



8TH EHEALTH NETWORK 23 NOVEMBER 2015
COVER NOTE BY SECRETARIAT

Topic 3: Policy developments in mHealth and a proposal for setting up a mHealth subgroup

Issue at stake

At the 7th eHealth Network Meeting an overview was given on the follow-up actions to the public consultation on the Green Paper on mHealth. The members of the eHealth Network further received written information about the follow-up actions (Ares (2015) 2426136 – 10/06/2015) and outcomes of the stakeholder meeting on 6 July 2015 on quality and reliability of mHealth apps (Ares (2015)2979284 – 15/07/2015).

Under this agenda topic an update on the follow-up actions to the mHealth Green Paper will be presented.

Furthermore, the eHealth Network is invited to decide to establish a sub-group on mHealth.

Summary of document

Annex 1 provides an overview of the follow-up actions to the mHealth Green Paper public consultation.

Annex 2 includes a proposal to establish eHealth Network sub-group on mHealth to facilitate collaboration between interested Member States.

Format of procedure in the eHN

The Commission Chair will introduce the topic and give the floor to the DG CONNECT representative who will present an update on the mHealth Green Paper follow-up actions and introduce the proposal to establish a sub-group on mHealth.

The eHealth Network members are invited to:

- Take note of the presentation on the state-of-play and give their feedback on the follow-up actions.
- Decide to establish a Network sub-group on mHealth.
 - The eHealth Network Members are invited to give their position on the proposal and express their interest to participate in the sub-group.
 - A Member would need to volunteer as the Chair and as the Rapporteur.
 - The Members should consider in advance their interest in participating in the work of the subgroup. A group of a maximum of 15 Members, including the Chair and the Rapporteur, is envisaged.

OVERVIEW OF THE FOLLOW-UP ACTIONS TO THE MHEALTH GREEN PAPER PUBLIC CONSULTATION

The Commission's public consultation on the [Green Paper on mobile health](#) (April 2014) collected stakeholder views on how to tackle the challenges to the mHealth market in Europe. The [results of the public consultation](#) were published in January 2015.

As a follow-up to the Green Paper on mHealth and the public consultation DG CONNECT has organised two stakeholder meetings to further discuss possible policy actions, in particular as regards data protection and quality and reliability of mHealth apps. The first open stakeholder meeting took place on 12 May 2015 in Riga ([summary of the meeting](#)). The second meeting specifically dedicated to quality and reliability of mHealth apps took place on 6 July 2015 in Brussels ([summary of the meeting](#)).

The main follow-up actions are as follows:

1) Legal framework

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. In the context of medical devices regulatory framework, the MEDDEV guidance and the manual on borderline and classification is being updated to clarify qualification and classification of stand-alone software and apps used in healthcare within the regulatory framework of medical devices (led by DG GROW).

2) Privacy Code of Conduct for mobile health apps

The Commission is facilitating the development of an industry-led code of conduct for mobile health apps, covering privacy and security issues. A drafting team, consisting of industry members, was set up in March 2015.

The Code of Conduct is targeted at app developers and its purpose is to provide easily understandable guidance on how to respect EU data protection rules in relation to mHealth apps. The aim of the code is to help promote users' trust and it can be used as a competitive advantage by those who are signatory to it. Furthermore, it will help to raise awareness of the data protection rules and facilitate compliance with data protection rules at EU level.

An overview of the process, approach and methodology of the code of conduct has been presented to stakeholders at two open stakeholder meetings. A first draft of the code will be presented at a meeting that is taking place on 7 December. Once finalised, the aim is to submit the code of conduct to the Article 29 Working Party established under the Data Protection Directive (EU MS Data Protection Authorities) for approval.

3) European standard on quality criteria for the development of health and wellness apps

In order to enhance the quality of health and wellness apps, the Commission has proposed in the 2016 Rolling Plan for ICT standardisation a standard on quality criteria for the development of health and wellness apps (e.g functionality, usability, reliability). The standard could be based on the publicly available specification PAS:277 recently published by the British Standards Institution (BSI) and would provide guidance to app developers by setting out principles to follow throughout the app development life cycle, including testing, maintenance and risk management.

4) Collaboration on common assessment methodologies

In the two open stakeholder meetings stakeholders confirmed that it would be useful to work on common assessment methodologies for mHealth. The Commission is planning to set up a working group representing different stakeholders to develop guidelines for assessing data validity and reliability of mHealth apps, in particular in the context of linking data to the electronic health records. These guidelines could be used by public authorities, health care providers, professional and patient associations, developers and other relevant bodies. The group will have a membership of maximum 20 organisations. Civil society, research and industry members will be selected based on a public call for expression of interest open until 4 December 2015. Member State public authorities are invited by the Commission to join the group. Public authorities from 9 Member States (Austria, Malta, Portugal, United Kingdom, Poland, Czech Republic, France, Spain and Sweden) have already expressed their interest in a response to the invitation sent in July.

5) Supporting research and innovation

Actions in the Horizon 2020 work programme for 2016-2017 include funding of research and innovation in the field of big data, digital security for healthcare, empowering patients and citizens, and improving digital health literacy. A grant to WHO and ITU is foreseen for establishing an EU mHealth hub.

The mHealth hub is expected to become the focal point for expertise on mHealth in the EU. The hub should act as a convening platform to bring together experts and innovators for institutionalising best practices in mHealth whilst avoiding the creation of silos and fragmentation in mHealth knowledge across the EU. One of the objectives will be to support the development and implementation of mHealth strategies in selected pilot countries or regions.

PROPOSAL TO ESTABLISH AN eHEALTH NETWORK SUB-GROUP ON mHEALTH

1. Context

mHealth is a fast growing field with around 165,000 health apps¹ currently available on the two leading platforms (iOS, Android). The large number of lifestyle and wellbeing apps available with no clear evidence on their quality and reliability is raising concerns about the ability of consumers to assess their usefulness, thus potentially limiting their effective uptake for the benefit of public health.

Ensuring quality of input data is also essential for linking apps to the electronic health records and for the effective uptake in clinical practice. With the increasing use of apps for health and chronic disease management, the demand from users to be able to link data from apps to their personal health records is expected to grow.

There are already concrete examples in the Member States on the uptake of mHealth solutions in healthcare systems (e.g monitoring for chronic heart failure patients, diabetes management). In some Member States initiatives aiming to develop quality and assessment frameworks for health apps have been launched as well as pilots for including use of apps in the reimbursement schemes.

2. Purpose and deliverables

The sub-group should collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States.

Topics to be considered by the sub-group could include:

- regulatory approaches;
- quality and assessment frameworks;
- need for guidelines and recommendations to users, incl. health professionals;
- education and awareness raising of users, incl. health professionals;
- reimbursement strategies;
- linking data from apps to the electronic health records;
- a common repository of approved lifestyle and wellbeing apps.

The sub-group should produce a report on national mHealth strategies with recommendations for further collaboration on mHealth at European level by the 10th meeting in autumn 2016.

3. Organisation

The subgroup should consist of 10-15 Members, including a Chair and a Rapporteur. Health and Wellbeing Unit of the DG CONNECT will provide the logistical support to the group.

For the year 2016, 2-3 face-to-face meetings is foreseen.

¹ [Patient adoption of mHealth](#), IMS Institute for Health Informatics