EHTEL
EUROPEAN HEALTH TELEMATICS ASSOCIATION

EHTEL Response

to the

Public consultation on the Commission's Green Paper on mobile health

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Prepared by the
EHTEL Board of Directors
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Content

Note to the European Commission: Refer to Annex for general information on respondent.

0 Introduction / High level messages by the EHTEL Association

0.1 EHTEL's understanding of mHealth

From its longstanding work on eHealth with stakeholders in the field of health and social care,

- ⇨ EHTEL understands mHealth as one more enabler for the overall transformation of the health and care domain to focus on prevention, proactive management of chronic conditions and patient empowerment.
- ⇨ EHTEL understands mHealth, however, as just one additional member in the large family of health-IT enablers: Mobile health services are already in existence under the broader headline of eHealth and are sometimes labelled as telehealth, home care etc.
- ⇨ EHTEL ackknowledges mHealth also as a quantum leap for the use of mobile platforms for wellbeing given the ubiquity and userfriendliness of mobile platforms.

For the mHealth consultation – it is crucial to understand that (i) management of healthcare and (ii) maintenance of wellbeing are two distinct concepts –both contributing to citizen's health.

0.2 EHTEL's recommendations on mHealth:

As a consequence, EHTEL has four recommendations. The recommendations are as follows:

1) The first recommendation of EHTEL is to differentiate mHealth in clinical settings from mHealth apps belonging to the wellness domain in any further work.

a) By clinical settings, EHTEL refers to the use of mHealth technologies in an environment under the supervision of health professionals e.g. to

- Access personal health data in an Electronic Health Record (EHR) residing at the healthcare provider's infrastructure (concept of integrated apps),
- Support health coaching for chronic patients,
- Collect health data remotely for clinical monitoring purposes,
- Support patients in their adherence to medical prescriptions.

It should be noted that this distinction has an emphasis that differs from the classification of health apps e.g. as class II in the light of the medical devices directive 93/42/EEC[1] or the implications of the FDA guidence on mobile medical applications[2]: The emphasis is on integrating health apps to a clinical network.

[1] cf. MEDDEV 2.1/6 January 2012: http://ec.europa.eu/health/medical-devices/files/meddev/2_1_6_ol_en.pdf

[2] http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

b) By wellness domain, EHTEL refers to the use of mHealth technologies at a consumer level, with a focus on the consumer market of wellness apps, out of the control of clinicians. e.g. to take better care of their wellbeing or the wellbeing of their relatives for prevention and fitness purposes. In a wellness setting, an app may collect physiological data from the citizen and provide health advice using the data. Citizens have the choice to keep the data local on their device or share it via the cloud. It is of utter importance to inform the user on any data shared by the app with a third party. Examples of health apps available on the consumer market can be found at www.myhealthapps.net.

EHTEL answers to the questions of the green paper will illustrate this recommendation.

2) The second recommendation of EHTEL –building on the understanding of the two domains **– is**,however, not to create silos. Instead, we recommend a **mutual learning process**: **Healthcare delivery organisations may take advantage of the innovation momentum from the consumer market and the lessons learned by the use of mHealth by consumers. In turn, developers of mHealth apps for consumers should take advantage of good practices from the clinical setting, e.g. in terms of privacy and safety.**

3) The third recommendation of EHTEL is to balance innovation and privacy when connecting mHealth apps to the cloud and particularly when running Big Data analyses: EHTEL is dedicated to move forward the innovation agenda in healthcare and access to Big Data plays an important role here. Wellness apps are often linked to cloud services that provide the user with inspiring feedback, e.g. when learning how other peers perform against fitness measures. Given the numerous wellness apps that are given away free of charge at the large mobile app stores, EHTEL has serious concerns that European Data Protection rules are adequately observed by all services provided with the support of mHealth. **Hence EHTEL recommends (rec. 3a) that priority is given to educate both users and entrepreneurs on the potential risks and the correct implementation of existing regulations. EHTEL recommends (rec. 3b) using a stepwise informed consent for (consumer) mHealth apps:** The Article 29 Data Protection Working Group[3][4] and the National Data Protection Authorities (e.g. CNIL for France) provide the necessary advice targeted to this field. This point is much more critical in the consumer market than in clinical settings where we typically observe a high degree of awareness for privacy and security - accompanied by well managed implementations.

