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

eHealth-units

Summary minutes
9th Meeting of the eHealth Network
7 June 2016

Venue: Beurs van Berlage, Amsterdam

co-chairs:
Clemens-Martin Auer, Director General, Federal Ministry of Health, Austria
Martin Seychell, Deputy Director General for Health and Food Safety, DG SANTE

1. Introduction

[These summary minutes were prepared by the Secretariat of the eHealth Network in accordance with the rules of procedure. They will be published together with accompanying documents and presentations on the European Commission (EC) website http://ec.europa.eu/health/ehealth/events after having taken into account any comment provided by Network's members.]

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

There were 26 Member States present at the eHealth Network meeting. The list of participants will be published on the abovementioned website.

2. Opening an approval of agenda

The MS co-chair informed the Members of some adjustments to the agenda. Furthermore, the Members were informed that the Dutch State Secretary of Health, Welfare and Sport will speak after lunch.

There were no comments on the agenda and it was approved.

3. Appointment of Member State co-chair

The Commission co-chair explained the procedure. The sitting MS co-chair volunteered to take up another 2 year term of co-chairmanship in case of no response. There was no Member volunteering for the position. Thus Clemens-Martin Auer was appointed for another 2 years unanimously starting from the 10th eHealth Network meeting. The Portuguese Member supported by all MSs thanked for the very good work that Clemens-Martin Auer has done during his 4 years of co-chairmanship.

4. Topic 1: Implementation of the eHealth DSI

A. Tapani Piha gave a presentation on the application for CEF funding by the Member States:
The call for proposals ended mid-March 2016. There are 20 Member States that applied for CEF funding to build the eHealth NCP and all proposals were declared eligible by the external evaluators.

The total requested funding amounted € 13 million while only € 7.5 million in the 2015 budget was foreseen leaving a gap in the funding. The presentation (attachment 01) will be published on the eHN website.

The Commission will produce a report with recommendations on which MS gets funding. This report will be submitted to the CEF Telecom Committee by the end of June 2016. Negotiations with the MS who get funding will start by fall 2016 after which work in the MS can commence early 2017. It was mentioned that it is important that MS go live in a synchronized manner so that health data can be exchanged. A second call under the CEF 2017 work programme will possibly be created. Countries that are not included in the 2015 funding can then re-apply in 2017.

B. eHDSI work plan and budget 2016:
In the 8th eHN meeting it was agreed that the eHN has a say in the eHDSI annual work plan and budget for building the core services. The work plan and budget 2016 was agreed by the eHOMB in May 2016.

Discussion:
It was mentioned that the budget is "a posteriori" since the year had already started. There are some obscurities in the work plan 2016 that have not yet been discussed. A discussion should still take place on the governance model in finding a way how the interests of MSs are better heard.

Doubt was expressed that the budget will be spend in the best way for building the horizontal building blocks and the imbalance in what the MSs need to invest to build the generic services. The important aspect of the work plan is the planning and the understanding of the heading of the tasks description.

Conclusion:
The MSs did not adopt the work plan and budget 2016 but took note of it. The EC can continue its activities building the core services. The work plan, with revised heading for clarity, and budget 2017 will be presented in the 10th eHealth Network meeting.

C. Country guide for the implementation of the NCPeH:
The JAseHN CEF deliverables – relation map was presented explaining the relationship of the JAseHN deliverables to the building of the eHDSI. The presentation (attachment 02) will be published on the eHN website.

Discussion:
It is mentioned that MSs need to commence preparatory work in building the NCPeH in the coming 6 months.

Furthermore, it was expressed that a governance model should be ready soon for the benefit of the preparations in the national healthcare systems MSs are making to connect to the eHDSI. Though, there is already a governance model in place adopted in the 8th eHN meeting, there are several elements that need to be improved to make sure that the model also works in practice. Technical documents can be adopted at technical level unless politically important, documents should be forwarded to the eHN. In the 10th eHN meeting it is important to create clarity between the roles of JAseHN and the new eHDSI structures and between the eHDSI structures themselves

Conclusion:
The country guide for the implementation of the NCPeH was adopted by consensus.

5. Topic 2: Identification for the exchange of personal health data

A presentation was first given by Mr Andrea Servida (DG CONNECT) on the eIDAS Regulation that need to be put in place by all MSs by September 2018. The presentation focussed on the recognition of eID and the mandatory elements of the Regulation for the MSs. The presentation (attachment 03) will be published on the eHN website.

