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

eHealth-units

Summary minutes
3ⁿᵈ Meeting of the eHealth Stakeholder Group
27 April 2017

Venue: Albert Borschette Congress Center, Brussels

Introduction

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

Approval of the agenda, the minutes of previous meeting and tour the table

Participants approved the agenda and the minutes of the previous meeting held on 5 October 2016 in Brussels without changes.

After the welcome and adoption of the agenda, the chair invited new representatives of the organisations to introduce themselves and to give a brief account of their activities.

1. Blueprint to innovate health and care in Europe

Peter Wintlev-Jensen, DG CNECT, gave an overview of the state of play of the common stakeholder vision on the transformation of Europe's ageing society in a Digital Single Market known as the Blueprint. He emphasised the goals and concrete steps necessary for scaling up, stressing mainly the importance of a solid base of evidence and of inclusion of the demand side in large-scale implementation of innovative services.

2. Medical Device Regulation

Salvatore Scalzo, DG GROW, presented the current status of the revision of the EU Medical Devices Legislation: The current directives will are replaced by two new regulations: 1. Medical Devices Regulation (MDR), 2. In-Vitro Diagnostic Medical Devices Regulation (IVDR). Main features include stricter pre-market control of high-risk devices with experts at EU level, a new classification system for IVDs based on international guidance, the establishment of the "EUDAMED" database on medical devices, the clarification of the roles and responsibilities of economic operators, UDI system. Once effective, the new regulations will be applicable in all Member States. The MDR will be fully applicable in spring 2020, IVDR in 2022, with the governance structure being a key derogation.

3. Updates from DG CNECT

Digital Single Market and the Digital Health and Care Taskforce
Miguel Gonzalez-Sancho gave an overview of recent activity in the Commission. A new focus has been put on the role of digitalisation in health and for ageing societies and the European dimension: A Commission task force has been set up by DGs SANTE and CNECT which was joined by DG RTD and also involved GROW and JUST. One aspect of this work is to look forward to the next multiannual financial framework and possible funding options.

The mid-term review of the Digital Single Market strategy identifies health as a vital element in realising the desired societal impact in the DSM.

mHealth
Miguel Gonzalez-Sancho summarised current activities on mHealth:
- Code of Conduct on apps' data privacy
- Working Group on the validity and reliability of apps' data: A number of concerns have been raised such as:
  - How to address apps which by definition do not fall under the Medical Devices Directive, but which do in fact act as medical devices
  - Borderline products - the classification should be done only under one legislative act - MedDev Directive

  Going forward, these and other questions related to apps as medical devices will be addressed in the Software Group under the Medical Devices Regulation
- The eHealth Network's subgroup on mHealth will work on issues listed above. It has identified areas of specific relevance for mHealth and others to be discussed further in the general context of eHealth.
- Support for the large-scale deployment of mHealth with the WHO - ITU mHealth Hub in EU (project started on 1 March 2017)

Horizon 2020 Work Programme
Horst Krämer, DG CNECT, gave a brief overview of the status and direction of the next work programme of Horizon 2020, specifically Societal Challenge 1, "Health, Demographic Change and Wellbeing". The work programme is prepared against the background of the interim evaluation of Horizon 2020 and to be adopted in Q4 2017.

eHealth Week May 2017 and Estonian presidency eHealth event (October 2017)
Terje Peetso, DG CNECT, introduced the programme of eHealth week 2017, to be held in Malta from 10-12 May. The events is organised by the Commission, the Presidency, HIMMS and WHO. The overarching theme is Data for Health: the key to personalised sustainable care. The eHealth Week is preceded by the 11th Meeting of the eHealth Network on 9 May.

A High-level eHealth Conference will take place in Tallinn on 16 – 18 October 2017 under the auspices of the Estonian Presidency of the Council of the European Union. The title of the conference is "Health in Digital Society. Digital Society for health."

At the conference a stakeholder declaration to support the wider use of data in health sector is planned to be adopted and sessions will be organised to discuss various topics to be covered in the declaration. ECHAlliance is coordinating the preparatory work.

Connectivity needs for eHealth Services
Herve Dupuy, DG CNECT, addressed stakeholders with a status update on connectivity objectives and to ask for their input on what is the current situation of the broadband connectivity for European hospitals in view of current and future connectivity needs.

In September 2016 the Commission defined strategic connectivity objectives for the Digital Single Market by 2025 ("The Gigabit Society Communication"). Among others Gigabit connectivity (= 1Gbps and more) should be available for all main providers of public services, including hospitals and medical centres.

4.   Updates from DG SANTE

eHealth Network meeting and Joint Action supporting the eHealth Network (JAseHN)
Sevala Malkic, DG SANTE, gave brief recap from the 10th eHealth Network (eHN) meeting held on 21 November 2016 where following topics were discussed: The EU eHealth strategy towards 2020; Implementation of the eHealth Digital Service Infrastructure; Secondary use of health data; Legal agreement on cross-border exchange of health data; eID; mHealth; National eHealth strategies and projects and other eHealth related developments relevant for the eHealth.

