European Commission

Green Paper on mHealth: what's next?

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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
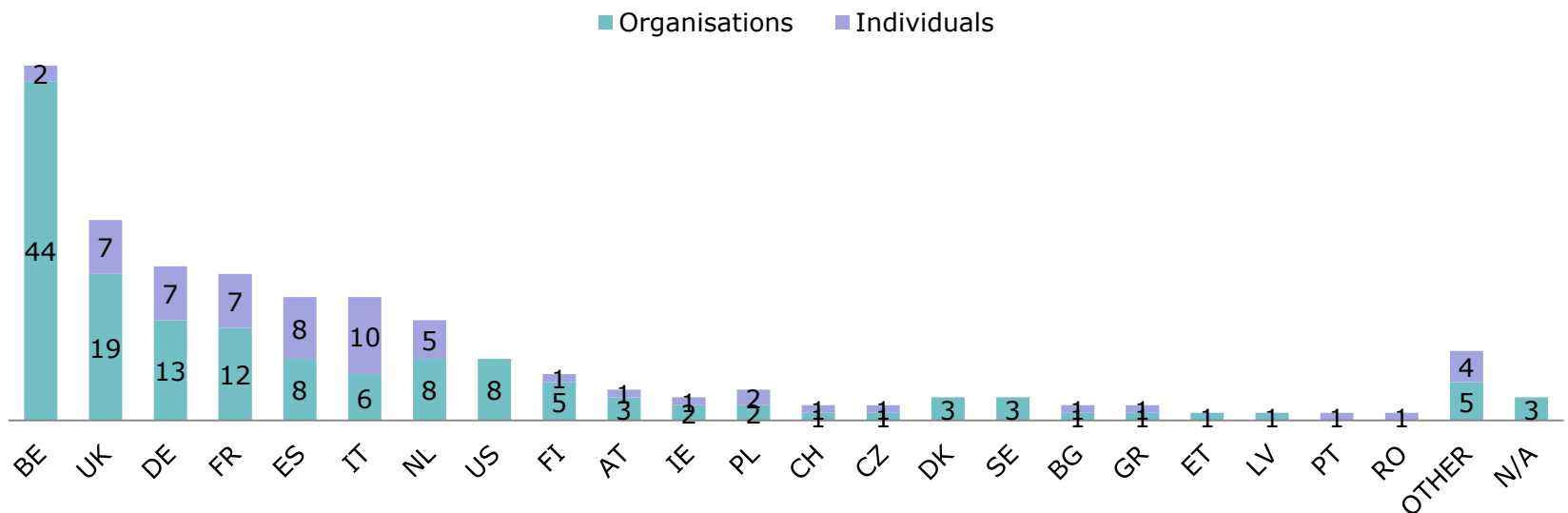
1.2 Staff Working Document (SWD)

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)
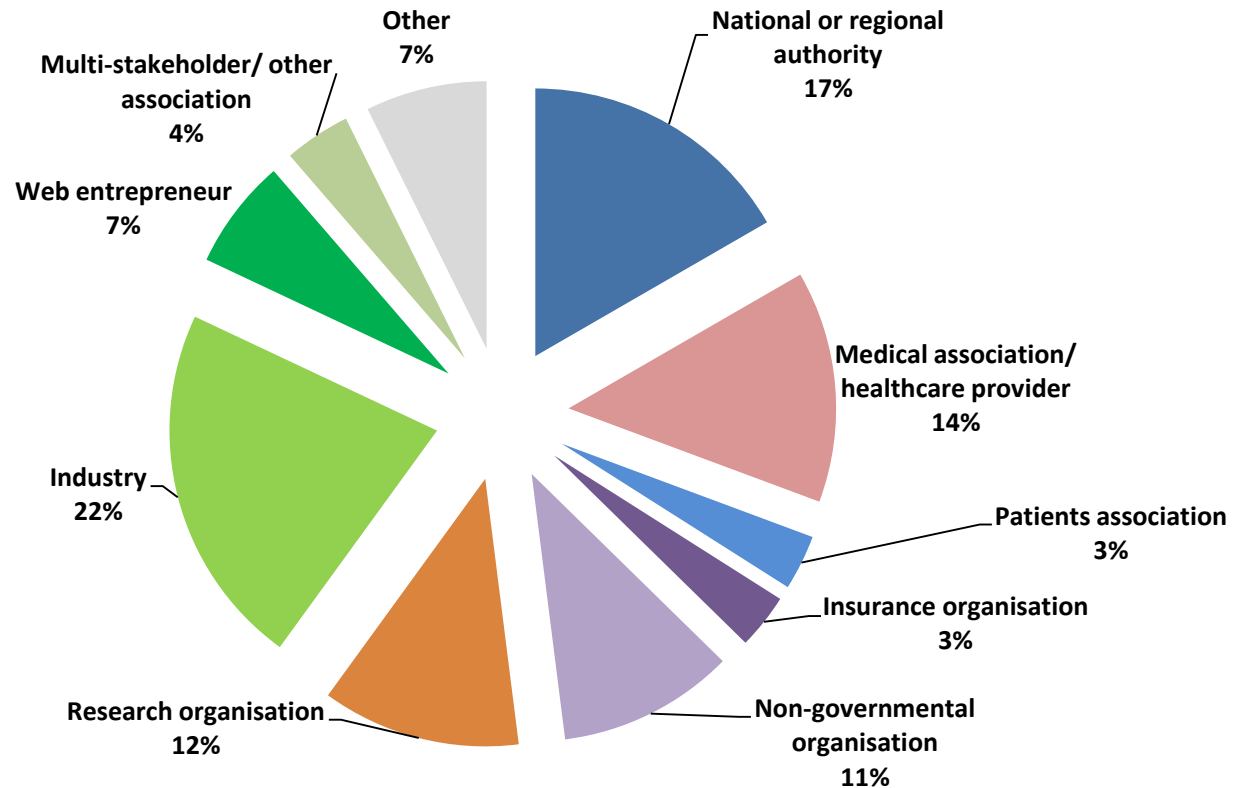
2.1 Outcome of the consultation

➢ **211 responses** received

➢ 71% from organisations / 29% from individuals

Geographical distribution of responses

■ Organisations   ■ Individuals

	BE	UK	DE	FR	ES	IT	NL	US	FI	AT	IE	PL	CH	CZ	DK	SE	BG	GR	ET	LV	PT	RO	OTHER	N/A
Individuals	2	7	7	7	8	10	5		1	1	1	2					1	1			1	1	4	
Organisations	44	19	13	12	8	6	8	8	5	3	2	2	1	1	3	3	1	1	1	1			5	3

2.2 Distribution of responses by sector

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

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