eHealth/mHealth

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eHEALTH ACTION PLAN 2012 – 2020

Published by the Commission on 7 December 2012

Tackles eHealth challenges related to:

- PERSONAL HEALTH (CHRONIC DISEASE MANAGEMENT, PREVENTION AND HEALTH PROMOTION)
- HEALTH SYSTEMS (UNLOCKING INNOVATION, ENHANCING PATIENT-CENTRIC CARE, ENCOURAGING ORGANISATIONAL CHANGES, CROSS-BORDER CARE, UNIVERSALITY, EQUITY…)
- LEGAL / MARKET ASPECTS (IMPROVING LEGAL AND MARKET CONDITIONS)

Green Paper - context

The **eHealth Action Plan 2012-2020** recognised current and potential benefits of mHealth apps, and potential associated risks

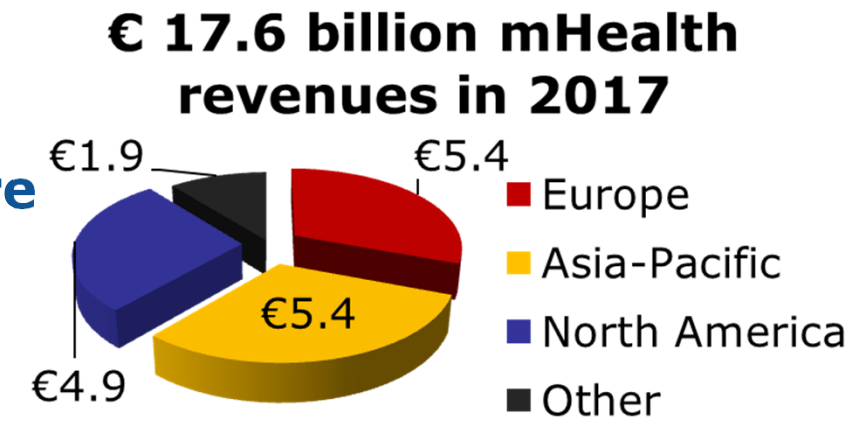
- **more clarity needed on legal framework**
- **questions on the use of collected data**
- **demand for quality and transparency**

⇨ *eHealth Action Plan announced the Green Paper on mHealth*

mHealth potential – "triple win"

- **Potential for citizens**
  - → ***More empowered patients, self-management, engagement***
  - → ***More accurate diagnosis and treatment***
  - → ***Earlier detection, increased prevention***
  - → ***Quality of life***
  - → ***Access***

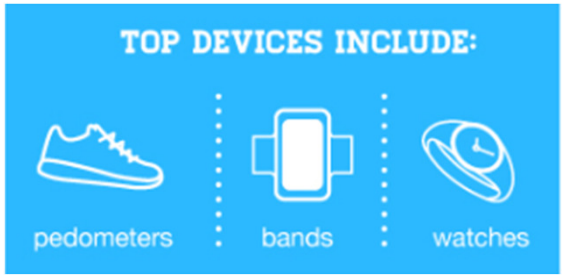
- **Potential for healthcare**
  - → ***more efficient and sustainable healthcare***



- **Market potential**

Trends in mHealth

Health and fitness apps are among the **fastest growing** apps categories in terms of use, with **time spent** in health and fitness apps **growing 51%** over the year to August 2014. Localytics, September 2014



Apps + Wearable Devices = The Future of Mobile Health

More than half of today's health and fitness app users plan to incorporate a **wearable device** into their lives. Mobiquity, The Appification of Health and Fitness, April 2014

