

EFA "Meet and Greet",
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Workshop: mobile Health

Claudia Prettner, Policy Officer,
Unit for Health and Well-Being, DG CONNECT

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Green Paper on mHealth

- The **Green Paper** launched a broad consultation to collect ideas to unlock mHealth potential in Europe
- It is accompanied by a **Staff Working Document** on the EU legal framework applicable to lifestyle and wellbeing apps
- Consultation closed on 10 July 2014 (3 months)

mHealth - definition

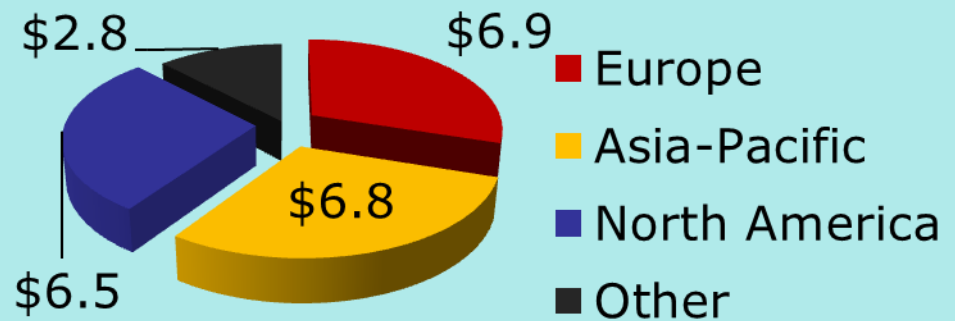
- **mHealth** - medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (*WHO definition*)
- **Examples:** disease self-management and remote monitoring devices; apps connecting to sensors measuring vital signals; tools offering fitness and dietary recommendations;

mHealth market



rapidly growing market

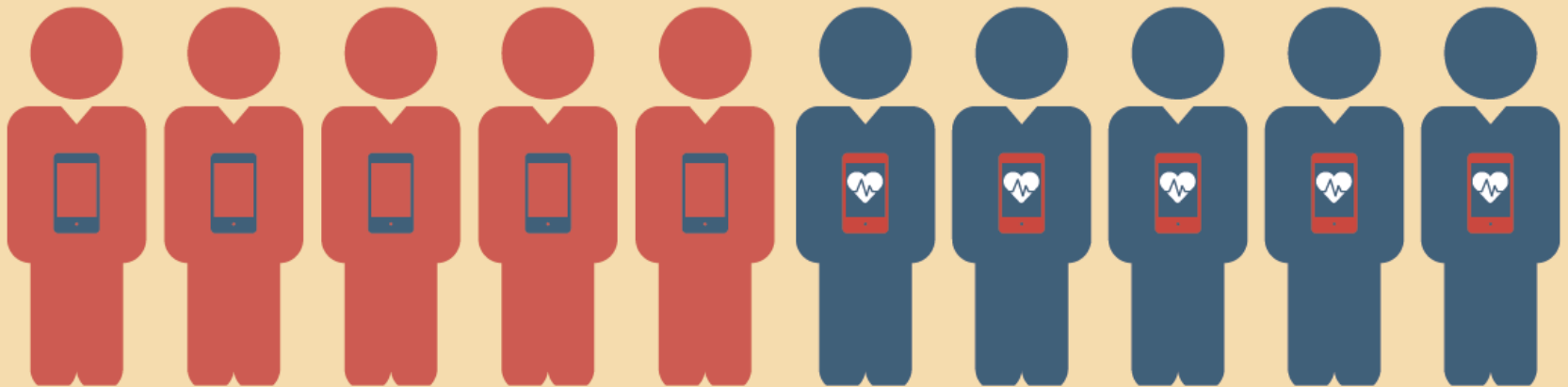
US\$ 23 billion mHealth revenues in 2017



Source: GSMA and PwC, *Touching lives through mobile health*, February 2012

By 2017, **3.4 billion people** worldwide
will own a smartphone

1/2 will use **health apps**



Benefits



early diagnosis & better treatment



patients care for their own health & having healthier lifestyle



increased prevention



more efficient & sustainable healthcare



health professionals could **save 30%** of their **time** spent on accessing & analysing information

Barriers



lack of knowledge among mHealth manufacturers about the legal framework



data protection & trust



lack of interoperability between healthcare systems in the EU



safety of mHealth apps

Identified issues and questions - I

➤ Data protection

- Which security safeguards could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?

➤ Legal framework

- Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?

Identified issues and questions - II

➤ Patient safety

- Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

➤ Reimbursement

- Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?

Outcome and next steps

211 responses received

- **71%** from organisations
 - Most active countries: Belgium, UK, Germany & France – notable participation from the US
- **29%** from individuals
 - Most active countries: Italy, Spain, UK, Germany
- Summary report November 2014
- Further actions announced in 2015

Potential for allergies/resp. diseases

An app...

- informing about air quality
- warning about pollen level
- providing information on allergens in food
- to track and manage asthma

Safety aspects – "medical" apps

Medical Devices Directive:

- Covering apps that have a medical purpose
- Safety and performance requirements
- Clinical evaluation
- Conformity assessment procedure
- CE marking

Safety aspects – "wellbeing" apps

- Legal vacuum – currently no laws at EU level on safety aspects
 - General Products Safety Directive and Liability for defective products Directive do not apply
- Problem?
 - App providing false/incomplete information on allergens
 - App providing wrong information on medicine not to be taken during pregnancy



eHealth inducement prize: Food Scanner (“best-in-class” contest)

- Awarded to the most significant development towards a portable prototype
- To enable citizens to detect nutrition facts and **allergens** in several types of food using a non-invasive and non-destructive approach
- To be launched early 2015

For more information: CNECT-HEALTH-PRIZE@ec.europa.eu



Thank you!

Claudia.Prettner@ec.europa.eu

Website: <http://bit.ly/EUeHealth>

Newsletter: <http://bit.ly/eHealthinFocus>

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