

Digital Agenda

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mHealth and EC policies

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**Consultation Workshop - organised by MovingLife FP7 CSA project
mHealth in a Socio-economic Context
18th of January 2012**

**European Commission
Avenue de Beaulieu, Brussels, Building 25, Room 0/S9**



Definition of the eHealth Market *)

“The **eHealth market** can be defined as comprising the following four interrelated major categories of applications:

1. **Clinical information systems**

- a) **Specialised tools** for health professionals within care institutions (e.g., hospitals). Examples are Radiology Information Systems, Nursing Information Systems, Medical Imaging, Computer Assisted Diagnosis, Surgery Training and Planning Systems.
- b) **Tools for primary care and/or for outside the care institutions** such as general practitioner and pharmacy information systems.

2. **Telemedicine and homecare, personalised health systems and services**, such as disease management services, remote patient monitoring (e.g. at home), tele-consultation, tele-care, tele-medicine, and tele-radiology.

3. **Integrated regional/national health information networks** and distributed electronic health record systems and associated services such as e-prescriptions or e-referrals.

4. **Secondary usage** non-clinical systems

- a) Systems for health **education** and health promotion of patients/citizens such as health portals or online health information services.
- b) Specialised systems for **researchers** and **public health data collection and analysis** such as bio-statistical programs for infectious diseases, drug development, and outcomes analysis.
- c) **Support systems** such as supply chain management, scheduling systems, billing systems administrative and management systems, which support clinical processes but are not used directly by patients or healthcare professionals.”

*) Lead Market Initiative - eHealth Taskforce report 2007

eHealth http://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm



Relevant policy hooks

- European Innovation Partnership on Active and Healthy Ageing,
 - http://ec.europa.eu/information_society/activities/einclusion/deployment/ahaip/consultation/index_en.htm
 - Strategic implementation plan (SIP), November 2011
- Digital Agenda for Europe, Key Actions 13, 14 (telemedicine), 8 (radio spectrum policy)
 - <http://ec.europa.eu/digital-agenda>
- eHealth action plan (under preparation)
 - Public Consultation eHealth Action Plan 2012-2020: <http://tinyurl.com/eHAP2012>
- DG SANCO Council Conclusions on Innovation in the Medical Device sector
 - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF>.
- Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices (DG SANCO, Medical Devices Unit)
 - DG SANCO, under preparation, expected publication 1Q2011
 - Implicit classification of mHealth apps, telemedicine and web based systems, work in progress
- Revision of the regulatory framework for medical devices (DG SANCO, Medical Devices Unit)
 - consolidation and simplification
 - new and emerging technologies have challenged the current framework
- Commission Staff Working Paper on the applicability of existing EU legal framework to telemedicine services, scheduled for 3Q2012
 - Licensing; conditions for processing health data; issue of reimbursement; new Directive 2011/24 on the patients rights in cross-border healthcare; liability
- Data protection directive



Recent EC funded eHealth research (FP7) or deployment (CIP) projects with mHealth elements

- AP@home (diabetes)
- CAALYX (FP6, continuation in CIP)
- CD-MEDICS (point-of care diagnostics)
- HeartCycle (cvd, tailored drugs for patients)
- Help4Mood (depression recovery)
- ICT4DEPRESSION (depression recovery)
- INTERSTRESS (psychological stress)
- METABO (diabetes)
- Mobiguide (clinical-guideline-based guidance for professionals and patients)
- MONARCA (mental health, bipolar disease)
- **MovingLife (roadmapping)** for mHealth, primary focus for clinical-medical use)
- Nephron+ (renal care)
- REACTION (diabetes)
- Renewing Health (**large CIP** covers three most prevalent chronic diseases, includes mobile element)
- SENSORART (cvd)
- **SmartPersonalHealth (roadmapping)**, Continua health alliance, final report available)
- SmartHEALTH (point of care diagnostics, FP6, finished)
- StrokeBack (stroke)
- One project on Patient Guidance Decision Support System
- Research project under negotiation with strong mobile element
 - **Pre-Commercial Procurement project on mHealth solutions applied in public healthcare**