European Commission initiatives on e- and mHealth

Fundamental Rights Forum, 22 June 2016

WG 24: E-health: improving rights fulfilment through innovation

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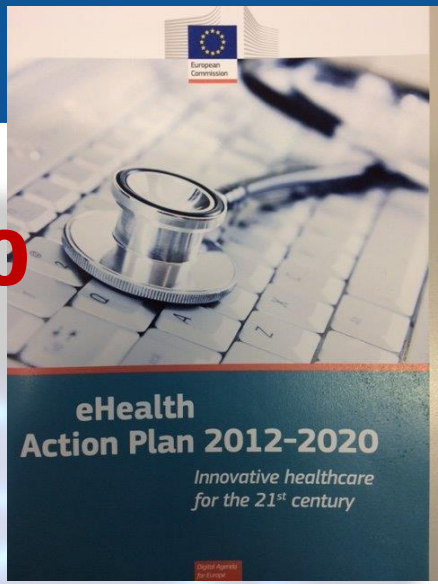
eHealth Action Plan 2012 – 2020



Operational objectives:

- ⇨ Achieve wider interoperability of eHealth services ;
- ⇨ Support research, development and innovation;
- ⇨ Ensure wider deployment & facilitate uptake;
- ⇨ Promote international cooperation.

mHealth

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

Green Paper on mHealth and public consultation (2014)
→ asking stakeholders for their inputs on how to overcome the main challenges to mHealth deployment, e.g.:

- data protection
- the legal framework
- patient safety
- mHealth's role in healthcare systems
- international cooperation and web entrepreneurs' market access

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

mHealth

Code of Conduct on mHealth apps

Context and scope

- Green Paper consultation identified importance of **strong privacy and security** tools to increase trust in mHealth apps;
- Agreement to work on a Code of Conduct on mHealth apps at stakeholder meeting in March 2015
- **Legal basis** in Article 27 of the Data Protection Directive (Article 40 of the GDPR);
- Code of Conduct as a **voluntary** instrument;
- Scope: covering **data protection principles** to be followed in the development of mHealth apps (apps processing health data);

Objectives and process

- Objectives:
  - Raising awareness and facilitating compliance with data protection rules at EU level;
  - Increased trust by citizens;
  - Competitive advantage.
- Parties involved:
  - drafting team made up of industry members;
  - the EC facilitating and coordinating the process;
  - external editor to assist the drafting;
- Current state of play: Draft Code is finalised and was submitted to the **Article 29 Working Party** for their review on 7 June 2016 http://bit.ly/1Y66Sdp

Content of the Code of Conduct

- About the Code of Conduct:
  - Introduction
  - Objective
  - Scope: mobile apps which process personal data, including health data
  - Governance

- Practical Guidelines for app developers
- Annex I – Data Protection Impact Assessment (template)
- Annex II – Privacy notice (sample)

Practical Guidelines – I

- **User's consent:** free, specific and informed (explicit consent for health data);
- **Main principles**: Purpose limitation, data minimisation, Privacy by design and Privacy by default;
- **Information requirements**: name and contact of the developer, purpose of processing, categories of data;
- **Retention of the data**: not longer than necessary;
- **Security measures**: technical and organisational measures to protect personal data against accidental or unlawful destruction, loss, alteration, disclosure, access etc.;

Practical Guidelines – II

- Use of **advertisement** in apps: context-related ads – Opt-out, personalised ads – Opt-in;
- **Secondary use** of the data: compatible with the original purpose, otherwise new consent needed;
- **Disclosure** to third parties for processing operations: information of the user, binding legal agreement;
- **Transfer to third countries**: based on legal guarantees (such as adequacy decisions, European Commission Model Contracts);
- **Personal data breaches**: checklist, notification duty;

