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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products

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DRAFT

eHEALTH NETWORK 7TH NOVEMBER 2012

Subject: Point 1 of the agenda: Strategic priorities of the eHealth Network-Multiannual Work Programme 2012-2014

For endorsement: updated draft suggested by the Secretariat, after consulting the eHealth Governance initiative

INTRODUCTION

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

The eHealth Network's Secretariat, after consulting the eHealth Governance Initiative, puts forward to the eHealth Network's Members the following updated version of Multiannual Work Programme 2012 -2014 for endorsement. The measures herein are not legally binding and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

The Multiannual Work Programme builds on the strategic priorities on eHealth specified in the Cross border Directive. It reflects Network Members' priorities expressed in the first Network's meeting and takes into account European projects and initiatives and national developments and needs.

PRIORITY 1: ADOPT COMMON MEASURES ON EIDENTIFICATION AND AUTHENTICATION FOR EHEALTH UNDER DIRECTIVE 2011/24/EU, ART.14

Final Outcome:

- Common identification and authentication measures based on national solutions to support electronic transferring of data in cross-border healthcare settings.

Intermediate outcomes:

- Policy paper "Conclusions on eID EU Governance for eHealth Services" - May 2012 (adopted)
- eID & Authentication practices for eHealth in the EU Member States based on a questionnaire - November 2012
- Position paper on the Commission proposal for an eID Regulation - May 2013
- Road map giving a strategic approach to common measures on eID for eHealth under Directive 2012/24/EU and analysis of its implications (Risks, legal challenges, cost, benefits) - November 2013

Inputs

Relevant EU legislation to be taken into account:

- Proposal for a General Data Protection Regulation - COM(2012) 11 final (launched January 2012 and with a start-up period from 2014 to 2016)
- Proposal for a Regulation on mutual recognition on eID and eSignature COM(2012) 238/2 (Launched June 2012 and expected to be adopted end 2013/beginning 2014)
- Proposal for a Regulation on cyber security (expected to be proposed by the EC end 2012/beginning 2013)
- Proposal for a European Standardisation Regulation (COM 2011/315, 1 June 2011)

Relevant Recommendations to be taken into account:

- CALLIOPE Recommendations "Towards secure, unambiguous and portable electronic identification of EU citizens" (Completed, 2010)

Other projects and Studies:

- STORK /STORK 2.0 Large Scale Pilot Projects on cross-border eIdentification (completed)
- STORK 2.0 Large Scale Pilot Projects on cross-border eIdentification, including identification of roles (Ongoing; from 2012 to 2015)
- EC study on interoperability guidelines for ePrescriptions (Empirica; results to be delivered by the end of 2013)

PRIORITY 2: ADDRESSING SEMANTIC AND TECHNICAL BARRIERS TO INTEROPERABILITY

Final outcome:

- Guidelines on semantic and technical interoperability

Intermediate outcomes:

- Discussion paper on semantic and technical interoperability - November 2012
- Semantic and technical interoperability roadmap (stepwise approach and intermediary milestones) - May 2013

Inputs

Relevant EU legislation to be taken into account:

- Proposal for a European Standardisation Regulation, COM 2011/315, 1 June 2011

Relevant Recommendations to be taken into account:

- Semantic Sustainability Recommendations of epSOS Large Scale Pilot (submitted to the EC in October 2012)
- CALLIOPE Recommendations “Towards a European-wide infostructure - semantic interoperability” and “Towards an internal market for eHealth services- technical interoperability” (Completed in 2010)

Other projects and Studies

- Semantic Health Network of Excellence (Ongoing, from 2011 to 2014)
- EC study on European Interoperability Framework for eHealth (Deloitte; results expected by the end of 2013)

PRIORITY 3: ADDRESSING LEGAL BARRIERS TO INTEROPERABILITY, INCLUDING DATA PROTECTION ISSUES

Final outcome:

- Guidelines on legal interoperability

Intermediate outcomes:

- Network's report on the Commission proposal for a Regulation on data protection November 2012
- Legal Interoperability Roadmap for cross border exchange of electronic Health Records and ePrescriptions -2014

Inputs

Relevant EU legislation to be taken into account:

- Proposal for a General Data Protection Regulation - COM(2012) 11 (launched January 2012 and with a start-up period from 2014 to 2016)
- Directive 2011/24/EU, and its supporting legislation relevant to the scope of Articles 14 and 11

Relevant Recommendations to be taken into account:

- Legal Sustainability Recommendation of epSOS Large Scale Pilot (submitted to the EC in October 2012)
- CALLIOPE Recommendations for “Legislation and regulation as facilitators - Legal and regulatory interoperability” (2010)

Other projects and Studies

- EC study on interoperability guidelines for ePrescriptions (Empirica)(Ongoing; Results to be delivered by the end of 2013)
- EC study on European Interoperability Framework for eHealth (Deloitte, results to be delivered by the end of 2013)
- EC legal study aimed to examine national laws on electronic health record systems and services in the EU Member States and how they interact with cross-border eHealth services and exchange of health data (Health for Growth Programme – 2013; study to be launched in February 2013; results to be expected in the first half of 2014)

PRIORITY 4: GUIDELINES ON PATIENTS SUMMARY SET OF DATA FOR CROSS BORDER ELECTRONIC EXCHANGE, UNDER THE CROSS BORDER DIRECTIVE

Final outcome:

- Guidelines on non- exhaustive list of data to be included in patient's summary
- Guidelines for cross-border electronic exchange of patients' summary data set

Intermediate outcomes:

- Non-exhaustive data set for patients summary that can be exchanged across borders - November 2013
- Guidelines on technical and semantic interoperability of the selected data set, including the coding, classification and terminologies set and their semantic transformation process in a multilingual environment - 2014

Inputs

Relevant EU legislation to be taken into account:

- Proposal for a European Standardisation Regulation (COM 2011/315, 1 June 2011)

Relevant Recommendations to be taken into account:

- Recommendations of the epSOS Large Scale Pilot on Patient Summary set for cross -border exchange (Ongoing, from 2008 to December 2013)
- Semantic Health Net on chronic heart failure and cardiovascular prevention (Ongoing, from 2011 to 2014)

Other projects and Studies

- EC study on European Interoperability Framework for eHealth (Deloitte, results to be delivered by the end of 2013)

PRIORITY 5: GUIDELINES ON INTEROPERABILITY OF ePRESCRIPTIONS (ART 11 OF THE CROSS BORDER DIRECTIVE)

Final outcome:

- Guidelines on interoperability of ePrescriptions

Intermediate outcomes:

- Discussion of the Network on interoperability of European and national databases for medicinal products - November 2012
- Roadmap on interoperability of electronic prescriptions - 2013
- Discussion paper on guidelines for electronic prescriptions - May 2014

Inputs

Relevant EU legislation to be taken into account:

- Implementing Act (Directive 2011/24/EU) on mutual recognition of (paper) prescriptions
- EU Regulation on pharmacovigilance 1235/2010 of 15 December 2010
- Proposal for a European Standardisation Regulation (COM 2011/315, 1 June 2011)

Relevant Recommendations to be taken into account:

- Interoperability of ePrescriptions: recommendations of the epSOS Large Scale Pilot (Ongoing, from 2008 to December 2013)

Other projects and Studies

- EC feasibility study on ePrescriptions (Empirica; results to be expected by the end of 2013)
- EC study on European Interoperability Framework for eHealth (Deloitte; results to be expected by the end of 2013)

PRIORITY 6: SUSTAINABILITY

Final outcome:

- Recommendations on the governance of the Connecting Europe Facility (CEF) – May 2013