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

eHealth-units

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Summary minutes 4th Meeting of the eHealth Stakeholder Group 24 October 2017

Venue: Albert Borschette Congress Center, Brussels

Introduction

The fourth meeting of eHealth Stakeholder Group (eHSG) was attended by invited members of the eHealth stakeholder group and Commission staff. The meeting was chaired by Tapani Piha, DG SANTE, Head of Unit B3 Cross-Border Healthcare (morning session) and Miguel Gonzales-Sancho, DG CNECT, Head of Unit H3 — eHealth, Well-being and Ageing (afternoon session).

Welcome and introduction

The meeting was opened by Despina Spanou, Director for the Directorate for Digital Society, Trust & Cybersecurity. She emphasised the importance of ongoing activities with regard to the digitisation in the health care sector, specifically the preparation of the Communication on Transformation of Health and Care in the Digital Single Market.

Participants approved the agenda and the minutes of the previous meeting held on 27 April 2017 in Brussels without changes.

1. Results from the Public Consultation

Nearly 1500 contributions were received in response to the public consultation on the Communication on transformation of health and care in the Digital Single Market which was closed on 12 October. There is a clear positive response towards the ideas put forward by the Commission with more than 80% of respondents agreeing that sharing health data can be beneficial to improve treatment, diagnosis and prevention of disease across the EU. Nearly 55% report not having access to digital health services. Privacy and security are key concerns. The heterogeneity of electronic health records is seen as an additional main barrier and therefore the most important tasks for the EU to overcome these barriers are: to develop standards for data quality and reliability (60%), to standardise electronic health records (57%), to propose health-related cybersecurity standards (54%) and to support interoperability with open exchange formats.

The results of the public consultation will be made available when the Communication is adopted at the beginning of 2018.

2. Short recaps from recent events

a. Estonian Presidential Conference

The digital society for health' took place in Tallinn from 16 to 18 October. Over 600 digital health experts from Europe and across the globe have gathered in Tallinn to exchange knowledge and share best practices as part of the eHealth Tallinn conference. The conference focused on the impact that a digital transformation of healthcare systems could have on society as a whole.

European Connected Health Alliance (ECHA) representative gave a presentation of the Digital Health Society Declaration launched under the high-level eHealth conference in Tallinn. The Digital Health Society, initiated by the Estonian Presidency of the Council of the European Union and ECHAlliance have assembled an eHealth Declaration that includes more than 100 European organizations' proposals for developing eHealth in Europe. The Declaration has been launched in July 2017. The Declaration describes the bottlenecks that hamper the development of e-health, such as the lack of people's trust in e-services in Europe, the lack of interoperability between different information systems, the lack of a clear legal framework, and the inadequate training of healthcare professionals. Proposing solutions for overcoming these obstacles, the document emphasizes the need for unified approaches to the development of data exchange infrastructure, raising people's awareness of the use of e-health solutions and implementing the European Union Data Protection Regulation in a way that it does not create unnecessary obstacles to the free flow of data between member states.

The Declaration and the conference discussions will support the conclusions of the Council of the European Union, which are due to be adopted by the health ministers at the December health ministers' Council.

b. Stakeholder workshop on GDPR and health data

Workshop on General Data Protection Regulation (GDPR) implementation and health data took place on 23 October 2017 in Brussels. The event was co-organised by co-organised by DG CNECT, DG SANTE, DG JUST and DG RTD and more than 190 participants from Member States, industry, research and associations attended the workshop. Purpose of the workshop was to exchange on practical implementation of the EU GDPR with respect to health-relevant data, sharing of experiences and good practices and identifying drivers and challenges regarding processing of personal data concerning health. The meeting concluded with an invitation to participate in the consultation on guidelines and to liaise with national Data Protection Authorities as they are the first points of contact on GDPR implementation and compliance.

3. Updates from DG SANTE

eHealth Network meeting

The 11th eHealth Network (eHN) meeting took place on 10 May 2017 in Malta, followed by the eHealth week 10-12 May. Several important topics were presented and discussed such as: EU strategy and activities on digital health; Implementation on eHealth DSI; Agreement for the exchange of health data; mHealth; eHealth interoperability and standardisation; Cybersecurity; Secondary use and access to health data; National eHealth strategies, EU projects, and other eHealth related developments.

Further, the draft agenda for the upcoming 12th eHN meeting was presented. This meeting will take a place on 28 November 2017 in Brussels.

eHealth Network Multiannual Work Plan (MWP) 2018-2021

The scope of the MWP 2018-2021 is in line with the objectives of the eHN as outlined in the article 14 of Directive 2011/14. The four main areas and priorities for the MSs are following:

- a) Empowering People
- b) Innovative use of health data
- c) Enhancing continuity of care
- d) Overcoming implementation challenges

In total 5 meetings were held in the period from January – September 2017. The eHSG representatives provided their written input to the document. The MWP 2018-2021 is scheduled for adoption in the 12th eHN meeting on 28 November.

