



Summary minutes
13th Meeting of the eHealth Network
15 May 2018

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

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

Introduction

There were 27 Member States represented at the Network meeting and Norway as observer. Italy had informed the eHealth Network Secretariat in advance that they would not be able to participate.

Opening and approval of the agenda

The Commission co-chair opened the meeting. There were no comments on the agenda and the list of participants was shared during registration for the meeting.

The Secretariat informed the eHealth Network about the housekeeping.

The Commission co-chair welcomes both Commissioner Vytenis Andriukaitis and Roberto Viola, Director-General of DG CONNECT, for their presence at the eHealth Network in light of the recently adopted Communication on the Digital Transformation in Health and Care.

Welcome by Commissioner Andriukaitis

Commissioner Andriukaitis gave a short speech highlighting the following points:

- interoperability is essential in making the EU competitive at a global stage;
- interoperability is improved through the implementation of the eHDSI;
- the eHealth Network made this progress possible;
- political will is needed to make further progress in interoperability;
- the Commission intends to amend the Implementing Decision under the Cross-border healthcare Directive to better reflect the current times and to make it more sustainable for the future;
- Member States governments were asked to continue working towards health systems' interoperability in the EU.

Agenda point 1) EU strategy and activities on digital health

Communication on the Digital Transformation in Health and Care

Summary

The Commission co-chair introduced the agenda point and gave a short background on the rationale of the Communication. The Communication is part of a larger package of measures under the Digital Single Market (DSM). A collaborative effort with Member States (eHealth Network) is needed to achieve the implementation of the Communication. In addition, the hope is expressed that the eHealth Network recognizes the topics in the Communication and the incentive to do more.

The Director General of DG CONNECT, Mr. Roberto Viola, gave a general overview of the Communication in light of the larger DSM “data” package adopted on 25 April 2018. The ambition of the DSM package is to achieve the following:

- make the economy of the EU more competitive globally;
- provide better services to our citizens.

The Communication is the result of a dialogue with the field starting with the public consultation and then the digital health event in Tallinn (Estonia) in October 2017.

The Commission presented the new Multiannual Financial Framework (MFF) on 2 May 2018. The Commission particularly looked at digital health and care in the DSM. The current CEF programme will be replaced by the Digital Europe Programme. Under this programme the current DSIs will be continued. They, as services of public interest, will be one of the five priorities. The others are high performance computing, cybersecurity, AI, and digital skills. The new CEF programme will focus on connectivity.

The Commission co-chair informed the eHealth Network about the specific actions proposed under the three pillars of the Communication. Pillar 1 is very relevant for the eHealth Network as it tackles topics that the Network has worked on during the past three years. The Commission considers that the Implementing Decision¹ needs to be modified to clarify the role of the eHealth Network in the eHDSI and its role in the promotion of eHealth in the EU.

The Member State co-chair mentioned that the eHealth Network evolved into a decision making body for the eHDSI. Therefore, an amendment of the Implementing Decision is welcomed to better reflect the current situation and to make it sustainable for the future.

The Member State co-chair proposed to set up a sub-group under the eHealth Network working on the contribution of the eHealth Network in the implementation of the Communication, with a special focus on the input and comments to the future Commission proposal to amend the Implementing Decision, ensuring Member States’ involvement from the onset.

When it comes to the amendment of the Implementing Decision, the Commission informed the eHealth Network that it will follow the regular process:

- Consultation with the Member States (the eHealth Network sub-group and the eHealth Network);
- Proposal send to the Comitology Committee;
- Committee vote on the proposal;
- Implementing Decision is adopted by the College.

The Commission further explained the rationale behind their proposal regarding the Commission Recommendation on technical specifications for a European electronic health record (EHR) exchange

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011D0890>

format. The Commission Recommendation does not aim to harmonise the EHRs but rather to create a tool to exchange EHR across borders. This requires a structured work process that considers the needs of the Member States properly. Therefore, the establishment of a sub-group dealing with such an exchange format for EHR is proposed focusing on the policy analysis and on the liaison with and advice to the Commission. The intention is to have a proposal ready over the summer and adoption by the College by the end of 2018.

