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eHealth & Health Technology Assessment

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Final summary minutes (version 30/06/2014) of the 5rd eHealth Network meeting 13 May 2014, Athens

INTRODUCTION

These draft summary minutes are prepared by the Secretariat of the eHealth Network in accordance with the rules of procedures. The summary minutes will be posted on the European Commission (EC) website (<u>http://ec.europa.eu/health/ehealth</u>) after having taken into account any comment provided by Network's members.

WELCOME AND OPENING

The Chairs (Paola Testori Coggi, Director General of SANCO, European Commission, and Clemens-Martin Auer, Director General for Health, Austria) welcomed the members of the eHealth Network.

All Member States were present, except BG.

No interests were declared for the assessment of a potential conflict.

A list of the participants, without contact details, will be attached to the minutes and placed on the website of the EC.

The agenda was unanimously adopted.

APPOINTMENT OF MEMBER STATE CO-CHAIR

The Commission Chair explained the procedure for election of the Co-Chair of the eHealth Network as from the 6th meeting. No Network member had expressed their interest to the post of the Member State Co-Chair.

Following this information, Clemens Martin Auer, the Austrian member, was unanimously re-appointed as Co-Chair of the eHealth Network for a period of two years.

The Network thanked Clemens Auer for his active dedication.

TOPIC 1: NEW MULTI-ANNUAL WORK PLAN

Introduction

The Chairs introduced the topic. As agreed during the meeting in November 2013, an agreement is needed on a new Multi-Annual Work Plan 2015-2018. The new MWP will be used as the principal document for the work of a new Joint Action on eHealth. This new Joint Action is expected to start by the end 2014, and it will take over the preparatory work for the eHealth Network done thus far by the eHealth Governance Initiative (eHGI).

The new MWP was drafted by a sub-group of the eHealth Network (DE, IE, ES, FR, HR, NL, AT, PT and UK). SANCO has provided the secretariat of this sub-group. The Chairs thanked the members of the sub-group for their contribution.

The new MWP has four main chapters:

- Interoperability and standardisation
- Exchange of knowledge
- Assessment of implementation
- Global cooperation and positioning

These chapters reflect the willingness of the sub-group Members to both explore new possibilities of cooperation, but also make sure that agreements made are implemented and assessed.

It was noted that the timetable for the tasks is impossible to fix for the moment. The final indicative dates will be aligned with the work plan of the new Joint Action, to keep the synergy between the two processes. The final indicative dates will be shared with the eHealth Network during the meeting in November 2014.

It was made clear that the elements included in the current MWP, not yet delivered, remain valid and are not repeated in the new MWP.

Open points within the implementation of the current MWP will be addressed, as deemed appropriate, by the eHealth Network in the period 2015-2018.

Discussion

The Chairs proposed that the topic on page 8 "Implementation of recommendations of Electronic Health Records legal study" is broadened to "Implementation of recommendations on legal interoperability", including the recommendations on the legal study on Electronic Health Records. This change was accepted and will be reflected in the MWP.

A discussion took place about the global positioning and relations of the eHealth Network. It emerged that the scope of the current description should be broadened. Therefore it was suggested to change on page 11: "eHealth services are part of the Transatlantic Trade and Investment Partnership (TTIP). The actions and follow-up of the TTIP negotiations should be reflected in the Work Plan of the eHealth Network.". The new sentence will read: "eHealth services are part of the Transatlantic Trade and Investment Partnership (TTIP) and of other bilateral trade negotiations for which the EC has been given a mandate to negotiate. The actions and follow-up of these negotiations

should be reflected in the Work Plan of the eHealth Network.". This change was agreed upon and will be reflected in the MWP.

An extra point in the MWP will be added on page 11 point A. It was agreed to have a preparatory convergence meeting among Member States to coordinate input before WHO and OECD meetings on eHealth related topics, not interfering with the responsibility of the Member States. Furthermore the MWP shall be sent to the WHO and the OECD with the request to take it into account in there planning activities. This point is agreed upon and shall be reflected in the MPW.

Clarification was made on point B on page 6. The MWP is not focused on a specific eID for eHealth. The trans-sectorial Regulation on eID is used instead.

Wording in point A on page 6, the functioning of the eHealth National Contact Points is decided at national level. Therefore a change is suggested: "Adopt guidelines on legal arrangements between eHealth NCP, providing a minimal set of agreements between the Contact Points", should read: "Adopt guidelines on legal and/or contractual arrangements between eHealth NCP, providing a minimal set of agreements between the Contact Points.". This change is agreed upon and shall be reflected in the MWP.