4) As a fourth recommendation, EHTEL would like to highlight that mHealth is far from being mature. Therefore, further research should be undertaken on issues such as transforming data from mobile and personal devices into relevant information for healthcare professionals and health policy makers.

[3] cf. Article 29 Data Protection Working Group Opinion 05/2012 on Cloud Computing (WP 196, 01.07.2012)

[4] cf. Article 29 Data Protection Working Group Opinion 02/2013 on apps on smart devices (WP 202, 27.02.2013)

1 Data protection including security of health data

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

The following security safeguards in mHealth solutions could help prevent unnecessary and unauthorised processing of health data:

The security safeguards depend from the "data flow" design of the underlying service:

1) If the data is originating from the mobile device based on some user interaction and measurements by sensors or locally connected devices (e.g. blood sugar measurement via blutooth connected device), then these measures apply:

- ⇨ The first level (safest) would be to not store any data connected to any personal identifier. This is possible when the information is only for immediate use.
- ⇨ The next level is to keep data on the phone only. Except for theft or loss of the device, this means that data is only sharable under the control of the user.
- ⇨ The level of sharing beyond this will require some level of trust with the cloud operator. Furthermore all health data should by encrypted using established/certified encryption mechanisms. It is recommended to use end-to-end encryption of health data, so that it can only be explicitly shared with someone authorised to see the data. In addition, time limitations provide an additional mechanism for limiting unauthorised access to the information.
- ⇨ Cloud services must be with trusted third parties (However, there are many challenges in defining what is a trusted third party. In Scandinavia and countries like Estonia there seems to be a high level of trust in governmental infrastructures. The case from UK where a government in need of cutting costs and look for revenue where possible suddenly discusses selling data from the NHS to pharmaceutical industry, illustrates how problematic this can be.)

2) If the mhealth solution is used in clinical settings to provide the local user with access to his personal and/or electronic health record (PHR/EHR) stored in the server platform of her/his health or wellness service provider (the same applies if a health professional communicates with the EHR of a patient) the approach has evidently to differ:

- ⇨ Secure authentification should be in place to identify and authorise the user.
- ⇨ When accessing personally identifiable information e.g. in an EHR the minimal security safeguard will be user name and password.
- ⇨ Given today's technology and data breaches, a two-factor authentication either using a biometric identification of the user or using SMS text one time transaction numbers as known from online banking is strongly advisable.
- ⇨ Using one time passwords with other tokens than the mobile would be safer - yet it could also deter people from using the solution because it is too much trouble.

1.2 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?

These principles could be best implemented in mHealth apps in the following ways:

Again, the distinction given for question 1.1 comes into play.

1) If the data is originating from the mobile device based on some user interaction and measurements by locally connected devices, then these measures apply:

- ⇨ Data minimisation = collection of only the data that is relevant and necessary for the purpose of the app
- ⇨ It is important to create customer awareness of what data is actually collected by the app. User agreements must be required to be more specific about what data is collected and what the vendor can and cannot do with it. The challenge today is that the value of a new app is the number of users that the app has – user agreements are often kept open in order to not limit a future purchaser of the app or the company in how data submitted by the users can be used.
- ⇨ User involvement in design (provided that their input has an actual influence on design) can ensure that only data that is related to the service is collected.
- ⇨ Data protection by design = data protection is built into a new product from the start of the design and development process, and not an added feature. http://www.privacybydesign.ca/index.php/about-pbd/7-foundational-principles/
- ⇨ Awareness of how data protection by design can be implemented. EU Commission can initiate processes to develop methods for "data protection by design"
- ⇨ Sharing of open solutions for data protection. EU Commission should invest in projects to develop and share experience on data protection by design best practices.
- ⇨ User involvement in design (provided that their input has an actual influence on design) can help developers to understand user expectations and requirements regarding privacy and security of data.
- ⇨ EU should also encourage design guidelines that emphasise data protection by default.

2) If the mhealth solution is used to provide the local user with access to his own EHR or the EHR of a client (patient/citizen) standard rules for managing EHRs in the clinical context apply.

2 Big data

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

In our opinion, the following measures are needed to realise the potential of mHealth-generated Big Date in the EU:

Big data is not defined anymore as by the volume of data but by the form of the data, i.e. if the big data analysis method applies. Mobile devices as such will clearly not be the devices for handling big data, but they are one of the main methods for collecting big data (for example from monitoring personal measures/behaviour patterns) and also devices for receiving feedback on the data. Discussing big data means that mobile devices are connected to data warehouses (clouds) where the data is managed and merged to other data before feeding it back (for support/advice etc). Big data needes mobile technology to create data.