The Member State co-chair also mentioned that there will be a discussion in the informal Council under the Austrian Presidency to get a better understanding on the infrastructure needs in healthcare.

Discussion

The Members of the eHealth Network made the following comments:

Estonia:

- expressed support for the Communication and emphasized that digital is the way forward;
- agrees with the Member State co-chair's proposal that Member States need to be actively involved in the development of an exchange format for EHR;
- mentioned that more investment in interoperable infrastructures is needed;
- wishes to see further support for the eHDSI (strategic infrastructure) and centrally managed funds (for interoperability);
- supports the extension of the eHDSI with new use-cases;
- agreed with the amendment of the Implementing Decision;
- supports the actions under pillar 2 noting however that there are already a high number of fragmented initiatives and that it is necessary to bring them together;
- suggests to look into how the Digital Health Society can be involved in the implementation of the actions under the Communication.

Germany:

- agrees with the direction that the Commission is taking;
- notes that the proposal for an exchange format, its need, its scope and its relation to the eHDSI is not clear. Drawing on national experience, clarity on definitions are essential to make progress;
- supports the proposal to set-up a sub-group of the eHN and underlines that the needs of the eHN shall stand in focus and underlined that there is more than the semantic issues on establishing an exchange format;
- asked for more clarity on the timing of the actions in the Communication

United Kingdom:

- expressed that the actions in the Communication are coherent;
- mentioned that Member States could use the help of evidence that digitisation leads to cost effectiveness;
- underlined that the eHealth Network needs to reflect on how to work together with experts from industry and academia;
- pointed out that the Communication does not address the challenge in helping the clinical workforce with improving their clinical practice through digitisation.

Portugal:

- welcomed the initiatives in the Communication;
- mentioned that the Communication requires Member States to approach things differently at national level;
- emphasized that not only an amendment of the Implementing Decision is needed but also the way of representation in the eHealth Network.

- expressed the need of consistency between the calls under Horizon 2020 and the initiatives that need to be incentivised.
- suggested setting-up of a sub-group to deal with the input for a proposal on an exchange format.

Sweden:

- expressed their support towards the Communication and mentioned that it is a step in the right direction building forth on what the eHealth Network has started;
- emphasized that it is necessary to have a bottom-up process actively involving Member States when determining a definition of exchange format;
- supported the creation of a sub-group that works on providing input in the creation of an exchange format.

France:

- mentioned that they welcome the questions raised by the Commission in the cover note;
- expressed that they are not yet sure whether they would be in favour of amending the Implementing Decision;
- agrees to the creation of a sub-group that discuss and agrees on the right first actions and not about the amendment of the Implementing Decision.

Conclusions

The eHealth Network agreed to set up a sub-group on the implementation of the Communication on the Digital Transformation of Health and Care (DSM Communication sub-group). The Member State co-chair will lead this sub-group in his capacity as the Austrian Member to the eHealth Network. Other Member States willing to participate in the sub-group are: PT, FR, DE, EE, NL, and IE. The sub-group will have a broad scope and discuss how the eHealth Network should contribute to the implementation of the Communication and in particular focus on the revision of the role of the eHealth Network, through the amendment of the implementing act. On pillar 1, the Group should provide input to the Commission proposal for the review of the Implementing Decision. With regards to pillar 2, it should not cover all aspects, (research, genomics). Pillar 3 was identified to be of interest to the sub-group as well. A first meeting of this sub-group is to take place before the summer break.

No sub-group (or working group) under the eHealth Network is to be established dealing with the work regarding the Commission Recommendation on technical specifications for a European electronic health record (EHR) exchange format. Instead, the liaison and consultation work with the Member States shall be integrated in the work plan of the eHAction. Consequently, Portugal (as Coordinator of the eHAction) is the leader of this process. The scope should be defined and the tasks where this work will be carried out within the eHAction work structure needs to be identified.

