European Commission Green Paper on mHealth
GSMA Response

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About the GSMA

The GSMA represents the interests of mobile operators worldwide. Spanning more than 220 countries, the GSMA unites nearly 800 of the world's mobile operators with 250 companies in the broader mobile ecosystem, including handset and device makers, software companies, equipment providers and Internet companies, as well as organisations in industry sectors such as financial services, healthcare, media, transport and utilities. The GSMA also produces industry-leading events such as Mobile World Congress and Mobile Asia Expo. Follow the GSMA on Twitter: @GSMA .

In the European Union, GSMA Europe represents over 100 operators providing more than 600 million subscriber connections across the region. www.gsmworld.com/gsma_europe.

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Executive Summary

The GSMA welcomes the European Commission's Green Paper on mobile health ('mHealth') as an important step in unlocking the potential of mHealth in Europe. The rapid increase of connectivity and the unique network and service capabilities of mobile operators provide a great opportunity in the area of health, as highlighted in the Green Paper.

Given the wide reach of mobile networks and services that are becoming ever more intelligent, there is a unique opportunity to develop new and innovative models for collaborative and integrated care systems that put the patient at the centre. mHealth solutions can support healthcare professionals deliver high quality, consistent and efficient healthcare (wherever and whenever needed) and empower individuals to manage their own health more proactively and effectively. In addition, mobile solutions can help bridge the burden of care in areas where the number of healthcare professionals are insufficient for the range of healthcare specialities.

A recent report by PWC, commissioned by the GSMA, estimates that mHealth could save 99 billion EUR in healthcare costs to the EU GDP in 2017, if its adoption is encouraged. The same report indicates that mHealth could enable 11.2 million people with chronic conditions and 6.9 people at risk of developing chronic conditions to extend their professional lives and improve their productivity. This would add 83 billion EUR to the EU GDP in 2017.[1] This is a tremendous opportunity, particularly in light of the current economic crisis, the increasing burden of chronic diseases and an ageing population.

Despite this potential to realise significant healthcare savings and to provide benefits to so many citizens in Europe, the widespread deployment of mHealth services is still limited. Mobile operators are faced with a number of barriers and limited incentives for innovation and deployment. Overall, there is a need for more investment and legal certainty in the health sector as part of a 'Digital Europe'. It is a sector that needs more encouragement in the adoption of digital technologies and movement towards integrated and patient-centred care.

The GSMA is therefore pleased to be able to contribute to the consultation process launched by the Green Paper, and is looking forward to working with EU and national policymakers and regulators, end-users and other key stakeholders, on truly integrating mHealth into health services and making safe and trusted mHealth solutions widely available and accessible across Europe.

As a summarised reflection on the Green Paper, the GSMA would like to highlight the following key recommendations:

1) Building trust and confidence

To realise the opportunities and benefits offered by mHealth data, it will be essential to establish trust by patients and consumers with respect to how privacy and the security of data will be protected. Mobile operators have developed a range of important safeguards to ensure data protection, privacy and security, including technical standards, secure networks and identification services.

In addition, ensuring an appropriate EU regulatory and policy framework for data protection and privacy is of key importance. Regulatory measures should be proportionate and facilitate the use of data in creating patient-centred and sustainable healthcare systems.

In order to ensure legal certainty for industry as well as for end-users, the GSMA would like to urge the European Commission to address the current crossing and blurring of boundaries between different

[1] Socio-economic impact of mHealth – an assessment report for the European Union, PWC, May 2013

legislation that may apply to data protection and privacy. Examples include current[2] and proposed data protection legislation (GDPR)[3], the ePrivacy Directive[4] and the proposed Network and Information Security Directive[5].

2) Ensuring quality and safety

The EU regulatory instruments applicable for mHealth should be proportionate and risk-based, in order to ensure that innovative and transformative mHealth solutions that are safe and effective can reach and benefit consumers. Policy and regulatory initiatives relevant to mHealth should also recognise the pace of change in mHealth.

In those cases where, based on their intended use, mHealth solutions can be considered a medical device or accessory to a medical device, these should fall under EU medical device regulation. mHealth solutions that provide information only, that support fitness and wellness purposes, or are geared towards productivity improvements, may not need the full weight of EU medical device regulation. Application of general EU product safety and consumer related legislation will need to be clarified for this range of mHealth solutions.

In addition, healthcare professionals and patients can contribute to ensuring quality and safety, by means of being involved in the design and development of mHealth solutions and sharing experiences, allowing developers and/or manufacturers to introduce improvements if and when necessary. The importance of involvement of end-users in the development of mHealth solutions should be recognised in any actions resulting from the Green Paper.

