

# **EUROPEAN COMMISSION**

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

eHealth-units

# Summary minutes 12<sup>th</sup> Meeting of the eHealth Network 28 November 2017

Venue: Borschette Conference Centre, Brussels

#### **Co-chairs:**

Clemens-Martin Auer, Director General, Federal Ministry of Health, Austria Xavier Prats Monné, Director General for Health and Food Safety, DG SANTE Martin Seychell, Deputy Director General for Health and Food Safety, DG SANTE

[These summary minutes were prepared by the Secretariat of the eHealth Network in accordance with the Rules of Procedure. They will be published on the European Commission (EC) website <a href="http://ec.europa.eu/ehealth/events">http://ec.europa.eu/ehealth/events</a> after the comments provided by the Network's members and the eHealth Network's online platform <a href="https://webgate.ec.europa.eu/hpf/network/home/43">https://webgate.ec.europa.eu/hpf/network/home/43</a>.]

#### Introduction

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. The Commission co-chair was replaced by Martin Seychell, Deputy Director General for Health and Food Safety (DG SANTE) as from 11.00 hrs onwards.

There were 25 Member States represented at the Network meeting and 1 country as observer. The Member States not present at the Network's meeting were: Bulgaria, Hungary and Lithuania.

#### Opening and approval of the agenda

- The meeting was opened by the MS co-chair. The Commission co-chair informed the Members that he would have to leave at 11.00 hrs and would be replaced by his alternate.
- The agenda was approved by consensus.
- The Commission co-chair pointed out that a new MS co-chair should be appointed at the 13<sup>th</sup> eHealth Network meeting. The new MS co-chair will assume responsibilities directly after the 13<sup>th</sup> eHealth Network meeting. The eHN Secretariat will send in early February 2018 a call for interest. This call will close in April 2018 giving time for every Member to express their interest in the position.

# Agenda point 1) EU strategy and activities on digital health

# a) Strategic developments on eHealth and digital health

The Commission co-chair informed the eHealth Network about the developments of the Communication on Digital Health and Care, focussing on the results of the Public Consultation. To recap, the three pillars of the Communication are:

- 1. Citizens' secure access to health data and sharing of their health data across border;
- 2. Connecting health data to advance research, disease prevention, treatment and personalised medicine;
- 3. Use of digital tools to foster citizens' empowerment and person-centred care.

The results of the Public Consultation show support for further actions under the respective pillars of the Communication. The Communication is expected to be published in Q1-2018 (presentation available at the eHN online platform).

Many topics under the Communication show great complementarity with the eHealth Network's MWP 2018-2021. The Commission co-chair requested the eHealth Network to play an important role in the implementation of the Commission's Communication.

The new Joint Action (eHAction) will implement a considerable part of the MWP 2018-2021. The consortium has applied successfully. The coordinator of the new Joint Action (Portugal) gave a presentation on the content of the eHAction (available at the eHN online platform). The eHAction and the JAseHN have agreed on the formal transition of the activities on 21-22 June in Lisbon.

# **Digital Health Society Declaration (DHS)**

The Commission co-chair gave an introduction emphasizing the importance of synergizing our efforts in bringing the European digital agenda forward. The Estonian Member of the eHN, Mr. Ain Aviksoo, gave a short background on the Estonian Presidency's priority on digital health and the Digital Health Society Declaration that came out as a result of it. A short introduction was given to the four taskforces. Some of these perform complementary work to that of the eHealth Network and creates a link with the activities of the stakeholders.

The Commission recalled that synergy was needed with the eHN MWP. The Commission will examine what kind or resources can be brought to this process. The different work strands should give a coherent strategy. The MS co-chair pointed out that utmost transparency is needed along with the flow of information.

eHN Members who are interested in contributing to a task force should contact the task force leaders directly. A general presentation on the Digital Health Society initiative is available on the eHN online platform.

#### Discussion

The following points were made during the discussion:

- The new coordinator (Portugal) was thanked for the work in setting up the eHAction and for sharing the evaluation report. According to the evaluation report, the eHAction's proposal was considered a "good" one.
- The task of the eHAction is crucial as it is the main body to provide technical and scientific support to the eHealth Network.
- It is suggested to discuss possible improvements in relation to the Joint Action and the need to be flexible to include future developments in digital health.
- In relation to the DHS, it was mentioned that it facilitates the need for a "coalition of the willing" to move ahead in eHealth in a faster pace.

