

# eHealth Network

### **Summary minutes**

### 14<sup>th</sup> Meeting of the eHealth Network 13 November 2018

Albert Borschette Conference Centre, CCAB 4C, Brussels

**Chairs:** 

Director-General Health and Food Safety, DG SANTE President SPMS Portugal

#### Opening and approval of the agenda

The Commission co-chair opened the meeting and informed the eHealth Network members of the changes made in the summary minutes of the 13<sup>th</sup> meeting. Furthermore, the Commission co-chair excused herself for not being able to participate in the afternoon session of the meeting. The Member State co-chair will continue to chair the meeting after the lunchbreak.

The agenda of the 14<sup>th</sup> eHealth Network meeting was approved, since there were no comments.

#### Introduction new eHealth Network co-chairs

The Commission co-chair took the opportunity to introduce herself as being the new Director General of DG SANTE and also as new Commission co-chair of the eHealth Network. She looks forward to a fruitful collaboration in the coming years.

The Member State co-chair introduced himself and mentioned that he had agreed with the Commission co-chair to prepare a document for the eHealth Network summarizing the main topics to be discussed/ dealt with for the upcoming two years. This document is meant to provide a horizon for the eHealth Network that extends further than six-month timeframe wherein the meetings are being held. This document will be brought for discussion in the 15<sup>th</sup> eHealth Network meeting in June 2019.

## Agenda point 1) State-of-play on the implementation of the Communication on the Digital Transformation in Health and Care

a) Review Implementing Decision on providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth (2011/890/EU)

#### Summary

The Commission co-chair opened the topic and gave the background on the rationale for reviewing the Implementing Decision to integrate the eHDSI and the role of the eHealth Network its governance. The proposal for the review of the Implementing Decision will be brought forward for consultation in January 2019 where after it will be tabled in the Cross-border healthcare committee for adoption in February 2019. Be aware we do in parallel process with Commission, there might be some changes from the legal service, in particular. The role of the Commission / MS in data protection still needs to be clarified, but the analysis so far was that National Contact Points were joint controllers and COM was processor for processing of patients' data.

The Commission gave a short presentation on the work done by the eHealth Network sub-group on the review of the Implementing Decision [uploaded on the collaborative website for your information]. The presentation focused primarily on the main changes of the Implementing Decision enforcing/clarifying the eHealth Network as a policy making body and its role in the eHDSI (go-live decision-making). In addition, the role of the Commission and data protection is formulated in dedicated provisions.

#### Discussion

The following comments were made:

• The AT Member as chair of the sub-group, mentioned that there was a broad consensus among the sub-group members on the prepared document. Further mentioned that some tasks were explicitly mentioned for clarity reasons, despite the fact that Article 14 of Directive 2011/24/EU allowed a broad interpretation. Data protection issues should be also clarified, according to AT. In addition, a comment was made that there were some discrepancies

between the definitions used in the non-paper and those in the Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-border eHealth Information Services (hereafter Agreement). The Commission is requested to look into these definitions and harmonise the language as much as possible. Lastly, it was mentioned that the discussion should take place in the eHealth Network, unburdening the Cross-Border Healthcare Committee (CBHC-Committee). This should be done by informing the Members of the CBHC-Committee about the adoption of the review of the Implementing Decision. It is requested to hold an endorsement process after the 14<sup>th</sup> meeting (written procedure), to allow the swift adoption of the review of the Implementing Decision in the Cross-Border Healthcare Committee.