The strength of big data analysis is that it can reveal patterns by analysing across huge volumes of data. This means that the strength and power of applying a big data approach to health information means that data can be used for other purposes than originally intended when collected. EHTEL strongly suggests to distiguish clearly between the use of anonymised data and patient identifiable data. The rules for processing such data is clearly regulated and the European Commission should be able to capture best practice examples for both use cases from across Europe.

If data is foreseen to be later included into any kind of secondary analysis, the informed for the data subjects should be adopted to this use. Other practices would contradict with the right to know what data is going to be used for when agreeing to submit data. Any breaches of those regulations would not only violate people's trust in big data structures and systems but would also not be in comformance with legal and ethical requirements.

Member organisations of EHTEL have already developed infrastructure mechanisms that allow search across several databases with electronic health records where the data is analysed locally, within the safety structures protecting the health data, and only communicates aggregated results of the analysis to the researchers. This could be one approach to make investigations across several EHR-systems (big data analysis) without infringing on privacy. A similar strategy can probably be implemented in an mHealth setting.

Aside from Big Data, also the health data volume is a significant element: Given their ubiquity and versatile usage scenarios, mobile technologies will contribute to a significant increase in data generation in **clinical settings.** Thus – even setting aside the boost of the availability of health data in consumer settings – healthcare systems across Europe must plan now as to how they are going to deal with this tsunami of data....

3 State of play on the applicable EU legal framework

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

If NO, Please give your reasons on why you don't think so.

Life-style and wellbeing APPs are increasingly used to capture personal and health data. These data collections are - if at all – often based on a global user consent. While in theory, the European Data Protection directive and the respective National regulation should be enough to protect the privacy of the users - also outside the health(care) domain – in practice not all

producers and users of apps are aware of the regulatory framework and not necessarily educated to apply it correctly. In fact, there are so many apps out there in the app stores that are completely free standing of healthcare provider linkage and insight and of questionable effectiveness.

There are some projects trying to address how to design apps and ICT solutions on well being and lifestyle that will be really attractive and will be used. We observe a boom for apps and assume that there most likely be a wide uptake.

Hence the EU legal framework should be modernised by maintaining the data protection principles and translating and enforcing them in the lifestyle and wellbeing apps domain. This can be done by building on the principles of the Directives on Consumer Rights, Electronic Commerce and on Unfair Commercial Practices.

That having said, EHTEL is aware that safety and performance are regulated for those apps meeting the definition of a medical device through the medical devices regulatory framework.

3.2 Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts?

Yes.

3.2.1 In your opinion, why should enforcement be/~~not be~~ strengthened?*

In the data protection domain, the issue of informed consent needs to be better translated and enforced into the mobile Health, particularly the lifestyle and wellbeing domain. It is most important to legislate a "staged" patient consent for using the app as one step and then to ackknowledge any form of proactive contact or data use by a third party.

Guidance for mHealth devices used in cooperation with the health care authorities is also needed, when it comes to liability and responsibility matters. Mobile APPs - also in the lifestyle and wellness domain and not meeting the definition of a medical device provided by the medical devices regulatory framework – could harm the health of the citizen / patient for various reasons and liability has to be put adequately in place building on the principles of the Directives on Consumer Rights, Electronic Commerce and on Unfair Commercial Practices.

3.2.2 How can enforcement be strengthened?

The Working paper 202 "Opinion 02/2013 on apps on smart devices"[5] by the Article 29 Data Protection Working Party set up under Article 29 of Directive 95/46/EC provides good guidence on the subject of a staged consent. This should be made better known and enforced.

For instance: 3.4.1 Consent prior to installation and processing of personal data: "It is important to note the distinction between the consent required to place any information on and read information from the device, and the consent necessary to have a legal ground for

[5] Article 29 Data Protection Working Group Opinion 02/2013 on apps on smart devices (WP 202, 27.02.2013)

the processing of different types of personal data. Though both consent requirements are simultaneously applicable, each based on a different legal basis, they are both subject to the conditions of having to be free, specific and informed (as defined in Article 2(h) of the Data Protection Directive). Therefore, the two types ofconsent can be merged in practice, either during installation or before the app starts to collect personal data from the device, provided that the user is made unambiguously aware of what he is consenting to" (ibid, page 14).

