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eHealth & Health Technology Assessment

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

Subject: Topic 5 – Update on data protection Regulation

Issue at stake / request to eHealth Network
The eHGI has produced a policy paper on data protection. The paper attached makes several suggestions to the proposal for a general Data Protection Regulation, including the support for the original European Commission wording for the articles 81 and 83. The eHealth Network members are requested to: – discuss and comment on the information presented in this paper concerning the proposal of the data protection Regulation; – endorse the paper, and to inform the national delegations, negotiating the proposal in the Council, about the position of the eHealth Network.

Summary of document
The accompanying paper gives an overview of the current state of play on the proposal of a data protection Regulation by the European Commission. It gives an overview of the legislative process, and reflects on some critical issues for eHealth/ health within the proposal. It furthermore suggests improvements and actions to be considered in the negotiation process.

Format of procedure
Short introduction by co-chair Paola Testori Coggi, followed by a discussion and the possible endorsement of the paper.

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eHGI REPORT

ON THE DATA PROTECTION REGULATION

Proposed by the eHealth Governance Initiative

Date: 15 March 2013

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1. Progress since the 2nd eHealth Network meeting in November 2012

This document has been drafted in response to the conclusions of the 2nd eHealth Network discussion on the Data Protection Regulation item that "*the Regulation will be discussed again by the eHealth Governance Initiative and possibly re-discussed in the Network's 3rd meeting in Dublin*". It builds on the discussion paper on *Implications of the proposed General Regulation on Data Protection for Health and eHealth*. In particular, it considers the relevant elements of the Albrecht Report to the European Parliament's LIBE committee as well as of the February fact-finding meetings of the eHealth Network's co-chair and eHGI legal experts with LIBE and DAPIX representatives. It is submitted to the eHealth Network for information only.

The LIBE report was published on 17 December 2012 and the EC issued a press release on the report on 8 January 2013[1]. The draft report was discussed on 10 January 2013. The draft regulation was discussed by the Council on 8 March, however, with no significant discussion of health-specific issues. Nevertheless, given that health-related issues have been raised by a number of Member States and interested parties as well as during the fact-finding meetings, it is likely that future meetings of the Council and DAPIX will have an increased focus on eHealth.

During this period, eHGI members – both Member States and stakeholders – consolidated their positions. Within the eHGI itself, further consolidation aimed to produce a small number of high-level messages, which are presented in this document and which facilitated the informal exchange of the eHealth Network's co-chair and eHGI experts with representatives of the Council's DAPIX Working Group and LIBE parliamentary committee during a fact-finding meeting which took place on 20 February 2013.

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1 http://europa.eu/rapid/press-release_MEMO-13-4_en.htm?locale=en

2. Impact of the LIBE report on eHealth

The following aspects were highlighted in the discussion paper on the Data Protection Regulation presented during the 2nd eHealth Network meeting in November 2012.

2.1. Definitions

The eHealth Network has endorsed the eHGI proposal that

> *Definitions should be appropriately reviewed to ensure alignment with concepts, current usage and the needs of the diverse eHealth stakeholder community. In particularly challenging areas, especially those with rapid technological evolution – such as anonymisation and pseudonymisation – definitions should be set out clearly in the legislation, and the processing of data thereof should not be subject to any further requirements of the legislation other than compliance with applicable standards.*

The LIBE report attempts to further clarify anonymous data by suggesting objective criteria for it and it proposes amendments to Article 4 in the form of additional definitions.

eHGI suggests that

addressing the health-specific issues properly would benefit from

- *Amending Article 2 (material scope of the Regulation) to make explicit what is recognised in Recital 23, i.e. that the principles of data protection should not apply to data rendered anonymous.*
- *Amending further Article 4 (2) to also include a definition of anonymised and pseudonymised data.*

2.2. Processing of health data

The eHealth Network has endorsed the eHGI proposal that

> *Certainty should be improved in areas such as derogations on the grounds of public interest and in what concerns processing of health data scope beyond public health.*

Overall, the Regulation addresses the key issues relating to the processing of health data adequately, but clarity could be improved by appropriate amendments to avoid divergent interpretations in the future, especially with respect to patient consent for healthcare purposes and for secondary usage for research and public health and the right to be forgotten.

2.2.1. Consent

The differentiation of consent for the purposes of provision of care and for research will need further consideration. Specifically, the differentiation of consent in the provisions of Article 81 (1) a (which opens up the possibility of processing health data in the health sector within the boundaries and purposes of providing care and for sharing data in electronic health records without consent) and Article 81 (1) b and c (which regulates the processing of data for reasons of public interest in the area of public health and social care) is both practical and appropriate. However, the provisions for consent for purposes of research in the amendments proposed by LIBE introduce several risks. Specifically, the proposed amendments would allow Member States to introduce a law permitting pseudonymised data to be used without consent, but only in the event of "exceptionally high public interest".