Agenda point 2) Interoperability and standardisation

a) Discussion note on eHealth interoperability and policy actions to improve semantic interoperability in the EU

The Commission co-chair reminded the eHealth Network that the reason for having this topic on the agenda is that there are a number of recommendations that were not adopted at the 12th meeting in November 2017 addressing semantic interoperability. The discussion note is suggesting to set up a sub-group under the eHealth Network consisting of the national eHealth competence centres and experts (interoperability and/or semantic). This sub-group will be responsible for developing a work plan and timetable proposing a common way to the eHN for defining an EU-level strategy focusing on semantics integrated in the overall eHealth interoperability strategy.

Discussion

The following comments were made by the Members of the eHealth Network:

Estonia:

- supported the analysis that semantics is necessary to achieve national and cross-border interoperability and made a reference to the Estonian Council conclusion;
- agrees to the task set-out for the sub-group but there is a need to prevent any duplication of work since much work is already done by the Digital Health Society (DHS), Taskforce 1 led by the Netherlands. Therefore, it is necessary to find a way to work together;
- the DHS does not interfere with the decision making of the eHealth Network.

The Netherlands:

- supported the comments made by Estonia.

Portugal:

- suggested to revise the mandate of the eHMSEG semantic task force but eventually replace it in the future with a permanent group on semantic interoperability.
- emphasized that semantics are dynamic; every 3 months the catalogues needs updating etc especially, when moving towards the exchange of large data formats. Therefore, it suggested to establish a circle of semantic representatives;
- supports the set-up of an eHealth Network sub-group.

Germany:

- supports the idea of a permanent interoperability exchange under the eHN between the NCC and national semantic experts,
- underlines the need for being clear, that such a group shall not decide on standards, but shall give guidance and tools with the aim of more coordination and mutual transparency. It must also be clear, who has the mandate to work in the subgroup. Therefore it must be transparent, who provides input.

France:

- agrees to set up a sub-group that works on semantic interoperability but duplication of work needs to be prevented.
- underlined that it needs to be clear what the scope is of the new sub-group;
- mentioned that the sub-group should not discuss the creation of new standards but the use of existing standards focussing on the content.

United Kingdom:

- expressed that it is necessary to consider how to work with suppliers to implement standards and how to help users in better understanding the use of standards. It is therefore important to understand and to find ways on how to adopt and use standards easier;
- emphasized that duplication of work must be prevented.

Conclusions

There is common understanding among the eHealth Network, that a more permanent body or function is needed to deal with the issues identified in the “discussion note”. The eHealth Network gives a mandate to the eHMSEG semantic taskforce to look more broadly at semantic issues and to provide their advice on how the identified issues could be solved on the long term and in a sustainable way. The general exchange on interoperability shall be first picked up by the eHN sub-group dealing with the proposal for on the EHR exchange format, whereas further alignment and extension has to be foreseen.

The Commission will consider the strategic aspect of the interoperability discussion in the context of the implementation of the Communication and shall give assistance to the implementation of the permanent body or function that is to be installed.

b) Recommendations for the Rolling Plan on ICT standardisation

The eHealth Network adopted the Recommendations for the Rolling Plan on ICT standardisation.

Agenda point 3) Patient Access to health data

The Member State co-chair introduced the JAseHN recommendation paper concerning patient access to health data that is up for adoption.

Discussion

An eHealth Network Member mentioned that the first recommendation is not clear in why it only focusses on cross-border setting, a limited situation, and what exactly *eHealth data and access in an integrated way* means.

The Member State co-chair suggested and the eHealth Network approved to substitute the word "need" with "expectation" in recommendation 1.

Conclusion

The eHealth Network adopted the recommendation paper in consensus.

Agenda point 4) eHDSI implementation

a) State-of-play and next steps on the go-live of the eHDSI

The Commission gave a short presentation on the state-of-play on the go-live process of the eHDSI.

