COUNCIL OF
THE EUROPEAN UNION

Brussels, 11 December 2012

17568/12

SAN 325
TELECOM 255
MI 821

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	6 December 2012
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No Cion doc.:	COM(2012) 736 final
Subject:	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century

Delegations will find attached Commission document COM(2012) 736 final.

––––––––––––––––––––––––

Encl.: COM(2012) 736 final

Brussels, 6.12.2012
COM(2012) 736 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century

{SWD(2012) 413 final}
{SWD(2012) 414 final}

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century

TABLE OF CONTENTS

1. INTRODUCTION

Information and Communication Technologies (ICT) applied to health and healthcare systems can increase their efficiency, improve quality of life and unlock innovation in health markets.[1]

However, this promise remains largely unfulfilled, as expressed by Estonian President Toomas Hendrik Ilves, Chair of the independent high-level eHealth Task Force: "*We know that in healthcare we lag at least 10 years behind virtually every other area in the implementation of IT solutions. We know from a wide range of other services that information technology applications can radically revolutionise and improve the way we do things" (May 2012).*[2]

The first eHealth Action Plan[3] was adopted in 2004. Since then, the European Commission has been developing targeted policy initiatives aimed at fostering widespread adoption of eHealth throughout the EU[4]. Member States have dynamically responded by demonstrating a high level of commitment to the eHealth policy agenda, notably through their participation in major large scale pilot projects such as epSOS[5]. The adoption in 2011 of the Directive on the Application of Patients' Rights in Cross Border Healthcare[6] and its Article 14 establishing the eHealth Network, marked a further step towards formal cooperation on eHealth, with the aim to maximise social and economic benefits through interoperability and the implementation of eHealth systems.

Notwithstanding this substantial progress, barriers continue to exist that need to be addressed in order to reap all the benefits from a fully mature and interoperable eHealth system in Europe.

The new eHealth Action Plan aims at addressing and removing these barriers. It clarifies the policy domain and outlines the vision for eHealth in Europe, in line with the objectives of the Europe 2020[7] Strategy and the Digital Agenda for Europe[8]. It presents and consolidates actions to deliver the opportunities that eHealth can offer, describes the EU's role and encourages Member States and stakeholders to work together.

---

[1] eHealth is the use of ICT in health products, services and processes combined with organisational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals

[2] At the invitation of Commission Vice-President Kroes and Commissioner Dalli, a Task Force of thought leaders from politics, health and ICT was convened in May 2011. Its role was to examine the transformational role of technology in addressing the major challenges facing the health sector. http://ec.europa.eu/information_society/activities/health/policy/ehtask_force/index_en.htm

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF

[4] Examples include: eHealth action plan COM(2004) 356 final; the Lead Market Initiative for Europe and the associated eHealth Roadmap [COM(2007) 860 final Annex I – Commission Staff Working Document: SEC(2007) 1729], the Commission Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC), the Communication on benefits of telemedicine for patients healthcare systems and society (COM(2008)689 final)

[5] www.epsos.eu

[6] The Network was established under Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF - OJ L 88, 4.4.2011,p.45.

[7] Communication from the Commission Europe 2020 a strategy for smart, sustainable and inclusive growth - com(2010) 2020 final

[8] http://ec.europa.eu/information_society/digital-agenda/index_en.htm

2. CHALLENGES AND OPPORTUNITIES OF eHEALTH IN EUROPE

2.1. European healthcare systems facing challenges

Public health expenditure in the EU's 27 Member States was on average 5.9% of GDP in 1990, rose to 7.2% of GDP in 2010, and the projections show that expenditure may continue to grow to 8.5% of GDP in 2060 due to the ageing population and other socio-economic and cultural factors[9]. In addition, the long term care expenditure projection would on average almost double over the projection period[10]. Concurrently, the working age contingent is expected to fall dramatically from 61% to 51% of the total population while the share of the elderly (65+) and very old (80+) population in the EU is projected to grow respectively from 17.4% in 2010 to 30.0% in 2060 and from 4.7% in 2010 to 12.1% in 2060.[11]

The impact of these changes is already being felt today and is particularly acute at a time of increased pressure on public budgets, a steady decline in the number of health personnel,[12] higher incidence of chronic diseases and growing demands and expectations from citizens for higher quality services and social care.

