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3RD eHEALTH NETWORK 14TH MAY 2013
COVER NOTE BY SECRETARIAT

Subject: Topic 4 - eIdentification for eHealth

Issue at stake / request to eHealth Network

The eHealth Network is mandated to support Member States in developing common identification and authentication measures, as stated in the Directive on application of patients' rights in cross-border healthcare. The eHealth Network is foreseen to agree upon a road map giving a strategic approach to common measures on eID for eHealth (based on national solutions) in November 2013. During this eHealth Network, a position paper from the eHGI on the Commission proposal for an eID Regulation will be discussed.

The eHealth Network members are requested to:

- discuss and comment on the information presented in this position paper;
- endorse the position paper, in particular its proposed next steps, in view of the adoption of a road map in November 2013.

Summary of document

The position paper on eID follows the eHealth Network conclusions during the meeting in May 2012. It acknowledges that the proposed regulation on eID will be key to progress towards cross-border eHealth as it will ensure mutual recognition of notified eIDs among Member States. However, the future legislation does not address the full range of eHealth related issues and the Network should consider complementary measures. The paper also underlines some constraints related to the specificity of the eHealth domain such as high security and privacy concern and the wide diversity of solutions in Member States. The paper proposes a series of next steps, both at EU level, as within Member States.

Format of procedure

Short introduction by co-chair Clemens Auer, followed by a discussion and the possible endorsement of the position paper.



POSITION PAPER

REGARDING THE COMMISSION'S PROPOSAL ON eID REGULATION WITH RESPECT TO ITS APPLICATION TO eHEALTH

Proposed by the eHealth Governance Initiative

Date: 14th May 2013

1. The Regulation: a step forward for cross-border eHealth

The overall objective of the eHealth Network is to work towards establishing sustainable health, social and economic benefits of European eHealth systems and services. The goal is to enhance continuity of care through interoperable and secure eHealth services, to achieve a high level of trust and to ensure access to safe and high-quality healthcare in accordance with the Directive on patients' rights in cross-border healthcare (2011/24/EU).

A strategic priority of the eHealth Network, according to Article 14 of the Directive, is to agree on a set of common identification and authentication measures based on national solutions to allow trusted electronic transfer of patient data in cross-border healthcare settings. In pursuit of this objective, the Network adopted the Conclusions on eID EU Governance for eHealth Services in May 2012, setting forth the main principles for an EU eID Governance for eHealth.

The 2012 EC proposal on the eID Regulation provides the EU with an eID cross-sectoral framework for [cross-border] legal recognition of electronic ID and signatures and other electronic authentication systems. The principles of the proposal largely reflect the considerations expressed in the eID paper and adopted by the eHealth Network in May 2012. Indeed, mutual recognition of notified national e-Identification schemes could be applied in the healthcare sector in order to allow safe transfer of patient data. However, the eID Regulation does not address the full range of eHealth related issues; complementary measures for eHealth should be considered by the Network. This may result in voluntary guidelines for Member States to consider adopting.

2. eHealth specific environment and constraints

■ *Safety and privacy*

In healthcare an erroneous identification of the patient may have severe safety consequences, in contrast to other domains where the main security constraint is usually to prevent fraud through falsified documents or illegal access to information or services. Furthermore, because personal health information is sensitive, recommendations and rules have to be more strictly defined or extended to address the high level of confidentiality and assurance¹ for e-identification in healthcare).

■ *Diversity*

In 2012, the EC conducted a survey of eID & Authentication practices for eHealth in the EU Member States. Responses showed a great diversity of solutions – which result not only in technical barriers but also in practical difficulties for health professionals needing to access health information about their patients – and consequently reduced acceptability of solutions for cross-border identification.

Diversity has also arisen because some countries have decided to use cross-sectoral identification, while others have strictly separated eHealth identification². Accordingly, it is difficult to introduce new processes and means. While the EC has proposed the use of a cross-sectoral eID for cross-border data flows, it must be recognised that in many Member States, a health-specific identifier will be demanded.