The eHealth Network would make the first go-live decisions in November 2018 and shortly after the first countries could go live. There will be no extraordinary eHealth Network meeting in July 2018. Despite the postponement of the go-live decision of the eHealth Network to November 2018, the Commission urged Member States to continue working to be ready to go live according to the updated plan.

Discussion

The eHMSEG chair informed the eHealth Network that the delay in the go-live decision is not entirely due to the Member States, but also by the ecosystem of the project, and the participating Member States are working very hard to make progress. Furthermore, he expressed his concern about the audit availability. It seems that there are not sufficient timeslots for Wave 1 countries to go into operation this year. However, he underlines that the audit process is important and must be done in a rigorous way. He suggested that the eHealth Network secretariat shares with the Members the criteria used in the audit.

b) State-of-play opinion Article 29 Working Party

The Member State co-chair gave a short background on the request of an opinion by the Article 29 Working Party. The eHMSEG Legal Taskforce has analysed the opinion and concluded that there are no showstoppers but some amendment suggestions.

The eHMSEG Legal Taskforce leader gave a short update on the process preceding the Article 29 Working Party opinion. Furthermore, he informed the eHealth Network about the results following the analysis of the opinion.

The opinion mentioned eight issues that require attention. The next steps of the Legal Taskforce following the opinion are:

- further analysis of the opinion to develop a common agreement on the follow-up steps;
- prepare the necessary amendments to comply with the recommendations of the opinion;
- enable the signing of the agreement for the first wave countries.

The Legal Taskforce identified where amendment is most probable:

- the structure of the agreement: the Article 29 Working Party saw the need to fine-tune the procedure. The agreement itself should not be affected in case the annexes require amendments. The contraction parties should get a mandatory notification regarding to the amendments made in the annexes. The WP also discussed the procedure to amend annexes (mostly the eHealth Network decisions). In addition, the Article 29 Working Party suggest to build in a provision to allow a transition period for Member States to be enable them to comply to the changes in the agreement and annexes.
- the Agreement's provision aiming at excluding further processing under Art 6.4 GDPR seems to be misleading and unnecessary". The Article 29 Working Party finds this provision misleading and unnecessary. An amendment of the Agreement by deleting the sentence in question is necessary and would improve the legal certainty.

Discussion

Germany congratulates the eHN that the opinion of Art. 29 WP has being put forward. While it can be welcomed, that Art. 29 WP in principle agrees to the Agreement, it is clear that the Legal Subgroup of eHMSEG still has a lot of work with regard to monitoring and assisting the CBeHIS and implementation of the Agreement. In particular, it is also needed to carefully check what is in the annexes and amend them so that lawyers are being able to agree to them. Germany is willing to further support the Legal Subgroup of eHMSEG.

Portugal asked the eHealth Network to adopt the revised agreement as soon as possible to have it ready before the first wave countries go live.

France asked about the timing of the proposed amendments of the agreement as well as who will be in charge of, particularly as regards to the updates and simplification of the annexes.

The Member States co-chair noted that there are two options to adopt the amendments:

1. The amendments will be tabled in the next eHealth Network in November, or;
2. The amendments, since they will be minor in nature, can be dealt with through a written procedure.

Conclusion

The eHealth Network asked the eHMSEG Legal Taskforce to discuss in-depth the necessary amendments to the agreement and make a proposal on how to further deal with the Legal

Agreement. The Legal Task Force also needs to discuss how to deal with the annexes. The proposals will then be put for adoption in a written procedure for the members of the eHealth Network. A general documentation on the process of the Legal Agreement is required. Reason being that (new) experts who will join this process at later stage shall be able to get a good and transparent overview without having had to be involved in the previous processes.

Agenda point 5) European Reference Networks – State-of-play

Mrs. Concetta Cultrera, Deputy Head of Unit B3, who is leading the ERN team, gave a short presentation on the state-of-play of the ERNs.

