



Parlamentul României
Senat

Bucharest, 24 June, 2014

Courtesy translation

OPINION

**of the ROMANIAN SENATE, on the
GREEN PAPER FROM THE COMMISSION
on mobile Health („mHealth”)**

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The Senate of Romania has analyzed the different cross-border European-wide issues and the possible coordinated action at EU level that could contribute to the scale-up of mHealth in Europe.

Taking into account the report of our permanent Committee on European Affairs and Committee on Public Health, **the Plenum of the Senate**, during its session of the 24 June 2014, decided:

Art. 1 – At the point 3 of the *Green Paper on mobile Health („mHealth”)*, entitled *Issues at stake*, the point of view of the Romanian Senate is as follows:

I. At the subparagraph 3.1. – *Data protection, including security of health data*, the answers to the first two questions are:

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

The Senate considers that the use of modern scientific techniques should aim at obtaining a balance between the benefits of their extensive use and the important interests regarding private life. Any member state that wishes to have a pioneer role in the development of new technologies bears this responsibility.

The implementation of technological solutions (e.g. *smartphone*) that allow the collecting and processing of considerable amount of data – such as medical data – in the mobile health domain implies large-scale processing of personal data and may represent a risk for the protection of personal data of individuals and, implicitly, for the respect and guarantee of fundamental rights, especially private life wise. As an example, electronic communication between individuals

and various medical entities (physicians, hospitals, pharmaceutical or research units etc.) might be exposed to several risks, such as data loss or destruction – even accidental.

The Senate claims that the processing of medical data within health system has to be regulated, standardized and certified. Without standardization, the patients will not be able to know what happens with their personal medical data.

Therefore, the Senate considers that the following security guarantees will contribute to the prevention of unauthorized or futile processing of medical data by using mobile applications:

- a) data security shall be obtained by storage and replication within national data centers, which are designed and built in a way to ensure exceptional security levels;
- b) data storage on various devices and data transmission shall be operated only upon the consent of the device holder, under anonymity; moreover, only the patient shall be the decider if sharing data with other users;
- c) the setting that users can operate shall display not only an explicit consent (this type of setting implicitly raising several ethical issues), but also the option of choosing – as detailed as possible – the data he wants to send and the recipient, as well as options such as not sending data or storage data only on own device, deleting profile data, access journals etc. The user needs to have full control over the data.
- d) the user shall receive warnings regarding potential risks which can occur by operating the application or the device. Clear provisions about responsible parties are needed, in order to be applied when negative incidents occur.
- e) information exchange about collecting medical data shall be encrypted by using communication channels VPN type. In order to raise citizen trust, public keys – known also as asymmetric –, which proved their efficacy over time, shall be publicized and used. Such encryption method that might be used in medical applications and devices is PGP, or standard *OpenPGP*. Given the method, third entities would hardly be able to access unauthorized data of an individual, or of a group of persons with certain characteristics, without their consent.
- f) patient's medical data shall be accessed by the medical personnel through the qualified digital signature which confirms the identity and the access right to personal data;
- g) computer applications used by the medical personnel for registering and reporting medical data shall be 'user and password' protected;
- h) security of data storage shall be applied in the data transmitting location.

The protection of medical data organized in big volumes shall be accomplished by using both big storage equipments and electronic archives equipments, features that have to be taken into account by the developers of computer systems.

The Senate claims that – in the context of a future implementation of the m-Health – the above-mentioned security requirements shall be respected and applied also to the patient – medical personnel relationship.

2. *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?*

The Senate considers that:

- a) operation and device systems producers – as operators – hold important responsibility in guaranteeing personal data protection and private life protection of the users;
- b) operation and device systems producers shall comply to the principles of respecting private life, both in conceiving mHealth systems ("privacy by design") and in standard settings ("privacy by default");
- c) the principle of data minimization should be tackled and developed not only within mHealth domain;
- d) in order to ensure the principle of data minimization, computer applications – given the data owner consent – should allow access of a third entity only to a subset of absolutely

- necessary data. This can be obtained by re-encrypting existent data and by encrypting data yet not collected using also the third entity key. Cryptography with public PGP keys supports this functionality and it has been successfully used for some time in securing and authenticating e-mails.
- e) the applications for personal data collecting – through monitoring sensors – shall encrypt personal data in a way that data access or owner identification – without his consent – is prevented, by using powerful and efficient methods, before data conveying for storage on a local device or on storage designed centers;
 - f) application developers shall ensure the availability of the proper mechanisms that allow users to alter the parameters of data processing;
 - g) in order to comply to the obligations - security and confidentiality wise in mHealth, application developers and suppliers, as well as operating system and device producers shall permanently, systematically and comprehensively evaluate both the existent and future risks regarding data protection.

