Opinion of the European Economic and Social Committee on the '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 2012-20 — Innovative healthcare for the 21st century'

COM(2012) 736 final

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On 19 February 2013, the European Commission decided to consult the European Economic and Social Committee, under Article 304 of the Treaty on the Functioning of the European Union, on the

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

COM(2012) 736 final.

The Section for Transport, Energy, Infrastructure and the Information Society, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 30 April 2013.

At its 490th plenary session, held on 22 and 23 May 2013 (meeting of 22 May), the European Economic and Social Committee adopted the following opinion by 154 votes in favour, with 4 abstentions.

1. **Conclusions and recommendations**

1.1 The EESC welcomes the proposed eHealth Action Plan 2012-2020. However, the communication does not have a special chapter on the social aspect of providing services and further development of social and health care.

1.2 The EESC points out that the principal responsibility for the new plan's success lies with the Member States, although the Commission plays a vital supporting and coordinating role.

1.3 The human dimension must be at the heart of eHealth. The risk of 'being impersonal' and failure to pay attention to psychological factors should be avoided.

1.4 The EESC finds it particularly regrettable that the number of health workers is falling while demands on healthcare systems are increasing.

1.5 The EESC points out that the communication makes only partial references to how the new plan will be financed. A general overview is needed to establish what contribution is expected from the public sector, the private sector and – where appropriate – from patients and taxpayers in general.

1.6 The EESC highlights the need for full coordination among the programmes, activities, projects and working groups included in the communication in order to avoid the risk of overlap.

1.7 As regards standardisation of the necessary IT equipment functions, the need for proper monitoring by public authorities must be underlined in order to prevent the abuse of dominant positions, as has occurred in certain areas of ICT.

1.8 The EESC welcomes the decision to tackle another key aspect of interoperability, namely the main legal issues which stand in the way of a system of cross-border telemedicine being implemented.

1.9 The EESC welcomes the Commission's plans for the development of the economic fabric relating to eHealth, especially because of its support for SMEs, but the lack of detail and figures prevents a more precise assessment from being carried out.

1.10 The EESC stresses that the Connecting Europe Facility must not consist only of 'connecting systems', but must also enable people to become familiar with, understand and reap the benefits of connecting European citizens.

1.11 The new eHealth programme must aim to guarantee greater equality among European citizens as regards access to health services. Rolling out of broadband will play a key role in this connection.

To ensure that the inequality that already exists in access to healthcare does not also occur in eHealth, broader measures and bigger investments are required than those provided for by the ERDF (European Regional Development Fund).

1.12 Improving the digital health literacy A) of patients: taking account of the experience of the Sustains project, it is very important to train people how to access and use their own data currently 'locked away' in health information systems; B) of health professionals: it is vital to include knowledge of eHealth in training programmes.

2. **Introduction**

2.1 Although progress has been made since the EU launched the first eHealth action plan in 2004, there are still obstacles facing the development of an integrated European system. The reasons for this include:

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

— lack of interoperability between eHealth solutions;

— inadequate or fragmented legal frameworks;

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

2.2 The proliferation in Europe of products which are incompatible with one another is the inevitable consequence of a fragmented market and the non-existence, or lack of awareness on the part of major buyers, of communication and exchange standards. As a result, IT systems in countries, neighbouring regions or even within health centres often cannot be connected to one another. For example, in some cases, hospital radiology departments have tailor-made software that cannot communicate with programmes used in other departments of the same hospital.

2.3 In line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe, the new action plan seeks to address and remove these barriers, in addition to clarifying the policy domain and outlining the vision for eHealth in Europe.

2.4 The global eHealth market, which is growing strongly, may be worth USD 27,3 billion by 2016. In some cases, major European businesses are world leaders and, overall, it is estimated that there are 5 000 businesses in this sector.

3. **Commission proposals**

3.1 The Commission highlights the challenges facing European healthcare systems. Public health expenditure in the EU's 27 Member States may rise to 8,5 % of GDP by 2060 as a result of population development and other factors. During the same period, the size of the working population will decrease and the number of over-65s will go up. Another challenge is to ensure active European participation in the global eHealth market.

