Introduction
The fifth meeting of the eHealth Stakeholder Group (EHSG) was attended by invited members of the eHealth stakeholder group and Commission staff. The meeting was scheduled to be chaired by Despina Spanou, DG CONNECT, Director for Digital Society, Trust & Cybersecurity, (morning session) and Andrzej Rys, DG SANTE, Director for Health Systems, Medical Products and Innovation, (afternoon session).

Welcome and introduction
The meeting was opened by Despina Spanou, Director for the Directorate for Digital Society, Trust & Cybersecurity. The Director emphasised the importance of ongoing activities with regard to the digitisation in the health care sector, specifically (a) the citizen’s secure access to and sharing of health data, (b) the quality of data to promote research, disease prevention and personalised health and care (c) the deployment of digital tools for citizen empowerment and for person-centred care (d) the issues of privacy and cybersecurity.

The Director introduced the ‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market’ by the members of the EHSG.

Participants approved the agenda and the minutes of the previous meeting held on 24 October 2017 in Brussels without changes.

1. Recap on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market

The main points of the communication were presented by Miguel Gonzales-Sancho, DG CNECT, Head of Unit H3 – eHealth, Well-being and Ageing and Tapani Piha, DG SANTE, Head of Unit B3 Cross-Border Healthcare and eHealth: 1. eHealth is one of the priorities in the DSM strategy, 2. the important role of the EHSG in the implementation of the communication, 3. the use, the pooling and the sharing of data, 4. the potential in digitalisation of health and care by MSs, 5. the interoperability of health systems, 6. the collaboration of partners for enhancing personalised health and care, 7. the promotion of innovative solutions by SMEs and the industry in general, 8. the funding of the implementation of the communication by different instruments.

A discussion followed. The associations of medical professionals, medical students and patients expressed their positive reaction to the communication. The aim is citizen’s empowerment including health care professionals via concrete actions eg. development of digital skills, data privacy and security. It is a priority to safeguard data – ensuring cybersecurity and confidentiality.

2. Short recaps from recent events
a) Conference of Partners of the European Innovation Partnership on Active and Health Ageing
Anne Auffret, DG CONNECT, H3, summarised the main features of the 6th Conference of Partners of the European Innovation Partnership on Active and Health Ageing that took place on 27th and 28th February 2018 in Brussels, in order to take stock of what has been accomplished by the Partnership; to reflect on the future of the Partnership beyond the 2020 mandate; to bring together the demand and the supply sides; to enhance innovation to the market related to ageing.

It focused on the Digital transformation of health and care in the Digital Single Market. Particularly the contribution that EIP partners - Action Groups and Reference Sites - can make to the three priorities identified as part of the Digital Single Market strategy (mid-term review); (a) Enabling citizens’ secure access and use of health data across-borders; (b) Supporting a cross-border data infrastructure to advance research and personalised medicine; and (c) Empowering citizens through digital tools facilitating feedback and interaction with healthcare providers.

The Conference of Partners was also an opportunity for the European Commission to mobilise and engage a large constituency of stakeholders in the discussions around the future Multiannual Financial Framework and particularly on the potential to leverage co-investment in digital health and care transformation (including development and scaling up of data-enabled innovative digital solutions supported by cross-border connectivity and digital infrastructures). In some Member States, regional authorities are already engaged in discussions with national governments about the priorities for the next MFF (notably on FP9, CEF etc.). Different digital tools created by the partners can be used for capacity building and technical assistance to MSs. These tools can facilitate the relation between demand and supply side and upscale innovation technology.

On the one hand, the European Commission has very much taken into consideration the outcomes from EIP on AHA cooperation when defining the referred DSM health and care priorities (notably, the launch of the European digital health innovation repository, the digital health deployment twinning scheme or the Blueprint on digital transformation of health and care). On the other hand, the EIP on AHA will be an important platform for delivering on those priorities, through close collaboration between EIP on AHA partners, European Commission services, and other relevant actors involved in digital innovation of health and care in Europe. Active and healthy ageing is closely associated with harnessing and scaling-up of digital innovation. It forms a key aspect of the transformation of health and care in the context of the European DSM.