- FR: thanked the Commission and the chair of the sub-group for the achieved work, and noticed that a lot of progress has been made so far with regard to the Implementing Decision. France is awaiting the final contribution on data protection. The respective roles of Member States and Commission regarding processer and controller might have consequences on the Legal Agreement. Furthermore, there was a comment on whether there is still a possibility to provide comments after the eHN meeting. There are some discrepancies between definitions in the text that should be addressed. In addition, the Implementing Decision needs to define the "generic services".
- HU: thanked the sub-group for the work done. A question was raised on the advanced cooperation of the eHN. However, in the text of the non-paper it is mentioned that once a Member is participating in the eHDSI, it is bound by its rules. The HU Member asked how this could be enforced, considering the obligatory nature in a voluntary cooperation. Hungary also inquired what measures could be taken against member states that do not respect the rules of such cooperation
- PT: there has to be a legal link between the Directive 2011/24/EU that creates the conditions for cross-border exchange and the governance of the eHDSI services. The wording in the non-paper can be further refined. Another point made is that there is some trust building exercise to be made at eHN level, which is the reason this provision is in place in the non-paper.
- DE: Welcomes the Commission approach and wishes to work together with the sub-group to finalise the Implementing Decision. Further, the Member wants to emphasize the requirements stated in article 28 of the GDPR concerning the processing of data. Therefore, that the decision is taken only in February 2019 is welcomed so that further clarification on the data protection part can be provided and looks forward to work closely together on this.

The Commission co-chair concluded that:

- There were discussion on the definitions. Normally, in the context of legal clarity, only those terms that are being used in the enacting terms of the Implementing Decision need to be defined. But the Commission will look into the possibility to also include a definition for core and generic services. The Commission takes note on the necessity to further strengthening the possibility to enforce when a participating Member is deviating from the rules. Possibility is to further empower the eHN but the possibilities will be further discussed with the Commission legal service.
- The Member States were invited to provide immediate comments on the text to the Commission (eHealth Network Secretariat) by Friday 16 November. The Commission will then finalise its internal consultation.
- It is important that the discussions are held in the eHN and that the Cross-border healthcare committee only needs to formally approves the Implementing Decision.

b) Discussion on the Electronic Health Record exchange format

#### Summary

The Commission co-chair opened the topic and provided a short background in light of the Communication on the Digital Transformation in Health and Care. The proposal to develop an Electronic health Record exchange format (EHRxF) was discussed during the informal council of Health Ministers in Vienna, where wide support for this was expressed.

The Commission presented the background on the non-paper on an EHRxF [uploaded on the collaborative website for your information]. The baseline of developing the EHRxF are the eHN guidelines, the eHDSI, building blocks of CEF, and the outcomes of H2020 projects.

There is a political commitment at the Commission to go for adoption of the Recommendation early 2019. Nevertheless, the Commission continues its collaboration with the Member States in the eHN to provide the opportunity to comment on the Recommendation.

The Member State co-chair underlined that there has been extensive collaboration with Member States before the non-paper was brought forward to the eHN. All Member States were invited to send experts to workshops of the eHAction to provide input in the Recommendation.

- AT: welcomed the document and it is the first time to have a strategic document in draft which is outlaying the perspective and the necessity of a shared framework for standards and formats for an interoperable eco-space not only on EU-level but also in Member States' setting. It is important for Member States that there is a framework for standards instead of a fixed set of set, allowing the consideration of differences between Member States. It sends a clear signal to the market on what standards they need to follow in order to achieve interoperability. It is suggested that this Recommendation should also be brought forward to the Council to give an even stronger signal. Furthermore, this task is not only EU, but also global. It is important that Member States get sufficient time to provide their input to achieve impact.
- PT: mentioned that it is an excellent opportunity to create interoperable data. It reflects already the standards in place. But there needs to be a mechanism to update and review the EHRxF over time.
- EL: mentioned that the document shows a strong message of will to move towards interoperability. The EHRxF is in line with the efforts of the Greek government. Certain technical specifications are necessary, but not too much. Data protection issues remain important to be addressed in this document. The EHRxF should be able to be used for different use cases and it should therefore contain a certain amount of granularity.
- DE: welcomed the document and agrees on the principles. There are certain elements that requires clarification e.g. needs in research and healthcare. This clarification is needed before moving forward to adoption in February 2019. DE is offering to coordinate a voluntary group of Member States who would like to work on providing clarifications to the Recommendation. The first results can be provided early 2019 (January). The Member underlines that in order to have impact with the Recommendation, it is important that Member States get sufficient time to provide their input.
- FR: expressed concerns that this non-paper is not strategic enough as the general principles are not new. In 2008, the Commission produced a Recommendation on the same topic. But a technical format is not the most highest priority to move towards EU-level interoperability. Welcome the fact that more interoperability is needed, but questions that such a document with technical details will help to clarify what the EU is doing in this respect. Concern whether the Commission will take the comments of the Members into consideration in an updated version of the Recommendation. The title of the Recommendation "format" refers to

something technical, which is not the purpose of the Recommendation. Furthermore, information was asked about the 2017 Call on EHR.