4 Patient safety and transparency of information

4.1 What good practice exists to better inform end-users about the quality and safety of mHealth solutions e.g. certification schemes?

We know of the following good practice examples of informing users of the quality and safety of mHealth solutions:

For clinical settings, mobile access points to the EHR have of course to comply to the same safety rules (end-to-end encryption, storage of encrypted data, secure user authentication) as requested for desktop PCs or notebooks in clinical use. For the wellness domain so far no idely established[6] certification schemes are available, also because the applications evolve and change so quickly. However, basic principles should be stated (cf. the reference to the work of the Art. 29 Data Protection WP) and app developers can use these to declare their own apps according to those principles, as an optional, self-imposed quality certification.

From the US we have seen organisations, e.g. the Veterans Health Administration[7] and IMS Health in the private sector, that endorse principles of good mHealth design and security, e.g. so that vendors make a self-declaration. Also HIMSS is working on a mHIMSS set that might be useful to adapt to a European setting. A European set of good design principles and declaration of use of data could be a way to encourage good principles for mHealth services.

Good practice examples: User involvement and close cooperation with patient interest groups when developing apps – and where they have an actual influence on design decisions – is a way to ensure user interests are actually designed in fright from the beginning. In fact user involvment during the innovation phase has been found effective in creating solutions that are customed to user needs. This innovation method has been used for many e-solutions and it is important to promote it.

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

EHTEL recommends additional research to better understand the dynamic role of apps in the arena of health and care. This research is specifically needed in the area of integrated apps

[6] The US-enterprise Happtique - one of the first organisations to offer medical app testing had to revoke their certification system after public criticism of serious security flaws in the testing process / the tested apps.

[7] e.g. VA Mobile Health App Store at: https://mobilehealth.va.gov/

where it is made easy for citizens to directly interact with formal health and care services. This is an area that should be the focus for some future Horizon2020 calls exploring the areas of consent, governance, design inc interoperability, data quality, at scale deployment, safety, effectiveness and cross border issues.

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

The safe use of mHealth solutions in this domain is a challenge since citizens are free to choose which mHealth services to use. Some groups of patients, typically those with a chronic disease and/or complex multi morbidities, are not strong customer groups and not a big market, by volume and financial strength. Incentives should be in place to support development of mHealth systems and services for those patient groups.

EHTEL expects the development of a mixed economy with some solutions being free of charge, i.e. provided for free by the supplier or funded by the healthcare provider. Others may be part funded by the purchaser and other fully funded by the user. The service offerings sitting in behind may go from stand alone through to a full managed service. This means that there is a need for regional / national strategies to be worked through at this stage so that this emerging market can be appropriately supported and nurtured BUT also appropriately governed.

User involvement in design and establishing of requirements for the mHealth service can help put issues related to safe use that are of concern for the citizens into the design of new mHealth services.

5 The role of mHealth in healthcare systems and equal access

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

Yes

Some examples for the use of mHealth in clinical settings exist in diabetes and rehabilitation of COPD and cardiac patients, where the mHealth service is part of self management, and documentation of adherence to the treatment plan.

mHealth has not been addressed as a separate class of services or solutions in many countries, such as in Denmark and Norway, where the mobile phone market is already widely dominated by smart-phones and where eHealth services are available on those devices without using the notion of "mHealth". Also in Greece – e.g. in Thessaly, one partnering region in the large scale telemedicine trial RENEWING HeALTH, smart phones are used as gateway for connecting medical devices to the telehealth infrastructure; cf. http://www.renewinghealth.eu/en/cluster-2/region-of-central-greece.

In addion, several examples of eHealth services exist where citizens use a mobile device to access health information and administrative services, such as booking and reminders for appointments.

Clinical mHealth services, where an mHealth service is part of the treatment plan, are just starting to become more common. Some examples exist in diabetes and rehabilitation of COPD and cardiac patients, where the mHealth service is part of self management, and documentation of adherence to the treatment plan.

Maccabi Healthcare (Israel) has longstanding positive experience by using mobile apps that are connected with the EHR and other systems in the healthcare organisation. They enable both patients and health professionals to perform tasks that they would have needed a full PC or notebook for in earlier settings – e.g. using the online portal on their computer.

