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

eHealth-units

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9TH eHEALTH NETWORK 7 JUNE 2016, AMSTERDAM
COVER NOTE BY SECRETARIAT

Topic 6:   mHealth

Issue at stake
The Commission will present five policy actions for information and discussion: **Public consultation on safety of apps and other non-embedded software (to be launched in June)** Under the Digital Single Market Strategy, the Commission is exploring ways to adjust the existing EU legislative framework on general product safety, consumer rights and e-commerce to appropriately cover safety and liability issues related to the digital products in general, including health apps. The Commission will launch a public consultation on the safety of apps and other non-embedded software in Q2 of 2016 to gather views on possible EU tools to support safety and avoid adverse impacts of non-embedded software. **Draft Code of Conduct on privacy for mobile health applications** The European Commission is facilitating a code of conduct on mobile health apps which covers data privacy and data security. A drafting team consisting of industry members was set up in March 2015 The first draft was presented at an open stakeholder meeting in December 2015 and was subsequently open for consultation until mid-January. The draft is being currently finalised and will be submitted to the Article 29 Working Party (composed of all MS data protection authorities) for their endorsement. **Development of EU quality standards for mHealth apps by CEN** The European Commission 2016 Rolling Plan for ICT Standardisation includes an action to develop European standards to provide guidance to the eHealth and wellness apps' developers by setting out quality criteria and principles to be followed throughout the app development life cycle. The British Standards Institution (BSI) has developed a publicly available standard "PAS 277:2015 Health and wellness apps – Quality criteria across the life cycle – Code of practice" which will be the basis for the European standard. BSI will be in lead for this standardisation action which will be taken forward in CEN (TC251). Support from at least four Member States is needed to start a working item in CEN (TC251). **Draft guidelines for assessing validity and reliability of mHealth apps** In February 2016 the Commission set up a working group to develop guidelines for assessing data validity and reliability of mHealth apps. 20 organisations representing civil society, research institutions and industry were selected as members based on a public call for expression of interest. Member State public authorities were invited to join the group. Other stakeholders will be able to contribute to the draft guidelines via online consultations and open stakeholder meetings. The guidelines are expected to be drafted by the end of 2016. The first draft was presented and discussed at an open stakeholder meeting on 4 May 2016. The second draft incorporating the feedback from the stakeholders will be made public by the end of May to be presented and discussed at the eHealth Week in Amsterdam. The draft guidelines will be presented and eHN members are invited to express their views on the draft.

Report on the eHealth Network subgroup on mHealth

The mHealth sub-group was set up by the eHealth Network at its 23 November 2015 meeting to facilitate exchange of information and to produce a report on national mHealth strategies with recommendations for further collaboration on mHealth at European level by the 10th meeting in November 2016.

The first meeting of the subgroup took place on 5 April 2016 (the minutes of the meeting are attached). Estonia was appointed as the new Chair of the subgroup. Identification, authentication and legal issues relating to data protection were raised as most important issues of concern at the first meeting. A short questionnaire is envisaged to be sent out in June to map and collect information on the strategic approaches and activities at the national level. In addition a mapping of existing EU level activities will be carried out to identify the gaps and identify areas for collaboration that could complement the existing initiatives related to mHealth.

Summary of document

Draft report "EU guidelines on assessment of the reliability of mobile health applications" (will be send next week)

Draft Code of Conduct on privacy for mobile health applications (will be send next week)

Meeting minutes of the eHealth Network subgroup on mHealth (attachment 6.1)

Format of procedure in the eHN

Paul Timmers, Director DG CONNECT gives an update on the policy actions related to mHealth.

The facilitator of the guidelines development will present the draft guidelines for assessing the validity and reliability of apps. Members are asked to express their views on the draft.

The chair of the mHealth subgroup will give an overview of the group's activities and the state of play of the report on national mHealth strategies. Members are invited to express their views on the topics expected to be covered in the report.