EUROPEAN COMMISSION
DG HEALTH AND CONSUMERS
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

Discussion document: Role of the eHealth Network in standardisation activities

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1. PROPOSAL FOR A STANDARDISATION PLATFORM IN THE UPCOMING JOINT ACTION

The Commission proposal is to have an active involvement of the Standard Developing Organisations (SDOs) and standard profiling organisations in the new Joint Action (JA2). They will contribute in reaching the objectives related to "interoperability and standardisation" chapter of the Multi-annual Work Programme 2015-2018. These organisations (Standardisation Platform in the following) could have the role of 'Collaborating stakeholder' in the joint action. It is proposed that CEN, because of its status as European Standardisation Organisation, will be the coordinator of the SDO's involved.

The role of the Platform in the JA2, as decided by the Members involved, would be twofold:

1. It could provide assistance to the eHN in any decision concerning standardisation activities, by:

   - Reporting to the eHN on standardisation activities at EU and international level that are relevant for the eHealth sector;

   - Providing guidance to the eHN on technical specifications (see §2) and standardisation activities (§4); notably in the framework of the review of the Guidelines on patients summary (Ps) and ePrescription (eP);

   - Advising the eHN in contributing to the Annual Union Work Programme on European standardisation and to the Rolling plan for ICT standardisation (see §3).

2. It could propose and be involved in standardisation projects (e.g. developed by CEN) that the eHN deems necessary for the widespread adoption of eHealth systems and services in Europe and to achieve interoperability at EU and International level (see §5);

In addition, the role of the Platform would be beneficial to the visibility of the eHN policy agenda in international standardisation fora and organisations.

2. INVOLVEMENT IN THE IDENTIFICATION OF ICT TECHNICAL SPECIFICATIONS

The 'identification of ICT technical specifications' is the process set up by Regulation 1025/2012/EC. It requires the opinion of the Multi-Stakeholder Platform (MSP), even if the final decision is a prerogative of the Commission.

Although the Commission is assisted by the MSP, a direct consultation of the eHN could be highly beneficial in terms on transparency and sharing of common interoperability objectives. This is especially true in the eHealth sector where the identification processes, as well as other standardisations activities, appears to be insufficient to achieve interoperability at operational level without an active involvement of Members States at policy level.

Moreover, the identification of technical specifications that are not compatible with political decisions adopted by Members States could jeopardise interoperability decisions taken in the Network.

In this activity the eHN could be assisted by the Standardisation Platform setup in the JA2 on eHealth.

There are three options for the involvement or the consultation of the eHN in the identification process:

1) The eHN could be consulted in the initial phase of the process (which is initiated by the Commission on its own initiative or on proposal by a Member State) to express its opinion on the opportunity to start an identification process of eHealth technical specifications.

2) The eHN could express its opinion and be informed on the main developments by having a representation in the evaluation working group set up by the MSP (the eHealth WG) to deal with eHealth-specific technical specifications. This role could be played by the Standardisation Platform (or part of it) in the JA2.

3) The eHN could be formally consulted after the opinion of the MSP and before the formal decision of the Commission to identify some technical specifications. This is the moment when Regulation 1025/2012/EC provides for the consultation of 'the committee set up by the corresponding Union legislation, if it exists, or after other forms of consultation of sectorial experts'.

On 2 October 2014, the MSP gave a positive advice to the identification of 27 technical specifications, the Integrating the Healthcare Enterprise (IHE) profiles, dealing with ePrescription and the Patient Summary. These profiles were used in the epSOS project and are thus compliant with the eHN Guidelines. The final decision of the Commission on the identification of the IHE profiles is expected by the beginning of 2015, after the consultation mentioned in point 3) above.

3. INVOLVEMENT IN THE ANNUAL UNION WORK PROGRAMME AND THE ROLLING PLAN FOR ICT STANDARDISATION

The Annual Union Work Programme (AUW) on European Standardisation and the Rolling plan for ICT standardisation are the planning tools of the European Commission for standardisation activities. The AUW sets out the general objectives regarding the Commission's policy for standardisation. The Rolling plan for ICT standardisation sets out more detailed and ICT specific standardisation initiatives.