5.1.1 Please upload the evidence you have or paste link(s) to web sources.

From RENEWING HeALTH:

http://www.renewinghealth.eu/en/cluster-1/northern-norway

http://www.renewinghealth.eu/en/cluster-4/catalonia

http://www.renewinghealth.eu/en/cluster-3/region-of-southern-denmark

http://www.renewinghealth.eu/en/cluster-1/county-council-of-norrbotten

http://www.renewinghealth.eu/en/cluster-6/county-council-of-norrbotten

5.2 What good practice exists in the organisation of healthcare to maximise the use of mHealth for higher quality care e.g. clinical guidelines for the use of mHealth?

We know the following examples of good practice:

Modern concepts for care, such as the Chronic Care Model, put more emphasis on patient centred care and the whole chain of care, including prevention and self-management. Such concepts for how to organise care based on the patient's needs and the resources available around the patient are well suited for the promotion of mHealth.

Current practices are under development for diabetes care, where mHealth services for self-management has been shown to help some patients who are having problems with managing their blood glucose values (and thus are in high risk of developing severe health problems) and make lifestyle changes (type 2 diabetes).

Much focus has been on mHealth as an independent type of service, but it is as part of a chain of services we can really begin see the potential benefits of mHealth for higher quality care and begin develop guidelines for mHealth. While we can currently we cannot provide examples of clinical guidelines that include the specific use of mHealth, we can we would highlight the example given by Maccabi Healthwe Services are using the same clinical guidelines on doctors usage of the EHR (part of the decision support system). The system will provide the physician with alerts and reminders . This will also influence what kind of alerts and reminders are going to the patient via his mobile device

Research and evidence published in well-known medical journals are still needed to change practice and begin using mHealth as part of a treatment regime for specific patients.

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

Yes, some evidence

Preventive care takes time to prove, but we can see improved long-term blood glucose values for many T1D patients who have previously been struggling with managing their intake of carbs, insulin dosage, and activity. We have also seen improved adherence with COPD patients and heart surgery rehabilitation based on mHealth to motivate physical activity. Tailored interventions may strengthen these results, but further research is required to better understand how such mechanisms work or do not work on classes of patients.

The NST (Norwegian Centre for Integrated Care and Telemedicine) "funnel model" (also used by the EPITAL project in Denmark) is a general strategy that defines specific levels of interventions for people with chronic diseases. The concept is to have levels of increasing involvement of professional care services, but where the entrance of the funnel is low level interventions focusing on self management, but with access to support services when self management is not sufficient or changes in the condition occurs. This model is being implemented for mental health services as part of the MASTERMIND CIP EU project.

Evidence/links to examples: See the above references of RENEWING HeALTH and the project final report available at http://www.renewinghealth.eu/c/document_library/get_file?uuid=3fd11102-1e46-491e-879d-cb53379be1d3&groupId=28946

5.4 What policy action could be appropriate at EU and national level to support equal access and accessibility to healthcare via mHealth?

The following policy actions could be appropriate:

Promote universal access policies – eHealth and mHealth poses particular challenges in terms of universal access due to challenges of use with cognitive or physical disabilities. Limitations of smaller screens and touch-screens are a particular challenge for mHealth users. Weak adherence to good programming practice in terms of making apps and web-based information utilise the facilities built into most modern operating systems for universal access is also something that policies and regulations can change.

Identify groups that may suffer from significant barriers to access eHealth and Digital Society services: Frail persons, disabled persons, complex multi-morbidity patients, mental health patients, etc., and ensure programs with incentives to develop (clinical) mHealth services and best practices for user interfaces for these groups.

A crucial element is to allow patient access to their own EHR information via their mobile device.

From a funding perspective, EU structural funds and the Connecting Europe Facility should address mHealth as well.

6 Interoperability

6.1 What 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?

We think that the following should be done to increase interoperability of mHealth solutions:

Encourage governments to implement and require adherence to interoperability standards. they can build on the fact that guidence to use established standards and profiles are already available e.g. through guidelines from organisations IHE and Continua that support expedite interoperability, testing and certification. Action must be put in place to accelerate their adoption by public actors.

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

Yes, e.g. by governments. Countries with a strong health ICT industry are sometimes calling for governments to regulate or guide the market in terms of ensuring standards or specific requirements for interoperability (e.g. Israel, reference interview with Rachelle Kaye as part of the eHealth Strategy project conducted by NST (Norway) conducted for Czech Republic.

