EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

eHealth & Health Technology Assessment

Brussels,
sante.ddg1.d.3 (2015) 358449

Final summary minutes of the 6th eHealth Network meeting
18 November 2014, Brussels

INTRODUCTION

These draft summary minutes are prepared by the Secretariat of the eHealth Network in accordance with the rules of procedures. The summary minutes will be posted on the European Commission (EC) website (http://ec.europa.eu/health/ehealth) after having taken into account any comment provided by Network's members.

WELCOME AND OPENING

The Chairs (Andrzej Rys, Director for Health Systems and Products, DG SANCO and Clemens-Martin Auer, Director General for Health, Austria) welcomed the members of the eHealth Network.

The participants were informed that DG SANCO will be changed to DG SANTE on 1 January, due to organisational changes.

All 28 Member States were present, as well as Norway as an observer.

There were no comments on earlier minutes.

The agenda was unanimously adopted.

SPEECH FROM COMMISSIONER ANDRIUKAITIS

The Chairs welcomed Commissioner Andriukaitis who joined the meeting for a welcoming speech.

The Commissioner underlined the importance of a connected digital market, and of breaking down barriers with ehealth agreements. He also expressed the importance of the ePrescription guidelines, and welcomed the excellent initiative from Finland and Sweden to start working on a proper legal agreement to exchange medical data across borders. The Commissioner also pointed out the eHealth Network's important role in tackling the

future problems by better organised health systems supported by ehealth, and wished the network success in keeping up the momentum of the excellent work done so far.

TOPIC 1: ADOPTION OF GUIDELINES OF EPRESCRIPTION

Introduction
The Chairs introduced the topic, and clarified the setting under Art 11 (2b) under the directive on the application of patients' rights in cross-border healthcare. It is within this context these guidelines should be adopted. The chairs then welcomed Jeremy Thorp, Health and Social Care Information Centre (HSCIC), to give an introduction to the guidelines.

The eHealth Network guidelines are non-binding, and outline the agreement between eHealth Network members on how to move forward. Substitution, storage periods and national implementation are not within the scope of these guidelines.

Many countries had provided input to the document (at least 22 Member States, as well as Norway and Switzerland). The guidelines to be adopted today are the first release and there will be further development.

The MS Chair informed that adoption of the text is equal to the adoption of Sections 1-3, the rest is supporting information.

Discussion:
A discussion took place in which Member States welcomed the guidelines and the possibilities they will open for implementation.

There was a request for clarification on page 12, in cc 2, footnote under 11 describing the term *product* from ISO in relation to the fact that on page 10, section 3, chapter 1, paragraph 5, it was stated that these guidelines do not cover medical devices. This will be reflected in the adopted guidelines.

The discussion also involved the economic consequences when it comes to reimbursement and the cost of eprescription. Some countries have low prices on drugs right now; other countries have higher prices. These differences should be reflected in some way in the future.

Conclusion
The guidelines on ePrescriptions were adopted unanimously.
The chairs thanked everybody for their participation in this work, but specifically the UK member, Jeremy Thorp, for his work on the guidelines.

TOPIC 2: UPDATE ON CONNECTING EUROPE FACILITY (CEF)

Introduction
Jerome Boehm, SANCO, presented the CEF financial instrument and the proposed CEF Governance.

The CEF funding in 2015 is significantly lower (€15 mill. Proposed) than the Network's request, so a selective approach is needed. In the first stage, setting up the exchange for patient summary and eprescription is envisaged. The eHealth Network has a clear role in the preparation of CEF, a complex issue involving both money and sound governance.

The CEF rules require that the maturity of the digital infrastructure services financed is demonstrated, and that it is possible for the Member States to take over the maintaining of the services when the CEF financing will end. The intention is to support the core services, which must build as much as possible on the horizontal CEF building blocks. The main focus will be on the generic services to build connections between the Member States.

Discussion
The Chairs opened the discussion with a guarantee that the Member States will own this process, thus the involvement of representatives from the eHealth Network is necessary.

At the moment the Network has two subgroups (upkeep epSOS and the CEF-subgroup). The chairs asked for support to merge the two into one, and in that way renewing the CEF working group.

The Member States commented that the merger of the two groups seems logical. They also stated that the eHealth Network should put a priority on horizontal services and how they apply to national solutions, e.g. e-identification. Further, there must be identified markets in regard to existing national id-systems.

It is also necessary to have knowledge of the starting point in every Member State in order to know how much money that is needed. The adequacy of the draft budget of 15 million will need to be assessed in a later stage.