The second presentation was given by Alice Vasilescu (DG DIGIT) and Sebastiaan van der Peijl (Deloitte) on the eID building blocks for the NCPeH. The presentation (attachment 04) will be published on the eHN website.

6. Topic 3: Legal aspects of cross-border exchange of health data

A. Interim report about the work progress of the Multilateral Legal Agreement

Aneta Siskovic (task 6.2 leader) presented an update on the progress on the multilateral agreement (MLA) needed for the exchange of personal health data. An MLA is necessary because there is no EU-legislation that forces MSs to participate in the cross-border exchange of personal health data. The presentation (attachment 05) will be published on the eHN website.

The legal team encounters some difficulties since the merger with the JAseHN: 1) loss of MSs in the working group 2) financial (budgeting) challenges to organise meetings. Aneta Siskovic called upon the Members to participate in the process of creating the MLA.

The draft text of the MLA will be presented at the 10th eHN meeting (November 2016), however the task leader emphasized that extensity of the draft depends on the support of the number of legal experts from MSs. The final version of the MLA will be presented at the 11th eHN meeting (May 2017).

The MS co-chair mentioned that the nature of the MLA should be clear, emphasizing that a Treaty is impossible to achieve before the first exchanges of health data take place in 2018.

Discussion:

Some Members mentioned that certain building blocks for the MLA are already there in existing EU-legislation. It is therefore necessary to scrutinize what is already there and identify the gaps in EU-legislation. The team leader of task 6.2 agrees and confirms that no duplication of work will be done. With regards to the form of the MLA, it cannot take the form of an executive agreement as this is (in most cases) is only applicable to policy. Furthermore, the MLA will be written in broader terms allowing it to be also applicable to other use cases other than ePrescriptions and Patient Summaries.

The annex of the cover note is a legal analysis done by the ECs legal team on which EU-legislation can be used in the context of the MLA.

The MS co-chair raised the question to the Members what their expectations are towards the MLA. MSs agreed that the work done by the legal team is difficult but necessary to exchange personal health data. The purpose of the MLA is to create a circle of trust and not to create new EU legislation through an agreement. Concern was raised about the feasibility to have a MLA ready on time.

B. General Data Protection Regulation

Michele Voznick (DG JUSTICE) informed the members about the General Data Protection Regulation.

7. Topic 4: Implementation of the Digital Single Market Strategy

Katja Neubauer Team leader of the eHealth team in DG SANTE gave a short presentation on the implementation of the Digital Single Market Strategy, explaining the role of eHealth in achieving a DSM and emphasizing the 4 communications published by the EC. The presentation (attachment 06) will be published on the eHN website.

Paul Timmers informed the members about the European Cloud initiative (very much linked to Big Data), mentioning that there is an active dialogue with colleagues in health research since health is an important area for Big Data.

8. Visit Dutch State Secretary of Health, Welfare and Sport Mr M. Van Rijn.

The Dutch State Secretary of Health, Welfare and Sport visited the eHN meeting and addressed the Members.

The State Secretary's key message is that the Netherlands is investing in Personal Health Records to strengthen patient empowerment. Furthermore, the eHealth Network proved to be the platform to create sustainable infrastructure for cross-border exchange of health information and to share knowledge.

9. Topic 5: Standardisation and interoperability

A. Update regarding the work progress on a proposal for a platform of SDOs

Merik Seven (NICTIZ) as JAseHN Task 5.4 leader provided an update on the progress in forming an SDO platform. The task leaders informs the members that more time is needed to set up an SDO platform and that there are good business cases on which this can be built upon: International patient summary (started in May), Roadmap on Standardisation (under eStandards project). A final proposal on an SDO platform will be presented at the 10th eHN meeting.

B. Recommendation on the revised concept for updating the Patient Summary and ePrescription guideline

The JAseHN task 5.3 leader Jeremy Thorp informed the members of the proposal to revise the ePrescription and Patient Summary guidelines. The essence of the revision is to create a generic set of guidelines for the common parts of the existing guidelines and place the specific elements of the eP and PS guidelines in the annexes. The update of the guideline will be discussed during a workshop in Lisbon end of June.

Conclusion:
The proposal to revise the guidelines was adopted by the eHealth Network.

