Basic information

2013/2061(INI) INI - Own-initiative procedure	Procedure completed
eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century **Subject** 2.40.02 Public services, of general interest, universal service 3.30.06 Information and communication technologies, digital technologies 3.30.20 Trans-European communications networks 3.50.04 Innovation 4.20.02 Medical research 4.20.06 Health services, medical institutions 4.60.06 Consumers' economic and legal interests 4.70.07 European Regional Development Fund (ERDF)	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	AYUSO Pilar (PPE)	25/04/2013
	Shadow rapporteur TĂNĂSESCU Claudiu Ciprian (S&D) PARVANOVA Antonyia (ALDE) NICHOLSON James (ECR) ANDERSON Martina (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	IRIGOYEN PÉREZ María (S&D)	18/12/2012
REGI Regional Development	IMBRASAS Juozas (EFD)	19/03/2013

	FEMM Women's Rights and Gender Equality	RONZULLI Licia (PPE)	18/04/2013

European Commission	Commission DG	Commissioner
	Health and Food Safety	BORG Tonio

Key events

Date	Event	Reference	Summary
06/12/2012	Non-legislative basic document published	COM(2012)0736	Summary
18/04/2013	Committee referral announced in Parliament		
27/11/2013	Vote in committee		
05/12/2013	Committee report tabled for plenary	A7-0443/2013	Summary
13/01/2014	Debate in Parliament		
14/01/2014	Decision by Parliament	T7-0010/2014	Summary
14/01/2014	Results of vote in Parliament		
14/01/2014	End of procedure in Parliament		

Technical information

Procedure reference	2013/2061(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/11532

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE516.917	05/09/2013	
Committee opinion	REGI	PE514.579	26/09/2013	
Committee opinion	FEMM	PE516.618	04/10/2013	

Committee opinion	IMCO	PE514.574	08/10/2013	
Amendments tabled in committee		PE521.697	18/10/2013	
Amendments tabled in committee		PE524.557	26/11/2013	
Committee report tabled for plenary, single reading		A7-0443/2013	05/12/2013	Summary
Text adopted by Parliament, single reading		T7-0010/2014	14/01/2014	Summary

European Commission

Document type	Reference	Date	Summary
Commission document (COM)	COM(2012)0736	06/12/2012	Summary
Commission response to text adopted in plenary	SP(2014)320	26/05/2014	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2012)0736	31/03/2014	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	N7-0043/2014 OJ C 358 07.12.2013, p. 0013	27/03/2013	

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

2013/2061(INI) - 06/12/2012 - Non-legislative basic document

PURPOSE : to set up an eHealth Action Plan 2012-2020.

BACKGROUND : 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. **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.

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%.

The first eHealth Action Plan 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. For instance, the Commission Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC), theCommunication on benefits of telemedicine for patients healthcare systems and society.

The adoption of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare establishing the eHealth Network, marked a further step towards formal cooperation on eHealth. The **eHealth Network** set up by this Directive is the main strategic and governance body at EU level to work towards interoperability of cross-border eHealth services.

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.

CONTENT : the new eHealth Action Plan outlines the **vision for eHealth in Europe**, in line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe. 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:

(1) Achieving wider interoperability of eHealth services : the Commission recognises the need for an eHealth interoperability framework, building on eHealth roadmaps and the general European Interoperability Framework with its four levels of interoperability: legal, organisational, semantic and technical.

(2) Supporting research, development and innovation in eHealth and wellbeing to address the lack of availability of user-friendly tools and services : 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 usercentricity 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. The Commission shall support:

- Public-Private Partnerships and other actions involving research and innovation and translation of knowledge to clinical trials and demonstration projects;
- actions to improve the market conditions for entrepreneurs developing products and services in the fields of eHealth and ICT for wellbeing.

(3) Facilitating uptake and ensuring wider deployment : the Commission will leverage the Connecting Europe Facility (CEF) and the European Regional Development Fund (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.

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.

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.

(4) Promoting policy dialogue and international cooperation on eHealth at global level : the Commission shall enhance its work on data collection and benchmarking activities in health care with relevant national and international bodies (WHO, OECD) to include more specific eHealth indicators and assess the impact and economic value of eHealth implementation. It 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.

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.