The Chairs stated that the Network's position on e-identification in healthcare must be further specified, something that also is one of the tasks in the work plan.

In addition to the patient summary and ePrescription guidelines the Network should require further funding for other services as in its original request.

Conclusion
The eHealth Network decided in consensus to merge the two subgroups and asked the group to focus on the upkeep of epSOS cross-border services and CEF, and on implementation of eHealth deployments. The name of the merged sub-group is Implementation of eHealth DSIs. The sub-group will have two main tasks:

- supervision of CEF deployment;
- support of Member States with national effort to prepare for cross-border exchange.

The chair of the new sub-group is Portugal. Members in the new sub-group: DE, HR, NL, PT, SE, LU, AT, ES, DK, EL, IT, MT, FI, UK, BE, IE, GR, FR, PL, SI (20 MS).

The sub-group may to arrange meetings of smaller groups of Member States when needed.

TOPIC 3: UPKEEP OF CROSS-BORDER SERVICES

Introduction
This agenda topic covers three parts. First a report about the sub-group Chair, second a presentation concerning sustainable legal arrangements, third a presentation about an EU study on EHRs in Europe.

Report from the sub-group's Chair
Chair of the sub-group on upkeep of cross-border services Henrique Martins gave a presentation of the work of the group. He informed that Member States would like to restart the services. To restart the services there must be an agreement on

- a legal basis of understanding;
- technical solutions to connect;
- central services that are necessary to keep the services running.

The temporary legal agreement has been signed by five Member States.

Concerning legal aspects there are two different approaches; a long term legal agreement, and a temporary arrangement to restart the services.

Concerning the temporary solution, at the meeting on 12 November, a number of countries were ready to start the services. Many would prefer a technical solution that is run by a third party.

Proposal on sub-group for sustainable legal basis for cross-border exchange
The Chairs welcomed Aneta Blåder, member in the subgroup on upkeep of epSOS services, to present a proposal of establishing a legal sub-group to draft on a legal agreement.

The Chairs reminded that legal interoperability already is identified as a key issue for cross- border health in the work plan, so this proposal is only a way to speed up the work already decided.

Aneta Blåder informed about the earlier cooperation between the Nordic countries through which Sweden and Finland could agree on a common legal ground to sign a bilateral agreement on exchange on eprescriptions.

She suggested establishing a new legal subgroup consisting of lawyers from the Ministries of the Member states aiming at developing a legal framework (probably a multilateral agreement) for participating member states. The subgroup will have a core group (including technical experts) analyzing legal barriers and suggesting possible solutions within existing national legislations.

Discussion
The Member States thanked Sweden and Finland for the useful draft, and pointed out the specific problem with ownership during transmission; and the differences between the countries e.g. on patient consent. Some Member States would prefer only one procedure to sign a multilateral agreement, because it would be costly to a high number of bilateral agreements.

The eHealth Network noted that this is an important trust building exercise. The Network asked the European Commission to employ its lawyers on how to integrate the European

legislation (e.g. regarding liability issues) into this work. Liability issues are very challenging, but there are solutions.

MS Chair said that this group should not look too much on liability; rather focus on strategic questions regarding the multilateral agreement, and on legislation on a European level. The subgroup is in line with the work plan, and the scope is to find the legal solutions to cross border exchange, and consider other work already done (e.g. the legal interoperability study, epSOS paper on article 29).

Conclusion

The eHealth Network agreed to form a legal sub-group.

The eHealth Network secretariat will approach the Member States for these legal and "functional experts" who will work on the legality of cross-border transfer of health information.

Presentation of the results of the Study on Legal issues of Electronic Health Records

The Chairs welcomed Professor Jos Dumortier to present the results of the study on Electronic Health Records that had been commissioned by the EC in 2014.

The study provides an overview of the laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services. It is an analysis of the legal framework in the Member States, but it also includes a General Report with recommendations to the eHealth Network.

The study focused on sharing of health information between different systems. It started in one country (France) which resulted in a model for the national reports. This influenced the rest of the study, in which also Norway was included (in total 29 countries are covered). The Study was done in cooperation with lawyers in the Member States, who also were asked to interview national stakeholders. This resulted in a final report with a comparative analysis, which was discussed during a workshop in July.