# b) eHealth Network Multiannual Work Programme 2018-2021

The MS co-chair introduced the topic and mentioned that the proposal is in line with the current developments in digital health. The sub-group asked the eHN to make a decision on two topics:

1. Digital health literacy of patients (A3)

# 2. eSkills for health professionals (D2)

The questions asked were whether the eHealth Network was the correct body to discuss these topics and if it had the right instruments to work on them.

#### Discussion

Some Members have shown support for keeping the topics of digital health literacy and eSkills for health professionals in the MWP. Especially Digital health literacy is seen as a topic where the eHN could play a role in. The eHN should, in that respect, also be a platform where best practices on how to improve digital health literacy are shared.

The role of the eHN on the topic of eSkills for health professionals was more unclear. There might be thematic actions that deal with the topic of eSkills by the Commission (DG EMPL), however, decisions on this have not been taken. Despite that, there are organisations that do work on this topic and should be consulted by the eHN. Furthermore, the deans of medical schools have contacted the Estonian Presidency and are highly interested in this topic. The Estonian Member of the eHN has agreed to contact them in order to get a better understanding of their needs in terms of eSkills.

Furthermore, regarding the question of whether a topic should stay in the MWP, the eHealth Network should consider what it is it wants to do: deliver, enable, encourage, and promote. It is necessary for the eHealth Network to structure its actions along these lines to define its role. The form of the way the eHN work could change. The coming three years could be a good opportunity for the eHN to reflect on how it could contribute to the topic of eHealth/digital health in the EU.

#### Conclusion

The eHealth Network decided to keep both the topic of digital health literacy and eSkills in the MWP. The MWP was adopted by consensus, however, the coordinator of the new Joint Action (eHAction) agreed to prepare a list of topics and a proposal on how to deal with them for the 13<sup>th</sup> eHN meeting in May 2018. The eHAction will use the upcoming preparatory meetings to further concretise the topics.

A final version of the MWP will be available at the eHN online platform.

The coordinator of the eHAction has called upon the Members to provide more effort both in policy thinking as well as in technical contribution.

# Agenda point 2) Implementation of the eHealth Digital Service Infrastructure (eHDSI)

#### a) Reports and guidelines on electronic identification and professional registries

The MS co-chair explained that both papers were not on the agenda for adoption but merely for discussion. They could not be voted since the Member States have not been able to agree on an eID specific framework. However, it is a prerequisite to speed up the developments of electronic identification for cross-border exchange of data. At the time of the 12<sup>th</sup> meeting of the eHealth Network, the Member States did not fulfil this prerequisite. An eID framework for the second wave of the eHDSI cannot be achieved. In the preparation phase of the paper on eID, Member States could not agree on the security high as default.

The paper on professional registries also points into the right direction, however, also here Member States need to show more progress.

#### Discussion

The following points were made during the discussion:

- Member States utilize different ways of identification and authentication.
- It is not certain whether the level of security "high" is a legal necessity under the eIDAS Regulation and some Member States could not agree on this at the time of the meeting.

- The Agreement for the exchange of health data allows Member States to choose between electronic and non-electronic means of identification and whether this is notified or not under the eIDAS Regulation.
- The implementation of eID measures has financial implications. Therefore, it is necessary to balance the needs against the costs.
- In order to bring the paper on eID further, there needs to be more support at EU-level from Member States but also from the Service Provider (EC).
- In the case of cross-border services, there are hybrid solutions for eID that adhere different levels of security.
- In order to overcome complex discussions on digital identification, the solution might be to combine physical services (showing your ID) with a digital workflow.
- The Member States have to agree on a methodology, or have a level of consensus compromises need to be made in order for all countries to go into the same direction.
- Work on the document needs to be continued but it will not be in time for Wave 1 and 2 countries. However, Wave 2 countries already need to be compliant to the eIDAS Regulation.
- The Commission welcomed the proposal for hybrid solutions (digital and not digital) and suggested the followings in order to move ahead with the 6 recommendations:
  - o Recommendations 1 and 2 can be dropped as this has already been done.
  - Recommendations 4, 5, 6 are politically very important. The eHN should agree on these recommendations in the next eHN meeting in May 2018.
  - Recommendation 3 concerns implementation and should rather be handed over to the eHMSEG.

