



Summary minutes
11th Meeting of the eHealth Network
9 May 2017

Venue: Hilton Hotel, Portomaso Suite, Saint Julian's, Malta

co-chairs:

Clemens-Martin Auer, Director General, Federal Ministry of Health, Austria
Xavier Prats Monné, 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 with the accompanying documents and presentations on the European Commission (EC) website <http://ec.europa.eu/ehealth/events> after having taken into account the comments provided by the Network's members.]

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

There were 28 Member States represented at the Network meeting and 1 country as observer.

2. Opening and approval of the agenda

The meeting was opened by the MS co-chair.

The agenda was approved, with the following adjusted arrangement of agenda points under topic 8: 16, 19, 20, 17, 18.

3. Topic 1) EU strategy and activities on eHealth

Point 1 and 2: Mid-term review Digital Single Market Strategy, Implications for future work of the eHealth Network:

Deputy Director General Khalil Rouhana of DG CONNECT gave an update of the Digital Single Market Strategy and the forthcoming announcement of the mid-term review. The Commission co-chair then informed the Members about the upcoming initiative on Digital Health and Care in a dedicated Communication expected by the end of 2017. The initiative will be made up of three pillars:

1. Patient access to health data
2. Developing a data infrastructure to advance research, disease prevention and personalised medicine
3. Patient-centred integrated care and citizen empowerment

The Commission co-chair emphasized the need to work closely together especially on these initiatives and to align efforts. The Members were asked to share their view on how better collaboration can be established.

Discussion

Several Members of the eHealth Network expressed their willingness to optimize the work with the Commission and regret to be asked about their view only the day before the DSM strategy document publication. In this regard, they could not provide final statements.

However, some considerations were given:

- Citizens/patients should be the drivers for the initiative on digital health and care.
The Member State co-chair pointed out however that when it comes to the free flow of data and data protection, it is necessary to find the right balance as both could be conflicting. There is a greater need for free flow of data (data for research etc.) but at the same time not wanting to compromise on the protection of personal data. For that reason a balance needs to be made prioritizing on those types of data where the free flow is essential.
- Therefore we need to prioritise on what is most important. But a discussion is needed on how and where to prioritise.
- It is necessary that on national level there is a link (communication) between the IT agencies and the ministries of health. Through proper communication channels IT agencies can be informed about the work done at EU level. Healthcare is a powerful enabler for e-government, as it is about citizens and patients.
- Digital transformation, an important enabler for health is already happening in some Member States. Nevertheless the potential benefits of digital in healthcare needs to be evidence driven. Therefore, it is necessary that caution is taken when speaking about them.

Conclusion

Members called for alignment of efforts with the eHealth Network, and to further strengthen interaction between the Commission and the eHealth Network in due time.

Point 3: 3rd Joint Action on eHealth

The Commission co-chair informed the Members about the ongoing preparations of the 3rd Joint Action on eHealth. An update was given on the process of setting up the new Joint Action and deadlines. A series of preparatory meetings are scheduled to facilitate a coordinated approach to set up the new Joint Action.

Discussion

The Member State co-chair mentioned that PT had expressed interest in coordinating the new Joint Action on eHealth. Several Members expressed their support to the idea of PT coordinating the new Joint Action.

Conclusion

The Commission co-chair concluded that Members of the eHealth Network had noted Portugal's willingness to be the Coordinator for the 3rd JA on eHealth, and several Members had expressed their support.

Point 4: Draft eHealth Network multi-annual work programme 2018-2021

The rapporteur of the MWP sub-group (PT) presented the draft MWP. An overview was given of the complex interdependencies of various projects and the work of the eHealth Network. Furthermore, the MWP takes into account 3 EU-legislations: GDPR, eIDAS, NIS. Also, the Members were informed that stakeholders are invited to provide their comments on the MWP until the end of May.

Discussion

The following points were mentioned in the discussion:

- The draft MWP is a good basis for further discussion. The chosen structure matches the needs.
- There should be a focus on citizens, providers, society, and implementation.
- There is need to further support the cross-border exchange of health data but activities that were not successful in the current JA should not be included again.
- Standards remain an important topic to be considered as they are the basis of cross-border exchange.
- The patient perspective needs to be secured in the MWP.
- The category on innovative use of health data needs to be further elaborated, possibly with real use cases, privacy aspects of health data (non-commercial uses).
- The category on implementation challenges was well received, since most Member States are in different stages of implementation.
- Need to discuss what is of the common interest and what is feasible for the eHealth Network to do. It will be a challenge but nevertheless important to distinguish what could be taken up by the new Joint Action and what not. Also, it is necessary to consider who other than the new Joint Action could take up some of the actions of the MWP.
- Interoperability and standards is an open issue, despite the fact that much work has been already done.

Conclusion

The current draft version of the MWP provides a good basis for further development. There is a consensus on the proposed 4 pillars. The sub-group will take the comments of the eHealth Network into consideration when drafting a new version of the MWP.