The Network agreed that the indicative timing for the opinion on cloud computing is too late. Either the task should be strengthened, like guidelines on cloud computing, or the timing should be brought forward in the MWP.

Clarification requested on the authentication and authorization mentioned in point B on page 6. The current eID Regulation focuses on authentication and not on authorisation. Some members asked if this will be addressed by the eHealth Network. The eHealth Network agreed that authorisation is part of the work of the eHealth Network, even if it will not be part of the Regulation. This point is agreed upon and shall be reflected in the MWP. Furthermore, an explanation note from DG CNECT will be requested on what is needed for the health area on eID, and on what is covered or not.

The question was raised if there should not be a greater focus on telemedicine and the uptake of those services. The eHealth Network should scale up the work on guidelines and standardization in this area, and the lessons learned from the EU financed projects.. Page 9 point A states: *"Report on the uptake of telemedicine services within the EU"*. This will be changed in *"Report on the uptake of telemedicine services within the EU, and recommendations on the lessons learnt by Member States that have already deployed these services"*. This change is agreed upon and shall be reflected in the MPW.

On page 12 last paragraph regarding the nomination of the partners for the new Joint Action, the word *instead* shall be changed into *also*. This change is agreed upon and shall be reflected in the MWP. The Joint Action will come up with the time line, and that it will be brought to the eHealth Network. It is important the new Joint Action brings together more technical bodies that are responsible for implementation of eHealth at national level.

Conclusion

With the changes mentioned above the content of the new Multi-Annual Work Plan is adopted, taking for the moment out the indicative dates. The revised MWP 2015-2018, including all the changes, is attached to the minutes.

The timing of the tasks and deliverables will be agreed upon in line with the set-up of the new Joint Action. The agreed timing in the Joint Action will be brought to the eHealth Network in November 2014. Some tasks and deliverables will be carried out by dedicated sub-groups of the Network.

Points specifically mentioned by eHealth Network Members as priorities:

- Trusted eHealth National Contact points (page 6 point A)
- Electronic Identification for eHealth (page 6 point B)
- Sharing of national eHealth strategies (page 9 point A)
- Update & revision of EU eHealth Guidelines (page 8 point A)

TOPIC 2: UPKEEP OF EPSOS SERVICES

Introduction

Technical, legal and organisational engagement is necessary to upkeep the services running currently under the epSOS pilot. There is a need of an eHealth Network subgroup to maintain the activities and make sure the investments are maintained.

The Members of the eHealth Network were requested to express their commitment to maintain the services running under epSOS, and to declare if they want to participate in the sub-group to make the bridge to the CEF.

Discussion

Portugal is thanked for the leadership in this. Member States welcomed the maintenance of these services.

There is a strong reason to create a stable legal and contractual base to ensure the services move from a pilot environment to permanent structures. The legal framework used in epSOS can be the basic model for the permanent structure. Also the use of SNOMED CT for semantic interoperability should be available.

Nordic countries have already decided to continue work on the exchange of ePrescriptions.

The work of the sub-group should be aligned with the content of the new MWP.

Conclusion

An implementation sub-group is formed to maintain and upkeep the services piloted under the epSOS project. The goal is to maintain the engagement of Member States and the make sure that the eHealth National Contact Points infrastructure is preserved until the CEF takes over (with the use of the OpenNCP solution). This sub-group will be led by Portugal.

The following countries expressed the willingness join the sub-group: DK, DE, EL, ES, HR, IT, LU, MT, AT, PT, FI, SE, UK. NL expressed after the meeting their interest to join the sub-group in writing.

Norway and Hungary also expressed support, but will not join the sub-group at the moment. They would like to have the possibility to join later.

TOPIC 3: CONNECTING EUROPE FACILITY (CEF).

Introduction

The Chairs invited Paul Timmers, Director H of DG Connected, to introduce the purpose of the CEF financial instrument, which aims at supporting projects of common interest for the deployment of digital services infrastructures. Ultimately, its role is to support the development of a Digital Single Market.

To make sure that the eHealth domain is represented in the CEF work plan 2015, an eHealth Network sub-group was set up in November 2013, with the support from the eHealth Governance Initiative.