3.2 Aims:

— achieving wider interoperability in services;

— supporting research, development, innovation and competitiveness;

— facilitating uptake and ensuring wider deployment of eHealth;

— promoting policy dialogue and international cooperation in this area.

3.3 Measures include facilitating cross-border interoperability (technical and semantic elements, quality labelling, certification); adopting a green paper on health, improving market conditions for businesses and increasing citizens' digital literacy (Competitiveness and Innovation Framework Programme and Horizon 2020).

4. **The EESC's view - General observations**

4.1 The EESC welcomes the proposed eHealth Action Plan 2012-2020.

4.2 However, the EESC believes that the plan should include a special chapter on the social aspect of providing services, covering in particular the proper approach to the digital divide, availability of technology, the ability to use it, or an analysis of social inequalities in health which run the risk of increasing. It should also cover broader development of social and health care, which could be facilitated enormously with the use of ICT.

4.3 The EESC points out that, given the distribution of competences, the principal responsibility for the action plan's success lies with the Member States. At present, there are clear differences among the Member States in the extent to which eHealth has been implemented.

The Commission plays a vital supporting and coordinating role, underpinned legally by Articles 114, 168, 173 and 179 of the Treaty on the Functioning of the European Union in particular. There must be full cooperation and active participation on the part of the Member States and the Commission within the framework of the eHealth network (Directive 2011/24/EU).

4.4 eHealth must foster mutual trust between patients and professionals by avoiding the risk of 'being impersonal' and failing to pay attention to psychological factors. The human dimension must be at the heart of eHealth. However, the EESC notes that according to some European patient rights organisations, such as the European Patients Forum (EPF), the process is driven more by technology than by patient needs. This concern must be taken into account.

4.5 IT cannot be a substitute for a lack of staff. The EESC finds it particularly regrettable that the number of health workers is falling while demands on healthcare systems are increasing. ICT is merely a tool to help those women and men who everyday carry out the self-sacrificing work of providing healthcare to patients, and to help facilitate the relationship between patients and health professionals.

4.6 The EESC points out that the communication makes only partial references to how the new plan will be financed. A general overview is needed to establish what contribution is expected from the public sector, the private sector and – where appropriate – from patients and taxpayers in general.

4.7 The EESC highlights the need for full coordination among the programmes, activities, projects and working groups included in the Commission communication, and the need to avoid the risk of overlap.

4.8 Organisational change by health service providers is key to the success of the new eHealth plan. Implementing access to e-Health cannot be the sole responsibility of top administrative levels, and nor can the public as final users be expected to bring it about. Intermediary organisations providing health services have to take steps to adapt their structures and their staff to these new service models.

5. **Specific comments**

5.1 *Interoperability*

5.1.1 Technical and semantic aspects

5.1.1.1 In general, the EESC welcomes the Commission proposal on interoperability, although points out that it is not enough to introduce the possibility of exchanging data or documents using common medical protocols, because there are also problems of a semantic, organisational or legal nature which have to be resolved.

5.1.1.2 Semantic interoperability

The Commission proposal should clarify the relationship between the various programmes, activities or work groups – such as the 7th framework programme and ISA – and SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms), the most wide-ranging, accurate and important encoded, multilingual and comprehensive clinical terminology in the world, distributed by the International Health Terminology Standards Development Organisation (IHTSDO). The latter is a non-profit organisation whose members include various EU countries, the USA and Australia.

5.1.1.3 Standardisation

There are multiple providers of software and hardware for eHealth. It is vitally important to make progress, within the framework of regulation (EU) No 1025/2012, on the process of standardising necessary functions, with a view to offering industry and users – especially those who are in a position to make purchasing decisions – a more attractive framework, fewer risks and a more cost-effective and useful investment. The EESC underlines the need for proper monitoring by public authorities in order to prevent the abuse of dominant positions, as has occurred in certain areas of ICT.

5.1.1.4 The organisational aspect

The EESC welcomes the Commission's decision to present specific measures geared towards integration and cooperation in the EU. The pilot project epSOS (European Patients Smart Open Services) [1], will facilitate the drafting of the specific measures to be announced by the Commission aimed at integrating cross-border eHealth processes.

