Innovation through Legislation

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EU-US eHealth Marketplace,
Boston, 23 October 2012

1. Digital Agenda for Europe (DAE)
2. EIP on Active and Healthy Ageing (EIP)
3. EU-US Memorandum (MoU)
4. eHealth Task Force
5. EU eHealth Action Pan (eHAP)
6. SWP on Telemedicine
7. Promotion of Law Incubators in the EU
8. mHealth relevant policy

Innovation in eHealth

Key policies:

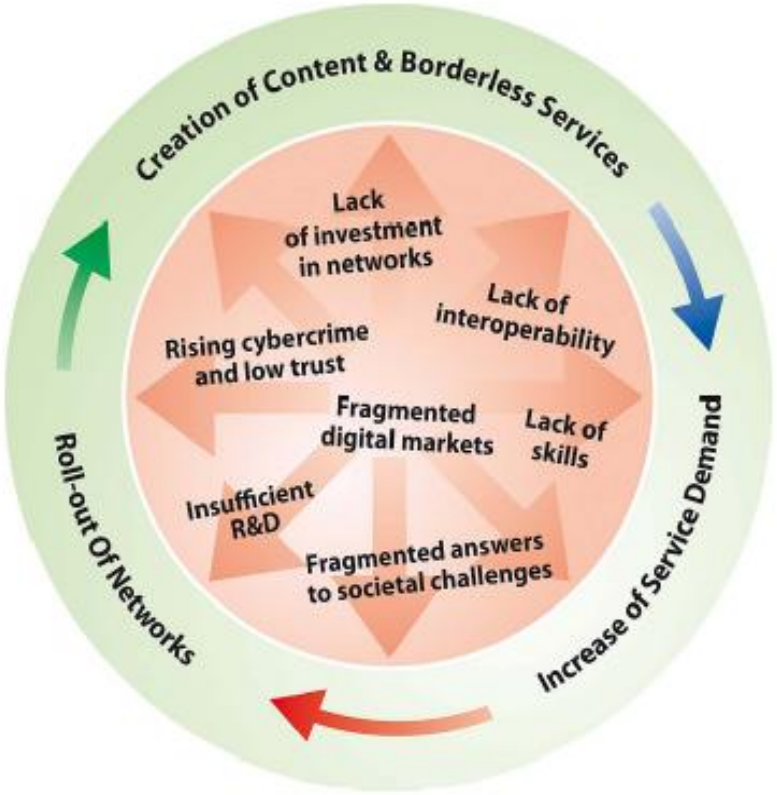
Digital Agenda for Europe

European Innovation Partnership on Active and Healthy Ageing

EU-US Memorandum of Understanding

eHealth Task Force Report

1. Digital Agenda for Europe:



Sustainable economic and social benefits for all from a flourishing digital economy

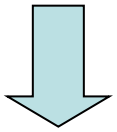
eHealth in the DAE

Sustainable healthcare and ICT-based support for dignified and independent living

Actions: on track

eHealth actions in DAE

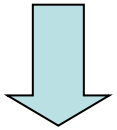
<u>KA 13</u> Undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services;



EMPOWERMENT

eHealth actions in DAE

KA14 Propose a recommendation defining a minimum common set of patient data for interoperability of patient records […] by 2012



CONTINUITY OF CARE + INTEROPERABILITY

+ Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015 through stakeholder dialogue

2. European Innovation Partnership on Active and Healthy Ageing

Objectives and headline target

A triple win for Europe:

Enabling EU citizens to lead healthy, active and independent lives until old age

Improving the sustainability and efficiency of social and health care systems

Developing and deploying innovative solutions, thus fostering competitiveness and market growth

Overarching goal by 2020:

Increasing the number of healthy life years (HLYs) by 2 in the EU on average

http://ec.europa.eu/active-healthy-ageing

3. EU-US Memorandum of Understanding on eHealth

Signed: 17/12/2010 by EC / US Dept Health and Human Services

- Cooperation surrounding health related information and communications technologies