- FI: expressed their support for the document and have no objections to the level of technical details. Expressed difficulty with the notion of pushing specific technicalities in countries. FI has a lot of legacy systems, and out of experience it takes approximately 3 years to implement changes. But agrees it is good to have common goals.
- NL: congratulated the Commission with the substantial move forward. Acknowledges the need to work on interoperability at EU-level. However, the difficulty lies in the implementation and the current document does not completely reflect decentralised systems like that of NL. Decentralised systems require a different approach concerning implementation than centralised systems. The NL will continue to provide support to the group for input to have especially the decentralised perspective embedded in the document. However, concerns are expressed that the speed by which the document is to be approved could have a detrimental effect on its quality. This document should take the opportunity to put the patient at the centre. Currently the focus is mostly on professional-to-professional exchange of health data. While already in the council conclusions of December 2017 and other documents already provided the political opportunity to move forward on putting patients at the centre. Furthermore, the Member suggested that semantic interoperability needs to be an integral part of the Recommendation.
- EE: thanked the Commission for the non-paper and expressed optimism. Agree to further investments. Strongly support open governance framework and the development of a roadmap. Need glossary of terms to prevent misinterpretations. Agree with NL that it lacks a profound connection between patient and professionals.

The Member State co-chair explained that this document should be seen as a tactical document. Need to look at it not only from interoperability and format, but it also pointing to next steps on where agreement is needed. Emphasized that this Recommendation is crucial to be as strong and as concrete as possible.

#### Conclusion

- There will still be an opportunity for Member States to provide input in the Recommendation. The Members are invited to provide their comments, which they had already prepared for the eHN, in writing by Friday 16 November 2018.
- The Commission underlines that the eHN remains the platform to provide input in the Recommendations and emphasizes the inclusive process on how to implement the EHRxF.
- There will be a TCon organised by the working group under the eHAction working on EHRxF on 23 November 2018.
- A face-to-face meeting will be organised by DG CNECT on 5 December 2018 to give Member States the opportunity to provide their input.
- c) EU action on Immunization and information

#### Summary

The Commission co-chair opens the topic and gave the floor to:

- 1. DG SANTE Unit C3 on Crisis management and preparedness in health.
- 2. The representative of the Joint Action on vaccination.
- 3. The European Centre for Disease Prevention and Control (ECDC).

[the presentations are uploaded on the collaborative website for your information].

The Member State co-chair mentioned that this topic was brought on the agenda, to discuss with the eHN whether there should be a mechanism between the Joint Action on Vaccination and the eHN. Furthermore, the eHN was asked how they see the development of the vaccination passport in light of the eHDSI Patient Summary.

- EL: mentions that there should be some kind of cooperation between Joint Action on Vaccination and eHAction. Also, informed the eHN about the vaccination situation in Greece.
- EE: expresses that the vaccination topic on the eHN is welcomed and support continued information exchange between both the Joint Action on Vaccination and eHAction. The idea of using vaccination information in the eHDSI should be further explored.
- FR: welcomes the topic on the eHN agenda. Supports the exchange of knowledge between Joint Action on Vaccination and eHAction. It is however too premature to speak of a permanent group.

#### Conclusion:

Both Joint Actions (Vaccination and eHAction) should establish collaboration and the eHN should be informed on this.