4. Topic 2) Implementation of the eHealth Digital Service Infrastructure

Point 5: Policy paper on how to assess Member States overall readiness to go live & recommendation report to Go Live

The Member State co-chair presented the topic on how to assess the Member State overall readiness to go live. The document is an essential guide during the policy decision process regarding the implementation of the eHDSI. The technical details are not meant for the eHealth Network, as it is a policy making body. The eHealth Network will decide upon the readiness of Member States to go live. The Members are invited to adopt the document.

Discussion

The following points were mentioned during the discussion:

- The eHealth Network has the capacity to refuse a Member State to go live in case it is not considered to be ready. The reasoning behind such a decision should be made very transparent.
- The adoption of the policy document is necessary as by November the eHealth Network needs to make a decision which Member States of the first wave can go live. Currently, the

preparatory work in Member States is ongoing. Therefore knowledge is accumulating and the Member States should share information about their national activities to achieve synergy.

- The Commission thanked JaseHN for the work done and the preparation of the document, which distinguishes between political responsibility of the eHealth Network and technical responsibility of eHealth Member State Expert Group (eHMSEG) to prepare MS and Central Solution to exchange the data. Currently the work is ongoing to find a solution on how to audit the eHealth National Contact Points. The proposed solution should enable the audits to be finalised in time for the decision to go live, so the first countries can go live in 2018. In this regard the role of eHMSEG is central. Standards are essential to the implementation process. Proper auditing process with transparent change management process is crucial for the success of the eHDSI.

Conclusion

The new version of the policy paper and the recommendation report was adopted by consensus.

Point 6: Policy paper on eID specific framework for eHealth – Release 1

The Member State co-chair introduced the topic and mentioned the eHealth Digital Service Infrastructure would greatly benefit from the eID implementation, and we are late to consider implementation of eID solutions. The presented document is focussing on methodology for the first version of a guideline for MSs, but the next release is necessary to complement it.

Discussion

The following points were mentioned during the discussion:

- eID is an important topic and more information is needed about different options and implications. The Commission is requested to help MSs moving forward on this complex topic. The Commission mentioned that there are several studies ongoing about the use of eID for different health use cases. Specifications for Wave 2 of the eHDSI will incorporate the information coming from these studies.
- A Member mentioned that the policy paper does not seem mature enough for adoption and suggested to postpone until the document includes all the needed information.
- Another Member argued that the adoption is needed to test the solution in autumn.

Conclusion

The present version of the methodology policy paper was adopted by the eHealth Network by consensus with the notion that work still needs to be done.

Point 7: Guideline on the interoperability of Electronic Professional Registries

In the interest of time, the Member State co-chair suggested postponing the discussion through written comments and addressing them directly to the authors of guideline. All Members are invited to engage in the task.

Point 8: State-of-play on European Reference Networks

The Commission co-chair informed the Members about the 24 European Reference Networks (ERN) launched in Vilnius in March 2017.

Discussion

Due to the time pressure, no presentation was made by the Commission (presentation to be annexed to the minutes). So there was a short discussion on what role the eHealth Network should have in the ERNs and on the possibilities/necessity to have consistency between the ERN and the eHN committee's work on this topic (i.e. guidelines convergence between the ERNs and the eHDSI).

Conclusion

The Secretariat is requested to provide the eHealth Network with an informative documentation (roadmap, proposed planning and platform functionalities) about ERNs as input for the discussion in the next meeting in November 2017.

5. Topic 3) Agreement for the exchange of health data

Point 9: Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in CBeHIS, including two supporting documents

The Member State co-chair introduced the topic and gave the floor to L. Kamper and T. Trupec of the JAseHN to present the Agreement and the supporting documents. The eHealth Network was invited to a discussion before the adoption of 1) the Agreement, 2) the recommendation for the request of the eHealth Network to the Article 29 Data Protection Working Party for their opinion on the Agreement and 3) the recommendation for the governance and implementation of the Agreement.

Discussion

Several Members mentioned their high concerns in adopting an Agreement before consulting the Article 29 Working Party. They therefore suggested postponing the adoption of the Agreement until an opinion of the Article 29 Working Party is received.

The Member State co-chair and a Member underlined that adoption of the Agreement is necessary for the CEF first wave countries to move forward. It is mentioned that the Agreement foresees the possibility for amendments after having received the opinion of the Article 29 Working Party.

Conclusion

Because consensus on the adoption of the Agreement and supporting documents could not be reached, the Member State co-chair decided to call for a vote in compliance with Article 7 of the eHealth Network's Rules of Procedure.

France, Germany and 7 other Member States, proposed to abstain (as opposed to voting against) in order not to interfere with the progress of "wave 1" countries and emphasizes that this vote will not be considered as an acknowledgment to 'sign' the Agreement as it is. The advice of the national DPA and Article 29 Working Party is essential. For some Members States national legislation may need to be aligned to the new rules.

The vote result was as follows:

- YES: 19 Members
- NO: 0 Members
- Abstain: 9 Members

According to Article 7(2) of the Rules of Procedure, for the adoption a two third majority of Members present is needed. Since all Members were present (28), a two third majority of Yes votes was

(rounded up) 19 Members while 9 abstained from voting. Pursuant to Article 7(1) of the Rules of Procedure, abstentions shall not prevent the adoption of deliberations by consensus.