II. At the subparagraph 3.2. – *Big data*, the answer to the next question is:

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

The Senate considers that:

- a) an important measure would be the anonymisation of data from individual level, the direct beneficiaries of large volume of data being not the patients, but professional organizations, institutions of state / government involved in national health strategies etc.;
- b) the benefits of submission/ registration in various programs that involve the collection, the access and the processing of the mHealth data should be explained and promoted in common knowledge;
- c) to strengthen the good faith and for the use purpose of personal data, programs should ensure a high level of transparency. At any time, citizens should be able to find out the progress and the results of the use of their personal data. Moreover, they should have the possibility and even be encouraged to be actively involved on a voluntary basis, for example, in various processing and innovation programs involving large volumes of data on the specific context of mHealth.

III. At the subparagraph 3.3. - *State of play on the applicable EU legal framework*, the answers to the two questions are:

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

The Senate considers that further efforts are required, particularly in finding more specific definitions and providing standardization and interoperability of mHealth systems.

For an equitable access to the mHealth applications, the consolidation of EU legislation should aim, above all, to provide a uniform (re)formulation of the legal framework at national and European level.

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

The Senate considers that it is necessary to strengthen the enforcement of actual EU legislation in the field of mHealth, possibly by creating a European body responsible for collecting data about the specific national rules of implementation and with the preparing a possible uniform application in all Member States.

IV. At the subparagraph 3.4. - *Patient safety and transparency of information*, the answers to the next two questions are:

6. *Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?*

The Senate considers that:

- a) actions are necessary to conduct prospective comparative and/or retrospective studies in order to demonstrate the effectiveness of mHealth solutions;
- b) another action could be the approval/certification of computer applications by the competent authority in the medical field. Individual assessment of the health status of the patient is not desirable. Any appreciation of the conclusions resulted from the medical data collected by the computer devices should be settled by doctor.

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

The Senate considers that the ensuring the safe use of mHealth solutions is possible by providing citizens with reliable equipment, easy to use, that can ensure the protection of transmitted data and the safety of users during the operation.

V. At the subparagraph 3.5. - *mHealth role in healthcare systems and equal access*, the answers to the next four questions are:

8. *Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems?*

The Senate sustains that mHealth solutions are already implemented in several countries. In Romania the pre- and intra-hospital telemedicine systems are incorporated in the national emergency care system and qualified first aid, as well as in a telemedicine pilot project.

9. *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)?*

The Senate considers that health IT applications are a complementary phase of health care. IT solutions can be particularly useful as an alternative in situations where the direct contact between doctor and patient is not possible, or situations of monitoring from the distance, if decided so by the doctor. A software solution must not replace a health care professional, but be a solution of necessity.

In Romania, the use of the pre-hospital telemedicine system between the special fire emergency responders and the emergency units of hospitals allowed a faster data transfer and interpretation of transported patients, and early activation of the measures of the national program for the treatment of acute myocardial infarction (AMI), prior to the patient arriving at the hospital, contributing to a significant decrease in AMI mortality in Romania.

10. *Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?*

The Romanian experience showed that, the use of pre-hospital telemedicine systems in situations referred to in the previous paragraph, decreased IMA mortality and increased the proportion of patients that recovered without any post-MI sequelae, with lower expenses for the treatment of the complications and with an obvious benefit through the reintegration of the recovered patients in the economic and social circuit.

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

The Senate considers that the actions that support equal access to mHealth services should aim at ensuring access to telemedicine consultations for patients coming from disadvantaged areas and setting functional telemedicine networks between family physicians' offices / family doctors' offices and ambulatories and ensuring adequate funding of these activities.

In order to ensure equal access to health services through mHealth, the Senate considers that proofs for the clinical benefits and the safety of patients must be provided. Also, the economic benefits must be analyzed by taking the necessary costs for the training of the medical staff and patients into account, as well as the cost of the equipment itself. The existing telecommunications infrastructure must not be ignored.

Another important element is the cultural context and the acceptance degree for the mHealth and e-health solutions among both patients and healthcare staff. The development decisions and directions must take all these aspects into account.

The equal access to healthcare through mHealth and its accessibility could be supported by:

- a) providing economic, material and human resources, necessary to ensure equitable health services in order to overcome territorial, gender differences, etc.;
- b) development of pilot projects on target groups;
- c) development of useful and easy to use applications for mobile devices, also suited for the elderly and disabled persons;
- d) promoting mHealth services to the population through information and training campaigns, adjusted to the specific needs of target groups;
- e) permanent analysis of the satisfaction degree of mHealth applications users;

Such actions should be considered as alternatives when, for various reasons, the doctor-patient relationship is impossible or delayed, affecting the health state.