Deep-rooted structural reforms are needed to ensure the sustainability of the health systems while securing access to services for all citizens. As part of those efforts, Europe must reduce its overall regulatory burden while ensuring safety. eHealth and wellbeing are areas with high growth potential and possibilities for innovation notably by unlocking effective health data exchange. However, the challenges of the economic crisis, market fragmentation and other barriers as discussed below limit the benefits of eHealth for healthcare, the health systems, the economy and the individual citizen and have prevented the market for health services from developing as rapidly as was hoped for in 2007 when the Commission selected eHealth as one of six promising lead markets.[13]

2.2. Opportunities: building on market potential

Despite the economic crisis, the market potential of eHealth is strong. The global telemedicine market has grown from $9.8 billion in 2010 to $11.6 billion in 2011, and is expected to continue to expand to $27.3 billion in 2016, representing a compound annual growth rate of 18.6%[14]. The well being market enabled by digital technologies (mobile applications, devices) is rapidly growing. The convergence between wireless communication technologies and healthcare devices and between health and social care is creating new businesses. Redesigning the delivery of care and the 'silver economy' are highly promising markets.

eHealth can benefit citizens, patients, health and care professionals but also health organisations and public authorities. eHealth – when applied effectively - delivers more personalised 'citizen-centric' healthcare, which is more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalisation. It facilitates socio-economic

---

[9] See the 2012 Ageing Report: Economic and budgetary projections for the 27 EU Member States (2010-2060), chapter 3 at http://ec.europa.eu/economy_finance/publications/european_economy/2012/2012-ageing-report_en.htm

[10] See the 2012 Ageing Report: Economic and budgetary projections for the 27 EU Member States (2010-2060), chapter 4 at http://ec.europa.eu/economy_finance/publications/european_economy/2012/2012-ageing-report_en.htm

[11] http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KE-ET-10-001

[12] Green Paper on the European Workforce for Health COM(2008) 725 final of 10.12.2008

[13] http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/files/final-eval-lmi_en.pdf

[14] According to BCC Research study of March 2012

inclusion and equality, quality of life and patient empowerment[15] through greater transparency, access to services and information and the use of social media for health.

Such benefits have been demonstrated when using telemedicine for managing chronic conditions, mental health and health promotion[16]. Similar benefits have been identified for technology assisted therapies, which can effectively complement routine clinical care and improve the cost-efficiency of the treatments as well as when using interoperable electronic health record and ePrescribing systems, if pursued with the necessary rigour[17]. Once the value of benefits begins to cover investment costs, the net benefit expands and becomes substantial. In countries under adjustment programmes, eHealth has gained significant importance as a means to improve the efficiency and effectiveness of systems and their control, and the reduction of expenditures[18]. Finally, facilitation of eHealth is one of the concrete actions to promote free movement of EU citizens within the EU[19].

2.3. Barriers to deployment of eHealth

Despite the opportunities and benefits, major barriers hamper the wider uptake of eHealth[20]:

- lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals;

- lack of interoperability between eHealth solutions;

- limited large-scale evidence of the cost-effectiveness of eHealth tools and services;

- lack of legal clarity for health and wellbeing mobile applications and the lack of transparency regarding the utilisation of data collected by such applications;

- inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services;

- high start-up costs involved in setting up eHealth systems;

- regional differences in accessing ICT services, limited access in deprived areas.

Several barriers can contribute to one market failure e.g. the important issue of the lack of health data exchange can only be tackled by addressing in a coordinated way fragmented legal frameworks, lack of legal clarity and lack of interoperability.

---

[15] "Patient empowerment is a process to help people gain control, which includes people taking the initiative, solving problems, and taking decisions, and can be applied to different settings in health and social care, and self management" [ENOPE 2012].

[16] Staff Working Document Accompanying eHealth Action Plan – innovative healthcare for the 21st century.