The main activity of the ERNs is clinical advice for patients that either do not have a clear diagnosis and/or not have an established treatment. Within the Clinical Patient Management System (CPMS), a virtual panel allows doctors in the ERNs to communicate with each other, to exchange clinical information and experience. Because the information that runs through the system is sensitive personal data, even if pseudonymised, the Commission notified the CPMS to the European Data Protection Supervisor (EDPS) which gave a positive opinion on the compatibility of the CPMS in relation to the GDPR. According to the latest figure (10 May 2018), there were 138 panels opened since its launch in November 2017.

The ERNs have a governance with the ERN Broad of Member States and the ERN IT Advisory Group. The Coordinators' Group of the 24 networks are also consulted. The governance bodies develop the common strategy and guidelines to make sure the ERNs are working in a homogeneous way. In addition to the clinical work, research, registry and e-learning activities are being developed as well as tailoring of the dataset for the specific needs of ERNs.

The current challenges of the ERNs include:

- making sure that ERNs are integrated in the national health systems. For that, assessments of the legal and policy frameworks of Member States are done. Member States need to develop a pathway that facilitates patients' access to referral to an ERN;
- ERNs need to go beyond their clinical activity, in particular by developing a framework for research within the CPMS.

Discussion

Several Member States made comments on the state-of-play of ERNs:

- request to share the feedback from the European Data Protection Supervisor and the experience concerning eID to the group responsible for the implementation of the eHDSI;
- convergence between ERNs and other DSI services to create efficiencies;
- investigate how the eHMSEG can be involved in the ERN;
- concerns about the privacy of the data, as it is possible to trace back the data to an individual (pseudonymisation);
- need to act firmly towards a company providing IT services that is approaching doctors to integrate their healthcare systems into the platform they offer;
- the paper on Patient Registries scheduled for the agenda point 10 is an attempt to map out activities to identify a convergence strategy;
- an important convergence aspect to consider is semantic interoperability and the use of the guidelines adopted by the eHealth Network on Patient Summaries and ePrescriptions;

MS co-chair noted that the request of convergence is understandable but this can only happen if the eHealth Network and the eHealth Member State Expert Group know what needs to be converged.

The Commission underlined that the ERNs are a voluntary cooperation between entities in Member States. In the ERN Board of Member States consists of the representatives appointed by the Health Ministries. It gave the following explanations

- the Commission will share the opinion from the EDPS, which is publicly available on its website. The hospitals deal consent using a model form, which EDPS considered as best practice;
- it is difficult to anonymise data of patients with very rare diseases. Further, there is need to be able return to a patient case, for example when new tests or treatments become available. Therefore, the data is pseudonymised within CPMS. Only the hospital that is in charge of the patient in the Member State knows the identity of the patient;
- the CPMS is an IT tool where health professionals in ERN member hospitals are the users;
- in the 12th eHealth Network meeting a note about the differences between ERN and eHDSI was presented;
- the ERNs use as much as possible common solutions based on the guidelines of the eHealth Network. However, in some cases it is necessary to develop tailored solutions because generic guidelines are not fit for purpose;
- the Commission took note on developing a convergence strategy. However, proposals from the eHealth Network are welcome.

Conclusion

The eHealth Network came to the conclusion that:

- the Commission and the Members share similar concerns and desire on the way forward;
- the Network urges the Commission to find ways to streamline eHealth systems as much as possible.

The Commission committed to invite an eHealth Network representative to the ERN IT Advisory Group.

Agenda point 6) Appointment Member State co-chair

The Commission co-chair gave an introduction prior to the appointment of the new Member State co-chair and thanked the current Member State co-chair for his dedicated work and his contribution to create better health in the EU.

The Member State co-chair noted that there was one candidate announced in advance, the Portuguese Member of the eHealth Network, Henrique Martins. The Member States co-chair asked if anyone would like to put forward another candidacy at the meeting. None else was suggested.

The Member States co-chair asked Henrique Martins to elaborate on his ideas as the applicant to the position of eHealth Network Member State co-chair.