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

2013/2061(INI) - 14/01/2014 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on the eHealth Action Plan 2012-2020 –Innovative healthcare for the 21st century in response to the Commission Communication on the same issue. Parliament noted that equal access to high-quality universal healthcare is recognised as a fundamental right, but that access to a healthcare system is in many cases restricted as a result of either financial or regional constraints. eHealth systems can play an important role in improving these health inequalities. It also stressed the gender aspects of eHealth in the resolution and asked the Commission and the Member States to ensure equal access for women to the field of eHealth, not only as patients but also as caregivers (professional or not), ICT specialists and policymakers, highlighting the fact that women were involved at all levels of the health sector throughout their lives.

Parliament stated that Union action in the field of eHealth, based on Article 168 TFEU, should consist of helping all competent authorities at local, regional, national or state level to coordinate their efforts at national and cross-border levels and supporting their actions in fields where EU intervention can provide added value.

In this respect, Members welcomed the Commission Communication entitled 'eHealth Action Plan **2012-2020:** Innovative healthcare for the 21st century', which updates the eHealth Action Plan adopted in 2004 by putting in place further actions, especially as regards improving access to health services, reducing health costs and ensuring greater equality among European citizens. They urged the Commission to continue working towards the wholesale adoption of eHealth throughout the EU.

Parliament also welcomed the Commission's intention to launch a study regarding the legal aspects of eHealth services. It stressed, however, the need to take effective measures concerning reimbursement, liability and data protection. It emphasised the importance of strengthening the role of

healthcare professionals such as doctors, pharmacists and nurses, as well as of patients and patient organisations, in the implementation and development of the eHealth Action Plan, keeping in mind that patients should have the possibility of viewing, using and consulting information concerning their health.

The Commission and the Member States were called upon to play a major part in bringing different stakeholders together in order to share experience and best practices and to focus in particular on its central role in supporting the sharing of best practices on rare diseases.

Accessibility: Parliament emphasised that eHealth applications must be accessible to everyone and that, when developing any product or software application, accessibility should be a mandatory condition, in order to prevent any inequality with regard to access. It recommended that the necessary steps be taken to close the digital gap between the different regions of the Member States. Equal access should be ensure for women to the field of eHealth, not only as patients but also as caregivers (professional or not), ICT specialists and policymakers. The Commission and the Member States are also called upon to:

- pay particular attention to digital literacy and to technical training in order to ensure that eHealth tools, especially telemedicine, are genuinely effective and accessible for the whole population;
- provide the economic, human and material resources necessary to ensure that access to and use of eHealth services will not add to the territorial inequalities already affecting access to existing ICT services;
- encourage and promote eHealth services designed for (informal) family carers so as to support them in their often heavy caring tasks and to enable them to provide the best care possible;
- encourage eHealth solutions for isolated women, not only those living in remote areas but also home-bound women lacking the mobility and /or (social) support network they need in order to maintain their health and well-being;
- bring forward guidelines and legislative proposals to fill the legal gaps that currently exist, in particular in the field of responsibilities and liability, and to ensure effective implementation of the eHealth system across the EU;
- proceed with guidelines and legislation on the legal and data protection considerations relating to eHealth, in particular legislation enabling secure sharing, processing and analysis of data, in order to balance data protection with data access;
- continue their efforts to implement Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, which is aimed at establishing an eHealth network;
- ensure the technical standardisation and interoperability of ICT enabled solutions and of data exchange at all levels of European healthcare systems, while developing guidelines for the EU-wide interoperability of these systems;
- run eHealth awareness and IT literacy training campaigns (taking into account social and territorial inequalities) aimed at overcoming the lack of knowledge and trust among patients, the general public and healthcare professionals;
- to promote a gender-balanced approach to healthcare and medicine and, when implementing the eHealth Action Plan, to take into consideration the specific needs of women and girls as healthcare beneficiaries.

In the light of these considerations, Parliament called for the establishment of a platform for collaboration in research between patients, academia, industry and professionals in order to ensure the delivery of an effective and all-inclusive eHealth policy.

Members considered the proposed cuts to the Connecting Europe facility for broadband and digital services deeply regrettable. They hoped that financing for this area under Horizon 2020 will be maintained.

The Commission is urged to come forward with a **"mHealth action plan" for mobile devices,** which should include guidelines on market surveillance of mHealth apps in order to ensure data protection and the reliability of the provided health information, as well as to guarantee that these apps are developed under appropriate medical scrutiny.

It is also urged to dedicate resources within future research and development framework programmes to eHealth.