While explicit consent for processing personal data in the context of research could increase the level of protection, as the data is no longer controlled exclusively by the professional in the context of care provision, the burden for running studies involving person identifiable data (e.g. longitudinal studies) and the organisational overhead – including in addressing several conflicting national regulations in the case of international studies – could create a significant barrier to research. Specific consent is also not compatible with the approach taken in many research studies, where a broad consent model is used. Article 83 provides an alternative legal basis for processing for research purposes, therefore consent for processing will not be required.

The amendment proposed by LIBE requires each Member State to draw up its own legal guidelines on the use of pseudonymised data without consent. Allowing a fragmented approach across the EU would compromise the work of cross-border research collaborations and could render work on rare diseases in smaller countries almost impossible as a critical mass of study subjects is frequently not present in smaller countries.

eHGI suggests that

- *The original wording of Articles 81 and 83 is maintained in order that a level playing field for healthcare research can be created across Europe.*

Further clarification would also be beneficial concerning consent in Article 7(4), which specifies that "consent shall not provide a legal basis for the processing when there is a significant imbalance between the data subject and the controller". Whilst it is understood that in certain cases, such as employment, it is important to have such safeguards, it could create ambiguities as to possible imbalance between the doctor and the patient.

In addition, in healthcare, it may be argued that the act of seeking and agreeing to treatment is considered as equal to explicit consent; indeed a doctor cannot provide treatment without processing patients' personal data. This clarification in the Regulation would also avoid red tape.

eHGI suggests that

- *For the purposes of providing care, it would be of benefit to eHealth to clarify, in the Regulation, that the act of seeking medical care from a health professional should be considered as "explicit consent" to the processing of health-related data necessary for that interaction (e.g. in Recital 25);*
- *The Regulation should explicitly clarify that Article 7(4) does not apply to the health sector;*
- *The Regulation should furthermore clarify that the act of seeking and agreeing to treatment should be considered as equal to explicit consent to the processing of personal data under Article 4(8) and as proof under Article 7(1).*
- *Article 83 and its associated research derogations are maintained and clarified as the Regulation moves through the legislative process.*

2.2.2. Right to be forgotten

From the clinical, financial and research perspective, there are implications for deleting data from electronic records. Most importantly, incomplete medical records may harm patient care in circumstances where the treating physician has an incomplete record. Statistical analyses might also be weakened, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.

Article 17.3 (b) introduces an exception to the retention of personal data "for reasons of public interest in the area of public health in accordance with Article 81 (Processing of personal data concerning health)"; however, reference to the public interest is in both cases neither precise nor sufficient. The narrow scope of public health must be replaced by the broader scope of "for health purposes in accordance with Article 81".

eHGI suggests that

- *Article 17(3)(b) should be clarified in order to exclude the possibility of erasing data concerning health in order to avoid unwanted consequences for individuals.*

3. Specific issues arising for cross-border eHealth

The EU legal framework for cross-border health services and its transposition where appropriate to national laws are expected to create conditions of legal interoperability. The Data Protection Regulation in particular will indirectly achieve legal interoperability on privacy issues in cross-border eHealth by regulating national practices. As such, the Regulation does not address cross-border issues in a specific way. However, Recital 122 is very helpful in making reference to "specific and suitable safeguards" without, however, prescribing such safeguards.

epSOS established such safeguards in order to run the pilots. These included agreements on security levels, a consent policy and organisational measures to support this policy. While agreements between epSOS pilot countries were sufficient to facilitate the pilots, these are not sustainable beyond the end of the project.

Creating, adopting and implementing such safeguards for cross-border eHealth services is a pre-requisite for deployment and sustainability. Therefore – in addition to legislation – Member State agreements on common policies, mechanisms and measures are needed, which as a whole will ensure the proper and transparent treatment of privacy in the context of cross-border eHealth. These comprise an EU eHealth "Information Governance" framework, which should be considered as part of the broader CEF governance.

eHGI suggests that

- *The eHealth Network undertakes action to secure the legal sustainability of the epSOS services, in particular in the form of (i) agreements on specific and suitable safeguards and (ii) common policies, measures and mechanisms through which these agreements will be applied and monitored in practice;*
- *The eHGI undertakes to present the eHealth Network with a proposal of a Legal Interoperability Roadmap (i.e. a pathway and plan) towards an eHealth Information Governance Framework for sustainable cross-border eHealth services, which will be complementary to the Data Protection Regulation.*