European Economic and Social Committee

TEN/551
EU framework on "mHealth" and "health and wellbeing applications"

Brussels, 10 September 2014

OPINION

of the
European Economic and Social Committee
on the
Green paper on mobile health ("mHealth")
COM(2014) 219 final

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Rapporteur: **Isabel Caño Aguilar**

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Rue Belliard/Belliardstraat 99 — 1040 Bruxelles/Brussel — BELGIQUE/BELGIË
Tel. +32 25469011 — Fax +32 25134893 — Internet: http://www.eesc.europa.eu

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On 10April 2014, 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

Green Paper on mobile health ("mHealth")
COM(2014) 219 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 1 September 2014.

At its 501st plenary session, held on 10 and 11 September, 2014 (meeting of 10 September), the European Economic and Social Committee adopted the following opinion by 180 votes to 1 with 1 abstention.

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1. Conclusions and recommendations

1.1 The EESC wishes to emphasise the importance of mobile health (mHealth), which performs a number of healthcare-related functions and is a technology of the future that is being used by more and more people across the world.

1.2 The EESC welcomes the Green Paper, because of the contribution that mHealth can make to European healthcare systems, which are facing increasing challenges as a result of demographic change.

1.3 The EESC considers that the priority must be to improve healthcare, not to cut costs. The success of mHealth requires the participation of healthcare professionals, dialogue with patient organisations, the promotion of mutual trust between patients and professionals and the provision of incentives and training plans for the latter. Close dialogue also needs to be established with industry in this field.

1.4 The EESC recommends that information campaigns be conducted on all aspects of mobile health.

1.5 The new legal framework substantially improves the protection of personal data, as stipulated by the EU Charter of Fundamental rights, but there is currently no technological means of preventing improper access to mobile communications.

1.6 Macro data are essential to medical research. The EESC considers that: a) patient anonymity should always be upheld, b) data-mining programmes should be promoted, c) consideration should be given to prohibiting big data from being patented or sold and d) technologies and rules also need to be established for metadata.

1.7 There is a need to regulate, by means of a regulation: a) "healthcare" within the meaning of Directive 2011/24/EU, b) safety and wellbeing apps and c) cross-border health care, which is not covered by current legislation.

1.8 Rules should be drawn up for the standardisation, certification and approval by the authorities of mobile health and wellbeing systems.

1.9 The Commission should consider putting in place binding national strategies to guarantee equal access to mobile healthcare.

1.10 Technical and semantic interoperability under the European Interoperability Strategy is hugely important to ensuring the widespread use of mHealth.

1.11 Adequate knowledge of the regulations and the use of approved equipment will help mitigate the liability of manufacturers and medical professionals.

1.12 International cooperation on mHealth, also involving the WHO, should prioritise establishing a list of medical devices, ethical principles, and data protection and interoperability provisions. Consideration should be given to placing m-Health on the agenda for the TTIP negotiations between the EU and the United States.

1.13 It is essential to look into removing the regulatory, economic, structural and technological barriers that damage European industry. SMEs have an important role to play in mHealth.

2. Gist of the Green Paper

2.1 According to the World Health Organization, mobile health (or mHealth): is "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".

2.2 mHealth has considerable potential in the field of healthcare, with an approach based on improving prevention and the quality of life, healthcare that is more effective and sustainable and patients that are more empowered and active.

2.3 Given the exponential growth in mobile device users (totalling some 6 billion people worldwide), mHealth also has an estimated market potential of USD 23 billion by 2017.

2.4 In 2017 mHealth could potentially save a total of EUR 99 billion in healthcare costs in the EU.

3. General comments

3.1 The EESC wishes to emphasise the importance of mHealth, which fulfils a number of healthcare-related tasks and is a future technology that is being used by more and more people across the world.

3.2 The EESC welcomes the Green Paper, since mobile health can improve European healthcare systems, which are facing increasing challenges as a result of demographic change and the need to address the treatment of chronic diseases, obesity (a growing problem in the EU), smoking and many other problems.

3.3 The EESC would point out that although the EU will play a key coordinating and supporting role, responsibility for setting up and managing healthcare systems falls to the Member States, many of which are facing serious budget constraints.

3.4 In developed countries, mHealth is driven by the "imperative" to cut healthcare costs The EESC feels, however, that the priority should be to improve the healthcare that people receive.

3.5 Suggestions by the EESC for ensuring the success of mHealth:

- the involvement of healthcare professionals in setting it up;
- dialogue with patient organisations;
- dialogue with the app-producing industry;
- initial and ongoing training of healthcare staff in the use of mobile technologies and incentives to encourage them to do so;
- fostering trust between patients and professionals by avoiding the risk of "being impersonal" and failing to pay attention to psychological and social factors[1].