#### Conclusion

The MS co-chair concluded that JAseHN should continue work that aims to complete the documents so that they would be ready for adoption in the 13<sup>th</sup> eHN meeting taking into consideration the comments made.

# b) eHDSI implementation topics

# eHDSI update on the progress and new timing of the go-live decision

A letter was sent by the eHOMB chair (Mr. A. Rys) to the eHealth Network. In this letter it was explained that the go-live timetable was slightly revised. This means that the go-live would take place by the end of June. A solution was found on the technical elements as well as how the audit will be carried out. The eHN needs to take a decision of granting Member States the right to join the eHDSI. This decision will be scheduled for the 13<sup>th</sup> eHN meeting. There is currently a secure audit system and the audits are done gradually. 9 Member States have informed that they would surely go live and several others might follow suit. The idea is to do 2 audits per month, meaning 6 audits done by March 2018. This does not cover the 9 countries, however, these countries were asked whether they wish to have an early audit or a later one. In May 2018, the eHN will have 6 applications which have been audited and scrutinized by the eHMSEG. The timetable is also subjected to the discussion on the developments with the Agreement and the opinion of the Article 29 WP.

#### Discussion

A question was raised regarding to what extend the clinical patient management system of the ERN – that came live on 20 November 2017 – is related to the eHDSI. This point is addressed as the last topic under agenda point 2b.

## eHDSI Work Plan and Budget 2018

The Commission informed the eHN Members about the rationale behind the proposed Work Plan and Budget 2018. This Work Plan and Budget is based on the need to provide support for Wave 1

countries that go live in 2018 and also to prepare Wave 2 countries. The Work Plan and Budget 2018 consist of 2 parts: eHDSI and ERN part. On the ERN part, operational support should continue, while on the eHDSI part, it still needs to be decided how to set up operational support.

#### Discussion

The eHMSEG chair mentioned that there were issues raised by countries on the stability of information in light of possible changes, more specifically, the discussion regarding TESTA and the recent issue on eDelivery certificates. The Commission had responded to these questions through a signed letter. However, there are still open issues, in particular on eDelivery standards. In the response it was mentioned that there will be changes in the process of transmitting information and that this will most likely have impact on Wave 3 countries. Also, the question still remains on what implications there are of the decision on the outstanding issues. As of yet, Member States cannot anticipate on the impact of these decisions.

#### Conclusion

The Commission mentioned that if there were changes coming for instance in terms of the eIDAS Regulation, the planning needs to be realistic. Furthermore, the call for better governance and structures, as well as the operational management for going live are noted by the Commission.

The Work Plan and Budget 2018 with a mid-term review in May 2018 were adopted in consensus.

# Information on systems developed for European Reference Networks and for the exchange of ePrescription and Patient Summary

The Commission referred to the note explaining the differences between the IT systems for the eHDSI and the ERN. There are some commonalities that include part of the IT tools for cross-border healthcare, the use of the same standards, and building blocks.

#### Discussion

In the discussion, some eHN Members pointed out a few elements on which further clarification would be needed, such as on some differences between the ERN and the eHDSI. However, the question was mostly on how to make sure there is convergence between these two different IT systems. For the eHN, it is ultimately important that the ERN is consistent with the adopted guidelines and operational instruments. Despite the need to converge and to consider developments in both the eHDSI and the ERN, convergence (if possible) can only be seen on the long-term.

# Agenda point 3) eHealth interoperability and standardisation

- a) Policy paper proposing actions to promote the use of common standards or technical specifications in eHealth within the EU
- b) Report on European semantic interoperability in eHealth and recommendations

The leader of Work Package 5 (Nictiz, NL) of the JAseHN gave a short presentation (provided on the eHN online platform) on both deliverables and explained what these deliverables entail. Of both deliverables, the recommendations were presented for adoption, knowing it was not a final solution but a step forward to bringing standards activities in the EU on a more elaborate level and especially ready for cross-border patients. The question remains on who would be responsible in taking these recommendations forward.

#### Discussion

Several Member States mentioned that they could not adopt the recommendations due to the fact that there were still many open issues on the content and also because some of the recommendations do not provide or are not clear on a way forward. However, they have acknowledged that these topics are important and progress is needed.