#### Agenda point 2) Investment in eHealth digital infrastructure

- a) Follow up of informal health Council (11 October 2018) under the Austrian Presidency: guideline for targeted EU-wide support and investments in eHealth infrastructure.
- b) Reporting from the survey regarding the development of the guideline for targeted EU-wide support and investments in eHealth infrastructure

The Commission co-chair opens the agenda point and informed the eHN that this topic stems forth from the informal council meeting of Health Ministers in Vienna. It is suggested to take both agenda points at the same time as they are related.

The Commission is then given the floor to give a short presentation on the results of the survey that was disseminated to the eHealth Network Members on 9 October 2018 [the presentation is uploaded on the collaborative website for your information].

The Commission co-chair suggests that in follow-up of the informal Council meeting of Health Ministers in Vienna, a sub-group under the eHealth Network works on a guideline for targeted EU-wide support and investments in eHealth infrastructure.

- AT: informs the eHN about the intention of the Austrian Presidency when it comes to investment in digital infrastructure of healthcare providers. Underlines that healthcare providers are the ones that produce healthcare data. Therefore, it is important that they are made ready for the digital age. The national and EU funding instruments need to concentrate the coming years on investment in digital infrastructure of healthcare providers. The guidelines need to provide a clear overview on what kind of infrastructure they need to invest in. It is necessary to agree on the elements in which funding is needed. The eHN together with the Commission should draft this document and present it to the Council. The AT Member proposes that an eHN sub-group works on this guideline.
- HU: asks whether it is possible to share the results of the survey to the eHN.
- FR: also asks whether it is possible to share the results of the survey of those countries that agree to share their results. Also, asks the Commission if there is a specific document on the various investment instruments.

• PL: data should be put into relevant use for instance H2020 or Digital Europe Programmes. Asks whether the data collected will be used for other relevant purposes.

The Member State co-chair suggests that the eHN sub-group set-up in May 2018 to work on the Implementation of the Communication (lead by AT), will continue to work on developing this guideline. eHN Members are invited to contribute in the sub-group on investment guideline.

#### Conclusion

- A mandate is given to the current eHN sub-group on Implementing the conclusions of the informal EPSCO to continue and work on Investment Guideline. The AT Member will continue to lead this sub-group.
- The following eHN Members expressed their support and intention to contribute in the subgroup: EE, IE, FR, DE, PT, CZ.
- The eHN Secretariat will share the data of the survey with the eHN
- 17 countries responded, incentive for other countries to respond
- Work with OECD on Health at a Glance, it would be interesting for them to have access to the data if the eHN Members agree with that. This can be notified through an email to the eHN Secretariat.
- There are various upcoming EU funding programmes that can be used for investments in ehealth: ESIF (Regional Development Fund, European Social Fund +), Digital Europe, Horizon Europe. Other funding programmes are also available, such as Structural Reform Programme, (ESFI), Invest EU.

#### Agenda point 3) eHDSI implementation

- a) Go-live decision to exchange ePrescription and Patient Summary through the eHDSI
- b) State-of-play of signing the Multilateral Legal Agreement

#### Summary

The Member State co-chair opens the agenda point and gave a background on how the eHN arrived at the point of making the decision to exchange ePrescription and Patient Summary through the eHDSI.

#### Discussion

The eHMSEG co-chair provided an overview of the eHMSEG recommendations, supporting FI, EE (eP), LU (PS-B) and CZ (PS-B) to go live, once the recommendations of auditors would have been met and this would have been checked and certified by them.

With regard to Czech Republic (PS-A, ie sending patient summaries of own citizens), the discussion was more complex. The eHMSEG chair admitted that eHMSEG could not provide a recommendation and referred the decision to the eHealth Network. Several members underlined that it is the role of eHMSEG to provide a recommendation. The issue at hand is that the information is not always structured nor coded and it only comprises information from the last encounter with the doctor. Several Member States have raised their concern if approval to CZ is given to go-live, as this might affect the integrity of the criteria used to determine whether a Member State is eligible to go-live. This might create a precedent for other Member States, which could harm the circle of trust. Furthermore, it is raised that the information that CZ is able to provide (last encounter information), does not constitute a Patient Summary as defined in the Guidelines. It is agreed that it is better to have data than no data, but this exchange of data cannot be called a Patient Summary. It is rather to be called

patient health information. For that reason, caution is expressed to give clearance to go-live to CZ for PS-A. Furthermore, in order to make a decision to go-live for a Member State, the eHN should have a recommendation from the eHMSEG.