[17] Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02-2009): http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf

[18] Idem

[19] EU Citizenship Report 2010 – Dismantling the obstacles to EU citizens' rights COM(2010) 603 final (see action 7)

[20] More information in the Staff Working Document Accompanying eHealth Action Plan – innovative healthcare for the 21st century. See also recommendations of the EU eHealth Task Force

3. VISION

The vision of this Action Plan is to utilise and develop eHealth to address several of the most pressing health and health systems challenges of the first half of the 21st century:

– to improve chronic disease and multimorbidity (multiple concurrent disease) management and to strengthen effective prevention and health promotion practices;

– to increase sustainability and efficiency of health systems by unlocking innovation, enhancing patient/citizen-centric care and citizen empowerment and encouraging organisational changes;

– to foster cross-border healthcare, health security, solidarity, universality and equity;

– to improve legal and market conditions for developing eHealth products and services.

The Action Plan addresses the barriers and the following operational objectives:

– achieving wider interoperability of eHealth services;

– supporting research, development and innovation in eHealth and wellbeing to address the lack of availability of user-friendly tools and services;

– facilitating uptake and ensuring wider deployment;

– promoting policy dialogue and international cooperation on eHealth at global level.

The Action Plan emphasises cross-border activities but it should be noted that work done at the EU level has a strong effect at the national level and vice versa. Therefore, the Action Plan encourages national and regional authorities, healthcare and social care professionals, industry, patients, service providers, researchers and EU Institutions to closely work together.

4. ACHIEVE WIDER INTEROPERABILITY IN EHEALTH SERVICES

The Commission recognises the need for an eHealth interoperability[21] framework, building on eHealth roadmaps and the general European Interoperability Framework[22] with its four levels of interoperability: legal, organisational, semantic and technical.

The eHealth Network set up by Directive 2011/24/EU is the main strategic and governance body at EU level to work towards interoperability of cross-border eHealth services.

The Network has the task of producing guidelines on eHealth, as foreseen in the same Directive, and on an interoperability framework for cross border eHealth services.

By 2015, the Commission, with the endorsement of the eHealth Network, will propose an eHealth Interoperability Framework based on the results of studies, pilots and research

---

[21] Interoperability is where two or more eHealth applications (e.g. EHRs) can exchange, understand and act on citizen/patient and other health-related information and knowledge among linguistically and culturally disparate clinicians, patients and other actors or organisations within and across health system jurisdictions, in a collaborative manner.

[22] http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

projects.

4.1. Addressing the technical and semantic levels by fostering EU-wide standards, interoperability testing and certification

Interoperability of ICT-enabled solutions and of data exchange is the precondition for better coordination and integration across the entire chain of healthcare delivery and health data exchange, while unlocking the EU eHealth single market.

The use of European and international standards is a way to ensuring the interoperability of ICT solutions in general[23]. In eHealth however, such standards are often not specific enough[24]. With the advice of the eHealth Network, more detailed specifications, for example for public procurement, will be identified in the framework of the new EU standardization regulation[25], contributing to the technical and semantic levels of the eHealth Interoperability Framework. The eHealth Network has the specific objective to draw up guidelines on a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders.

In addition to, European and international standards and specifications, interoperability testing, labelling and certification processes are also essential. Several projects are successfully testing and implementing standards, open and secure architecture, clinical workflows and subsets of terminologies[26] as well as making policy recommendations, to prepare the deployment of eHealth services on a large scale. The Commission proposes to boost interoperability by further developing and validating specifications and components.

From 2012 onwards the Commission will support the eHealth Network in producing guidelines on a dataset for patient summary records to be exchanged across borders, common measures for interoperable electronic identification and authentication[27] in eHealth and will enhance security of health information and eHealth services and interoperability of databases for medicinal products.

By 2015, the Commission will seek the endorsement of the eHealth Network to:

•   establish the semantic and technical cross-border interoperability specifications and assets necessary for the eHealth Interoperability Framework;

•   propose an EU interoperability testing, quality labelling and certification framework for eHealth systems.

Assets, such as vocabularies, will be taken from past projects or ongoing projects developed under CIP, FP7, the ISA work program[28] and in the future Horizon 2020 and be used and maintained under the proposed Connecting Europe Facility (CEF, see 6.1).