VI. At the subparagraph 3.6. - *Interoperability*, the answers to the next two questions are:

12. *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?*

The Senate does not consider that further action is needed, and supports the implementation of actions already proposed, at least of those on the minimum data set, in all European countries by 2020.

13. *Do you think there is a need to work on ensuring interoperability of mHealth applications with Electronic Health Records? And if yes by whom and how?*

The Senate considers that ensuring interoperability of mHealth applications with Electronic Health Records is mandatory. This must be ensured by the administrators of both systems and should be provided starting with the conceptual construction of the electronic health care systems.

VII. At the subparagraph 3.7. - *Reimbursement models*, the answer to the next question is:

14. *Which mHealth services are reimbursed in the EU Member States you operate in and to what extent?*

The reimbursement for services using mHealth technologies is possible in Romania since 2012, through their inclusion in the framework contract for medical care services, in the social health insurances managed by the National Health Insurance. It is possible to pay for medical services and diagnostic advice provided by family doctors to remote areas through the rural telemedicine system developed by the Ministry of Health. These are emergency services, regular consultations for chronic diseases, active monitoring consultations through integrated management plan for chronic diseases with a major impact on disease burden and consultations provided for

homebound patients. Due to the lack of infrastructure developed by the Ministry of Health, these services are, however, extremely limited at present.

VIII. At the subparagraph 3.8. - *Liability*, the answer to the next question is:

15. *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?*

The Senate considers that both the manufacturers of the mHealth solutions and the healthcare professionals who use them, should be informed and should be aware of the limitations of the mHealth systems, compared to standard traditional medical services, and avoid the use of mHealth tools in inappropriate and unsuitable situations that may result in risks to patients (eg the audio-visual telemedicine consultation can't replace, at the current level of technological development, consultation and direct contact between the classical doctor and the patient).

From the legislative point of view, the access to the mHealth services without discrimination must be ensured. Also, any information on possible costs involved in using health services should be widely accessible and available to consumers/users, so that the decision to use / purchase be made knowingly.

IX. At the subparagraph 3.9. - *Research and innovation in mHealth*, the answer to the next question is:

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

The Ministry of Education, as the state authority for research, technological development and innovation (RD & I), has already published for consultation, the final version of the draft government decision for the approval of the strategy document, namely *the National Strategy for research, development Technology and Innovation for 2014-2020*, and the main tools for implementation - *National RDI Plan 2014-2020*, and part of the Operational Programme for Competitiveness with the thematic objective "Strengthening research, technological development and innovation for 2014-2020". According to these documents, the fields of: Health and Information and Communication Technology, in which the thematic topics related to the mobile health applications are national priorities and priorities of the *Smart Specialization Strategies* will be the subject of the funding based on competitiveness.

At European level, the specific topics on research and innovation received by the European Commission from the Member States are proposed by the Committee for the Programme: Health, demographic change and well-being - for *the European Programme for Research and Innovation Horizon 2020*, in consultation with the researchers. The Ministry of National Education is representing the Romanian interests at this committee.

As specific priority topics for research, innovation and implementation in the EU mHealth, the Senate proposes:

- a) the improvement of the communications and the increase of the reliability of data transmission from distance;
- b) the creation of the embedded devices in order to collect and transmit the basic medical data which will be easy to use by the ordinary patients.

X. At the subparagraph 3.10. - *International cooperation*, the answers to the next two questions are:

17. *Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?*

The Senate considers that the interoperability and the functioning based on uniform standards of the mHealth systems and the implementation of these systems, including the medical services of highly specialized diagnostic and treatment should be ensured in order to allow the access to these services without additional expense or minimal cost of transport for patients in remote or inaccessible areas.

18. Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to boost mHealth deployment?

The Senate considers that the following examples of positive experiences in other non-European areas (USA, Asia) could be assumed by the EU:

- a) the home examinations via telemedicine;
- b) the services of specialized medical imaging interpretation between localities, states or continents;
- c) the management of the hospital departments by remote experts, with onsite technical personnel.

XI. At the subparagraph 3.11. - *Access of web entrepreneurs to the mHealth market*, the answers to the next two questions are:

19. 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?

The Senate considers that the issues of market access may be the subject of a judicial analysis, when a failure of that market occurs. To prevent these failures, a unrestricted, open and non-discriminatory market for all entrepreneurs in the field should be ensured.

20. 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?

The Senate considers that the involvement of the industry and the entrepreneurs in mHealth could be enhanced through widespread information for the business environment related to all initiatives of this kind.

p. President



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