3) Creating transparency of information

End users should be able to make informed decisions about the use of mHealth solutions. Transparency of and access to appropriate information on the benefits and types of mHealth solutions available in Europe, including information on their regulatory status, possible medical input received and the organisation(s) responsible for the development of the mHealth solution, is therefore key.

Centralisation of information through national and European data bases would be an important step forward, in order to provide a clear and accessible overview of mHealth solutions that have received CE marking and the developers and manufacturers of these mHealth solutions.

Healthcare professional, patients' and consumers' organisations can also play a key role in providing users with guidance and information on mHealth solutions. Initiatives in this area, such as European and/or national directories of mHealth solutions managed by end-user organisations, should be encouraged by the European Commission and Member States.

4) Enabling equal access and inclusion

Because of their reach, mobile solutions have the ability to support equal access to healthcare and reduce health inequalities in the EU. However, in order to facilitate widespread access to mHealth, innovative funding and reimbursement mechanisms based on health outcomes will need to be developed and implemented. Exchange of good practices at EU and national level and EU projects could be promoted and facilitated by the European Commission, for example through relevant EU Programmes.

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[2] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data

[3] Proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)

[4] Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

[5] Proposal for a Directive concerning measures to ensure a high common level of network and information security across the Union

Given that lack of awareness and mHealth skills are important barriers to the accessibility and use of mHealth, awareness raising campaigns addressing end-users, including healthcare professionals and patients, should be developed at EU and national level, as well as targeted mHealth training and education programmes.

The GSMA would also like to highlight the importance of recognising 'inclusion' in any follow up action to the Green Paper, taking into account that there are over 80 million people in Europe with a disability who could benefit from mobile solutions, but may not have access to them.[6]

5) Improving interoperability

One of the major factors to make mHealth a success, is to put in place the foundations that will enable the technology to reach scale and ensure solutions can be used across systems, networks and borders.

The use of common interoperable standards will not only ensure that e.g. apps being developed are secure, robust and meet the end-users' needs, it will also reduce the cost and complexity of developing apps for healthcare. The GSMA would like to refer to and call upon the EU to recognise the important work in this area of the Continua Health Alliance (now part of the Personal Connected Health Alliance), in particular in establishing ITU recognised standards (ITU-T H.810) for end-to-end interoperability.

6) Strengthening international cooperation

The ability of mobile operators to deploy mHealth services with consistent, replicable approaches and solutions around the world will be a key factor to achieve scale and therefore lower cost. To facilitate this, it will be essential to ensure harmonisation of regulatory approaches around the world. Dialogue and collaboration between the EU and other markets, in particular the US (FDA), therefore needs to be enhanced. In addition, international cooperation and exchange of good practice with respect to interoperability adoption and the use of mHealth data should also be strengthened.

[6] http://disabilitynewsservice.com/2014/05/technology-possibilities-for-disabled-people-are-beginning-to-explode/

Questions raised by the Green Paper: the GSMA's response

Data protection, including security of health data

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

Data are crucial to the emerging mHealth ecosystem. As recognised in the Green paper, mHealth data have the ability to empower people in the management of their health, and support healthcare professionals' understanding of and response to patients' behaviours and needs, increasingly in more personalised and effective ways. In addition, mHealth data can help to identify patterns of broader importance to communities and societies – patterns that may require proactive policy intervention and management.

To realise these opportunities will require establishing trust by end-users with respect to how privacy and the security of data will be protected. A key aspect of trust is ensuring secure safe and effective access to data by end-users, including patients and healthcare professionals, by approved devices and applications. However, the provision of mHealth services may involve the collection, sharing and use of data in real-time between multiple parties in commercial, social network and enterprise contexts (and hybrids of the two) and involve 'bring your own devices' (used by doctors or nurses, for example).

This will require an approach that addresses the full lifecycle of data across a large network of users and organisations. Any regulatory instrument should be based on clear principles and be technology and service neutral. In addition, regulation should support a privacy by design approach to address specific risks arising from the collection and use of data across different stakeholders and environments.