Further, the draft agenda for the upcoming 11th eHN meeting was presented. This meeting will take a place on 9 May 2017 in Malta followed by the eHealth Week during 10-12 May.

Thereafter, Stephan Schug gave an overview of the JAseHN deliverables prepared for the 11th eHN meeting (presentation).

eHealth Network Multiannual Work Plan (MWP) 2018-2021
Sevala Malkic, DG SANTE, presented the work of the subgroup of the eHealth Network on MWP 2018-2021. The scope of the MWP 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

Two meetings were held on 27 January and 7 March and the next meeting is scheduled for June 2017. In the first meeting some of the representatives of the stakeholder groups were invited to participate.

Involvement of the stakeholders is important for the work of this group therefore the Commission has invited stakeholders to provide their comments to the draft MWP 2018-2020 with a deadline of 22 May.

The 3rd Joint Action on eHealth
Sevala Malkic, DG SANTE, gave an overview of the activities related to the 3rd Joint Action on eHealth foreseen in the Health Programme 2017. This JA 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. Deadline for the nomination of the Competent Authorities is 11 May 2017.

European Reference Networks (ERNs)
Tapani Piha, DG SANTE, presented the state-of-play of the ERNs based on Article 12 of the Directive of patients' rights in cross-border healthcare (2011/24/EU). The 3rd ERN conference and the kick-off meeting were held on 8-9 March in Vilnius. He presented a general overview of the IT system for ERNs (presentation).

eHealth Digital Service Infrastructure (eHDSI)
Sevala Malkic, DG SANTE, gave an overview of the developments with regards to the implementation of the eHDSI under the Connecting European Facility (CEF). This digital infrastructure will facilitate cross-border exchange of ePrescription (eP) and Patient Summaries (PS). The MSs have started the preparatory work with regard to the implementation of the Generic Services in their countries. The next Call for financial support for countries will open in May 2017 and it is expected that 6-9 new MSs will apply. The priority will be given to new countries joining the exchange of eP/eD and PS. Proposals can be submitted by EU Member States or EEA countries participating in the CEF Telecom programme. Important element of the impact criteria will be the possibility to link to the national infrastructure. CEF financing for the call for proposals for the Generic Services will provide a maximum of co-financing of EUR 1.000.000 per MS.

5. Working Groups report presentation

1) *Citizen and Data*: Anne Moen reported on the work of this large 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.

2) *Care Continuum*: Ana Carriazo of the Reference Sites Collaborative Network reported on the work of the group on Care Continuum: An initial draft report was issued in March with only little response. 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.

3) *Interoperability and Standards*: Catherine Chronaki pointed out that the group's work combines short and long term perspectives: standards have to be created on an iterative process. As examples for results from the group's research and consultations, she mentioned SQL as the most popular standard in documentation systems as well as IHE standards. The group is a vehicle to support all groups, especially Citizens & Data and Reimbursement.

4) *New and shifting Balances*: Kjartan Olafsson introduced the work of the group [presentation].

5) *Reimbursement*: Hanneke Fischer reported on the collection of input on the White Paper, among others through eHealth week. It is to be drafted during summer. A main purpose is to overcome a project oriented approach and to avoid duplication of digital and traditional processes.

6. AOB
Access to documents available at the eHealth Stakeholder Group's specific on-line site will remain exclusive to the members but flexibility on the number of representatives and experts per member can be reconsidered. However, any application for access via the Health Policy Platform must be supported by a Member or an Alternate.

Next meeting
The next meeting will be held on 24 October 2017 in Brussels.

<div align="center">***END***</div>

Members of the eHealth Stakeholder Group for the period 2016 – 2018

1. AESGP - Association of the European Self-Medication Industry

2. AGE Platform Europe

3. BEUC - The European Consumer Organization

4. CED - Council of European Dentists

5. CEN

6. COCIR - European Coordination committee of the Radiological, Electromedical and Healthcare IT Industry

7. CPME - The Standing Committee of European Doctors

8. DIGITALEUROPE

9. EASPD - European Association of Service providers for Persons with Disabilities

10. EFMI - European Federation for Medical Informatics

11. EFN - European Federation of Nurses Associations

12. EHTEL - European Health Telematics Association

13. EMSA - European Medical Students Association

14. EPF - European Patients' Forum

15. EPHA - European Public Health Alliance

16. ESC - European Society of Cardiology

17. ESR - European Society of Radiology

18. Eucomed

19. European Connected Health Alliance

20. GSMA

21. HL7 International Foundation

22. HOPE - European Hospital and Healthcare Federation

23. IHE-Europe

24. PCHA - Personal Connected Health Alliance

25. PGEU - Pharmaceutical Group of the European Union

26. Reference Sites Collaborative Network (RSCN)

27. The European Institute for Innovation through Health Data

28. UEHP - European Union of Private Hospitals

29. UEMO - European Union of General Practitioners

30. VPH Institute