The group mentioned the different EIP on AHA actions taken place not only at national but also at regional and at local level. A new eHealth Action Plan will not follow the current one. The communication is a new step on the digitalisation of health and care.

b) Joint Declaration on Access to 1 million sequenced genomes in the EU by 2022

Miguel Gonzalez-Sancho, DG CONNECT, H3, informed the group for the session ‘Joining forces and data to personalise healthcare’ organised during the Digital Day 2018 that took place in Brussels on 10th April 2018. It is a commitment on linking databanks on an EU level to create stronger cross-border research partnerships, EU-wide research collaboration on personalised medicine and introduction of research results into clinical environment and practice. This commitment contributes to the following outcomes: (a) Stronger cross-border research partnerships; (b) EU-wide research collaboration on personalised medicine; (c) Introduction of research results into clinical environment and practice.

The declaration on “Towards access to at least 1 Million Sequenced Genomes in the European Union” is signed by 14 countries (Czech Republic, Estonia, Spain, Italy, Cyprus, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Finland, Sweden, United Kingdom, Bulgaria) and 2 other countries (Croatia and Greece) who signalled their intention to do it soon. Hopefully others will join in the future.

This initiative is supported by MSs and contributes to implementing the communication, notably, the stated goal of “better data to promote research, disease prevention and personalised health and care”.

3. Updates from DG CNECT
  a) Silver Economy Study
Horst Kramer, DG CONNECT, H3, provided an update of the study on the European Silver Economy. The so-called Silver Economy concept has caught the attention of policy makers and economic operators alike: the ageing population promises more economic growth and jobs. Next to being profitable for businesses, the Silver Economy should be connected to a positive and socially inclusive identity for older adults in Europe. According to the study, a supportive policy environment, with the right incentives and support measures will be key to facilitate this transition. Although intended to aid the Commission in its development of a European strategy, this study is also relevant to other policy makers in European member states and regions as well as industry decision makers.

The Silver Economy will rewrite the rules about market drivers in existing sectors as well as create wholly new industries, at the intersection of demographic and technological change, with major export potential. Many of these areas will however need new standards and policy mixes to facilitate their growth and earlier realisation of their benefits for older people.

The Silver Economy Awards complements the study.

b) Key results achieved from EU funded research and innovation on ICT for Active and Healthy Ageing

Carolien Nijenhuis, DG CONNECT, H3, gave the key findings of a new European Commission study which analyses the impact on society of EU-funded Research and Innovation in technology for active and healthy ageing. Active and Healthy Ageing has enjoyed an increasing presence over recent years in the key R&I European initiatives. The report includes recommendations for future R&I projects related to active and healthy ageing.

c) mHealth policy actions

Birgit Morlion, DG CONNECT, H3, gave an overview of DG CNECT mHealth activities to update the stakeholders:

Following the Green Paper on mHealth in 2014, following activities have taken place:

(a) Code of Conduct on apps' data privacy – industry led group (with several public consultations) drafted the Code of Conduct which is currently with the Article 29 Working Party under the Data Protection Directive. First feedback from the Article 29 WP was received in May 2017. The code was then revised by the drafting group, adapted to the comments received and streamlined with the upcoming GDPR. The revised version was be submitted in December 2017 to the Article 29 Working party, in accordance with the Article 27.3 of the Data Protection Directive for a positive opinion. The topic was scheduled on the agenda of the 115th meeting of the Article 29 Data Protection Working Party (10 and 11 April) and we are waiting for their official feedback;

(b) mHealth Hub project – a H2020 coordination and support action to link existing European research networks on mHealth in Europe. With the support of the WHO-ITU (the beneficiaries of this project), the selected national implementations will create precedence for mHealth at scale in Europe, pave the way for other member states to follow suit and serve as a transfer of knowledge and experience from the global WHO-ITU Be Healthy Be Mobile initiative to the mHealth Hub in Europe. In future, the mHealth Hub will serve as a standalone resource for EU member states to support them in deploying and regulating mHealth in their national health services. The Hub will will bring together researchers, projects, knowledge and lessons learnt from individual mHealth projects and clinical trials.