---

[23]   EU Study on the specific policy needs for ICT standardisation, http://ec.europa.eu/enterprise/sectors/ict/files/full_report_en.pdf

[24]   European countries on their journey towards national eHealth infrastructures, EU Study, http://www.ehealth-strategies.eu/

[25]   http://ec.europa.eu/enterprise/policies/european-standards/documents/official-documents/index_en.htm

[26]   Among others www.epsos.eu and www.semantichealthnet.eu

[27]   Directive 1999/93/EC on a Community framework for electronic signatures http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0093:EN:NOT

[28]   The ISA programme helps European public administrations setting up efficient cross-border and cross-sector electronic information exchange and collaboration. The ISA Joinup platform allows professionals to share interoperability solutions for public administrations and to find semantic interoperability assets. https://joinup.ec.europa.eu/

4.2. Addressing the organisational layer

This aspect of interoperability is concerned with how organisations, such as public administrations in different Member States, cooperate to achieve their mutually agreed goals. In practice, organisational interoperability implies integrating business processes and related data exchange and finding instruments to formalise mutual assistance, joint action and interconnected business processes in connection with cross-border service provision.[29]

The epSOS project has defined how Member States can cooperate and integrate their processes in order to deploy eHealth services across Europe. The eHealth Network and the CEF foresee to implement these results and thereby address the next phase of cross-border eHealth processes.

Building on these developments, the Commission will support, from 2013, concrete steps towards greater integration of processes for cross-border eHealth. It will make proposals on organisational issues with the aim of facilitating cooperation in the EU.

4.3. Addressing legal issues

Bringing down legal barriers is vital for deploying eHealth in Europe. The Directive on the application of patients' rights in cross-border healthcare will contribute to achieving such an objective as it clarifies patients' rights to receive cross-border healthcare, including remotely via telemedicine.

The Commission Staff Working Paper on the applicability of the existing EU legal framework to telemedicine services[30] clarifies the EU legislation applicable to issues such as reimbursement, liability, licensing of healthcare professionals and data protection encountered when providing telemedicine across borders.

From 2013 the Commission will engage in discussions on legal issues affecting eHealth, within the eHealth Network and other fora, such as the European Innovation Partnership on Active and Healthy Ageing (EIP AHA), as well as cross-sectoral legal work linking eHealth to other ICT-led innovation, with the first conclusions foreseen in 2013-2014.

The Commission will also initiate discussions among the Member States on reimbursement schemes for eHealth services based on criteria of effectiveness and efficiency.

In 2013 the Commission will launch a study under the upcoming Health Programme 2014-2020[31] aimed at examining Member States' laws on electronic health records in order to make recommendations to the eHealth Network on legal aspects of interoperability.

Empowering citizens and patients: review of data protection rules

It is essential to establish safeguards to allow citizens to use health and well being applications with confidence and subsequently ensure *'the integration of user-generated data*

---

[29]   http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

[30]   http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF

[31]   http://ec.europa.eu/health/programme/policy/proposal2014_en.htm

with official medical data so that care can be more integrated, personalised and useful for patients[32].

Effective data protection is vital for building trust in eHealth. It is also a key driver for its successful cross-border deployment, in which harmonisation of rules concerning cross border exchange of health data is essential.

In January 2012, the Commission adopted a proposal for a regulation setting out a general EU framework for data protection[33] with a view to modernising current data protection rules and strengthening their harmonisation[34].

The eHealth Task Force report and the responses to the public consultation[35] for the eHealth Action Plan both point to a strong interest in discussing the concept of 'ownership' and control of data while providing more clarity on the conditions for accessing and re-using health data for research and public health purposes and the flow of such data across health and care systems, if suitably protected.

Data protection issues also need to be addressed in respect to the use of cloud computing[36] infrastructures and services for health and wellbeing data processing.

eHealth and wellbeing ICT initiatives should integrate the principle of privacy by design and by default as well as make use of Privacy Enhancing Technologies (PET's), as foreseen in the proposed Data Protection Regulation. The latter contains new principles which will allow the deployment of trustworthy tools e.g. the principle that controllers will be accountable for their data processing, carry out data protection impact assesments and comply with strenghtened security requirements[37].