From a mobile operator perspective, mobile networks apply very strict security safeguards to protect end-user data for all services, including mHealth. Specific safeguards that play a key role in ensuring data protection and privacy include:

- Industry-defined and global **technical standards**: these standards enable a range of security features that provide authenticity, confidentiality and integrity to verify the identity of communicating parties and to protect traffic and data against interception and modification.
- **Secure networks**: the mobile industry has developed enhanced security mechanisms to meet the needs of other industry and market sectors. The GSMA works closely with the standards development community to further enhance the security features available to protect mobile networks and their customers.
- **Identification services**: building on the security of their networks, mobile operators can provide specific identity services offering a further level of authentication, beyond the simple use of the device. There are a number of different solutions in place, varying from a simple SMS authentication service, through to mobile signatures that are embedded in the device/SIM, containing specific information about the end-user, such as patient ID.
- **Lost and stolen handset reporting policies and mechanisms**: these have been established by mobile operators to ensure customers can report and bar access to services and lock down lost or stolen devices, and prevent unauthorised tampering of unique device identifiers.[7]

[7] http://www.gsma.com/publicpolicy/wp-content/uploads/2012/10/Security-Principles-Related-to-Handset-Theft-3.0.0.pdf

GSMA recommendations:

- While ensuring data protection and privacy for EU citizens, regulatory measures should be proportionate and facilitate the use of data in creating patient-centred and sustainable healthcare systems and meet broader public policy objectives, leading to important societal benefits, such as limiting disease outbreak or controlling chronic disease trends through collection and analysis of data.
- In order to ensure legal certainty for industry as well as for end-users, the GSMA would like to highlight the need to address the current crossing and blurring of boundaries between different legislation that may apply to data protection and privacy. Examples include the current and proposed data protection legislation (GDPR), the ePrivacy Directive and the proposed Network and Information Security Directive.

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?

Policy or regulatory proposals should not overly focus on 'app developers' but take a holistic approach that also addresses other ecosystem entities, such as operating system vendors and chip and device manufacturers, in order to ensure end-to-end lifecycle protection.

It is clear from GSMA research[8] that end-users want to ensure their personal health data are collected, transmitted and stored securely. They are also concerned about third parties and secondary non-health related uses of their data. These concerns can make individuals reluctant to disclose personal information or inhibit their use of mHealth services.

In order to address these concerns and to build confidence and trust for mobile users, the GSMA has established a Mobile Privacy Initiative, including a set of Mobile Privacy Principles[9], as well as a set of Privacy Design Guidelines for Mobile Application Development[10]. The Guidelines are intended to ensure apps are developed in ways that respect and protect the privacy of users and their personal information. They have influenced the development of other national guidelines in Canada, the US and elsewhere.

GSMA recommendations:

Good practices for mHealth app developers should be promoted at EU and national level, including:

- The creation of a simple and effective impact assessment process to help developers determine what data are required, to justify their collection and use, and based on this, establish what key data protection and privacy principles apply.
- Establishing a clear transparency process, providing users with simple, contextually appropriate notices, to explain what will happen to their personal data if they install and use the app, with particular focus on non-obvious secondary uses of data. Additional key measures:
  - making users aware of privacy default settings and how to use them;
  - ensuring important information is not hidden and users are not misled;
  - ensuring only the minimum data necessary for the tasks the app should perform are collected and processed, i.e. collecting data for potential future uses is not allowed;
  - notifying users when certain actions have particularly intrusive privacy implications, for example when geo-location information is being collected;
  - providing app user with contact details of those responsible for responding to questions about privacy and security of the app's functionality (the 'data protection officer').

[8] http://www.gsma.com/publicpolicy/mobile-privacy-consumer-research-insights-and-considerations-for-policymakers
[9] http://www.gsma.com/publicpolicy/wp-content/uploads/2012/03/gsmaprivacyprinciples2012.pdf
[10] http://www.gsma.com/publicpolicy/wp-content/uploads/2012/03/gsmaprivacydesignguidelinesformobileapplicationdevelopmentv1.pdf

- Ensuring that data security is a high priority when developing the app and as such is integrated in its framework ('privacy by design'). For example, when storing or transmitting personal data like usernames, passwords or any other sensitive information, it should be ensured that only established cryptographic methods and codes are used.

Big data

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

As highlighted in the Green Paper, 'Big Data' have the potential to boost healthcare research and innovation. Big Data can play a key role in tracking trends and limiting or even preventing disease outbreaks. There are examples of mobile operators partnering with government agencies/authorities to analyse population behaviour, such as in the context of the Mexican flu pandemic[11]. However, the message is that more can and should be done.

Most Big Data initiatives are currently very local and largely based on local or national IT systems. In order to truly unlock the potential of Big Data from a European healthcare perspective, mHealth and patient generated data must become a universally accepted component of healthcare systems. Moreover, mHealth data integration with Electronic Health Records is necessary, in order to establish data repositories allowing for Big Data analytics to generate novel insights into citizens' health status, disease progression and management, public health and personalised healthcare.