Other Member States, though, showed support for the recommendations and suggested that they should be taken up by a Digital Health Society Task Force or even that an eHN sub-group should be created that could come up with some proposals. However, they acknowledged that on the content some improvements could be made. This is due to the fact that it is difficult to foresee all possible issues in interoperability.

The recommendations were purposefully drafted in a general way to ensure progress instead of trying to provide a final solution in interoperability issues which would be difficult. These recommendations try to find a way forward.

There are many recommendations made, and thus, it is necessary to make a prioritization but it also requires a roadmap on how to move them forward.

Furthermore, in order to move forward these documents need to be updated. However, in order to do that, it is important that the Member States provide the necessary support/commitment.

#### Conclusion

The MS co-chair concluded that both deliverables presented were considered as not mature for adoption. Documents should be re-worked. EE offers NL to help with this. The topic of eHealth interoperability and standardisation shall be put on the agenda for the 13<sup>th</sup> eHealth Network meeting again.

## Healthcare providers' digital infrastructure in support of exchanging health data

The MS co-chair introduced the topic informing the eHN that large parts of the digital infrastructure in the health sector (particularly the software of health professionals in the outpatient sector but also the hospital information systems) are not fit for cross-border data exchange due to lacking interoperability. This topic is put on the eHN agenda to initiate the discussion and to ensure that this topic is taken up in the future. It is important to match public health needs and the capabilities of the healthcare sector to fulfil these needs. In order to achieve that objective, the Commission and the Member States need to make sure that appropriate funds are made available for public and private providers to support the interoperability of this digital infrastructure.

## Discussion

Several Member States have acknowledged the importance of aligning the infrastructural capabilities of healthcare providers and the needs in terms of public health and share the analysis that currently the majority of healthcare providers are not ready to exchange health data cross-border. There is support to bring this topic forward. The eHealth Network Members therefore need to make a case on this topic in the healthcare sector, creating awareness of this topic.

The Commission mentioned that there might be possibilities for funding (smart specialisation strategy, innovation procurement). The MS co-chair will take the discussion forward with the Commission (and the eH Network).

#### Agenda point 4) Patient access to health data and telemedicine

# a) Report on EU state of play on telemedicine services and uptake recommendations

As the lead in preparing this document, the Portuguese Member of the eHN shortly presented the content and recommendations.

## Discussion

There was a short discussion on how the recommendations will be taken up forward and on the need to do some further thinking on the next steps. The MWP 2018-2021 under topic A4, the topic of telehealth is included, creating an opportunity to do further work. However, it is essential that the work on telehealth is done with the support of the Commission.

#### Conclusion

The Commission co-chair concluded that the recommendations shall be used provisionally as basis for future work on telehealth over the coming year, and that the Commission would report back to the eHN in a year's time on the use made of the recommendations.

#### b) Patient access to Electronic Health Records and health data portability

Mr. Sprenger (Nictiz) who is co-leading this JAseHN task gave a presentation on the report on the EU state of play on patient access to eHealth data (available at the eHN online platform). Furthermore, an overview was given on the draft recommendations for patient access to electronic health records that are planned for adoption in the 13<sup>th</sup> eHN meeting.

#### Discussion

Norway mentioned that there are many possibilities for patient access to health data, but that the report does not look into the possibilities for patients to manage their own health data. However, it was explained that this is closely linked to patient consent, and that this was not part of the scope of the report and survey done. This is a relevant topic that might need to be looked at in the future.

The Commission mentioned that these recommendations are of importance since they are closely linked to the developments under the Commission's Digital Single Market. Therefore, the eHN Members are called upon to make the adoption of the recommendations happen in the next eHN meeting.

# Agenda point 5) Agreement for the exchange of health data

# State-of-play on the Agreement for the cross-border exchange of health data (CBeHIS)

The leader of the eHMSEG legal task force Mr. Pajic gave a background on the development concerning the Agreement after its adoption in May 2017 and the opinion of the Article 29 Working Party.

