European Commission initiatives on e- and mHealth

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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.
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.
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](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;
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
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](http://bit.ly/1U3tEmE)
Thank you!

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