Focus:

- key areas where scope for progress for the benefits of patients, healthcare systems and the economy
- interoperability standards and specifications for EHR systems as well as the development of a skilled health IT workforce
- important step to tackling market defragmentation by creating global conditions for common approaches to interoperability and standardisation

4. eHealth Task Force

- *Unique group of individuals with outstanding expertise in sectors relevant to eHealth*
- *Report (May 2012) "Redesigning health in Europe for 2020"*
- *Identifies critical preconditions for the effective implementation of eHealth…*

eHealth Task Force

FIVE RECOMMENDATIONS:

1. *Create a legal framework to manage the explosion of health data*
2. *Create a beacon group of Member States committed to open data and eHealth*
3. *Support health literacy*
4. *New rules to define how to integrate official and user data*
5. *Re-orient EU funding and policies*

5. eHealth Action Plan

Duration: 2012 – 2020

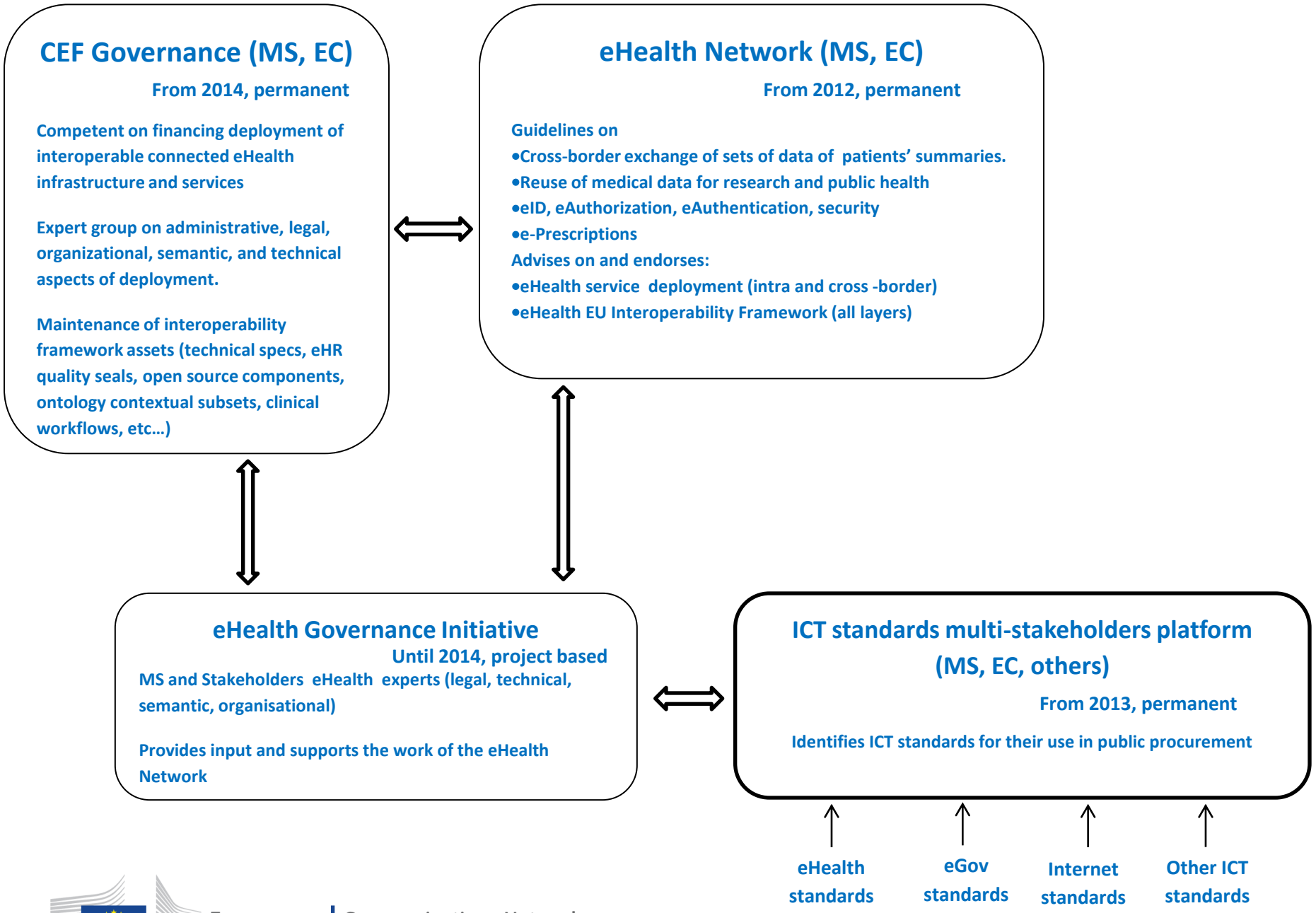
Operational Objectives include:

