Green Paper on mHealth: what's next?

Pēteris Zilgalvis, J.D.,
Head of Unit, Health and Well-Being, DG CONNECT
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1.1 Green Paper on mHealth

The Green Paper...

- was adopted on 10 April 2014
- launched a three months consultation asking stakeholders for their views on issues and barriers related to mHealth
- inputs will help identify the way forward at EU level so that mHealth can reach its full potential
1.2 Staff Working Document (SWD)

The Green Paper is accompanied by a **SWD on the EU legal framework applicable to lifestyle and wellbeing apps**

→ to raise awareness among stakeholders on EU rules in the field (e.g. data protection, medical devices, consumer protection)
2.1 Outcome of the consultation

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

Geographical distribution of responses

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<th>Individuals</th>
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Legend: Organisations, Individuals
2.2 Distribution of responses by sector

- National or regional authority: 17%
- Medical association/healthcare provider: 14%
- Patients association: 3%
- Insurance organisation: 3%
- Non-governmental organisation: 11%
- Research organisation: 12%
- Industry: 22%
- Web entrepreneur: 7%
- Multi-stakeholder/other association: 4%
- Other: 7%
3.1 Data protection and security

Issues:
- Lack of data security
- Lack of users' trust
- Concern of data misuse

Requested:
- Strong privacy and security principles
- Data encryption and authentication
- Secured networks to prevent data interception
3.2 Legal framework

**Issues:**
- Unclear application of EU rules in the field
- Legal vacuum regarding safety aspects of lifestyle and wellbeing apps

**Requested:**
- Safety and performance requirements of lifestyle and wellbeing apps not adequately covered → need for legislation or soft-law (e.g. quality labels, code of conduct)?
- Stronger enforcement
3.3 Patient safety and transparency

Issues:
- Lack of transparency and information on reliability
- Quality and safety

Requested:
- Guarantee of quality and independency of information
- Evidence on effectiveness of mHealth solutions
- Safety requirements/quality guidelines
3.4 Other issues

- More **evidence** on economic benefits needed
- Lack of **interoperability** between mHealth solutions and between mHealth solutions and EHRs
- Lack of **reimbursement** models and lack of incentives for healthcare professionals to adopt mHealth solutions
- Need for more **research** in the field of mHealth
- Barriers for **web entrepreneurs** to access the market
4.1 Next steps

- Publication of a **summary report** in December 2014, providing an overview of the comments and actions put forward by respondents

- Follow-up actions to support mHealth deployment under **Horizon 2020**
  - Use of big data in healthcare
  - Cybersecurity

- **Support Member States** in deploying mHealth (e.g. WHO-ITU initiative)
4.2 Next steps

- Close collaboration with **Member States** and strengthening cooperation at the **international** level
- **Involving stakeholders** in assessing and developing policy actions
- Potential launch of an **Impact Assessment** in 2015 (if deemed necessary)
- **Further policy actions** to be announced in 2015
Thank you for your attention

peteris.zilgalvis@ec.europa.eu

@PZilgalvis