There were several issues identified among which is the drafting of the Model PIN. The Model PIN will be shown to the patient at the point of care. For the Model PIN, it is clear what is needed of Article 13 and 14 of the GDPR. The leader of the eHMSEG legal task force asked for urgent support by all the Member States for the specific parts concerning the Model PIN, and reminded the eHealth Network members to ensure communication with their national DPA representatives in Article 29 WP to facilitate communication, as agreed in 11<sup>th</sup> eHN meeting.

Furthermore, the legal task force reached out to the Member States who are participating in the eHDSI and asked where they stand with the Agreement. There were 18 responds of which 2 mentioned that they have signed, leaving 16 yet to be signed. From these 16 countries there are 12 of which there were no obstacles foreseen in signing the Agreement.

The legal task force members will be invited to the Article 29 Working Party meeting next time. Further, they have received a list of questions from the Article 29 WP on which they are currently working together with the Commission to prepare a note to the Article 29 WP to answer their questions. There will be a meeting on 7 December 2017 organised by the eGovernance sub-group under the Article 29 WP. The next meeting or t-con will take place in January 2018.

There are issues to be resolved on eHMSEG level e.g. no common policy for supervision, audit, monitoring of legal tasks. Furthermore, there are issues to be resolved on MS level e.g. Art29 WP pointed out the need to conduct DPIA.

#### Discussion

An eHN Member had asked for the questions of the Article 29 WP to be disseminated to the eHN.

## Agenda point 6) EU legislation and legislative proposals

#### a) Network and Information Security Directive (NIS Directive)

The Commission co-chair introduced the topic and gave DG CONNECT (Mr. Cunningham) the floor who presented the state-of-play of the implementation of the NIS Directive. Furthermore, Mr. Cunningham informed the eHN about the projects on cybersecurity that are currently ongoing.

These projects are addressing a holistic solution to storage and transfer of health data. Secure access and storage on mobile devices will also be addressed in the projects. This specific topic will become an important issue in the upcoming year. Also, the projects are looking at the analysis of the applicable legal frameworks and societal aspects and will pilot the solutions in at least 3 associated States. They began the work in January 2017 and will finalise the project by the end of 2019.

DG CONNECT was supported by Ms. Liveri from ENISA (EU Agency for Network and Information Security) who shortly informed the eHN the activities on cybersecurity in the healthcare domain. She further informed the eHN about the report on the implementation of the NIS Directive which will be provided to the eHN once it is available. The presentation of DG CONNECT on the NIS Directive is available at the eHN online webpage for your information.

#### Discussion

An eHN Member asked DG CONNECT whether it is possible to have the executive summary of the results of the mentioned projects. However, more information can only be given after the first evaluation of the project takes place, mid-2018.

Another Member mentioned that the cost burden of keeping health data secure is becoming significant. This is not well reflected in discussions by Ministers of Health. The more digital a country becomes, the more it is vital to invest in digital security. The costs of digital security should not be underestimated and the respective ministries should be informed about this. The Commission also needs to look at how it can financially support Member States in the investments they need to make to fulfil the EUs digital needs.

#### b) Legislative proposal on the free flow of non-personal data

The Commission co-chair introduced the topic and gave DG CONNECT (Mr. Weidler) the floor who presented the state-of-play of the legislative proposal on the free flow of non-personal data. The presentation of DG CONNECT is uploaded on the eHN online webpage for your information.

# Agenda point 7) National eHealth strategies, EU projects, and other eHealth-related developments

# a) Presentation eHealth strategy Estonia

The Estonian Member of the eHealth Network gave a presentation on Estonia's eHealth strategy. The presentation is uploaded on the eHN online webpage for your information.

## b) Nordic council: Nordic eHealth benchmarking

The Danish Member of the eHealth Network together with Mr. Nøhr of the University of South Denmark gave a presentation on the Nordic collaboration on eHealth working on eHealth indicators. The presentation is uploaded on the eHN online webpage for your information.

# c) International Organization for Migration (IOM): development of electronic personal health record (e-PHR) for refugees

Ms. Beauclercq gave a presentation on the development of an electronic personal health record for refugees by the International Organization for Migration. The presentation is uploaded on the eHN online webpage for your information.

# Agenda point 7) AOB & Closing

- The Member State co-chair thanked the speakers for their contribution.
- The Member State and Commission co-chair thanked all the eHealth Network Members and other participants for their participation.
- The 13<sup>th</sup> eHealth Network meeting will take place in Brussels on 15 May 2018.