



# Procedure file

| Basic information  |                                |                     |
|--|--------------------------------|---------------------|
| INI - Own-initiative procedure   | <a href="#">2013/2061(INI)</a> | 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  |
|  | <b>ENVI</b> Environment, Public Health and Food Safety |   | 25/04/2013 |
|  |  | PPE <a href="#">AYUSO Pilar</a>               |            |
|  |  | Shadow rapporteur                             |            |
|  |  | S&D <a href="#">TĂNĂSESCU Claudiu Ciprian</a> |            |
|  |  | ALDE <a href="#">PARVANOVĂ Antonia</a>        |            |
|  |  | ECR <a href="#">NICHOLSON James</a>           |            |
|  | Committee for opinion                                  | Rapporteur for opinion                        | Appointed  |
|  | <b>EMPL</b> Employment and Social Affairs              | The committee decided not to give an opinion. |            |
|  | <b>ITRE</b> Industry, Research and Energy              | The committee decided not to give an opinion. |            |
| European Commission                    | <b>IMCO</b> Internal Market and Consumer Protection    |   | 18/12/2012 |
|  |  | S&D <a href="#">IRIGOYEN PÉREZ María</a>      |            |
|  | <b>REGI</b> Regional Development                       |   | 19/03/2013 |
|  |  | EFD <a href="#">IMBRASAS Juozas</a>           |            |
|  | <b>FEMM</b> Women's Rights and Gender Equality         |   | 18/04/2013 |
|  |  | PPE <a href="#">RONZULLI Licia</a>            |            |
| Commission DG                          | Commissioner   |   |            |
| <a href="#">Health and Food Safety</a> | BORG Tonio   |   |            |

| Key events |  |                               |         |
|------------|--|-------------------------------|---------|
| 06/12/2012 | Non-legislative basic document published   | <a href="#">COM(2012)0736</a> | Summary |
| 18/04/2013 | Committee referral announced in Parliament |                               |         |
| 27/11/2013 | Vote in committee                          |                               |         |
| 05/12/2013 | Committee report tabled for plenary        | <a href="#">A7-0443/2013</a>  | Summary |
|            |  |                               |         |

|            |                                |   |         |
|------------|--------------------------------|---|---------|
| 13/01/2014 | Debate in Parliament           |    |         |
| 14/01/2014 | Results of vote in Parliament  |  |         |
| 14/01/2014 | Decision by Parliament         | <a href="#">T7-0010/2014</a>  | Summary |
| 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 54       |
| Other legal basis          | Rules of Procedure EP 159      |
| Stage reached in procedure | Procedure completed            |
| Committee dossier          | ENVI/7/11532                   |

### Documentation gateway

|   |             |  |            |      |         |
|---|-------------|--|------------|------|---------|
| Non-legislative basic document                      |             | <a href="#">COM(2012)0736</a>  | 06/12/2012 | EC   | Summary |
| Document attached to the procedure                  |             | <a href="#">N7-0043/2014</a><br><a href="#">OJ C 358 07.12.2013, p. 0013</a> | 27/03/2013 | EDPS |         |
| Committee draft report                              |             | <a href="#">PE516.917</a>  | 05/09/2013 | EP   |         |
| Committee opinion                                   | <b>REGI</b> | <a href="#">PE514.579</a>  | 26/09/2013 | EP   |         |
| Committee opinion                                   | <b>FEMM</b> | <a href="#">PE516.618</a>  | 04/10/2013 | EP   |         |
| Committee opinion                                   | <b>IMCO</b> | <a href="#">PE514.574</a>  | 08/10/2013 | EP   |         |
| Amendments tabled in committee                      |             | <a href="#">PE521.697</a>  | 18/10/2013 | EP   |         |
| Amendments tabled in committee                      |             | <a href="#">PE524.557</a>  | 26/11/2013 | EP   |         |
| Committee report tabled for plenary, single reading |             | <a href="#">A7-0443/2013</a>   | 05/12/2013 | EP   | Summary |
| Text adopted by Parliament, single reading          |             | <a href="#">T7-0010/2014</a>   | 14/01/2014 | EP   | Summary |
| Commission response to text adopted in plenary      |             | <a href="#">SP(2014)320</a>  | 26/05/2014 | EC   |         |

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

**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), the [Communication 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

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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 21<sup>st</sup> 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 Commissions 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 ensured 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.

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.

Lastly, Members 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.

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

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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 ensured 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.