Therefore, the Agreement and the supporting documents were adopted by consensus with a qualified majority.

6. Topic 4) mHealth

Point 10: Report state-of-play of the sub-group on mHealth

The Commission co-chair introduced the topic and gave the floor to the Estonian Member of the eHealth Network and chair of the mHealth sub-group, A. Aviksoo, to present the report. He presented an outline of a comprehensive set of actions that should be carried out in order to support the uptake of mHealth solutions. Furthermore, he proposed the extension of the sub-group's mandate until the 13th meeting to monitor and prepare the uptake of the proposed activities in the new Joint Action on eHealth.

Discussion

A comment was made by a Member on how the eHealth Network sees itself involved in the debate on the ongoing work on the Medical Devices Directive and the interaction with the mHealth domain. Furthermore, a Member asked about the current state-of-play of the mHealth Code of Conduct.

The Commission explained that there will be a meeting with the Article 29 Working Party in the week of 15 May. Furthermore, the Commission noted that there were a fundamentally different views on guidelines by stakeholders, but also a lot of common interest. Much happening in Member States and regions. The main concern is borderline products, those who could be defined also as a medical device.

Conclusion

The eHealth Network agreed with the continuation of the mHealth sub-group.

7. Topic 5) eHealth interoperability and standardisation

Point 11 & 12: Preliminary report on European Semantic Interoperability in eHealth & Preliminary report on proposing actions to promote the use of common standards or technical specifications in eHealth within the EU

The topic was introduced by the Member State co-chair. The task leader of the JAseHN responsible for work gave a short introduction of the topic.

Discussion

There were no comments made on the draft deliverables.

Conclusion

The eHealth Network asked the Joint Action to continue finalising the deliverables to be submitted for the eHealth Network in November 2017.

8. Topic 6) Cybersecurity

Point 13: ENISA cybersecurity activities

The Commission co-chair introduced the topic and gave ENISA (EU Agency for Network and Information Security) the floor to present their recent and upcoming activities on cybersecurity in the healthcare domain. Furthermore, ENISA informed the Member States about the activities regarding the implementation of the NIS Directive (Network Information Security).

Discussion

There was a comment made by a Member on the activities of ENISA in block chain technologies. ENISA responded by mentioning that its activities in block chain technologies only focusses on the financial sector. A report on block chain by ENISA will be provided.

9. Topic 7) Secondary use and access to health data

Point 14: Report on how to handle health data for purposes other than patient care

The Member State co-chair introduced the topic and presented the report that was drafted by the JAseHN. The Members were then invited to discuss the content of the report and to provide their comments.

Discussion

There were no comments made by the Members on the report.

Point 15: Draft report on EU state-of-play on patient access on eHealth data

The Member State co-chair introduced the topic and presented the report that was drafted by the JAseHN and mentioned that this report is still a draft. The final report will be presented at the 12th eHealth Network meeting and will provide input for recommendations.

Discussion

The Estonian Member encouraged the eHealth Network to continue working on this topic and to look forward to the recommendations that follow from this report. The narrative of the analytical part of the report needs to be further developed to highlight the policy objectives.

Conclusion

“Patient access” is an identified category by the sub-group on multi annual work plan, therefore the document was forwarded to the sub-group for their consideration.

10. Topic 8) National eHealth strategies, EU projects, and other eHealth-related developments

Point 16: Digital Health Strategy Malta

The Member State co-chair introduced the topic and gave the floor to the Maltese Member of the eHealth Network to present the Maltese strategy on digital health.

Point 17 – 20: EU projects and other eHealth-related developments

The Member State co-chair introduced the following consecutive topics:

- Point 19: Report on the establishment of a platform for the sharing of national eHealth strategies: the Portuguese Member presented the document. The Commission has mentioned that it will look into the possibilities to follow-up on the recommendations (to host the platform) but cannot commit to any major investment of resources.
- Point 20: Information paper on supporting preparatory convergence meetings between eHN and WHO: the French representative presented the report. Both co-chairs outlined this work is important and should be continued. The Commission co-chair emphasizes that Europe should be proud about what we all achieved so far.
- Point 17: ValueHealth Project: D. Kalra was invited to present the result of the ValueHealth Project looking into possible new use cases in the eHDSI.
- Point 18: Personal Connected Health Alliance: S. Meunier from the Swedish Association of Local Authorities presented the activities of the Personal Connected Health Alliance and the need for end-to-end interoperability.

11. AOB & closing

- The Member State and Commission co-chair thanked all the eHealth Network Members and other participants for their participation.
- The Maltese Member and his team were thanked for their hospitality in hosting the 11th eHealth Network meeting.
- Furthermore, the Estonian Member informed the Members about the upcoming eHealth event in Tallinn from 16 – 18 October 2017.
- The Member State co-chair informed the eHealth Network Members that the 12th eHealth Network meeting will take place on Tuesday 28 November 2017 in Brussels.

The 11th eHealth Network meeting in Saint Julian's Malta was closed.