With regard to the Multilateral Legal Agreement, a number of Member States have signed. The eHN Secretariat has received a copy of the signed Agreement from CZ, EE, FI, IE, LU.

#### Conclusion

- The eHN unanimously agreed to give its approval for FI, EE to go-live for receiving (EE) and sending ePrescriptions (FI).
- The eHN unanimously agree for LU and CZ to go-live for Patient Summary B.
- The countries can go-live once the auditors have checked that there are no further issues.
- The eHN asked the eHMSEG to make a clear recommendation on whether CZ should go-live with Patient Health Information.
- To this end, for Patient Health Information, CZ will submit a commitment letter to the eHMSEG by Friday 23 November 2018 providing additional information on what they are proposing to tackle the pending issues concerning sending Patient Summaries. The eHMSEG will meet on 12 December 2018 to discuss, inter alia, whether to issue a recommendation for CZ to go-live with Patient Health Information. The eHN will vote on this eHMSEG recommendation by written procedure. A review of this decision will then be done during the 15<sup>th</sup> eHN meeting on 12 June 2019.
- c) eHDSI Work Plan 2019

#### Summary

The Member State co-chair opens the agenda point and gives the floor to the Commission who presented the proposal for the eHDSI Work Plan 2019.

The eHealth Network is asked for their approval of the eHDSI Work Plan 2019.

#### Discussion

The Member State co-chair asked under which header communication falls in the work plan. The Commission explained that communication is an important part especially for the first Wave. There are some discussions with the Member States on how to best tailor communication needs. The Commission will support the communication efforts for the eHDSI.

#### Conclusion

As there were no further questions and comments, the eHealth Network adopted the eHDSI Work Plan 2019 in consensus.

#### Agenda point 4) eHAction

#### Summary

The Member State co-chair opens the topic and mentions that there are for the moment not much to discuss as the eHAction had only started recently. The Joint Action follows the multiannual work programme 2018-2021 of the eHealth Network.

a) Introduction to eHAction (timeline of deliverables)

The Member State co-chair gave a short presentation on the eHAction and the recently held activities [the presentation is uploaded on the collaborative website for your information]. The timetable is presented and can be found in the presentation and the cover note. The timetable gives a clear overview on what the eHAction will be working on for the coming years.

b) eHealth Network sub-group on mHealth (discontinuation)

The Member State co-chair mentions that the recommendations of the mHealth sub-group are taken up in work package 4 of the eHAction under task 4.1 Mobile health and health apps reliability, which is lead by Estonia. Therefore, it is suggested to formally discontinue the sub-group.

c) eHAction deliverables:

The Member State co-chair gave a short introduction on the upcoming eHAction deliverables to the eHN. The information notes give an idea on what can be expected and which methodology will be used to produce the deliverable. The eHN Members are given the opportunity to provide comments on all the deliverables tabled on the agenda.

- EE: gives a clarification on WP 4 that it is not only a framework on how to uptake the use of mHealth and telemedicine but also how to use the data stemming forth from these digital solutions. Digital literacy is also a topic addressed under WP 4.
- DE: concerning security framework, agree with the challenges, but it might be too ambitious to develop a common security framework. The Member suggests adjusting the title into making it a more realistic task. The Member welcomes the activity under task 7.2 and expressed the need for a coordinated approach. This should be done with the early involvement of relevant national experts and DG JUST. Therefore, the Member proposes a small drafting group to review the draft questionnaire. There is need to coordinate the results with existing implementing structures. The Member expresses its willingness to contribute to this task.
- FI: asks whether the use of data collected by mHealth devices is integrated in a task in the eHAction. Although WP4 touches upon this topic, it does not in detail.
- FR: mentions that it is important to understand how task 7.2 relates to the activities in WP6 on legal issues. There is a need to be a clearly link between the work of these two work packages.
- PL: enquires whether the task on digital health literacy would also look into analysing the health professional perspective (digital skills). However, the task only focusses on patient empowerment and looks at the perspective of the patient only.
- NL: proposes to discuss the roadmap on future eHDSI use-cases sooner than after the fourth wave of the eHDSI. It cannot wait until 2020 for the discussion to start. Therefore, the Member requests to start the discussion on this topic already in the 15<sup>th</sup> eHN meeting.