GSMA recommendations:

- Encouraging the use of Big Data in healthcare by building up trust will be key. This could for example be achieved through EU and national awareness and education initiatives, demonstrator projects or studies supported through EU Programmes such as Horizon 2020 or the EU Public Health Programme.
- Further work by the European Commission, Member States and European Parliament aiming to clarify and identify bottlenecks and/or gaps in the applicable legislation should be undertaken:
  - The ongoing debate on the proposed General Data Protection Regulation offers an important opportunity to establish a regulatory framework that recognises the importance of data in healthcare, while ensuring protection of data and privacy.
  - The eHealth Network could play an important role in creating the right legal and ethical framework in order to ensure big data can address important cross-border health challenges.
  - The GSMA would encourage the EU Institutions to consider the interplay between consent, purpose limitation, legitimate interests and exemptions. A consent based approach to Big Data will not work in practice – we would suggest examining how Big Data in mHealth may be utilised under guidelines or codes of conduct that bind parties to compliance with their requirements.

[11] http://www.wired.co.uk/news/archive/2013-10/17/nuria-oliver

State of play on the applicable EU framework

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

Safety for end-users is essential in creating the foundations to ensure trust in mHealth solutions, and is therefore at the centre of mHealth services design. EU regulation on medical devices and in vitro diagnostic medical devices (IVDs) provides the framework for assuring safety and performance of those mHealth solutions (including apps) that can be considered a medical device, IVD or accessory to a medical device or IVD, based on 'intended use'.

The GSMA welcomes the proposed new EU regulations on medical devices and IVDs as an important opportunity to clarify the application of medical device regulation in the area of mHealth. This need for clarity particular applies to generic consumer products that are used as components of mHealth solutions but which are not intended to be used for health purposes. In addition, clarity is needed with respect to lifestyle and wellbeing applications. Currently mHealth investments and initiatives are often hampered by legal uncertainty and lack of clarity with respect to regulatory requirements.

GSMA recommendations:

- The EU legal framework applicable to mHealth should strike the right balance between ensuring quality and safety, and stimulating innovation. In order for the mHealth sector to reach its full potential, clarity and consistency in the application of EU regulatory instruments through proportionate and risk based approaches will be key:
    - EU medical device regulation should be applied in a balanced way, based on 'intended use'. mHealth solutions often (and increasingly) consist of generic consumer products that are not specifically intended for health purposes. Examples include general purpose software, connectivity and mobile phones. If not intended to be used for medical purposes, these products should not fall within the scope of medical device regulation. This should be ensured through clear definitions of 'medical device' and 'accessory to a medical device' in the regulation.
    - Many mHealth solutions are for lifestyle and wellness purposes, or support administrative functions, that do not affect e.g. diagnosis, disease management or treatment related decisions. These do not require the full weight of medical device regulation. In order to ensure quality and safety of lifestyle and wellbeing apps, the application of general EU product safety legislation needs to be clarified.

Patient safety and transparency of information

What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?

It is very important for users, as well as insurers, to be aware of the regulatory status of an mHealth solution and the corresponding level of scrutiny these may have been subject to, as well as possible input from healthcare professionals or possible studies conducted, in order to assess their quality, safety and fitness for use. Some important good practices in this area are already referred to by the Green Paper.

GSMA recommendations:

- We believe an important part of the responsibility of providing information on quality and safety lies with the manufacturer or developer, who should provide clear 'labelling' of his product:

- For those mHealth solutions which qualify as a medical device or IVD, this responsibility will be based on EU medical device or IVD regulation and will lead to CE marking.
- Information related to quality and safety requirements for other (e.g. lifestyle and wellness) mHealth solution should be provided by the manufacturer or developer based on other general product safety and consumer related EU legislation.

- The GSMA would also like to highlight the important role that consumers', patients', healthcare professional and other third party organisations can play in providing information on mHealth solutions and their quality and safety. Some good practices in this area are already referred to by the Green Paper: the NHS Health Apps Library in the UK and 'my health apps' developed by PatientView. More mHealth directories, based on reviews/assessments by healthcare professionals, patients or consumers in general, could be encouraged and developed at EU and national level.
- Centralised mechanisms, e.g. EU and national databases, for better visibility of those mHealth solutions that have received CE marking under EU medical device and IVD regulation are also needed, as it currently can be challenging for consumers to find information on mHealth solutions available in Europe, their regulatory status and the manufacturers and/or developers responsible for these mHealth solutions.

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

Access to accurate and easy to understand information is key in ensuring safe use of mHealth solutions. As highlighted in the previous response, mHealth solutions available to EU citizens should be accompanied with information on e.g.: regulatory status (CE mark yes or no); whether any studies were conducted or input from healthcare professionals received; guidance of use, including a clear recommendation how and when to contact a healthcare professional whenever appropriate; manufacturer and/or developer.