The conclusion is that there is a strong and accepted diversity between the Member States different laws. A question is if this diversity will be an obstacle for cross border exchange. The main reflection is that most of these obstacles cannot be solved on high level and that the practical solutions must be a guide on how to handle this. There are though a few obstacles with e.g. liability, and the data protection which remains a main problem, that must be solved on a high level. Few examples of the recommendations were presented, including the one on consent, patient access and secondary use of data. The current fragmentation between electronic health records hinders cross-border collection and exploitation of "big data". The study therefore recommends harmonised rules regarding secondary use of health data. An electronic health records "code of conduct" on this issue could be a first step.

All results of this study, including all national reports, will be available on the European Commission SANCO website.

Discussion

The possibility for the patient to opt-out was discussed; some Member States could relate the recommendations to its own laws, others believed that the suggested possibility to opt-out might be a problem.

There was also a concern regarding the proposed General Data Protection Regulation which is not compatible with some Member State laws. The chairs commented that Member States need to follow the negotiation process on Data Protection Regulation in this crucial moment when the Council is close to an agreement on the articles related to research and health. The Italian Presidency proposes many changes affecting health and research and these are currently discussed.

Conclusion
The Legal Study on Electronic Health Records will be taken further in the next eHealth Network meeting.

TOPIC 4: DISCUSSION ON PATIENT REGISTRIES GUIDELINES

Introduction
The Chairs welcomed Metka Zaletel from Slovenia to present the Summary of the Guidelines on registries done within the PARENT Joint Action (Work Package 5). PARENT is a joint effort by the Member States and European Commission to improve secondary use of data from patient registries in a cross border setting (there are 20 member states participating in the PARENT Joint Action work).

A patient registry is in this project defined as "an organised system that collects, analyses and disseminates data on a group of people defined a particular disease, condition, exposures, or health-related service, and that serves scientific, clinical and/or public health (policy) purposes." This PARENT work is aimed to develop and disseminate methodological guidelines, recommendations and IT tools for efficient and rational governance of patient registries. The Joint Action will organise a workshop with the Member States' experts in the area of registries to discuss these guidelines sometime in February- March 2015.

Discussion
Commission Chair opened the floor to discuss how to endorse this document. Some Member States showed an interest to participate in the workshop and discuss further what to do with the guidelines. The Member States also stressed the importance to involve people that work with registries every day in this initiative, and proposed a commentary process. There was also a discussion about the need to connect registries to electronic health records, and that the data model must be compatible with the data model for the authentic source of electronic health records. One Member States concluded that a lot of information is collected today; the problem is to learn how to use it.

Conclusion
Commission Chair asked the Member States to send their comments on the full Registries Guidelines by the end of January to the coordinator of the Joint Action.

There will be further information about the time and place for the workshop, which is an important forum to handle this issue. After this process the eHealth Network will have the opportunity to endorse in full or some parts of the Patient Registries' Summary Guidelines or Comprehensive Guidelines during next meeting in May 2015.

TOPIC 5: STANDARDISATION PROCESS AND EHEALTH

The Chairs welcomed Paul Timmers, Director for Sustainable & Secure Society, DG CONNECT, to present the European eHealth standardization strategy, in which the eHealth network has an important role to play.

Paul Timmers related more use of common international standards to the vision of an EU single market. Use of common standards will avoid fragmentation of the market, for example opening up a larger market for small, local suppliers. Increased use of common standards will also generate lower costs and make it easier to choose new suppliers. The activities set out in the European standardization regulation 1025/2012, are put forward on the basis of the Annual Union Work Programme for European standardisation and the Rolling Plan for ICT standardisation. The regulation also sets out the obligation on the standardisation organisations (CEN, CENELEC and ETSI) to have transparent standardisation processes and stakeholder involvement.

Paul Timmers presented two options in the further work with standards for eHealth. The eHealth Network can either decide to make a revision of its guidelines independently from international standardisation developments, mainly US-led by HL7, or closely collaborating with CEN, highlighting the benefits of taking advantage of their well-established process based on inclusion and consensus and representing EU perspective at international level.

Paul Timmers also reported on the identification process of the 27 Integrating Health Europe (IHE) profiles that received positive recommendation by the Multi-Stakeholder Platform. The eHealth Network will be asked to advise on this by written procedure. He concluded the presentation proposing a Public Procurement of Innovative solutions (PPI) incentives scheme that could boost interoperability in Europe.

The Chairs welcomed Stephen Kay, Vice-Chair of CEN/TC 251 Health Informatics. Stephen Kay said that the challenge in standardisation is a very strong disconnect between policy and practice. CEN tries to bridge this gap. Health is a global concern; therefore standards should mainly be developed on an international level (as ISO), but there is also a need for cooperation on European eHealth standards. The eHealth Network has a central role and mandate within eHealth, and there is a need to combine its efforts with CEN in order to define a coherent EU eHealth standards approach.