10. Topic 6: mHealth

Paul Timmers presented the state-of-play regarding the EC activities on mHealth. The presentation (attachment 07) will be published on the eHN website.

A. Public consultation on the safety of apps and other non-embedded software

This regards apps that are downloadable on the device (non-embedded). The public consultation was launched in June 2016 and is open for 12 weeks.

B. mHealth privacy Code of Conduct (CoC)

The current state-of-play is that the draft CoC is finalised and published online after receiving comments from the stakeholders. On 7 June 2016 the CoC was sent to the Article 29 Working Party (under the Data Protection Directive). Ultimately the CoC will be signed by app developers. Oliver Schenk (Germany) thanked the EC for its facilitating work and underlined that Germany welcomes the progress and follows the process closely.

C. Development of EU quality standards for mHealth apps by CEN
This refers to PAS 277 work of BSI on health and wellness apps quality criteria across the lifecycle.

Andrew Ruck of CONSARD presented the work done in coming to a guideline on EU quality standards for mHealth apps. The presentation will be published on the EC website.

D. Report on the eHealth Network subgroup on mHealth
The chair of the subgroup Ain Aaviksoo (Estonia) gave a short update on the progress of the eHealth Network subgroup on mHealth. The next meeting will take place in September 2016 and a first draft of the report of the subgroup will be discussed. The position of rapporteur of the subgroup is still open to those who are interested.

Oliver Schenk (Germany) thanked Estonia for chairing the group and shortly presented a scientific study on mhealth, which has been financed by the German MoH and translated in a summary version into English:
http://www.bmg.bund.de/fileadmin/dateien/Downloads/A/App-Studie/charismha_abr_v.01.1e-20160606.pdf.

E. Guidelines for assessing validity and reliability of mHealth apps
Core drafting team started in February 2016. The guidelines should come out by the end of 2016.

11. Topic 7: eHealth strategies and projects
A. eHealth strategies
The Netherlands (attachment 08) and Portugal (attachment 09) presented their national eHealth strategy and activities. Their presentations will be published on the eHN website.

B. Projects
Donna Henderson of the NHS presented the results of the EC funded project "United4Health" on the development of 19 telehealth services in 10 countries and the formulation of a number of policy messages. The presentation (attachment 10) will be published on the eHN website.

It was mentioned if telemedicine could be taken up further, and questioned whether the current dedication on telemedicine in the JAseHN is sufficient and if telemedicine could be more under the attention of the eHealth Network. This will be discussed during the upcoming coordination group meeting of the JAseHN. Also the EC was asked what the follow-up is on telemedicine. Though the EC is interested in this topic, the allocation of resources currently is on building the eHDSI.

12. Topic 8: other eHealth-related developments
A. Mid-term review of the eHealth Action Plan 2012-2020
The eHealth Network is mentioned many times in the eHealth Action Plan. It brings together eHealth in the EC, MSs and stakeholders and covers areas as interoperability, research and innovation, uptake and awareness raising, and international cooperation.

A public consultation on the mid-term review of the eHealth Action Plan will be launched. Information on this public consultation could be found on the EC website https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

Please refer to the presentation (attachment 11) that will be published on the eHN website.

International cooperation is an integral part of the eHealth Action Plan, however it is not precise on which elements this cooperation should take place. The WHO and OECD are mentioned as organisations of cooperation on the aspect of eHealth.

B. eHealth Stakeholder Group

A newly mandated eHealth Stakeholder Group was formed and met for the first time on 18 May 2016. The group consists of 30 stakeholders representing patients, civil society, research and academia, and eHealth industry. The eHealth Stakeholder Group was formed through an open call for interest. The terms of reference of the open call for interest is publicly available on the website: https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-ehealth-stakeholder-group-members

The eHealth Stakeholder Group convenes twice a year. The next meeting will take place on 5 October 2016.

13. AOB

The members of the eHealth Network are thanked for their commitment to coming to the eHealth Network.

The 10th eHealth Network meeting will take place on Monday 21 November 2016 in Brussels.

The Maltese eHealth Network member Hugo Agius Muscat informed the members that the eHealth Week 2017 will take place from Wednesday 10 May until Friday 12 May 2017. The 11th eHealth Network meeting will take place on Tuesday 9 May 2017.

The Dutch Ministry of Health, Welfare and Sport was thanked for their hospitality for hosting the 9th eHealth Network meeting in the Beurs van Berlage in Amsterdam.