- eHealth interoperability Framework
- Supporting Research, Development and Innovation in eHealth
- Encouraging wider deployment and facilitating eHealth uptake
- International cooperation

Adoption foreseen: November 2012

eHealth Action Plan – Addressing the legal layer

- Staff Working Paper on the applicability of the EU legal framework to cross-border telemedicine, adoption in October 2012
- Support for legal work linking eHealth and ICT-led innovation
- Guidance on how to apply EU data protection law in the area of eHealth data (empowering citizens and patients following adoption of DP regulation)
- Tackle the lack of legal clarity around 'mHealth' and 'Health & Wellbeing apps': Green Paper on Legal Framework applicable to Health & Wellbeing Apps by 2014


CEF Governance (MS, EC)
From 2014, permanent
Competent on financing deployment of interoperable connected eHealth infrastructure and services
Expert group on administrative, legal, organizational, semantic, and technical aspects of deployment.
Maintenance of interoperability framework assets (technical specs, eHR quality seals, open source components, ontology contextual subsets, clinical workflows, etc…)
eHealth Network (MS, EC)
From 2012, permanent
Guidelines on
•Cross-border exchange of sets of data of patients' summaries.
•Reuse of medical data for research and public health
•eID, eAuthorization, eAuthentication, security
•e-Prescriptions
Advises on and endorses:
•eHealth service deployment (intra and cross -border)
•eHealth EU Interoperability Framework (all layers)
eHealth Governance Initiative
Until 2014, project based
MS and Stakeholders eHealth experts (legal, technical, semantic, organisational)
Provides input and supports the work of the eHealth Network
ICT standards multi-stakeholders platform (MS, EC, others)
From 2013, permanent
Identifies ICT standards for their use in public procurement
eHealth standards
eGov standards
Internet standards
Other ICT standards

6. SWP on Telemedicine

Purpose:

- Mapping existing EU legislation that applies to telemedicine

Focused topics:

- **Licensing:** Does the telemedicine provider also need to be licensed/registered in the Member State of the patient?
- **Data Protection:** What are the conditions for the legitimate processing of personal data related to health?
- **Reimbursement:** Will the cross-border telemedicine service be reimbursed?
- **Liability:** What is the liability regime applicable in case there are damages?
- **Relevant jurisdiction and applicable law in case of damage:** What is the relevant jurisdiction and the law applicable in case of damages?

Adoption foreseen: *November 2012 (along with the eHealth Action Plan)*

SWP on Telemedicine – licensing

- ***Does the telemedicine provider also need to be licensed/registered in the Member State of the patient?***

  - Directive 2005/36 on recognition of professional qualifications is not applicable: it requires physical presence of the health professional in the patient's country

  - **Most telemedicine services are Information Society Services =>** E-Commerce directive is applicable –> country-of-origin principle

    Exceptions: telemedicine services provided by traditional telephone and services provided in the presence of the patient

SWP on Telemedicine – reimbursment

National level

It is up to the Member States to decide whether telemedicine is reimbursed.