In response to the recommendations of the eHealth Task Force and following the adoption of the proposed Data Protection Regulation, the Commission will make use of the mechanisms foreseen in the Regulation, to provide guidance on the application of the EU data protection law in respect of health services.

Tackling the lack of clarity on legal and other issues around 'mobile health' ('mHealth') and 'health & wellbeing applications'

The growth in the mobile health and wellbeing market has been accompanied by a rapid increase in the number of software applications for mobile devices (or 'apps'). Such applications potentially offer information, diagnostic tools, possibilities to 'self-quantify' as well as new modalities of care. They are blurring the distinction between the traditional provision of clinical care by physicians, and the self-administration of care and wellbeing. Network operators, equipment suppliers, software developers and healthcare professionals are all seeking clarity on the roles they could play in the value chain for mobile health.

---

[32] eHealth Task Force Report of May 2012

[33] Commission proposal for a regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data: http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

[34] See EDPS Opinion on the data protection reform package, para. 298 and 299, 7 March 2012: http://www.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2012/12-03-07_EDPS_Reform_package_EN.pdf

[35] http://ec.europa.eu/information_society/activities/health/ehealth_ap_consultation/index_en.htm

[36] Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. (The NIST Definition http://csrc.nist.gov/publications/PubsSPs.html#800-145)

[37] http://ec.europa.eu/justice/data-protection/article-29/index_en.htm

The Commission has proposed on 26 September 2012 two Regulations to strengthen the European regulatory framework for medical devices and *in vitro* diagnostic medical devices. These proposals, accompanied by a Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals, aim at improving the level of health protection in the EU, while at the same time improving the functioning of the internal market and fostering innovation and competitiveness of these two sectors.[38]

The Commission also published in 2012 guidelines on 'stand-alone software used in healthcare within the regulatory framework of medical devices'[39] in order to define the criteria for the qualification of stand-alone software as a medical device and the application of the risk classification criteria to such software.

Given the complexity created by 'mHealth' and 'health and wellbeing applications' in particular, further clarification is needed on the legal framework applicable to these specific areas. The rapid developments in this sector raise questions about the applicability of the current frameworks, the use of the data collected through these applications by individuals and medical professionals, and whether or not and how they will be integrated in healthcare systems. Clarity of information and 'user-friendliness' are also important to consider. This needs to be achieved without over-regulating as it is an emerging cluster of technologies with lower costs and risks, but also with lower profitability.

The challenges include ensuring that the market for health and wellbeing applications meets citizens' demands for quality and transparency. This should be facilitated by high-quality and comprehensible information on the use and performance of these applications and ensuring interoperability between health and wellbeing areas.

In response to the recommendations of the eHealth Task Force, it is proposed that by 2014, the Commission will adopt a Green Paper on mHealth and health and wellbeing applications.

5. **SUPPORTING RESEARCH, DEVELOPMENT, INNOVATION AND COMPETITIVENESS IN eHEALTH**

5.1. **Supporting research, development and innovation**

Short-term and mid-term research priorities include health and wellbeing solutions for citizens and health professionals, better quality of care, including of chronic diseases, while increasing citizens' autonomy, mobility and safety. Particular attention is paid to the design and user-centricity of mobile technologies and applications. There will be an additional focus on ways of analysing and mining large amounts of data for the benefit of individual citizens, researchers, practitioners, businesses and decision makers.

Longer-term research objectives address topics that can promote synergies between related science and technologies, and accelerate discoveries in the area of health and wellbeing. They

---

[38] Proposal for Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2011/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM(2012) 542 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0542:FIN:EN:PDF; Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices, COM(2012) 541 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0541:FIN:EN:PDF; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals, COM(2012) 540 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0540:FIN:EN:PDF

[39] http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf

include *in silico* medicine for improving disease management as well as prediction, prevention, diagnosis, and treatment of diseases. The eHealth Task Force recommended earmarking EU funds for user-driven innovation, support for fast prototyping and low thresholds for access to funding. To maximise the impact of the EU level measures, the full spectrum of research and innovation activities will be supported. These include:

– Public-Private Partnerships and other actions involving research and innovation and translation of knowledge to clinical trials and demonstration projects[40];

– Pre-Commercial Procurement and Public Procurement of Innovation for new products, scalability, interoperability and effective eHealth solutions supported by defined standards and common guidelines.

