Statement of the European Council of Medical Orders on the use of mobile health (mHealth) in the European Union

The notion of mobile health[1] aims at the application[2] concerning health in the broad sense of the word, available by way of mobile devices (connected object).

Those applications have various aims such as welfare, health education, access to information, access to data, decision support, compliance support, surveillance of several physiological parameters and remote data collection. The services and tools they provide are various: therapeutic guide, calculator and medical scores, trend analysis, evaluation of medical procedures, first aid support, urgent actions, practical index cards, geolocation, contact with a panel of experts, contact with a patient, a community, scan a product or a drug.

Not all of them are used in the field of medicine; some belong to the domain of welfare and healthy lifestyle. The frontiers between those domains are hard to determine in a strict way.

Certainly, no technology can ever replace human interpersonal and singular relationships, which must remain the cornerstone of medical practice[3]. However, mobile technology is an opportunity to develop and improve health care and health policies providing that it is managed, not to curb innovation and creativity, but to guarantee the added value for patients' health and quality of life, with respect for their privacy.

By the present statement, the ECMO seeks to underscore the deontological aspects which have to be considered during the reflection on mobile health (mHealth), particularly in the European Union as a result of the Green Paper on mHealth[4] and the public consultation following that paper.

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1 According to the definition given by the WHO, mobile health covers 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 Computer software.
3 Statement of the European Council of Medical Orders, adopted in Bari on the 13th of June 2014.
4 COM(2014) 219 final.

1. A European legal framework should be provided for all mHealth applications and connected objects (including applications and connected objects related to the way of life and the well-being of people) which do not fall within the scope of the European medical device regulations in order to provide possible restrictions on their marketing based on the risks they would mean for human health and safety.

2. A high level of health and safety protection must be guaranteed to the patient whose medical support (diagnosis, patient's treatment and monitoring) is conducted by mHealth tools that are not medical devices as defined in the European legislation.

Technical reliability as well as application or connected object's performance are decisive for their use in the context of the monitoring of a patient, prevention, health education, compliance to treatment, and so on.

The appropriateness of medical support arising therefrom by a doctor or another health professional or by the patient himself depends on the accuracy of the recorded and transmitted parameter as of the response collected after processing of the transmitted data.

This requires compliance with independent assessment procedures of these tools, particularly established by computer scientists and health professionals in collaboration with medical orders and regulatory authorities in charge of ethics and professional conduct.

Developers, suppliers and sellers of applications related to health should be forced to provide in a transparent and immediately accessible way to understanding all the information concerning the object's reliability.

3. Public and regulatory authorities (both national and European) implementing policies that promote the use of mHealth devices commit to ensure public health through technical and technological security measures (point 1), and informational measures (point 5).

4. While providing medical support, the physician uses certified mHealth technologies (point 2), when their use is medically justified and motivated by the patient's interests.

The patient must be informed of the necessity, relevance, consequences and scope of the use of these technologies and be able to freely give consent.

The physician has to ensure that the patient is able to make a consistent use of this technology.

The physician should integrate information collected by mobile technology within the general framework of the support of the patient and the clinical examination in particular.

5. The patient's rights as a user of mHealth applications to his personal data protection, particularly those related to his health, must be respected by developers, suppliers and sellers so that appropriate safeguards are implemented.

Measures must be taken to ensure that regardless of their location (within or not the European Union), developers, sellers and other players in the market of applications comply with European legislation regarding the protection of mobile health users' privacy in the European Union.

Guarantees in terms of securing collection, transmission, storage and any other processing of personal data must be imposed in order to prevent access to personal data to any person not authorized by the user of the application or the connected object.

Developers and suppliers of mHealth applications must inform the users about the protection of collected data, the controller's identity as well as of the future of these data.

The exploitation for scientific research purposes of the data collected via these applications can only be considered in compliance with the ethical and legal principles under the control of ethics committees independent from research sponsors or suppliers of these objects and apps.