

EUROPEAN COMMISSION DG HEALTH AND FOOD SAFETY DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

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# SUMMARY MINUTES 8<sup>th</sup> meeting of the eHealth Network 23 November 2015, Brussels

#### Introduction

These summary minutes were prepared by the Secretariat of the eHealth Network in accordance with the rules of procedure. They 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.

The meeting was co-chaired by Xavier Prats Monné, Director General of DG Health and Food Safety (the European Commission Chair) and Clemens-Martin Auer, Director General of Federal Ministry of Health, Austria (the Member State Chair).

#### Opening and approval of agenda

The European Commission Chair (Xavier Prats Monné, Director General of DG Health and Food Safety) and the EU Member State Chair (Clemens-Martin Auer, Director General of Federal Ministry of Health, Austria) welcomed the members of the eHealth Network.

The Member State (MS) Chair opened the meeting and welcomed the Network Members as well as Xavier Prats Monné, the new Director General of DG SANTE, as the EC chair of the eHealth Network.

The European Commission (EC) Chair introduced himself to the eHN Members. He underlined that eHealth is a key element of the Digital Single Market of the Juncker administration. The Digital Single Market Strategy, presented to the Network in the last meeting, aims at moving from 28 national digital markets to a single one, and helping consumers and businesses to fully benefit from digital technologies. Specifically the strategy announces the launch of the Priority ICT standardisation plan to identify key priorities for standardisation and interoperability. The Commission has launched an open consultation to gather stakeholders' views. The Members are invited to participate in this public consultation. It is important for the Commission to know what the needs are of the Member States and other stakeholders, because the Commission is there to support them. He said that he is looking forward to work closely together with all the Members of the Network.

The Network approved the agenda of the meeting as revised, took note of general housekeeping rules, and agreed on procedure to adopt the decisions due to the extraordinary circumstances in Brussels affecting the participation of some Members. The procedure was agreed to be: 1) presentation for the topic, 2) discussion, 3) presentation of written comments received, 4) close discussion, 5) amendments to the documents will be send to the Members for their consideration, 6) Members can comment in writing until Wednesday 25 November. After that the documents are considered as adopted by the Network.

The MS Chair noted that the following Members were not present: BG, CY, CZ, DE, LV, LU, RO, SE, and the Observing Member (NO). He confirmed the following proxies HR to PT, NL to AT. DK and HR were on an audio connection in the morning session.

Topic 1. Implementation of eHealth Digital Service Infrastructure under the Connecting Europe Facility (CEF)

a. Financing and deployment of National Contact Points for eHealth (NCPeH) and the principal decision on NCPeH as a generic service under CEF

Documents Information on the CEF call for proposal (information from the Commission) FOR ADOPTION: Organisational framework of eHealth NCP (JAseHN D5.1.1)

The MS Chair introduced the topic and stressed the importance of the adoption of the documents under the agenda point 1a and 1b. He stressed that these documents will bind the MS in their application to the CEF call for patient summary and ePrescription for cross-border services. He added that the success of the application and the later deployment is a period to prove the maturity of their cross-border exchange, which until now was developed on the project-piloting basis, but would now need to be put in practice.

In addition to the adoption of these documents the MS Chair underlined that a principle decision would need to be made that the deployment of NCPeH is the implementation of the generic service under CEF.

Tapani Piha (EC) informed that the CEF call was published 19 November and the information was already distributed via email to the Network. It provides financial support of 7,5 million for Member States. He explained that the CEF call was meant for the setting up, deployment and operation of the NCPeHs in participating Member States. In particular, a successful application would need to be supported by the national authorities responsible. The action's duration is up to 4 years.

Henrique Martins presented the Guidelines for the Organisational Framework of NCPeH (JAseHN D5.1.1). He mentioned that the document builds to a large extent on the input from epSOS and EXPAND and mentioned that the legal as well as DSI subgroups provided input to the document. The focus of the Guidelines is on Patient Summary and ePrescription. European Reference Networks and patient registries are out of the scope of the document. The documents provides an Organisational Framework for the eHealth NCP in setting organisational principles and requirements towards the establishment of the National Contact Point for eHealth, presenting a process to guide MS along the path of "Preparation; Setting-up; Deployment; and Operation" of NCPeH.

## Discussion

A Member stressed the importance of CEF call and continued to ask what DG SANTE position is on the need or advisability to form a consortium. Tapani Piha explained that a consortium application is possible, and all the applicants in the consortium would need to fulfil the criteria as if applying individually.

A Member informed that its priority is not so much on the cross-border health information exchange but rather on the national deployment, and called to generalise D5.1.1. to other use cases in eHealth.