Cross-border level (when CB dimension)

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare:

- covers telemedicine services
- patients allowed to receive CB healthcare in the EU and be reimbursed up to the level applicable for the same treatment in their national health system.

SWP on Telemedicine – data protection

- **General principles of data processing in Directive 95/46/EC on Data Protection :**
- Health data are sensitive data – prohibition to process – **exemption:** preventive medicine, medical diagnosis, the provision of care or the management of healthcare services + professional secrecy

  Obligation of the data controller to implement appropriate security measures to protect personal data
- European Data protection rules currently being updated

SWP on Telemedicine - liability

- **Medical liability and services liability**
  - no EU legislation
  - National legislation applies
  - Applicable national law needs to be determined

- **EU consumer protection legislation**: liability for defective products

- **No liability of intermediaries** for transmitting data (ex. Internet service providers) for "mere conduit" or "caching" (e-Commerce Directive)

SWP on Telemedicine – open issues

- In practice, some Member States still requesting professionals to also be registered in their country in order to provide a healthcare service.
- The liability regime of healthcare professionals varies from one Member State to another.
- The definition of telemedicine as a medical act varies from one Member State to another (impact on reimbursement)
- The regime of Directive 2005/36/EC on the recognition of professional qualifications does not apply to professionals providing telemedicine.

  (It only covers healthcare professionals that physically move to another Member State to practice their profession.)

7. Promotion of Law incubators in the EU

FP7 work programme 2013:

Objective ICT-2013.11.5 Cross border services, investment readiness and legal advice for ICT SMEs, start-ups and entrepreneurs - sub-objective c)

A "law incubator" functions as a pro-bono legal clinic where law students are challenged to give legal advice (under the supervision of their professors) to companies and start-ups having to deal with the complexity of legal issues related to information and communication technologies.

Promotion of Law incubators in the EU

Form:

Coordination and Support Action -platform of law universities, covering specificities of different national legal systems in Europe

Activities:

-networking and coordination activities between the involved universities

-definition of the legal expertise to be provided to ICT start-ups and entrepreneurs

-elaboration of guidelines tailored to non-legal experts about the specific legal issues related to the ICT sector;

-dissemination activities about the services offered to the targeted audience.

Promotion of Law incubators in the EU

Publication date: *10 July 2013* ***Deadline:*** *15 January 2013 at 17:00:00 (Brussels local time)*

Relevant links

More information about the call can be found at:
https://ec.europa.eu/research/participants/portal/page/cooperation?callIdentifier=FP7-ICT-2013-10

Specifically on law incubators:
https://ec.europa.eu/digital-agenda/en/newsroom/8/1374

The text of the work programme is at:
http://cordis.europa.eu/fp7/ict/docs/ict-wp2013-10-7-2013.pdf
*(**Objective 11.5, "c" is at page 112).***

8. mHealth relevant policy

*Definition of the eHealth/mHealth 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 (cross border EHR+ePrescription)

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."**

mHealth in all market segments

Lead Market Initiative - eHealth Taskforce report 2007
eHealthhttp://ec.europa.eu/information_society/activities/health/policy/lmi_ehealth/index_en.htm

mHealth relevant Policy

Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices (DG SANCO, Medical Devices Unit)

- January 2012
- Implicit classification of mHealth apps, telemedicine and web based systems

Revision of the regulatory framework for medical devices

- new and emerging technologies have challenged the current framework
- consolidation and simplification
- EC proposal for a regulation on medical devices: 26 September 2012
- ***Privacy, security related directives***

mHealth regulatory framework

-EC Proposal for a Regulation on Medical Devices : *mHealth and health and wellbeing apps not specifically covered*

Question of what regulation applies to them should be addressed in a Green Paper

-EC Green Paper on Health and Wellbeing Apps

scheduled for: end of 2014

Conclusion: Innovation through Legislation

Using the tools at our disposal to reinvigorate our economies:

legislation as an enabler of innovation!

More information and contacts

eHealth

ec.europa.eu/ehealth

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