, that include a study on Patient identity in eHealth and a study on Legal and regulatory aspects of eHealth, started on January 1, 2006, and have relevance for eHealth interoperability issues.