A proposal containing 4 eHealth Digital Service Infrastructures (DSI) for funding was prepared:

1) Cross-border ePrescription and eDispensation service

ePrescription and eDispensation as piloted by epSOS extended by additional core services such as eSignature and eIdentification

2) Cross-border patient summary service

Patient Summary as described in the guidelines of the Network extended by additional core services such as eIdentification and eAuthentication

3) eHealth services for European Reference Networks

Virtual communication tools and telemedicine services for low-prevalence, rare and complex diseases including telemonitoring, virtual clinical boards, shared patient and knowledge databases and virtual training

4) Infrastructure services for interoperable Patient Registries

Registry of registries, registry assessment tools, repository of common data and process models for building patient registries, open source software components for building interoperable patient registries and to support data exchange between registries

Discussion

To make sure that infrastructure for cross-border eHealth services are taken on board by the CEF, the Chairs invited the eHealth Network to support a proposal for funding in 2015 of the 4 digital services infrastructures.

In the tour de table, members expressed a strong support to two of the four services; namely patient summaries and ePrescriptions, with the exceptions of 3 members having a neutral or negative position on ePrescriptions.

Many members were not enough informed or knowledgeable on the opportunity to support European Reference Networks and Patients Registries but only a few expressed a negative opinion.

In the end, the Network supported the inclusion of the four services, not to close the door to possible funding.

All members expressed an interest in sharing the services across borders and said they were in principle ready to deploy the national components of those services. On the other

hand, none was able to commit now the necessary funding because of national budgetary procedures.

Paul Timmers insisted on the following points:

- eHealth services are in competition for access to CEF funding with other digital services; hence:
- the need to provide evidence on the technical maturity and the financial sustainability of each of the 4 service, at national and EU levels
- the need to refine the budget, by identifying those components that can be identified as core services and generic services (as document in the CEF regulation and work programmes). For generic services, the national funding amounts to 25-30% (tbc)
- the timing for submitting this evidence is likely to be around May/June, in view of the adoption of the work programme 2015, by the end of the year
- should budget be insufficient in the WP 2015, the two less matured services could be committed in later years

He will provide the list of experts involved in the expert group of the CEF governance as well as the members of the CEF board itself.

The MS Chair asked which MS were willing to join the eHealth Network sub-group on CEF that was set up in November 2013. The new configuration of the sub-group is following: BE, DE, IE, GR, ES, FR, HR, LU, NL, AT, PL, PT, SI, SE.

Conclusion

The eHN endorsed the position paper on the contribution for the 2015 CEF work programme. The bid for commitment funds under the CEF in 2015 amounts to 38,3 million \in It covers the core and generic services of 4 digital services (DSI) at European level.

Two DSI are more technically mature and sustainable but the eHN supports the inclusion of the four of them.

The eHN recognizes that extra eHealth services such as telemedicine, could be identified in the upcoming years and therefore an extra bid could be made, for instance in 2017.

The EHN will further refine the division of the estimated costs between core and generic services for the 2015 commitment. Extra work is also needed to provide evidence on the financial sustainability of the services.

TOPIC 4: MHEALTH GREEN PAPER – INFORMATION POINT

Paul Timmers presented the mHealth Green Paper, which was published by the Commission on 10 April 2014.

mHealth is an emerging part of eHealth, where mobile Information & Communication Technologies are used to improve health products, services and processes. It is a

promising area to supplement the traditional delivery of healthcare, and complements rather than replaces it.

Stakeholders are requested to respond on a broad set of questions, ranging from safety measures to opportunities for mHealth apps. They are also asked to propose some actions in that area.

Paul Timmers urged MSs to take part to the consultation process, which is open until 3 July 2014.

TOPIC 5: GENERAL EU EHEALTH DEVELOPMENTS – INFORMATION POINT

In November 2013, several Members requested to have a regular up-date by the EC on general eHealth affairs within the eHealth Network.

Paul Timmers gave an update on the state-of play of the eHealth Action Plan, and in particular on the topics surrounding eID, eSense and the EXPAND project.

TOPIC 6: EPRESCRIPTION GUIDELINES

Introduction

The MS Chair set the scene, recalling the mandate foreseen in the Article 11 of the Cross-border Directive related to the adoption of the ePrescription guidelines by the EC.

The Chair then proposed the roadmap for the adoption of the guidelines.

The Guidelines will be based on the results of a study commissioned by DG SANCO on different options for interoperable ePrescription systems. These results will be elaborated by the eHealth Governance Initiative (eHGI) in at least one workshop to be held in September or October 2014.

The final version of the Guidelines is then expected to be approved by the eHealth Network in November 2014.

Discussion

The Chair gave then the floor to the Belgian representative, who is leading this process in the eHGI.

The members clarified the work that has still to be done to answer the opened questions about the draft text of the Guidelines, mainly related to semantic interoperability, the work being done by the European Medicine Agency (EMA) and reimbursement models.