Parliament called on the Commission to **publish every other year a progress review** as regards the implementation of the eHealth Action Plan in the individual Member States, showing how this tool has been modified in innovative ways to provide citizens with high-quality and efficient healthcare systems, and, in the light of this, to set effective indicators at national and Union levels to measure the progress and impact of the actions planned, paying particular attention to potential discrimination or to access inequalities that could affect consumers and patients.

Lastly, Parliament recommended that the Member States and the Commission, with the help of the European Institute for Gender Equality (EIGE), collect gender-disaggregated data on initial findings as regards the accessibility and impact of eHealth systems and tools, and called for steps to be taken to share best practices in eHealth implementation.

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

2013/2061(INI) - 05/12/2013 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report by Pilar AYUSO (EPP, ES) on the eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century in response to the Commission Communication on the same issue.

The report stated that equal access to high-quality universal healthcare is recognised as a **fundamental right**. However, access to a healthcare system is in many cases restricted as a result of either financial or regional constraints. eHealth systems can play an important role in improving these health inequalities.

Article 168 of the Treaty on the Functioning of the European Union stipulates that Union action must complement national policies and be directed towards improving public health. Therefore, Union action in the field of eHealth should consist of helping all competent authorities at local, regional, national or state level to coordinate their efforts at national and cross-border levels and supporting their actions in fields where EU intervention can provide added value.

In this respect, Members welcomed the Commission Communication entitled 'eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century', which updates the eHealth Action Plan adopted in 2004 by putting in place **further actions**, especially as regards improving access to health services, reducing health costs and ensuring greater equality among European citizens. They urged the Commission to continue working towards the wholesale adoption of eHealth throughout the EU.

The report also welcomed the Commission's intention to launch a **study regarding the legal aspects of eHealth services**. It stressed, however, the need to take effective measures concerning reimbursement, liability and data protection. It stressed the need to endorse the wider concept of eHealth, and emphasises the importance of **strengthening the role of healthcare professionals** such as doctors, pharmacists and nurses, as well as of patients and patient organisations, in the implementation and development of the eHealth Action Plan, keeping in mind that patients should have the possibility of viewing, using and consulting information concerning their health.

The Commission and the Member States were called upon to play a major part in bringing different stakeholders together in order to share experience and best practices and to focus in particular on its central role in supporting the sharing of **best practices on rare diseases**.

Accessibility: the report emphasised that eHealth applications must be accessible to everyone and that, when developing any product or software application, accessibility should be a mandatory condition, in order to prevent any inequality with regard to access. It recommended that the necessary steps be taken to **close the digital gap** between the different regions of the Member States. Equal access should be ensure for **women** to the field of eHealth, not only as patients but also as caregivers (professional or not), ICT specialists and policymakers. The Commission and the Member States are also called upon to:

- pay particular attention to digital literacy and to **technical training** for women, especially elderly women, in order to ensure that eHealth tools, especially telemedicine, are genuinely effective and accessible for the whole population;
- provide the economic, human and material **resources** necessary to ensure that access to and use of eHealth services will not add to the territorial inequalities already affecting access to existing ICT services;
- develop new eHealth tools that are accessible to and user-friendly for the elderly and for persons with disabilities;
- bring forward guidelines and **legislative proposals** to fill the legal gaps that currently exist, in particular in the field of responsibilities and liability, and to ensure effective implementation of the eHealth system across the EU;
- establish a **platform** for collaboration in research between patients, academia, industry and professionals in order to ensure the delivery of an effective and all-inclusive eHealth policy;
- proceed with **guidelines and legislation on the legal and data protection considerations** relating to eHealth, in particular legislation enabling secure sharing, processing and analysis of data, in order to balance data protection with data access;
- develop **data standards** for collecting, sharing and reporting on cross-border, health-related issues;
- continue their efforts to implement Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, which is aimed at establishing an eHealth network;
- ensure the **technical standardisation** and interoperability of ICT enabled solutions and of data exchange at all levels of European healthcare systems, while developing guidelines for the EU-wide interoperability of these systems;
- ensure **good governance of operations** related to health information on the internet;
- run eHealth awareness and IT literacy **training campaigns** (taking into account social and territorial inequalities) aimed at overcoming the lack of knowledge and trust among patients, the general public and healthcare professionals.

Members considered the proposed cuts to the Connecting Europe facility for broadband and digital services deeply regrettable. They hoped that financing for this area under Horizon 2020 will be maintained.

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