3.6 The EESC recommends that public information campaigns on mHealth be run, also pointing out its limitations and the need for health or wellbeing devices to be used correctly. People should be aware that for all the new possibilities such devices offer, there are just as many risks.

3.7 The EESC is concerned to note the effects of austerity measures and staffing cuts to reduce hospital expenditures. It also emphasises the need not to undermine public welfare systems.

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1 Opinion on eHealth (TEN/509, 2013), OJ C 271, 19.9.2013, p. 122.

4. Specific comments. Replies to the questions

4.1 Data security

4.1.1 *Which specific security safeguards in mHealth solutions could help to prevent unnecessary and unauthorised processing of health data in an mHealth context?*

4.1.2 Poor security is a barrier to the wider use of mHealth.

4.1.3 There are no solutions that can "prevent" improper access to healthcare data, although encryption and authentication mechanisms can reduce the risk to some extent. Data protection technologies are available on the market today, but there are no guarantees as to their reliability.

4.1.4 The EU's current legal framework for data protection[2] is now under review[3]. The new regulation, which is likely to enter into force in 2015, represents a considerable improvement as regards the right to the protection of personal data enshrined in the EU Charter of Fundamental Rights (Article 8) and in the TFEU (Article 16(2))[4].

4.1.5 In the EESC's opinion:

- Putting in place effective data protection technologies requires greater investment and research, both public and private. The third pillar of the digital agenda (trust and security) should lead to progress in this area.
- Although medical and wellbeing data are covered by the general rules, consideration should be given to including a specific chapter on this issue.
- The EU should try to ensure that the ISO 27001 standard is adopted at the international level.

4.1.6 *How could app developers best implement the principles of "data minimisation" and of "data protection by design", and "data protection by default" in mHealth apps?*

4.1.7 The principles referred to above are adequately addressed in the future legislation, but what is essential is to ensure they are fully complied with. Where "data minimisation" is concerned, apps developers must be transparent with regard to the products they offer.

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2 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995, p. 31.

3 Proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to processing of personal data and on the free movement of such data COM(2012) 11 final http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf.

4 EESC opinion SOC/455, of 23 May 2012, OJ C 229, 31.7.2012, p. 90.

4.2 **Macro data**

4.2.1 *What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU whilst complying with legal and ethical requirements?*

4.2.2 Big data, which are constantly increasing in volume, play a crucial role in research and in medical practice.

4.2.3 In the EESC's opinion:

- Because patients' trust is absolutely essential, they must be provided with adequate information on how data is to be used.
- Patient anonymity should always be upheld.
- EU-funded research programmes should include the objective of developing technologies for mining medical data.
- Consideration should be given to preventing big data from being patented or being used in commercial transactions.
- Big data should be made freely available to the scientific community, and
- Technologies and rules also need to be established for metadata.

4.3 **Legal framework**

4.3.1 *Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?*

4.3.2 The EU's current legal framework for "medical devices"[5] is now under review. The Commission has drawn up a number of guidelines for software creators and manufacturers of devices on what can (and cannot) be included, under current legislation.

4.3.3 There is no definition of what a "system" is, but there are specific requirements for products sold on the market that combine both devices covered by the law and those that are not.

4.3.4 Nor is a clear distinction made between "wellbeing only" devices (Mobile Wellness Apps) and those that are purely medical (Mobile Medical Apps).

5 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, (OJ L 17.7.93, L169/1). Also, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). Council Directive of 20 June 1990 on implantable medical devices (OJ L 189, 20.7.1990, p. 17).

4.3.5 Accordingly, there is a need to:

- Regulate, by means of regulation, a) "mHealth", in line with the established definition of "healthcare"[6] and b) safety and wellbeing apps.
- Because it is not covered by current legislation, consideration should be given to the issue of cross-border healthcare.
- Aims: a) to give legal certainty to manufacturers; b) to provide guarantees for both professionals and users; c) prevent the marketing of ineffective or dangerous products.

4.3.6 *Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if so, why and how?*

4.3.7 Yes, to ensure that mHealth is used effectively. Monitoring compliance with legislation is a complex task, given that there are more than 40 000 health and well-being devices available. It is therefore crucial for tasks to be coordinated and shared out between the Commission and the Member States.

4.4 **Patient safety and transparency of information**

4.4.1 *What policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?*

4.4.2 Apps should be covered by mandatory rules on:

- standardisation,
- certification,
- and approval by the authorities.

4.4.3 *How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?*

4.4.4 Personal wellbeing apps should meet the same requirements as those for medical purposes, since they also contain information on an individual's health.