The 3rd Joint Action on eHealth (eHAction)

The 3rd Joint Action on eHealth from the Health Programme 2017 is expected to further facilitate cross-border health care across the EU and overcome barriers in the implementation of digital solutions in Member States (MSs) healthcare systems and provide the necessary policy support to the eHealth Digital Service Infrastructure and in accordance with the eHN MWP 2018-2021.

The proposal was submitted on 28 September and 22 countries and 9 collaborative stakeholders will actively participate in the work of the eHAction. Next steps includes: evaluation, negotiation and finally signing of the

grant agreement foreseen for February 2018. The Coordinator of the eHAction is Portugal and kick-off meeting is foreseen to take a place in June in Lisbon.

Before submission of the proposal the eHSG representatives were invited to indicate their interest in participating in the 3rd JA on eHealth. Taken into account that preparation was ongoing during the summer period some of the eHSG representatives asked whether they could express their interest in participating in the eHAction during the negotiation period. This will be taken forward to the Coordinator of the eHAction and CHAFEA for their consideration.

JAseHn deliverable for the 12th eHN meeting

JAseHN representatives gave a short presentation of main deliverables that will be presented, discussed and/or adopted in the 12th eHN. Four deliverables will be put for adoption, 3 for discussion and 5 for information. Following four deliverables are scheduled for adoption:

- D5.2.1 eID specific Framework for eHealth Release#2
- D5.2.2 Policy Paper (was GL) on interoperability of registries for healthcare professionals
- D5.4.2 Policy Paper proposing actions to promote the use of common standards or technical specifications in eHealth within the EU
- D5.5 Report on European Semantic Interoperablility in eHealth

All deliverables are available on the online platform for eHSG.

4. Updates from DG CNECT

H2020 – draft publication Work Programme 2018-2020 CNECT gives an overview of topics with eHealth relevance from Societal Challenge 1 ("Health, Demographic Change and Wellbeing") in the new Horizon 2020 work programme. The main focus was on calls which are open in 2018 with deadlines for submission of proposals in April and November 2018, respectively. Topics include: Adaptive smart working and living environments supporting Active and Healthy Ageing, Exploiting the full potential of in-silico medicine research for personalised diagnostics and therapies in cloud-based environments, Prototyping a European interoperable Electronic Health Record (EHR), Supporting investment in smart living environments for ageing well through certification, Support to further development of international cooperation in digital transformation of health and care, Support to a Digital Health and Care Innovation initiative in the context of DSM strategy, Digital health and care services – support for strategy and (early) adoption, Digital health and care services, Toolkit for assessing and reducing cyber risks in hospitals and care centres to protect privacy/data/infrastructures, Raising awareness and developing training schemes on cybersecurity in hospitals, Smart and healthy living at home.

Horizon2020 web site: http://ec.europa.eu/programmes/horizon2020 Participants portal: http://ec.europa.eu/research/participants/portal SC1 Work Programme:

http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf

Cybersecurity: Building strong cybersecurity for the EU (CNECT)

The presentation included an introduction to the topic and its importance as President Jean-Claude Juncker stated in his recent State of the Union address. The main three elements of the Cybersecurity package were presented:

- EU Cybersecurity Act (proposal for a Regulation, COM(2017) 477 final)
 - ENISA, the "EU Cybersecurity Agency" with a permanent and more focused mandate
 - Information and Communication Technology cybersecurity certification to address the great need for cyber secure products and services and the major challenge regarding the fragmented EU landscape in the specific area
- EC Recommendation on Coordinated Response to Large Scale Cybersecurity Incidents and Crises (Blueprint, C(2017) 6100 final) setting a framework about how can EU and MS c work together in a cyberattack by setting out how cooperation could look in a cyber crisis in the political, operational and technical level.
- EC Communication "Making the most of NIS" (COM(2017) 476 final) aiming to put in place comprehensive and ambitious national strategies, ensure effective and adequately resourced national CSIRTs, ensure effectiveness of implementation and enforcement, align the national approaches on

Operators of Essential Services, extend the scope of the NIS Directive to additional sectors, e.g. public administration.

A framework for free flow of non-personal data in the EU DG CNECT presented the framework for the free flow of non-personal data in the EU, ie. the proposal for a Regulation (COM(2017)495). The presentation gave an account of the context and the main obstacles precluding the free flow of non-personal data in the DSM. The scope was specified, underlying that solely non-personal data are under the scope (the GDPR providing for the free movement of personal data). As regards impact of the proposal on the health sector, research could be potentially improved with analytics of large pools of data, provided they are anonymised.