■ *Online vs on-site electronic identification - two different situations?*

The proposed Regulation relates to the possibility for a European citizen to electronically access public information and services made available by any Member State using the electronic identification means of his/her own country³.

In eHealth, however, the most frequently encountered situation involves a patient abroad and a healthcare professional (or healthcare provider) who needs to access the patient's health information in his/her country of residence. This is what is referred to as an "on-site"⁴ situation, when the patient is at the point of care in the physical presence of the health professional. Three main contexts have to be considered, all concerning healthcare services in a hospital or medical practice: (a) unplanned care (non-life-threatening situation) (b) emergency care (c) planned care. In these three contexts, utmost importance is attached to identification and authentication of the health professional in addition to patient identification.

¹ Level of assurance – cf. requirements coming from standards such as ISO/IEC 29115

² Both organisational processes and technical means differ across Member States. Moreover, these differences are linked to national cultures far more than to sectoral differences, health and the healthcare systems being especially linked to social and cultural background as well as to the institutional framework of each Member State.

³ A precondition for the implementation of this capability is the interoperability of the identification means adopted in each Member State.

⁴ Sometimes called "on the spot" situation

The identity of the health professional needs to be authenticated in his/her national system according to his/her role so that he/she can then be allowed to securely access patient information in a foreign infrastructure. According to the mutual recognition principle, the foreign infrastructure must accept this identification and authentication (including the professional's role) as trusted. It will then allow access to safe services⁵.

In addition to the Conclusions on eID EU Governance for eHealth Services adopted in May 2012, this "on-site" cross-border process therefore involves:

- Authentication of the professional's eID and of his/her role so as to allow the other country's system to authorise access to personal health data⁶.
- A sufficient level of communication between European national systems to achieve this.
- *In turn, the eHGI proposes to also prioritise healthcare professionals' eID (as well as citizens' eID) as this represents a necessity for cross-border healthcare services.*

⁵ These include patient identification certification in the corresponding national database, setting up the conditions related to the therapeutic relationship and verification of consent.

⁶ Although the authorisation process itself is not addressed here, e-Identification of the HP needs to include sufficient information to allow this process. Once again, differences between countries arise relating to the relevant health professional role(s) and the means of identification.

3. Proposed next steps

■ *Mechanisms available in the proposed EU legal instruments*

• *The eHGI proposes to:*

- Consider the mechanisms available in the legal instruments proposed by the EU – particularly Article 8 of the eID Regulation, which foresees co-operation of Member States to ensure interoperability of electronic identification means – as a vehicle to bridge the gap between the eID Regulation and what is needed for eHealth.
- Identify specific aspects that should be dealt with, if necessary, through a mandate of the eHealth Network for common measures (Directive 2011/24/EU - Article 14). As stated above, these specific needs relate not only to citizens' eID but also to eID for health professionals.

■ *Actions at eHealth Network level*

• *Under the mandate of the eHealth Network, the eHGI should:*

Build upon the precise definition of health professionals' roles in the context of Directive 2011/24/EU and agree on a process for their verification. This will provide a minimum level of trust to allow for cross-border requests for patient information (which involves knowledge of who can access what in which situations); the service must be accessible and should recognise that professional roles vary between countries.

To this end, the eHGI will need to:

- Focus especially on the five health professions dealt with in Directive 2005/36/EC on mutual recognition of professions⁷ and work with DG Employment and DG MARKT, which have addressed these questions, notably in the Internal Market Information System (IMI).
- Define the minimum conditions for health professionals' identity and authentication systems – i.e. general procedures for establishment of the European mutual recognition mechanisms, specification of quality of assurance levels corresponding to the diverse situations – which could be legally implemented through Article 8. This involves designing a Member State's health professional registry framework, including minimum mandatory content, security constraints and reference to authentic sources⁸.

■ *Actions at Member State level*

• *The eHealth Network proposes voluntary Member State guidelines to assess the preparedness of*

- Their online registries of health professionals.
- Their eHealth schemes for eID to be notified to the Commission.

⁷ Doctors, nurses, dental practitioners, midwives, pharmacists

⁸ In accordance with the healthcare institutional framework of each Member State