The project will, amongst other tasks, work on the development of a common European framework for the assessment / endorsement of mHealth applications, which are or will be integrated in the health care systems or clinical practice. This through the assessment of existing certification schemes and best practices for mHealth apps in European countries or regions and identification of similarities between deployed certification/endorsement schemes for mHealth in the European countries or regions.
The first results of this mapping will be discussed with the eHealth Network (who has a subgroup on mHealth consisting of the representative of the competent authorities) during their next meeting 15 May 2018.

(c) Study on safety of non-embedded software (together with Service, data access, and legal issues of advanced robots, autonomous, connected, and AI-based vehicles and systems) started end of 2017 as a result of the public consultation on the safety of apps and other non-embedded software of 2016. Contrary to what was expected this consultation did not demonstrate that Health and Wellbeing apps may pose certain risk to citizens’ health and safety e.g. apps counting steps used for monitoring depression or apps measuring weight used for monitoring heart failure. However, as the number of responses was not very high and they did not identify major problems with safety of apps and non-embedded software the feedback from this consultation cannot be considered very conclusive. That’s why for the moment the Commission did not take any action further to this consultation except the launch of the study which will last one year and will cover at least six Member States. In the context of this study a workshop on “The safety of non-embedded software in the health sector” is organised 19 April in Brussels to present and validate the first findings.

The group asked about the procedure of the consultation and expressed the view that the majority of devices are safe. The code of conduct is in guidance by the regulatory framework.

4. Feedback from the Members

Francesca Cattarin, The European Consumer Association (BEUC), gave an overview of the investigation on connected health devices from a Norwegian counterpart on ‘Consumer protection and privacy in blood pressure monitors and blood glucose meters for home use’. The main conclusion were: (a) Health data should not be for sale, (b) Health data should only be used for medical research and to improve patients safety and quality of care, (c) For consumers to embrace digital solutions, there is a need to guarantee privacy and data protection, guarantee the security of the system and raise awareness among patients and health care professionals.

The discussion followed the presentation was focused on the use of anonymised data, the privacy and confidentiality of data and the use of a simple, clear and understandable consent form by the data owner to share data with a third party.

5. Updates from DG SANTE

a) EHealth Network meetings

12th meeting, November 2017 (report)

The meeting discussed the EU strategy and activities on digital health, implementation of the Digital Service Infrastructure, eHealth interoperability and standardisation, patient access to health data and Telemedicine, among other things.

The minutest are available at [https://ec.europa.eu/health/ehealth/events/eu_20171128_en](https://ec.europa.eu/health/ehealth/events/eu_20171128_en).

13th meeting, May 2018 (agenda)

The 13th eHealth Network (eHN) meeting will take place on 15 May 2018 in Brussels. Several important topics will be discussed such as: the Commission Communication on digital transformation in health and care, interoperability and standardisation, implementation on eHealth Digital Service Infrastructure (DSI) (e-prescription and patient summary) and other eHealth related developments.
b) The materials will be available at [https://ec.europa.eu/health/ehealth/events_en#anchor0](https://ec.europa.eu/health/ehealth/events_en#anchor0), and are already available on the EHSG platform. The 3rd JA on eHealth

The 3rd Joint Action on eHealth (eHAction) funded 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.

It consists of eight work packages (WPs 1, 2, 3 and 8 are mandatory). The Coordinator of the eHAction is Portugal and kick-off meeting is foreseen to take a place in June in Lisbon.