5.1.1.5 Legal aspects

5.1.1.5.1 The EESC welcomes the decision to tackle the main legal issues which stand in the way of a system of cross-border telemedicine being implemented [2]. Given that these are innovative technologies, the regulatory gaps and obstacles have not yet been fully resolved at international, or even at national level.

5.1.1.5.2 Granting licenses and authorisations to professionals and medical institutions

According to Directive 2011/24/EU on patients' rights in cross-border care, the legislation of the Member State of treatment applies (Art. 4(1)(a)) [3]. The EESC suggests considering reform of Directive 2005/36/EC on recognition of professional qualifications, which does not cover cross-border provision.

5.1.1.5.3 Data protection

Medical information is sensitive. Patients want to be able to control this information and access to it for their benefit. The discussion on the patient's right to block access to information about their own medical history should be analysed globally in order to achieve the same standards for all European citizens. The EESC points out that the lack of trust in the security of medical data may lead patients to hide vital information.

5.1.1.5.4 Protection of personal data is a fundamental right guaranteed by Article 16 of TFEU and the Charter of Fundamental Rights (Articles 7 and 8). Directive 95/46/EC provides for such protection in the event of the processing or free movement of data [4]. However, the scope granted to Member States in their implementation has lead to significant disparity in the level of protection, which currently represents one

[1] epSOS develops recommendations, technical specifications, system descriptions, organisational models, IT applications and tools, etc., which are aimed at improving interoperability at multinational level. In addition, **pilot systems have been introduced** in various regions.

[2] See Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, SWD(2012) 414 final.

[3] See Directive 2000/31/EC, Art. (3)(1) and (2) 'country of origin principle'.

[4] Also applicable are Directive 2002/58/EC on protection of privacy in the electronic communications sector and Directive 2011/24/EU.

of the biggest obstacles to cross-border telemedicine. The EESC must therefore reiterate its support for the proposed general regulation on data protection ([5]), as expressed in its opinion of 23 May 2012 ([6]).

5.1.1.5.5 Reimbursement

The country of affiliation (where medical care is received) must ensure that, where appropriate, the costs of cross-border care are reimbursed (Directive 2011/24/EU, Art. 7(1)). The EESC's view: there should be clear information for the patient on the conditions of reimbursement.

5.1.1.5.6 Responsibility for damage caused by professional error and supplies of medical equipment

This is a complex issue because, among other things, of the possibility that several stakeholders may be involved. As regards cross-border medical care, there is a general principle – the legislation of the Member State of treatment applies (Directive 2011/24/EU, Article 4(1)). Defective products are governed by Directive 85/374/EEC, which establishes the principle of liability without fault. The EESC's view: underpinned by existing legal bases, specific cases must be dealt with using case-law.

5.1.1.5.7 Applicable jurisdiction and legislation

Another very complex subject which must be dealt with according to current international norms and treaties. The EESC suggests that consideration be given to out-of-court systems for conflict resolution, such as arbitration and mediation.

5.1.1.5.8 Right of access

The level of access by patients and citizens to medical information and their personal medical history has increased. Some regions have increased the level of services by providing care centres and service 24 hours each day, for the whole population, for selected groups of patients at risk or for entire regions. Patients may make their own appointments and have appropriate access to the information contained in their medical history. This encourages the patient to take active responsibility for their healthcare and for prevention. The EESC's view: the right of access in the case of cross-border care should be regulated.

5.1.1.5.9 Mobile health and wellbeing

The EESC welcomes the Commission's decision to address mobile health and wellbeing applications (mobile eHealth) in the Green Paper to be presented in 2014. This is a particular aspect of eHealth, which is growing strongly at the present time as a result of widespread use of mobile devices (smart phones, tablets, etc.) and special software for these devices (apps). The popularity of such tools means that the technical and legal aspects related to their use should be regulated.

([5]) COM(2012) 11 final – 2012/0011 (COD).

([6]) EESC exploratory opinion on *The digital market as a driver for growth*, OJ C 229, 31.7.2012, p. 1.

5.2 *RDI*

5.2.1 The EESC regards as appropriate the areas of research which the Commission proposes should be supported under Horizon 2020's 'Health, demographic change and wellbeing' programme.

