mHealth assessment guidelines

*Introduction*

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Context - Green Paper on mHealth

The **eHealth Action Plan 2012-2020** recognised potential benefits and challenges related to mHealth apps

**European Commission Green Paper on mHealth** *(10.04.2014)*

- Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps

**Public consultation** *(April-July 2014)*

- Summary of the results published in January 2015
Mobile health

"medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistance (PDAs), and other wireless devices" (WHO, 2011)
Why is it important?

- health monitoring
- lifestyle
- daily activity

With this data, your doctor will make a better diagnosis & give the best treatment.

Patients can take control of their health: accessing their records or getting reminders about their medication.
Green Paper on mHealth (April 2014)

*Issues addressed in the public consultation:*

- Data protection
- Legal framework
- Patient safety and transparency of information
- mHealth role in healthcare systems
- Reimbursement models
- Interoperability
- Liability
- Big data
- Research and innovation
- International cooperation
- Web entrepreneurs' market access
Outcome of the public consultation
Safety and transparency

- Large number of lifestyle and wellbeing apps available with no clear evidence on their quality and reliability
- Need for certification schemes/quality labelling
- Common criteria, standards, protocols and guidelines are needed for patient safety
- Importance of sharing and transferring best practices
- Education and information for end-users
Outcome of the public consultation

Legal Framework

- Safety and performance requirements of lifestyle and wellbeing apps should be clarified, through legislation, guidance or certification/quality labelling

- Need to clarify the borderline between apps that are medical devices and others, e.g. by guidelines

- **Strengthened enforcement** of medical device and data protection rules needed
Open stakeholder meetings

- Riga, 12 May 2015 - eHealth Week
- Brussels, 6 July 2015 - meeting on quality and reliability of mHealth apps

Outcome

- A common understanding, that there are health and safety risks related to mHealth apps which need to be addressed
- Support for developing guidelines and common assessment methodologies
Main follow-up actions

- **Guidelines for the assessment of the validity and reliability of mHealth apps**

- **Legal clarity**
  - medical devices legislation
  - consultation on safety of non-embedded software

- **Privacy and security**
  - Code of Conduct on privacy for mHealth apps

- **Quality standards to provide guidance to the app developers**
Guidelines development process

Aim

- To provide practical guidance and tools for assessing validity and reliability of mHealth apps data, covering possibly also other aspects related to the mHealth apps quality

A core drafting team was set up in February 2016

- a working group representing civil society, academia, industry, public authorities
- Mandate to draft the guidelines by the end of 2016

An open and iterative process

- Open consultations and meetings with the stakeholders (dedicated meetings in Brussels, conferences – eHealth Week, European Health Forum Gastein etc)
Guidelines - main principles

- Voluntary nature of the guidelines
- Address the needs of different target groups applying the guidelines (public or private bodies, health professionals, payers etc)
- Universal and applicable across Europe
- Build on the existing concepts and frameworks as much as possible, reflect the best European or worldwide expertise and best practice
- Involve all the interested stakeholders in the process
Legal clarity

- **Medical devices legislation**
  - New regulations negotiated in the Council and EP
  - Updated MEDDEV guidance 2.1/6 on qualification and classification of stand-alone software
  - Updated Manual on Borderline and Classification

- **Public consultation on safety of apps and other non-embedded software (launched 9 June 2016)**
  - open until **15 September**
Privacy and security

- **Code of Conduct on privacy for mobile health apps**
  - covering data protection principles to be followed in the development of mHealth apps (apps processing health data)
  - Industry drafting team (process started in Apr 2015)
  - Submitted to the endorsement of Art 29 Working Party under the Data Protection Directive
European quality standards

- European standard on quality criteria for the development of health and wellness apps
  - PAS 277:2015 on "Health and wellness apps – Quality criteria across the life cycle" (BSI, UK) suggested as a basis for a standardisation action to be taken forward by CEN
Thank you!

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