Henrique Martins announced that he will give up his position as the chair of the eHealth Member State Expert Group to avoid being in a double position when the go-live decisions are taken, as the recommendation is made by the eHMSEG.

In order to ensure continuity in the eHMSEG, the Commission co-chair suggested that the current Member State co-chair continues until 31 August 2018.

Conclusion

The eHealth Network appointed the Portuguese Member of the eHealth Network, Henrique Martins, as the new Member State co-chair to the eHealth Network. He will take up his role of the Member State co-chair from 1 September 2018 for a two year period.

Agenda point 7) Electronic identification for the exchange of health data

The Member State co-chair introduced the recommendation paper on Policies regarding eIDAS eID and Health Professional Registries. Furthermore, the Portuguese Member of the eHealth Network gave a short update on the HealthID project that they are coordinating.

Discussion

Member States continue to have open questions regarding the eIDAS Regulation and the GDPR. These questions should either be taken up by the eHMSEG and/or eHAction.

Germany finances a project that looks at technical options and legal questions. The report of the project can contribute to the debate.

France requested to adjust the wording of the second recommendation to “after discussion and validation at policy level”.

Conclusion

The eHealth Network adopted the recommendation paper by consensus modifies as suggested by France.

Agenda point 8) National eHealth strategies

The Member State co-chair introduced the topic and gave the floor to Franz Leisch, Director of ELGA GmbH. The presentation is uploaded on the eHealth Network webpage for information.

Agenda point 9) Stakeholders

Digital Health Society

Brian O’Connor gave a presentation on the developments and activities of the Digital Health Society initiative. The presentation is uploaded on the eHealth Network webpage for information.

eHealth Stakeholder Group

The Commission gave a short update on the eHealth Stakeholder Group and their meeting of 26 April 2018. An important feedback point was that the Group would want to have more interaction with the eHealth Network and it requested for the possibility of sending their documents directly to the eHealth Network.

The Commission announced that they will follow-up on this request.

Agenda point 10) Other eHealth topics

WHO mHealth hub

A presentation was given by a representative of the WHO, Per Hesvold, about the developments on the EU mHealth Hub, a H2020 funded project. The presentation is uploaded on the eHealth Network webpage for information.

Discussion

eHAction will work on a common eHealth assessment framework on mHealth that will be submitted to the eHealth Network.

The mandate of the eHealth Network sub-group on mHealth is still valid but it did not have any meetings during past 12 months.

Conclusion

The eHN agreed that there is a general need for alignment between the WHO, eHAction and the Network's sub-group on mHealth but there is no need to maintain two levels on mHealth in parallel. Therefore, eHAction and the eHealth Network sub-group on mHealth need to align to find a suitable work approach.

At the 14th eHealth Network meeting scheduled for November 2018, the Network shall decide on the continuation of the sub-group on mHealth. The Estonian member as chair of the eHealth Network sub-group on mHealth is in charge of this process.

Follow-up on the recommendation of the *PARENT JA Guidelines for Patient Registries*.

The UK member gave on behalf of JAsEHN a short presentation on the recommendation paper for follow-up of the PARENT JA Guidelines for Patient Registries.

Conclusion

The eHealth Network asked eHAction to follow-up on these recommendations.

Report on main eHealth activities outside of the EU

The French member gave on behalf of JAsEHN a short presentation on the report on main eHealth activities outside of the EU.

Conclusion

The eHealth Network thanked for the presentation and the work done, and took note of the documents.

Closing of the meeting

The Commission co-chair thanked the Member States co-chair, Clemens-Martin Auer, for his work at the helm of the eHealth Network for six year, from the very start of the Network.

The Secretariat to the Network for his and his team's part thanked Clemens-Martin Auer for very good collaboration where it was always possible to rely on his knowledge and understanding of the Member States' position and the true vision of taking eHealth ahead in the EU.

The Commission co-chair announced that Tapani Piha, Head of Unit responsible for European Reference Networks and Digital Health will leave the Commission on 1 September and thanked him and his team work for this and previous meetings.