mHealth

Guidelines on the assessment of data validity and reliability of mHealth apps

Guidelines on validity and reliability of mHealth apps

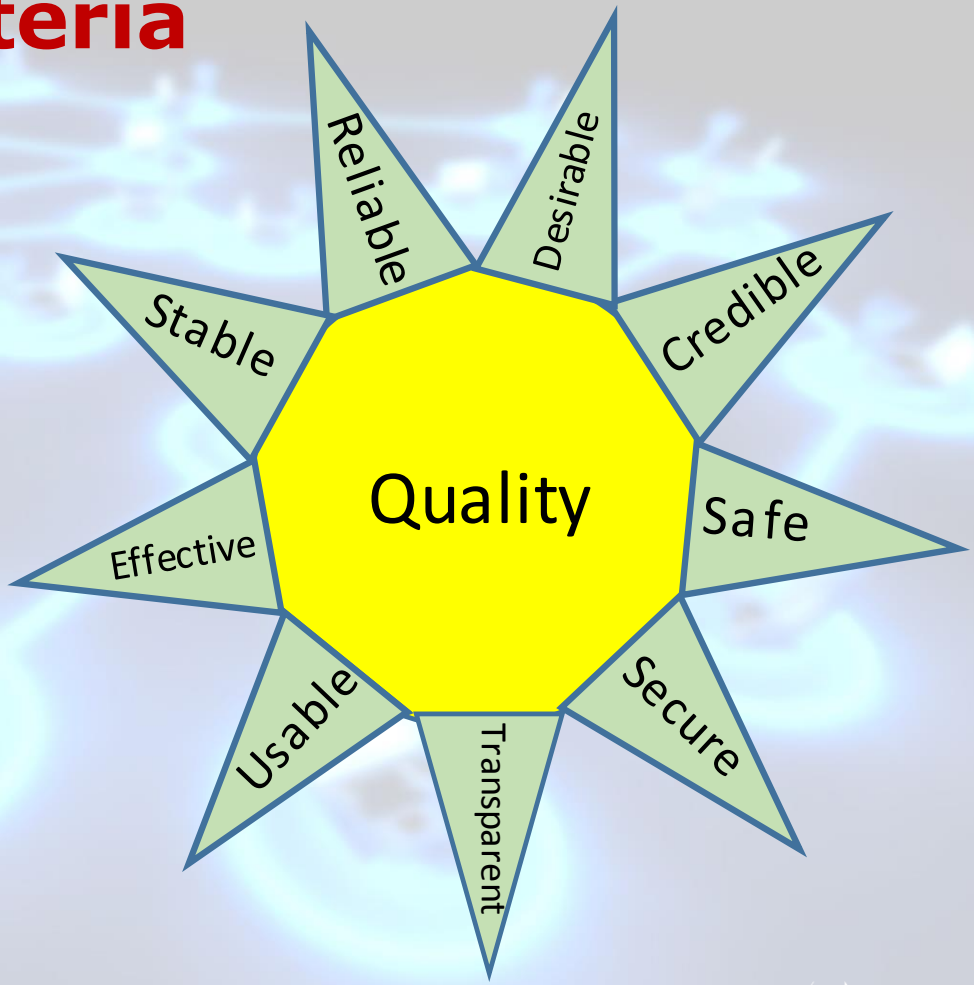
- Green Paper consultation identified the need for **certification schemes** to assess mHealth apps;
- A broad scope of health and wellness apps, **excluding** apps that are qualified as **medical devices**;
- **Voluntary** guidelines that could be used by public authorities, health care providers, professional and patients associations and others;
- For the purpose of linking apps to **electronic health records**;

Guidelines development process

- Core drafting team - a working group of 30 members representing civil society, academia, industry, public authorities (set up in February 2016)
- Open consultations and dedicated meetings with any interested stakeholders
- Second draft open for comments until end of August: surveymonkey.co.uk/r/TYRSX2K

Assessment criteria

A total of nine criteria have been identified based on the analysis of existing assessment frameworks that are relevant for the assessment of mHealth apps.



mHealth

Legal framework

Legal framework

- **Unclear application of EU rules on medical devices**
  - Revision of manual on borderline and classification and MEDDEV guidance (finalization after Medical Device Regulations adoption)
- **Lack of protection in case of unsafe or defective digital products (e.g. lifestyle and wellbeing apps)**
  - Public consultation on the safety of apps and other non-embedded software (next slide)

Public consultation on apps - I

- **Purpose**:
  - to gather input from stakeholders on their **experience** related to the safety of apps and other non-embedded software;
  - to obtain a better understanding of the **risks and problems** that non-embedded software pose and how these problems are dealt with;
  - the views gathered will help to define potential next steps and future policies at the EU level.

Public consultation on apps - II

- **Scope**: software and apps which are neither embedded, nor contained in a tangible medium at the time of their availability to consumers (non-embedded software);
- **Examples**: health and well-being apps, digital models for 3D printing or apps controlling electronic appliances;
- **Timeline**: open for public consultation until 15 September http://bit.ly/1U3tEmE

Thank you!

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