Discussion

MS Chair highlighted the importance of having the eHealth Network involved in eHealth related standardisation issues and of having a proper consultation of the Network on eHealth related standardisation initiatives. The eHealth Network is a strategic body with clear legal basis, so it is no intention to operationally work on standardisation processes, but there is a need for them to be involved in the decisions.

The Chairs opened the floor to the members for discussion, asking for any concern in having CEN involved in the strategic discussion on the direction of standardisation in eHealth, namely in the Joint Action. No concerns were raised in this regard.

Commission Chair highlighted the importance of cooperation with standardisation bodies in the Member States and the internationalisation aspects of standardisation, reporting on success stories experienced in the pharmaceutical sector.

The main elements that emerged during the discussion were:

- Clarification on the reporting mechanism of CEN to the eHealth Network: The Joint Action will report to the eHealth Network on standardisation issues.

- The interaction between national governmental authorities and national standardisation bodies and their involvement at international level. In this regard, the vice-chair of CEN/TC 251 reported that there is no unique approach on this and it depends on the Member State. The eHealth Network may help proposing appropriate specialists to participate in national mirror groups to CEN/TC 251.

- The timing of the standardisation activities: One Member State expressed possible concerns on starting standardisation activities too soon, on specifications that are not yet very mature; one Member State reported on the necessity to identify the relevant standards beforehand. Late adoptions or decisions on this could lead to high costs to convert legacy systems developed in the meanwhile.

- The inclusiveness of the standardisation process as regards other standardisation organisations and relevant stakeholders.

The Chairs noted that the multi annual work plan identifies standards as an area for the eHealth Network to work on. The discussion confirmed that the eHealth Network wants to be involved in standardisation issues, and that CEN will be one of the partners in the standardisation discussions through its participation in the new Joint Action.
This will allow the eHealth Network to have a clear vision on the standardisation issues and to explore the possibility of standardisation initiatives; the next step of assessing the guidelines will benefit of having CEN as one of the standardisation participants.
The MS Chair also highlighted the necessity of being inclusive in this action, as emerged during the discussion. On these issues, the Joint Action will report back to the eHealth Network.

Conclusion
The eHealth Network will take a role in planning future EU standardisation activities for eHealth, and welcomed the involvement of CEN, as well as other standardisation organisations, in the new joint action.

The option of starting a standardisation process of specific elements of the guidelines involving CEN will be further explored in the new joint action with the support of the Secretariat.

The eHealth Network took note that the European Commission will further develop the Public Procurement of Innovative solutions (PPI) incentives scheme and that the eHealth Network will be consulted through written procedure by the Commission for opinion on the identification process of the IHE technical specifications that have already received a positive opinion by the multi stakeholder platform.

TOPIC 6: REPORT ON MHEALTH GREEN PAPER RESPONSES

Paul Timmers presented the result of the consultation on existing barriers and issues related to mHealth deployment.

The three months consultation on the green paper was closed on 10 July 2014. The responses showed a number of benefits, for example within health prevention and efficient and sustainable health care, but also barriers regarding data protection and security, unclear application of rules and legal vacancy, and lack of information about reliability.

The next step will be an EU Impact Assessment process, involvement of interested Member States (co-impact assessment) – to share knowledge and analysis, and stakeholder events.

TOPIC 7: INFORMATION POINTS

New eHealth Joint Action
The Chairs informed that the process of setting up the new Joint Action has started, with 24 Member States participating, but some still missing. The first meeting was on 12 November, next meeting will be on 16 December. The proposal must be ready by the end of January 2015.

SNOMED CT
The eHealth Network secretariat informed about the on-going negotiations for a temporary agreement on the use of the terminology in the epSOS services between the European Commission and the owners of SNOMED CT, IHTSDO.

In the meantime, IHTSDO agreed to find a solution to non IHTSDO members to use SNOMED CT for cross-border purposes under the concept of EU epSOS.

Study on use of Big Data in health policy
Karolina Hanslik, SANCO D3, informed the eHealth Network about the document on the Use of Big Data in Public Health Policy and Research. The document contains: definitions of Big Data, current trends, opportunities in public health, challenges and some examples of its use by Member States. It will be used as a background report for the planned study on Big Data in healthcare to be financed by the Health Programme 2015 (once agreed).

CLOSING

The chairs thanked all representatives for their participation.

Next eHealth Network Meeting will be in Riga on Tuesday 12 May 2015.

The meeting was closed at17h30.