# Conclusions

Document D5.1.1 was adopted with an amendment that minor changes could be done already in 2016, while the review was set for 2017, because of the need for stability and experience before revision should be made.

It was as well agreed that D5.1.1. is open for other services than Patient Summary and ePrescription in the future.

The Network also agreed that the setting-up and deployment of the NCPeH constitutes the implementation of the generic service under CEF.

## b. Governance structure of the eHealth DSI/NCPeH

Documents: FOR ADOPTION: Governance structure of the eHDSI (proposal from the Commission)

Tapani Piha presented the governance model for the eHealth Digital Service Infrastructure during the CEF funding and explained the roles, responsibilities and composition of the bodies included in the governance. These include eHealth Network, the Operational Management Board (eHOMB), the Expert Group and auxiliary bodies involved in standardisation and stakeholders liaison.

# Discussion

One Member thought that the process is not yet in place and the agreement on the governance is premature, and together with another Member said that role of the MS is not strong enough. Tapani Piha explained that the model builds on the CEF governance model and is thus not new.

One Member suggested that the Network should approve an annual work plan and budget of the central services.

The EC Chair called for a transparent process generating trust of the MS. He stressed that the Member States will steer and decide on the speed of the process. He added that the EC has no intention to move without the full involvement of the MS.

# Conclusions

The document was adopted in consensus with the addition that the eHOMB would propose a work plan and budget on core services to the eHN for approval and that the revision will be done, if needed, already in 2016.

# c. Progress of the work towards a multilateral agreement on exchange of data under the eHDSI/NCPeH

Documents INFORMATION: Legal subgroup principles for a multilateral agreement (report from the subgroup)

Leonhard Kamper, in replacement of Aneta Siskovic (chair of the legal sub-group), presented (attachment 1) the work that has been done since February of this year on the multilateral agreement (MLA). The first draft of the MLA aims at setting its structure and key topics, whereas its final text still has to be elaborated during 2016.

The aim of the legal sub-group is to create a sustainable legal basis for the cross-border exchange of health data. The legal sub-group calls upon the Member States to participate in the drafting of the MLA under task 6.2 of the JAseHN.

#### Discussion

The MS Chair mentioned that the legal sub-group will be merged on 24.11.2015 with task 6.2 of the JAseHN.

In general Member States support the development of a MLA, but there were also some comments or concerns expressed.

A Member State mentioned that the use of an MLA should have a wider scope than is now foreseen, for instance for regional cross-border exchange. Possible use new use cases should be worked out in an annex or attachment to the MLA.

Another Member State expressed concern that the timing of the MLA is unfortunate, leaving a gap between CEF financing and the signing of the MLA, where no exchange of data can take place. There is a need to consider other legal possibilities to bridge this gap.

#### Conclusion

The developments in creating an MLA are welcomed by the Member States, with a few comments and concerns expressed.

A poll was held to see which Member State is interested in answering the CEF Call for Proposal.

Member States who might answer: ES, AT, PT, MT, HU, LT Member States where a political decision is needed: BE, EE, IE, FR, EL, PL, UK, SK Member States who were not able to answer: IT, SE, FI

#### d. Roadmap for the building of the core services

Document INFORMATION: Roadmap for the eHDSI (information from the Commission)

Philippe Loopuyt (DG SANTE, Head of Unit A4) elaborated on the activities to be done by the EC to build the core services for the eHDSI. The prepared non-paper for the eHN was discussed providing a vision of the EC with a clear division of responsibilities.

#### Discussion

There is one MS that supports the activities mentioned in the non-paper, but expressed the need to better document use cases. Another MS mentioned that there is a need to think about a common incentive. Then the role of the patient should be more prominent in the non-paper. Also it should be clearer what will happen with the non-paper.

Furthermore, a MS expressed its concern about the communication and the cost of that. There has to be a communication strategy. Each country cannot promote the CEF individually, thus there should be a central approach.

## Conclusion

In general the non-paper was well received by the MS regardless of some concerns and comments expressed. The non-paper is there for transparency and should motive/stimulate for the MS and the EC to collaborate. From the non-paper a plan and follow-up actions will be made for the next year (2016).

### Topic 2. Standardisation and interoperability in eHealth

## a. JAseHN platform consisting of the relevant SDOs

Documents: DISCUSSION: Proposal for a platform consisting of the relevant SDOs (JAseHN D5.4.1)

The purpose of this agenda topic is to agree on the intermediary steps to create a SDOplatform and to agree moving on with the proposed SDO-platform under construction. To clarify, the SDO-platform is not to create a European standard, but for exchange of information between the MS and the SDOs and to develop a common understanding. Michiel Sprenger (Nictiz) gave a presentation about the set-up of this SDO-platform as mentioned in the MWP 2015-2018. The presentation is attached for your information (attachment 2).