A coherent and detailed planning of standardisation work in eHealth is important for the actual implementation, at EU level, of standardisation needs for the sector.

The European Standardisation Organisations have been already invited to cooperate closely with the Commission and all stakeholders in European standardisation to develop proposals in support of the above mentioned area.

This collaboration could find concrete application in the Standardisation Platform that could be established under the JA2.

The eHN could agree on, and with the advice of the Standardisation Platform, endorse the future standardisation needs related to the interoperability of eHealth systems.

4. INVOLVEMENT IN STANDARDISATION ACTIVITIES

4.1. Standardisation activities on Patient Summary

The eHN adopted the Guidelines of Patient Summary in November 2013, based on the work done within the epSOS project.

In spring 2014, the US Standards & Interoperability (S&I) Office has proposed to the standardisation organisation Health Level 7 (HL7) to start a standardisation project for an International Patient Summary template (see §5 for details) in the context of the EU-US collaboration roadmap in eHealth.

The eHN could have an active role in this context by performing two parallel steps:

1) Contributing to the definition of the International Patient Summary template.

A systematic and formal contribution to the comparative analysis conducted on the structure of the US and EU patient summary documents would assure that the process will duly take into account what was agreed at policy level, with the adoption (and future the revision) of the Patient Summary guidelines, by the eHN.

It would also provide that the final outcome of the process, the International Patient Summary template, would be based on a right mix of US and EU considerations in sorting out differences in data definitions, coding, and value sets.

2) Launching a standardisation process with CEN aimed to have a European localised version of the International Patient Summary template based on the Guidelines adopted by the eHN.

The process would be done in parallel and would support the revision, agreed by the eHN, of the guidelines based on the experiences and feedback on their use in MSs.

The Standardisation Platform in the new JA, would report to the eHN on the developments and will take into account any concern expressed by its members.

The final expected outcome would be an "EU Patient Summary standard" endorsed by the Network and based on the reviewed version of the Patient Summary Guidelines. It would be a European version of the generic International Patient Summary.

The rationale behind this is the following: The current Patient Summary guidelines have a strong political value; they represent the willingness of Members States to achieve interoperability for cross-border exchange of medical information. Despite this, from an operational point of view, they are not yet mature to guarantee cross-border interoperability.

Having the guidelines supported by a European standard can facilitate their effective implementation by interested parties or software vendors, increasing their visibility at international level. Furthermore, the expected revision of the Guidelines would benefit from a controlled and more formal process set up by CEN.

4.2. Standardisation activities on ePrescription

The Guidelines for ePrescription were presented to the Network at this meeting for adoption.

In parallel, ISO has started a process to adopt an ISO/CEN standard on ePrescription. The draft guidelines are compliant with this standard. The ISO/CEN standard is expected to be published in 2015.

5. INFORMATION ON THE MEMORANDUM OF UNDERSTANDING EU-US – TRANSATLANTIC EHEALTH/HEALTH IT COOPERATION ROADMAP

The United States Department of Health and Human Services (US-DHHS) and the European Commission (EC) signed a Memorandum of Understanding (MoU) in December 2010.

To reach the objectives contained in the MoU, the European Commission and the Office of the National Coordinator (ONC) for Health Information Technology of the US have been working on a cooperation roadmap in eHealth.

Both the MoU and an early version of the Roadmap were presented to the eHN during its 4th meeting in March 2013.

One of the two shared objectives of the MoU deemed to hold immediate importance is the *'Development of internationally recognized and utilized interoperability standards and interoperability implementation specifications for electronic health record systems that meet high standards for security and privacy protection'*

The US-led proposal to start a standardisation project for an International Patient Summary template showed an imbalance between the US support to this project and the lack of representation of the EU perspective, highlighting the necessity to have an adequate representation in international standardisation committees to take into account and support the policy agenda developed by the eHN, as proposed in §4.1.

On the other hand, it could be ineffective to work on interoperability standards at US-EU level without considering the EU requirements for cross-border interoperability decided by the eHN. For this reason the eHealth Network could be consulted on the periodical updates of the Roadmap, specifically on those parts concerning the interoperability standards.