Deployment as well as research and innovation of care for an ageing population, including the ehealth solutions are also addressed by the Strategic Implementation Plan of the EIP AHA (SIP)[41]. It aims at enabling citizens to live independently for longer and in better health, make the cost of care more sustainable, expand the market for innovative products and services and increase EU's global competitiveness. Horizon 2020 and the upcoming Health Programme 2014-2020 will contribute to the aims of the EIP AHA.

During the period 2014-2020, research and innovation will be supported under "Health, demographic change and wellbeing" of Horizon 2020, in the areas of:

- an ICT and computational science and engineering framework for digital, personalised, and predictive medicine, including advanced modelling and simulation[42];

- innovative instruments, tools and methods for unlocking the value of data and for advanced analytics, diagnostics and decision making;

- new digital media, web and mobile technologies and applications, as well as digital instruments that integrate healthcare and social care systems and support health promotion and prevention;

- eHealth systems and services with strong user involvement, focusing on interoperability and the integration of emerging patient-centric technologies for cost-effective healthcare.

From 2012, the Commission encourages Member States involvement in the EIP AHA to help them develop and share their national (including regional) eHealth strategies, taking into account international recommendations, and deploying promising solutions for active and healthy ageing at a larger scale[43].

---

[40] Projects designed to prove the viability of new technologies offering potential economic advantage but which cannot be commercialised directly or to stimulate the up-take of innovative services or products by demonstrating the impact potential and the technical, organisational or legal feasibility of operational pilot services based upon the take-up of completed R&D work or already tested prototype services.

[41] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing&pg=implementation-plan

[42] Virtual Physiological Human http://ec.europa.eu/information_society/activities/health/research/fp7vph/index_en.htm

[43] National eHealth strategy toolkit. World Health Organization and International Telecommunication Union 2012. http://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

5.2. Fostering the development of a competitive eHealth market

Ensuring the right legal and market conditions for entrepreneurs to develop products and services in the fields of eHealth and wellbeing is important to support market growth in this area. The Commission will support, starting within FP7, mechanisms such as SME networking, eHealth week, and business modeling studies to facilitate closer cooperation among stakeholders, research bodies, industry and those responsible for implementing ICT tools and services, to enable faster and wider take-up of research results in the market. The Commission will support networking of European high technology incubators, which would provide legal and other advice and training to eHealth startups.

> Between 2013-2020, the Commission will support actions to improve the market conditions for entrepreneurs developing products and services in the fields of eHealth and ICT for wellbeing.

6. FACILITATING UPTAKE AND ENSURING WIDER DEPLOYMENT OF EHEALTH

6.1. Connecting Europe Facility

Among other objectives, the Connecting Europe Facility (CEF)[44] sets out to facilitate the deployment of cross-border interoperable ICT services of general interest such as eHealth by overcoming the barriers of the high initial investment costs and risks associated with this deployment. The results of the large scale pilot epSOS[45] (ending in 2013) and other projects and studies will be adapted and taken forward in the CEF.

The experience of epSOS has shown that bringing Member States together to build and deploy interoperable infra- and info-structures also contributes to deployment at national, regional and local level.

> By the end of 2013, the Commission will prepare the governance for the large scale deployment of interoperable eHealth services under the CEF 2014 – 2020, taking into account the recommendations of the eHealth Network.