## Discussion

There was a discussion on how to define a standards development organisation (SDO). This depends however on the definition that will be used for describing an SDO-platform. WP 5 leader Nictiz explained that this will be the task for the coming month to come up with a definition. Though the definition of an SDO should not be taken in a strict sense of the word. In the future organisations that comply to the definition could partake in the SDO-platform.

Furthermore, there was a discussion on the absence of ISO in participating in the platform. Nictiz explained that this is based mainly on the notion that the platform should focus on European organisations. Nevertheless there are ongoing discussions to determine the involvement of ISO in the platform.

# Conclusion

Overall there were no objections in creating an SDO-platform. Some MSs have expressed their support and said that this platform is useful to achieve interoperability. Nictiz continues the work in creating the SDO-platform. For the time being the platform operates "under construction". The final document will be submitted at 9<sup>th</sup> eHN Meeting in June 2016 for adoption.

#### b. eHealth European Interoperability Framework

Documents: ADOPTION: Refinement of the eHealth European Interoperability Framework (JAseHN D5.4.4)

The ReEIF was discussed in the 7<sup>th</sup> eHealth Network meeting in Riga before going for adoption by the eHN during this meeting. The ReEIF is a tool that should help MSs and should not be seen as mandatory. Merik Seven presented the small changes that were made to the ReEIF between the 7<sup>th</sup> and 8<sup>th</sup> eHN meeting. The presentation is attached for your information (attachment 3).

# Discussion

There was no extensive discussion on the ReEIF as this was already discussed during the  $7^{\text{th}}$  eHN meeting in Riga. A MS has mentioned that the use of an older version of the framework proved to be very useful.

## Conclusion

Since there were no major objections to the adoption of the ReEIF, the eHN adopted the ReEIF by consensus.

The document will be transposed to an eHN document format for publication.

#### c. SNOMED contract

A contract is under discussion with IHTSDO (owner of the SNOMED terminology) that makes it possible for MSs that are not a member of IHTSDO to use the SNOMED terminology (subset) for the purpose of CEF until end 2017. IHTTSDO helps the EC in developing terminology and are granting access of other EU projects into the terminology free of charge. The contract is not signed yet but the EC will inform the MSs about the developments.

## Discussion

There was a discussion on what the terminology subset contains for the purpose of CEF. The subset is based on the master value catalogue (MVC). A clause in the contract states that the MVC will be updated in the beginning of the contract and it can be reviewed during the contract.

Furthermore, there was a discussion whether this contract would be the first step towards a larger agreement with IHTSDO. This is not yet certain and should be seen at the end of the contract. For CEF purposes a small subset can be used, making it cheaper. However, the MSs can also opt for a full contract with IHTSDO, which means they have to pay membership contribution.

Conclusion

The MSs have taken notice of this information point on the agenda.

#### Topic 3. Policy developments on mHealth and a proposal for a mHealth sub-group

Documents: ADOPTION: Proposal to set up an eHealth Network subgroup on mHealth.

Peteris Zilgalvis (Head of Unit Health and Wellbeing, DG CONNECT) gave a presentation about the current state-of-play regarding the follow-up activities on mHealth. Furthermore, he proposed the creation of an eHN sub-group on mHealth. The purpose of the mHealth sub-group is to facilitate exchange of information on national mHealth strategies and discuss common challenges at the policy level. The subgroup is expected to produce a report on national mHealth strategies and come up with proposals for future collaborations. The presentation is attached for your information (attachment 4).

# Discussion

There was a discussion about the scope of the group on guidelines for assessing the validity of data. It was clarified that the scope of this group would not cover apps which are classified as medical devices which should be CE-marked and would not be reassessed. Regulation on Medical Devices most likely to be adopted next year by the Council and Parliament, is relevant in this context. The exact scope and criteria of the guidelines would be defined by the group but it is not the goal of this group to come up with a list of apps. There is also an aspect of competitiveness – the aim is that also more European platforms would offer possibility of linking apps and provide better quality services compared to some US based platforms.

With regards to the set-up of the sub-group on mHealth:

Several Member States expressed interest and were positive about the initiative, acknowledging this as an important topic. Some Member States stressed, however, that the mandate of the group and its link to other working groups needs to be clarified and close cooperation and convergence between different groups needs to be ensured. Also, a concern was expressed about the participation of relevant competent bodies in the group and that it needs to be ensured that the authority of national competence centers is not put into question.