The following discussion was mainly focused on the acknowledgement that further work on reimbursement issues is needed, also in the view of fraud detection.

One MS reported about their experience in implementing a specific algorithm for fraud prevention that gave positive results.

It was also stressed the urgent need of the outcomes of the work that EMA is currently doing on identification of medical products. It was noted the activities related to the identification of medical products should be consistent with those done in the context of Horizon 2020 programme.

It was also mentioned the need of classification guidelines for medical devices and the role of EMA in this regard.

Conclusion

The discussion highlighted a broad consensus on the importance of having ePrescription guidelines and the proposed way forward.

As regard the role of EMA, the MS Chair stressed the importance of having EMA activities aligned with eHealth strategies of the eHealth Network. EMA is thus invited to report on this to the eHealth Network in November's meeting.

The current draft guidelines on ePrescription will be revised taking into account the remarks and suggestions discussed by MSs.

The new version of the draft Guidelines will then be discussed in a subsequent workshop that will presumably take place in September or October 2014.

The final version of the Guidelines is expected to be adopted in November meeting of the eHealth Network.

TOPIC 7: Information points

Patient registries

M. Meglic (leader of the Joint Action "PARENT") presented the information paper on patient registries which contains information about the PARENT framework to be finalized by the end of 2014. The framework includes: the methodological guidelines on patient registries, the pilot Registry of Registries (<u>www.parent-ror.eu</u>) and a self-assessment functionality for registries.

The adoption of these guidelines is scheduled for the first semester of 2015.

The guidelines will be discussed at the PARENT JA workshop on 13 June. The members of the eHN are invited to that event.

Members were informed of the preparation of the new Joint Action on Patient Registries under SANCO Work Programme 2015 and invited to join the reflection process on the use of patient registries and products' registries using eHealth solutions notably for HTA purposes.

SNOMED CT

The Secretariat informed about the progress made on the discussion on SNOMED CT usage in cross border context.

There was a call for proposal under Horizon 2020 programme for an extensive study assessing the SNOMED CT. The results of the study shall be available by the end of 2015.

The Secretariat and the International Health Terminology Standards Development Organisation (IHTSDO) are discussing the framework for a free use of SNOMED CT for pilots and projects to reduce the administrative burden of the MSs and defining the EU subset of SNOMED CT for routine exchange of medical data across borders. The Secretariat will report on the outcome of the discussions at the next eHealth Network meeting. Some non-IHTSO members welcomed a possible agreement, and clarification was asked on how to define the scope of this cross border subset. It was clarified that the subset takes its origin from the epSOS project, but other projects using SNOMED CT will also be assessed.

One member asked for a written document on SNOMED CT for comments, and another representative added that similar EU negotiations on other standards would be also helpful.

Recommendations on health records and patient access to health data

Belgium presented a document describing the need for patient access to electronic health records. The document summarizes the experiences in Estonia and Sweden and makes a list of key open issues with some proposed solutions. The paper calls for a workshop bringing key projects in this field, providing input for recommendations to be submitted to the eHN.

One Member State expressed the willingness to collaborate on this topic, and stressed the need to clarify the access to patient summary and the remaining parts of electronic health records.

Authorization to access data

France presented the note on eldentification and Authentication which contains some recommendations at EU and national levels for enabling the cross-border authorization process to access personal data. The key message is that authentication (of health professionals) is needed for the implementation of cross border services even if the horizontal eID Regulation does not mention it. As regards to health, cross border consent mechanisms have to be worked out as well as health professional authorization (traceability of the care relationship with the patient with corresponding dates). These elements have to be taken into account in the legal and technical framework.

Horizontal legal aspects

Greece presented the paper on the legal aspects which is part of the current MWP. The paper puts forward two principles: eHealth Network should address the legal issues separately; the recommendations on how to exchange the data across border (post epSOS agreements) should be reflected in this document.

eHGI will deliver the legal interoperability road map as part of the contractual obligations.

CLOSING

Members were informed about the invitation letter to join the new Joint Action planned for mid-May.

The MS Chair summarized the meeting by stressing the key agenda points: adoption of the MWP and of the contribution to 2015 CEF work program, consensus on the epSOS sub-group.

Members of the Network were informed that the next meeting of the **eHealth Network** will take place on 18 November 2014 in Brussels.

The Chairs thanked Greece for hosting the eHealth Network and the eHealth Forum, and all the representatives for their participation.

The meeting was closed at 16h45.