- ⇨ It is important to develop methods and concepts for how mHealth data can be transferred into relevant information for the healthcare professional.
- ⇨ Interoperability between and among EHRs is needed to enable the access also by apps resp. mobile devices. To enable apps to communicate with the EHR could become an EHR vendor requirement via public and private procurement.

6.2.1 If you think so, please explain who should work to ensure interoperability and how should this be done?

Develop clear requirements of interoperability – does not have to be as standards, as standards are complicated and costly to implement for the type of companies that are currently driving the development of mHealth apps and services. New Zealand might be a good example in the way they have defined clear requirements for interoperability and report on the status for each region regularly. The reports are public and creates a pressure on local health authorities to keep the focus on interoperability, whilst allowing the use of different systems and vendors. Another example is the National Telemedicine Strategy of Denmark.

As mentioned, it is of crucial importance that public procurers include requirements for interoperability in their tenders.

Encourage the big actors in the medical instrumentation market to begin focusing on mHealth – too much of the market is dominated by small startup companies that have no previous experience with the healthcare industry, and little understanding of the complexity of modern healthcare. The small companies are important for the innovation and change, but the big companies are usually better at seeing the broader picture and total system integration.

It is important to develop methods and concepts for how mHealth data can be transferred into relevant information for the healthcare professional.

7 Reimbursement models

7.1 Which mHealth services are reimbursed in the EU Member State(s) you operate in and to what extent?

We do not support the wording of this question which implies to single out mHealth. The question should be addressed to eHealth in general and not mHealth which is a subset. The question is how should we treat virtual health care – be it by computer, mobile device, video conference, ePrescribing, eReferrals, teleconsultation etc. The rule of thumb needs to be that "the service is the service is the service" and should be reimbursed regardless of the technology used to deliver it.

As a consequence (cf. 5.1) , mHealth has not been addressed as a separate class of services or solutions in many countries, such as in Denmark and Norway, where the mobile phone market is already widely dominated by smart-phones and where eHealth services are available on those devices without using the notion of "mHealth". Also in Greece – e.g. in Thessaly, one partnering region in the large scale telemedicine trial RENEWING HeALTH, smart phones are used as gateway for connecting medical devices to the telehealth infrastructure; cf. http://www.renewinghealth.eu/en/cluster-2/region-of-central-greece.

In addion, several examples of eHealth services exist where citizens use a mobile device to access health information and administrative services, such as booking and reminders for appointments, e.g in the SUSTAINS project, cf. www.sustainsproject.eu.

7.2 What good practice do you know of that supports the refund of mHealth services e.g. payer-reimbursement model, fee-for-a service model, other?

We know of the following good practice that supports refunding of mHealth services:

(cf. 7.1) We do not support the wording of this question which implies to single out mHealth. The question should be addressed to eHealth in general and not mHealth which is a subset. The question is how should we treat virtual health care – be it by computer, mobile device, video conference, ePprescribing, eReferrals, teleconsultation etc. The rule of thumb needs to be that "the service is the service is the service" and should be reimbursed regardless of the technology used to deliver it.

8 Liability

8.1 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?

The following recommendations should be made:

- ⇨ Healthcare professionals: basic knowledge and skills to advice patients about general considerations regarding use of mHealth services
- ⇨ mHealth manufacturers need to understand the whole chain of care and how their systems and services fit into the big picture, particularly in clinical care settings.

9 Research and innovation in mHealth

9.1 What specific topics would you provide for EU level research, innovation and deployment priorities for mHealth?*

Our organisation would suggest the following topics for research & innovation and deployment priorities for mHealth (please mention the name of your organisation and the sector of your activity)

- ⇨ Transforming data from mobile and personal devices into relevant information to the healthcare professional
- ⇨ Support of clinical mHealth services for patient groups that are not interesting for the commercial market
- ⇨ Calls for research and innovation focusing on research and business innovation in the mHealth clinical market
- ⇨ Tailoring and personalised interventions that improve adherence and compliance
- ⇨ Support person centred care models by using mHealth; i.e. self management, patient empowerment, patient-centred virtual teams in chains of care.
- ⇨ Identification of training pathways for health caregivers to get customised to the daily use of mHealth in the clinical practice. Only the use of a tool creates the habit to that tool. If students are trained in their medical curriculum to use mHealth to monitor and empower patients, then once they become doctor or nurses they will seek and ask for these tools from their organisation or health care providers.