Several topics were mentioned that could be taken into consideration by the group such as focus on the empowerment of patients as opposed to technology outcome, the issue of identification and electronic signatures, as well as standards and interoperability in mHealth.

#### Conclusion

All MSs welcomed the initiative of the EC to set-up a sub-group on mHealth. The following MSs have expressed interest in joining the sub-group: BE, EE, NL, FI, DE, MT, AT, PT, UK, EL, IE, ES, FR, HR, LT, LV, HU, DK.

Belgium has offered to chair the mHealth sub-group and Estonia has offered to be the Rapporteur.

#### Topic 4. Recommendation on the use of the Patient Registries Guideline

Documents: ADOPTION: Proposal for a recommendation on the use of the Patient Registries Guideline.

During the 7<sup>th</sup> eHN meeting in Riga an update was given on the progress of the PARENT project. It was also agreed that during the 8<sup>th</sup> meeting the eHN is to endorse recommendations on the further use of the outcomes of the PARENT project.

A representative of the Slovenian permanent representation gave a presentation on the work of the PARENT Joint Action, its deliverables and the recommendations that are up for endorsement by the eHN. The presentation is attached for your information (attachment 5).

#### Discussion

There was no extensive discussion, as this topic was already discussed in the 7<sup>th</sup> eHN meeting. There was a suggestion to also populate the EU registries with the data from the MSs. Furthermore, a MS provided the eHN secretariat with amendments to the wording of the recommendations in writing. These amendments were all accepted and processed.

#### Conclusion

Since there were no major objections to the adoption of the PARENT recommendations and taken into consideration the amendments in the wording of the recommendations, the eHN endorsed the recommendations in consensus.

The document will be transposed to an eHN document format for publication.

#### **Topic 5. National eHealth Strategies**

Due to time constraints PT was asked to postpone their presentation on their eHealth activities until the 9<sup>th</sup> eHN meeting in Amsterdam. France presented its eHealth strategy/activities. The presentation is attached for your information (attachment 6).

#### Topic 6. Status report on the JAseHN

Documents: DISCUSSION: Report on the use of cloud computing in health (JAseHN D7.2.1) DICSUSSION: Report on the implementation of Patient Summary Guideline (JAseHN D6.1.1)

### JAseHN D 7.2.1

Jeremy Thorpe presented the results of deliverable 7.2.1, which is the report on the use of cloud computing in health (attachment 7). This report addresses the pros and cons of cloud computing in health. The intention of the report is that it serves as the basis for JAseHN task 7.2 to come to a code of conduct on how to handle secondary use of health data and recommendation on the de-identification of data for security use. The report tried to make it more practical for people who are considering on using cloud computing e.g. contractual arrangements.

## JAseHN D 6.1.1

Due to the absence of Croatia the report could not be presented but was shortly introduced by the MS chair. The report provides a reality test. It gives a good overview on how far the Member States are on the implementation of the PS guidelines. Extra attention is drawn to the conclusion on page 33.

#### Discussion

A MS raised the question why the report speaks of pros and cons instead of opportunities and threats. Jeremy Thorpe welcomed input on the report. A MS mentioned the importance and the use of cloud computing but need to consider the security of data.

#### Conclusion

The report on cloud computing positively welcomed as an information point on the agenda.

#### Topic 7. Stakeholder input to eHealth

The MS co-chair informed the eHN that an eHealth Stakeholder Group meeting took place on 10 September 2015. The message in that meeting was that stakeholders are welcomed to take place in eHealth discussions and take part in preparatory work. The Stakeholders are involved in the JAseHN through WP 4.

Furthermore, the renewal of the mandate of the eHSG is on its way and is published. The call of expression of interest will stay open until January 2016. The eHSG will have a maximum of 30 members representing different stakeholders. The aim is to discuss and contribute to the development of policy on EU level in a multidisciplinary manner, following the eHealth Action Plan. The eHSG will be the main platform for stakeholder input to the ongoing work of the eHealth Network and the JAseHN.

#### Closing / AOB & Closing remarks.

Edwin Maarseveen from the Dutch Ministry of Health presented the eHealth Week 2016 in Amsterdam. The eHealth Week will take place from 8 - 10 June 2016 in the Beurs van Berlage in Amsterdam. The 9<sup>th</sup> eHealth Network meeting will take place on 7 June 2016 in the Beurs van Berlage in Amsterdam.

PT informed that the past months there was interaction between EXPAND and members of the Rare Disease Joint Action. There will a workshop in December with follow-up in February 2016 to start thinking about the challenges and issues regarding ERNs and how interoperability should be taken into account.

The Members of the eHN are thanked for their presence and commitment.