4.5 **The role of mHealth in healthcare systems and equal access**

4.5.1 *Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems? What good practices exist in the organisation of healthcare to maximise the use of mHealth for higher quality care (e.g. clinical guidelines for use of mHealth)? Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?*

6 See Article 3 a) of Directive 2011/24/EU on cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

4.5.2 The PwC report cited by the Commission highlights the need for "further evidence" of the long-term economic and clinical benefits of mHealth (p. 21).

4.5.3 *What policy action could be appropriate at EU, as well as at national, level to support equal access and accessibility to healthcare via mHealth?*

4.5.4 According to the Treaties and the common values of the EU, the Commission should prepare policy actions for equal access to mHealth and bind Member States to prepare national strategies on telehealth services also addressing equal access.

4.5.5 mHealth should form an integral part of healthcare systems, accessible to everyone and not only to those who are better educated or in a better financial position.

4.5.6 The EESC wishes to express its fears that the development of mHealth could increase inequality in access to healthcare, *inter alia* for the following reasons:

- the digital divide,
- the uneven availability of broadband across the regions,
- the lack of specific measures for people with different disabilities,
- the high price of equipment needed by patients (smartphones, tablets, etc.).

4.5.7 For mHealth to become widespread, measures must be put in place to support inclusion in the digital society and targeting people with greater healthcare needs, such as the elderly, the chronically sick and people with disabilities, at reasonable prices.

4.6 **Interoperability**

4.6.1 *What, if anything, do you think should be done, in addition to the proposed actions of the eHealth Action Plan 2012-2020, in order to increase interoperability of mHealth solutions?*

4.6.2 Establish reliable and secure mechanisms for transferring medical data by means of medical devices.

4.6.3 *Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records?*

4.6.4 Yes. Data volumes are doubling every 18 months, and growth at this pace means that standards are essential. Standards have different functions in different healthcare fields, but interoperability standards are the cornerstone of usable interfaces between disparate systems.

4.6.5 It is important to push ahead with the semantic issue under SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms).

4.6.6 *And if yes by whom and how?*

4.6.7 The European Interoperability Strategy, in which the Commission and the Member States take part (with some Member States already having established standards in this area), would appear to be the appropriate framework.

4.7 **Liability**

4.7.1 *What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?*

4.7.2 Applicable law. Liability (whether contractual or non-contractual) for cross-border medical provision: the law of the Member State of treatment (Directive 2011/24/EU, Article 4(1)). Defective products: Directive 85/374/EEC, under the principle of liability without fault.

4.7.3 Healthcare professionals: to adhere to established protocols and use approved equipment and procedures; manufacturers: adequate knowledge of the legal requirements. In both cases, it needs to be established who will bear the insurance costs.

4.8 **Research and innovation in mHealth**

4.8.1 *Could you provide specific topics for EU level research & innovation and deployment priorities for mHealth?*

4.8.2 From the technical point of view, the existing Horizon 2020 programmes cover the main areas of research.

4.8.3 The EESC suggests that an assessment also be made of the social impact of mHealth, especially on the elderly, people with disabilities, immigrants and people on a low income.

4.8.4 *How do you think satellite applications based on EU navigation systems (EGNOS and Galileo) can help the deployment of innovative mHealth solutions?*

4.8.5 Advances in geo-positioning and better communications will undoubtedly improve the effectiveness of mHealth.

4.9 **International cooperation**

4.9.1 *Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how? Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?*

4.9.2 M-health should be on the agenda for negotiations between the EU and the USA on the TTIP, which started in July 2013.

4.9.3 Priority issues for international cooperation, with the participation of the WHO:

- a regularly updated list of apps considered to be for medical purposes,
- ethical principles,
- data protection in accordance with the ISO 27001 standard,
- interoperability.

4.10 **Access of web entrepreneurs to the mHealth market The apps market**

4.10.1 *Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they face? How can these be tackled and by whom? If needed, how could the Commission stimulate industry and entrepreneurs involvement in mHealth, e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership on Active and Healthy Ageing?*

4.10.2 Industry does indeed come up against a number of barriers:

- regulatory barriers (lack of clarity in legislation),
- economic barriers (further research is needed into the benefits to the healthcare system and the health incentives system needs to be remodelled),
- structural barriers (a lack of integration at the different tiers of healthcare administration), and
- technological barriers (quality standards, certification schemes, interoperability).

4.10.3 Problems should be addressed in line with the level of powers held:

- the Member States, for the organisation of the healthcare system within their borders;
- the EU for market fragmentation and the lack of legislative clarity.

4.10.4 The EESC emphasises the need to support European SMEs, as they could play a key role in the mHealth market.

4.10.5 Start-ups in Europe need better sources of funding, through both conventional channels (banks) and non-conventional ones (such as crowdfunding, among others). Risk finance (provided for in Horizon 2020) and public/private partnerships should help strengthen European industry.

Brussels, 10 September 2014.

The President
of the
European Economic and Social Committee

Henri Malosse