The relation between EHSG members and eHAction is important in bringing the stakeholders around the table. Members of EHSG will be asked about their role in the next joint action.

c) The 2nd Joint Action (JAseHN) deliverables

*JAseHN Joint Action will end its mandate at the end of June 2018 when the third Joint Action (eHAction) will take over.*

JAseHN representatives gave a short presentation of main deliverables that will be discussed or adopted in the 13th meeting of the eHealth Network. Two deliverables will be put for adoption, one for discussion, two for information and two still in preparation.

Following two deliverables are scheduled for adoption:
- D5.2.1 eID specific Framework for eHealth & D5.2.2 Guideline on interoperability of electronic professional registries
- D7.5.2 Recommendation Paper on patient access to electronic health record information

Deliverables are available on the online platform for EHSG. EHN takes into account the useful recommendations of the JAseHN.

d) ERN

European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. The first ERNs were launched in March 2017 involving more than 900 highly specialised healthcare units from over 300 hospitals in 26 EU countries. 24 ERNs are working on a range of thematic issues including bone disorders, childhood cancer and immunodeficiency.

The latest main achievements of ERNs: the launch of a clinical patient management system (an IT platform) – it provides cross border advice on diagnosis, prevention and treatment on complex cases, supporting providers and patients; the development of the communication and awareness strategy – how to reach the patients; the further development of governance mechanisms.

e) eHDSI

The building of the eHealth Digital Service Infrastructure is progressing: 22 Member States have made a commitment to join the system, and it is expected that the first exchanges of e-prescriptions and patient summaries take place still in 2018.


There was no discussion on EHDSI.
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 are 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). He presented a set of best practices, the need of having specific reimbursement criteria for digital products and services and a set of recommendations for relevant stakeholders, for having a reliable reimbursement system based on specific reimbursement criteria.

2) Citizen and Data: Work group leader Anne Moen (EFMI) delegated Catherine Chronaki (HL 7 Foundation) to present the work of this group. She highlighted the issues of trust and access of data; data ownership; custodianship-curation-consent from the different perspectives of citizens, health professionals, SDOs and industry; health systems. Sources and types of health data: provider generated, patient generated data and peer groups.

3) Care Continuum: Work group leader Ana Carriazo (Reference Sites Collaborative Network) reported on the work of the group on Care Continuum. She presented the concepts of continuity of care, of integrated care and of ehealth. She highlighted the ehealth elements to improve continuity of care by improving access to health care services, enhancing care coordination and enabling self-management.

4) 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. Further she referred to ongoing work on the eStandards Roadmap Methodology: (a) trust and flow: the basis of well-functioning health systems, (b) eStandards Compass: respect for perspectives of stakeholders, (c) eStandards Roadmap Components: reusing eHealth artefacts, (d) Co-creation, Governance, Alignment: bringing them all together.

There was a call that the deliverables by the ESHG are brought to the attention of the eHealth Network. The Commission, acting as secretariat to the Network, will take the measures to make sure that the deliverables, once ready, are communicated to the Network and given appropriate handling.

7. AOB

Mandate of the current EHSJ

EHSJ ends its mandate in spring 2019. The Commission will discuss about its role and the new call in September 2018.

Next meeting
The next meeting will take place in 12 October 2018. The date will be confirmed to the Members of the EHSJ in time prior the meeting.

***END***
Members of the eHealth Stakeholder Group attended the meeting on 26 April 2018

1. AESGP - Association of the European Self-Medication Industry
2. AGE Platform Europe – The voice of Older Persons at European Union level
3. BEUC - The European Consumer Organization
4. CED - Council of European Dentists
5. CEN - Cenelec – European Committee for Standardization
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 - Medical Technology Industry in Europe
19. ECHA - European Connected Health Alliance
20. GSMA - Global System for Mobile Communications Association
21. HL7 International Foundation
22. HOPE - European Hospital and Healthcare Federation
23. IHE-Europe - Integrating the Healthcare Enterprise Europe
24. PCHA - Personal Connected Health Alliance
25. PGEU - Pharmaceutical Group of the European Union
26. RSCN - Reference Sites Collaborative Network
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 - Virtual Physiological Human Institute