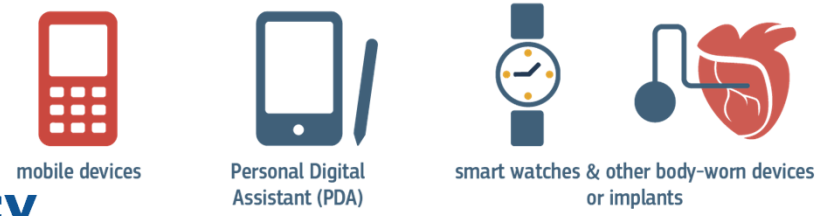


Mobile Health & Wellness 2014, Havas Worldwide Tonic

Green Paper on mHealth

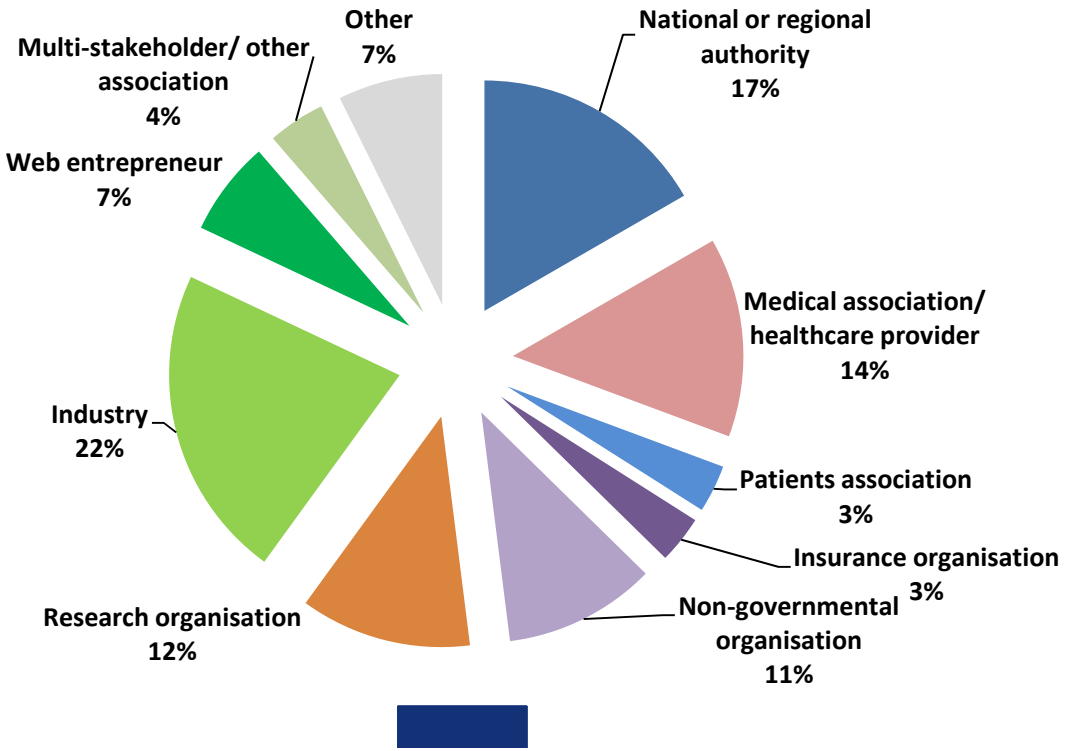
*The **Green Paper (closed July 2014)** asked stakeholders for their input on how to overcome the main challenges to mHealth deployment:*

- **data protection**
- **big data**
- **legal framework**
- **safety and transparency**
- **mHealth's role in healthcare systems**
- **interoperability**
- **reimbursement models**
- **liability**
- **R&I**
- **international cooperation**
- **web entrepreneurs' market access**



Outcome of the consultation

- ***211 responses*** received
- 71% from organisations / 29% from individuals



Results of the consultation
Privacy and security

- ***Importance to give citizens control over their data***
- *User's **consent** and **access controls** are crucial*
- ***Strong privacy and security tools** are needed to build users' trust*
- ***Data encryption** both "in transit" and "at rest"*
- ***Authentication mechanisms**, e.g. digital certificates, biometric parameters, tokens etc.*
- *Importance of **secured networks settings** to prevent data interception*
- ***Data minimisation, data protection by design and default***

Results of the 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*

Results of the consultation
Safety and transparency

- *Guarantee of quality and independency of information*
- *Safety requirements/quality guidelines*
- *Need for (voluntary)* ***certification schemes/quality labelling*** *to assess mHealth apps*
- *Sharing and transferring* ***best practices***
- *Importance of* ***standards*** *and* ***guidelines*** *for patient safety*
- *Setting-up of (national)* ***bodies to review*** *mHealth apps*

Next steps (1)

- **Continue involving stakeholders** to assess and develop policy actions
  - **Privacy and security - code of conduct (DPD Art 27)**
  - **Quality and reliability (-> certification / labeling)**
    - Build on existing public and private initiatives : NHS, BSI (PAS 277)
    - Common quality criteria for
      - health apps (accuracy, functionality, usability, transparency, …)
      - app development process (app life cycle)
    - Collaboration between public authorities on common assessment methodologies, mutual recognition and a common platform for certified health apps
    - EU guidelines for assessing the validity of data for the purpose of linking apps to the EHRs

Next steps (2)

- **Assessment of legislation need for safety of digital goods (applicability of GPSD)**
- Revision of medical devices guidelines (finalisation after adoption of medical devices regulation)
- Possible extension of the EU eHealth Interoperability Framework to cover mHealth
- Adaptation of consumer legislation to cover digital

Next steps (3)

- Follow-up actions to support mHealth deployment under **Horizon 2020 (WP2016/2017)**
  - **Patient empowerment**
  - **Use of big data in healthcare**
  - **Digital security**
  - **Digital health literacy**
  - **Interoperability**
  - **Support Member States** in deploying mHealth

Thank you for your attention!

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Website: http://bit.ly/EUeHealth
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