#### Conclusion

- The eHN had no objection to discontinuing the sub-group on mHealth.
- Next eHN meeting will have more time for the topic of future eHDSI use-cases to discuss. There might be a possibility that the next eHN will take place for 1.5 days. This means that in the afternoon (0.5 day) the eHN will start with an informal workshop on certain topics and the next day a full day for the eHN.
- d) State-of-play on EU Common Semantic Strategy

#### Summary

The Member State co-chair opens the topic and gave a short background on the rationale of the work of the work group on Common Semantic Strategy (CSS). A short presentation was given [the presentation is uploaded on the collaborative website for your information].

The Member State co-chair suggest the following next steps:

- Continue the work on the CSS under the eHAction for 6 months;
- Create an eHN sub-group in June 2019 to work on a CSS;
- Come with an EU Common Semantic Strategy by end 2019.

The eHealth Network is asked if it agrees with the proposed next steps to work on a CSS.

#### Discussion

- NL: the Member supports continuing the action under the eHAction. However, the timetable is ambitious also considering the resources it needs from the eHAction that are needed for other actions at a later stage. This issue needs to be addressed and solved by creating the necessary resources to do the work on the CSS.
- DE: welcomes the work on a CSS but underlines the need to take into consideration national decision making concerning semantics. The Member expresses that they are willing to contribute to the work on CSS and will provide their comments on the document.
- EE: the Member expressed the need that no duplication of work (EHRxF and CSS). Therefore, the Member reiterated that it is necessary that there is a link between the work on the EHRxF and the CSS. Agrees with NL that the issue concerning the funding of the work of the workgroup on CSS needs to be addressed as the current resources in the eHAction are already limited.

#### Conclusion

The Member State co-chair mentions that setting up an eHN sub-group gives the possibility for the Commission as eHN Secretariat to fund its activities. However, during the 13th eHN meeting, the Members did not agree on setting up an eHN sub-group on CSS. Therefore, the actions on CSS were for the time being brought under the eHAction.

#### Agenda point 5) Other eHealth-related topics

a) (I) Market study on Telemedicine done by PWC

The Commission had commissioned PWC Luxembourg to conduct a Market Study on Telemedicine. The purpose of this study is to get an overview of the telemedicine market in the EU and globally. Furthermore, the study includes an economic assessment of the cost-effectiveness of implementing telemedicine solutions in healthcare systems. Representatives of PWC Luxembourg were invited to present the results of the market study [the presentation is uploaded on the collaborative website for your information].

At the end of the presentation, the Commission and PWC agreed that the economic model in calculating the cost-effectiveness will be made available to the Members of the eHealth Network. Furthermore, the issue may be put on the agenda of the next eHealth Network meeting so that the Network can discuss the follow-up of the study.

b) I) Report back from the eHealth Stakeholder Group of 17 October 2018

The Commission informed the eHN about the last eHealth Stakeholder Group meeting of 17 October 2018. It was mentioned that the mandate of the eHSG will expire by the end of 2018. The various topic groups under the eHSG are given until mid-December to finalise their contributions. These contributions will be published and shared with the eHN.

The Commission informed the Members that they will look into creating a new mandate for the eHSG in 2019.

A Member of the eHN made a suggestion that in the future it is important that the topics of the eHSG are aligned with the needs of the eHN in order to achieve the best impact.

#### AOB & closing

- The next eHN meeting will take place in Bucharest, Romania on 11-12 June 2019. Further details will follow.
- The current national expert at DG SANTE will soon return to his national administration. He is warmly thanked for his outstanding work since early 2015 as eHN Secretariat.