6.2. Cohesion policy

The European Regional Development Fund (ERDF) provides in the current programming period (2007-2013) approximately EUR 15 billion to ICT priorities (or 4.4% of total cohesion policy funds) to ensure access to basic broadband (EUR 2.3 billion) and supporting ICT applications and services for citizens and SMEs (EUR 12.7 billion), for the 27 Member States. The 'Elements for a Common Strategic Framework 2014 to 2020'[46], defines several key actions for ERDF, which contribute to the wider use of ehealth services, such as to deploy innovative ICT applications that contribute to meeting societal challenges and opportunities such as eHealth, modernisation, structural transformation and sustainability of health systems (in particular integrated health and social care), leading to measurable improvements in health outcomes, including e-health measures. It also defines key action on reducing health inequalities, aiming to improve the access to services by marginalised groups. The EIP AHA

---

[44]   http://ec.europa.eu/commission_2010-2014/president/news/speeches-statements/pdf/20111019_2_en.pdf

[45]   www.epsos.eu

[46]   Staff Working Document SWD(2012) 61 of 14.3.2012

provides a strategic plan to enable and accelerate the deployment of innovation, including eHealth for active and healthy ageing.

During the period 2013-2020, the Commission will leverage the CEF and the ERDF for the large scale deployment of innovative tools, the replicability of good practices and services for health, ageing and wellbeing, with a particular attention to improving equal access to services.

6.3. Skills and digital health literacy

On the one hand, patient empowerment and digital health literacy are essential for successful eHealth deployment. On the other hand, eHealth facilitates patients managing their own conditions or healthy citizens benefiting from prevention measures. However, a significant barrier lies in the lack of awareness of eHealth opportunities and challenges for users (citizens, patients, health and social care professionals).[47]

From 2013, starting with the Competitiveness and Innovation Programme and continuing under Horizon 2020, the Commission will support activities aiming at increasing citizens' digital health literacy. For professionals (health and scientific communities) the focus will be on developing evidence-based clinical practice guidelines for telemedicine services with particular emphasis on nursing and social care workers.

6.4. Measuring the added value

It is essential to measure and assess the added value of innovative eHealth products and services to achieve wider evidence-based eHealth deployment and create a competitive environment for eHealth solutions. The close cooperation between Member States and stakeholders in Health Technology Assessment (HTA) under the Directive on Patients' Rights in Cross Border Healthcare and the EIP AHA will contribute to improving assessment methodologies and sharing clinical evidence on eHealth technologies and services.

From 2014, sets of common indicators will be made available to measure the added value and benefit of eHealth solutions, based on work funded by the Commission in partnership with stakeholders.

During the period 2013-2016, the Commission will assess cost benefits, productivity gains and business models, notably through Health Technology Asessment (HTA) .

7. PROMOTING POLICY DIALOGUE AND INTERNATIONAL COOPERATION ON EHEALTH AT GLOBAL LEVEL

The WHO, OECD and other international bodies have underlined the importance of a global coordinated approach to tackle the specific issues related to eHealth. Recent initiatives[48] have outlined the challenges of interoperability and specifically of the use of common terminologies at international level as some of the key components for market growth. In this context, the EU signed in 2010 a Memorandum of Understanding with the United States of America on interoperable eHealth systems and skills.

---

[47] See evidence overview in Staff Working Document Accompanying the eHealth Action Plan and responses to the eHealth Action Plan consultation. http://ec.europa.eu/information_society/activities/health/docs/policy/ehap2012public-consult-report.pdf

[48] http://ec.europa.eu/information_society/activities/health/docs/publications/2009/2009semantic-health-report.pdf and http://www.semantichealthnet.eu/

From 2013 the Commission shall enhance its work on data collection and benchmarking activities in health care with relevant national and international bodies to include more specific eHealth indicators and assess the impact and economic value of eHealth implementation.

From 2013 the Commission shall promote policy discussions on eHealth at global level to foster interoperability, the use of international standards, develop ICT skills, compare evidence of the effectiveness of eHealth, and promote ecosystems of innovation in eHealth.

8. CONCLUSIONS

EU health systems are under severe budgetary constraints, while having to respond to the challenges of an ageing population, rising expectations of citizens, and mobility of patients and health professionals. Fostering a spirit of innovation in eHealth in Europe is the way forward to ensure better health and better and safer care for EU citizens, more transparency and empowerment, a more skilled workforce, more efficient and sustainable health and care systems, better and more responsive public administrations, new business opportunities and a more competitive European economy that can benefit from international trade in eHealth.

The Commission will closely monitor the implementation of this Action Plan and report on the progress made and the results achieved.