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

We think that satellite applications can help the deployment of innovative mHealth solutions in the following manner:

- ⇨ Stable and accurate location services
- ⇨ Context awareness to support person centred care
- ⇨ Access to local health and care services when visiting or working in other regions of EU
- ⇨ Access to local wellbeing and fitness services

⇨ Warning systems regarding epidemics and active infections in local communities can help identify specific risk of infections based on where a person has been over the last period. (Special attention to privacy is important for such services).

10 International cooperation

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

The following issues should be tackled in the following manner to increase mHealth deployment in the context of international cooperation:

⇨ Development of good security and privacy mechanisms and policies for mHealth

⇨ Interoperability and mechanisms for sharing data from mHealth systems to professional health information systems (EHR)

⇨ Development of systems and services for complex multi-morbidity and weak groups

10.2 Which good practice in other major markets e.g. USA and Asia could be implemented in the EU to boost mHealth deployment?

The following good practice from other major markets could be implemented in the EU:

Health 2.0 conference and community to showcase startups and encourage exchange of ideas and visibility of European technology and companies.

The Veterans Health Administration "VA Mobile Health" that "aims to improve the health of Veterans by providing technologies that expand clinical care beyond the traditional office visit. VA's mobile health technologies support its vision of a patient-centered health care delivery model". HIMSS and partners with their mHIMSS initiatives and IMS Health with their certification programme for good mHealth apps.

Incentives for healthcare providers to to adopt novel interoperable technologies. A good example is the Meaningful use programme in the USA that has been succesful to increase the adoption of EHRs and other interoperable communications in healthcare like the download of patient data (blue button initiative).

11 Access of web entrepreneurs to the mHealth market

11.1 Is it a problem for web entrepreneurs to access the mHealth market?

To access the market of clinical settings, web entrepreneurs they need to comply with the rules applicable to the clinical domain.

EHTEL has, however, not identified problems in the wellbeing domain, particularly as the proliferation of smart phones is high in EU market - leading to a rapidly expanding market.

11.2 How can these be tackled and by whom?

(These challenges can be tackled in the following manner and by the following actors):

Please explain why you think that it isn't a problem.

The proliferation of smart phones is so high in the EU market that a huge market offers promising opportunities to entrerepreneurs.

11.3 If needed, how could the European 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 Commission can stimulate industry and entrepreneurs' involvement in mHealth in the following ways:

- ⇨ Develop a European counterpart to the Health 2.0 conference and community to showcase start-ups and encourage exchange of ideas and visibility of European technology and companies
- ⇨ Develop incentives for developing mHealth services for chronic care and person centred care models, with particular attention to commercially uninteresting groups that might be the ones that has the most benefit of using good mHealth services
- ⇨ Stimulate the use of mHealth as part of the chain of care can be a good way to stimulate the industry.
- ⇨ To facilitate the industrialisation of ideas and prototipes from the world of research and academia in collaboration with the industry.

12 Concluding remarks & references

12.1 Please write any concluding remarks you may have that the above questions didn't cover.

cf. Section 0: Introduction / High level messages by the EHTEL Association

13 Annex: General information on respondents [first part of questionnaire]

I'm responding as:
An individual in my personal capacity.
The representative of an organisation/company.

What is your nationality?*
Belgium

I agree that my name is linked to my response which will be published on the Commission's website.

Please enter your full name
EHTEL - European Health Telematics Association

Please enter your e-mail:
management@ehtel.eu

Is your organisation registered in the Transparency Register of the European Commission and the European Parliament?*
Yes

Please indicate your organisation's registration number in the Transparency Register.

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Please tick the box that applies to your organisation and sector.*

⇨ National authority

⇨ Regional authority

⇨ Health professionals/medical association

✓ **Non-governmental organisation**

⇨ Patients association

⇨ Insurance company

⇨ Manufacturing industry

⇨ App developing business

⇨ Web entrepreneur

⇨ Other

Please explain the type of organisation/company/business you represent.

EHTEL is a pan European multi-stakeholder forum providing a leadership and networking platform for European corporate, institutional and individual actors dedicated to the betterment of healthcare delivery through eHealth.

My organisation/business operates in:
Belgium

Please enter your organisation/company name.
EHTEL

Please enter your e-mail address.
management@ehtel.eu

Please enter your address.
49/51 rue de Trèves, B-1040 Brussels, Belgium