Ongoing studies

a) Study "Benchmarking Deployment of eHealth among General Practitioners":

The study will last only one year from the day of signature ie mid-July 2018. It follows on from a previous study which has identified key obstacles to adoption are in practice: difficulty in access and infrastructure, skills, a lack of incentives or motivation to use new technologies. Another important point is the divide between NHS systems and Continental Bismarck systems regarding adoption.

b) Telemedicine study

Kick-of meeting took place in September and it will last 13 months. The study will collect information on following 1) map out telemedicine products, services, platforms etc including mobile health applications and telemonitoring devices and available standards and guidelines as well as the lists of standardization bodies and associations that provide the guidelines; 2) map out market and operators; 3) examine barriers on access to telemedicine in the EU and possible solutions; and 4) undertake economic analysis.

5. Feedback from the Members

a) French initiative of "Dossier Pharmaceutique", by Integrating the HealthCare Enterprise

Jacqueline Surugue, representative of the Integrating the HealthCare Enterprises Europe gave a presentation on the French initiative. First pilot experience on Dossier Pharmaceutique (DP) took place in 2005 and engaged the community pharmacists. Second phase engaged community pharmacists and the hospital pharmacists. In the third phase it was enabled access to the DS to hospital doctors by help of "2 slot card reader". Next phase will focus on inclusion in the Electronic Health Record. At the moment 99.9% of the community pharmacies provide the DP, 390 hospitals subscribed to the DP, 5 billion drugs are in the DP data base and 4 million people have the DP. There are 5 million requests a day and in total 390 million patient data have been shared last year. The DP is considered as powerful tool at transition of care as 60% of all medication errors occur during the transition time.

b) Investigation on connected health devices, by The European Consumer Organization (BEUC) This presentation is postponed for the next eHSG meeting.

6. Report from the working groups – state of play and discussion

- 1) Reimbursement: Work group leader Sebastian Gaiser (Eucomed) reported on the work of the group where the main objectives is to define key principles (recommendations) that Member State can use as a reference when thinking and planning a national reimbursement system/framework for digital products and services (diagnostic and therapeutic). Final proposal should be completed by spring 2018 and presented in the next eHSG meeting.
- 2) New and shifting Balances: Work group leader Kjartan Olafsson (European Union of General Practitioners) introduced the work of the group [presentation]. First draft of the paper is envisaged to be ready spring 2018 and to be presented in the next eHSG meeting.
- 3) Citizen and Data: Work group leader Anne Moen (EMFI) reported on the work of this group which is mainly based on exchange of data and video conferences: She extended an invitation to other groups to bridge their respective work to the Citizen and Health data group. The Health Policy Forum platform is used to present updates (also to non-members). Timeline and expected outcomes were discussed. It was proposed to focus more on data ownership in order to optimise the work of the group.

- 4) Care Continuum: Work group leader Ana Carriazo (Reference Sites Collaborative Network) reported on the work of the group on Care Continuum. The main assignment for the group is a policy paper due by the beginning of 2018. The Health Policy Forum will be used for communication from now on. An invitation to join the work of the group was extended to the plenary.
- 5) Interoperability and Standards: Work group leader Catherine Chronaki (HL 7 Foundation) reported on the work of the group and enhanced that standards have to be created on an iterative process. Furth she referred to ongoing work on the eStandards. The work is expected to produce the paper by spring 2018 and to present in the next eHSG meeting.

7. AOB

Next meeting

The next meeting will take place in spring 2018 and the date will be communicated to the Members of the eHSG in time prior the meeting.

END

Members of the eHealth Stakeholder Group attended the meeting on 24 October 2017

- 1. AESGP Association of the European Self-Medication Industry
- 2. CED Council of European Dentists
- 3. CEN
- 4. COCIR European Coordination committee of the Radiological, Electromedical and Healthcare IT Industry
- 5. CPME The Standing Committee of European Doctors
- 6. DIGITALEUROPE
- 7. EFMI European Federation for Medical Informatics
- 8. EFN European Federation of Nurses Associations
- 9. EHTEL European Health Telematics Association
- 10. EMSA European Medical Students Association
- 11. EPF European Patients' Forum
- 12. EPHA European Public Health Alliance
- 13. ESC European Society of Cardiology
- 14. ESR European Society of Radiology
- 15. Eucomed
- 16. European Connected Health Alliance
- 17. HL7 International Foundation
- 18. HOPE European Hospital and Healthcare Federation
- 19. IHE-Europe
- 20. PCHA Personal Connected Health Alliance
- 21. PGEU Pharmaceutical Group of the European Union
- 22. Reference Sites Collaborative Network (RSCN)
- 23. UEHP European Union of Private Hospitals
- 24. UEMO European Union of General Practitioners
- 25. VPH Institute
 - JAseHN
 - DG SANTE
 - DG CNECT