Open stakeholder meeting on mHealth assessment guidelines

Introduction

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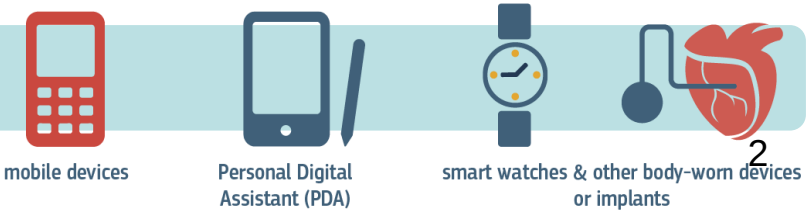
Context: Green Paper on mHealth (April 2014)

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*



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

Guidelines for assessing the validity and reliability of mHealth apps data

The idea was introduced at the 6 July meeting

Focus on:

- Health and wellbeing apps
- Reliability and validity of data to be linked to the electronic health records
- Common criteria and assessment methodologies

Vision

- Healthcare providers (HCP) able to recommend that a patient uses an app in a treatment, prevention or care plan, confident that the app and its data would be reliable

- HCP and patients are able to work with patient generated data by linking apps with the electronic health records or personal health records

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*

Process

- *Working Group – the core drafting team*
- *Facilitator – Consard Ltd (Andrew Ruck, Susie Wagner Bondorf, Charles Lowe)*
- *Open consultations and meetings with the stakeholders (two meetings in Brussels, conferences – eHealth Week, European Health Forum Gastein)*
- *Final draft by the end of 2016*

Related initiatives (1)

- *Data protection*
  - industry-led privacy code of conduct for mobile health apps (process started in Apr 2015)
- *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 (two new entries on mobile apps for the assessment of moles)
- *Digital Single Market strategy (6 May 2015)*
  - Public consultation on safety of apps and other non-embedded software (to be launched in May 2016)

Related initiatives (2)

- *European standard on quality criteria for the development of health and wellness apps*
  - based on the PAS 277:2015 on Health and wellness apps – Quality criteria across the life cycle (UK)
  - does not cover requirements for apps that are classified as medical devices
- *Policy discussions at the Member States level (eHealth Network subgroup on mHealth)*
- *WHO-ITU innovation hub for mHealth (under H2020)*

Thank you!

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