5.2.2 With the EU's appropriation for medical research in the 2014-2020 period still to be established, the EESC points out that the National Institute of Health (USA) invests USD 30 900 million annually for this purpose.

5.2.3 In light of the proposals drawn up by organisations representing the health sector, such as EPHA (European Public Health Alliance), the EESC suggests that research programmes take account of the following, among other things:

— Complementing other programmes, such as Health for Growth, by compiling reliable statistics on the development of diseases with a high incidence in the population: obesity, cardiovascular diseases, cancer, diabetes, etc.

— Coordination, given that traditionally researchers have worked independently and not communicated enough with each other.

— The conditions of patents for work paid for by the taxpayer to avoid the danger of socialising the risks of research while privatising the benefits ([7]).

5.3 The EESC welcomes the Commission's plans for the development of the economic fabric relating to eHealth, especially because of its support for SMEs, but the lack of detail and figures prevents a more precise assessment from being carried out.

5.4 In accordance with the results of the pilot project epSOS and of other projects and studies, the EESC stresses that the 2014 – 2020 Connecting Europe Facility must not consist only of 'connecting systems'. In addition, people must have the possibility to become familiar with, understand and reap the benefits of a 'connected citizenship'.

5.5 *Cohesion*

5.5.1 The new eHealth programme must aim to guarantee greater equality among European citizens as regards access to health services. As the Committee has already pointed out, it is clear that broadband access in all countries and full connectivity are key conditions for the development of telemedicine. Digital services in the regions, especially in rural and outlying areas, must therefore be consolidated ([8]).

([7]) EPHA Position on Horizon 2020 (June 2012). http://ec.europa.eu/research/horizon2020/pdf/contributions/during-negotiations/european_organisations/european_public_health_alliance.pdf

([8]) OJ C 317, 23.12.2009.

5.5.2 With the current ERDF programming period coming to an end, the EESC trusts that in the 2014-2020 period the current proposals to roll-out the latest technologies on a large scale throughout the EU will be carried out and that, above all, they will have a sufficient budget. However, to prevent the inequality that already exists in access to healthcare from also occurring in eHealth, broader measures and bigger investments are required than those provided for by the ERDF.

5.6 *Improving digital health literacy*

5.6.1 For the EESC, in the case of patients it is very important to train people how to access and use their own data which in many cases is currently 'locked away' in health information systems. In this connection, we would like to draw attention to the Sustains project, currently established in 13 European regions and which seeks to facilitate peoples' access to their medical data through 'personal medical files' and other added services in web environments.

5.6.2 In the case of the health community, it is vital to promote the inclusion of eHealth knowledge in the training programmes of clinicians and managers.

5.7 *Programme evaluation*

5.7.1 The EESC believes that the establishment of common values and evaluation programmes – to be carried out by the Commission - on the advantages of eHealth is one of the most interesting aspects, given that the speed of technological change often makes it impossible to determine its real usefulness. Surveys carried out stress that support for eHealth from the public and the medical community is directly linked to the belief that it will entail a verifiable improvement in the health system.

5.7.2 The EESC must also point out that a sound knowledge of the models and technologies which have a positive impact and a clear effort to promote them are essential for health models based on ICTs. In order to obtain this benefit, there must be flexible and dynamic evaluation methodologies, with a special focus on the overall evaluation of the service provided and not so much the technology itself. It is also necessary to include an evaluation of the service's effectiveness, covering its overall financial costs and benefits. Clearly however, economic effectiveness must not be the only criteria for recommending use of care models based on ICTs.

5.7.3 In general, among public authorities, industrial sectors and representative organisations, the predominant view is that eHealth (which covers a wide range of applications) may offer health benefits. The EESC shares this view, while pointing out that consideration should also be given to critical opinions, based on real experiences, which cast doubt on the cost savings and highlight problems: IT errors, 'cloning' of reports, possibility of fraud, high costs, etc.

5.8 *Promoting policy dialogue and international cooperation*

There is clearly a need for policy dialogue on eHealth at international level, as proposed by the Commission, given that developing countries are also making major strides in this area. This will make it possible to steer the use of ICT towards meeting the objectives of the United Nations and to apply them in a spirit of solidarity.

Brussels, 22 May 2013.

The President
of the European Economic and Social Committee
Henri MALOSSE