In addition, mHealth education and training will contribute to the safe use of mHealth solutions.

GSMA recommendations:

- Healthcare professionals, together with other end-users, should be involved in the design and development of mHealth solutions wherever possible, in order to ensure professional and relevant guidance is offered whenever needed.
- Initiatives aiming to raise awareness on the benefits and use of mHealth solutions should be implemented both at EU and national level.
- In addition, targeted education and training programmes enhancing mHealth skills with end-users should be developed at EU and national level.

mHealth role in healthcare systems and equal access

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

Compared to the penetration of smartphones and 3G/4G in the EU[12], the uptake of mHealth solutions within healthcare systems is still limited, mostly because of the barriers highlighted by the Green Paper.

[12] https://gsmaintelligence.com/

Whereas mHealth solutions are perfectly placed to support patient-centred healthcare, full integration of these solutions in healthcare systems require new 'business-models', allowing for funding mechanisms that are based on health outcomes and enabling access to mHealth solutions for patients and healthcare professionals.

GSMA recommendations:

- The GSMA would recommend the EU to stimulate and facilitate the collection and sharing of case studies where mHealth solutions have been fully taken up within EU healthcare systems.
- In order for mHealth solutions to be fully integrated and taken up within healthcare systems, EU Member States, with the support of the Commission, should stimulate the development and, most of all, implementation of innovative funding and reimbursement mechanisms, based on health outcomes and including costs related to mHealth solutions.

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)?

Hospitals in a range of EU Member States, including amongst others the UK, France and the NL, have introduced mHealth solutions to improve quality and efficiency of care. For example the Academic Medical Centre (AMC) in Amsterdam has recently introduced an app ('the Hospitality App') aiming to support older patients in ensuring they arrive in the hospital on time, find their way to their doctor and/or nurse and that they receive the information they need in relation to their treatment and care.[13] In addition, examples in the UK show that the use of mobile technologies can improve quality and efficiency of care, in particular in remote areas with an ageing population. The NHS Western Isles, covering islands off the North West coast of Scotland, introduced digital pens gathering and transmitting information from each patient visit in a secure way, freeing up nurses' time spent on administration and improving sharing of information between healthcare professionals, allowing for quicker follow up actions.[14] [15]

Although more difficult to find (because of the barriers as described), good practices also exist with respect to the use of mHealth solutions in chronic disease care: improved collection, transfer and sharing of data resulting from regular measurements that are key in managing diabetes or cardiovascular disease.[16]

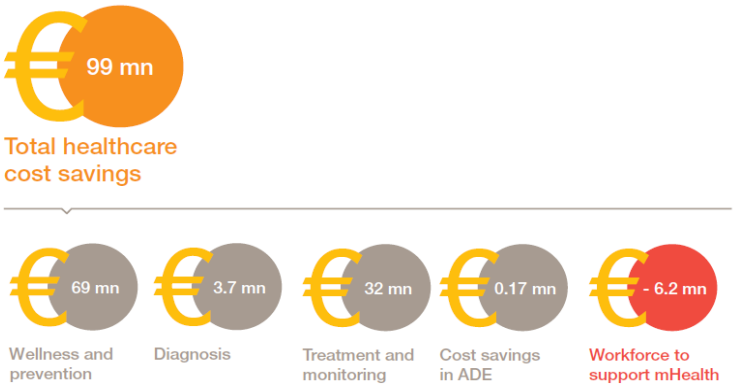
GSMA recommendations:

- An important step in ensuring maximisation of the use of mHealth to improve quality and efficiency of care would be to develop and implement mHealth education and training programmes for healthcare professionals and patients. mHealth modules should eventually be integrated in relevant general education and training programmes for doctors, nurses and other healthcare professionals.
- In addition, in order to maximise the use of mHealth for high quality care, we would recommend for the European Commission to explore the possibility of creating European clinical expert groups aiming to develop guidance with respect to the use of mHealth solutions in high quality care. In several countries, healthcare professional organisations are already getting actively involved in providing guidance and information on the use of mHealth apps. These experiences could be used in further initiatives to integrate mHealth into high quality care.

[13] https://www.amc.nl/web/Het-AMC/Nieuws/Nieuwsoverzicht/Nieuws/AMC-lanceert-Hospitality-App.htm
[14] http://image.guardian.co.uk/sys-files/Guardian/documents/2013/03/19/NHSWestern-Isles_FINAL.pdf
[15] http://www.welldoc.com/Clinical-Trials.aspx
[16] http://healthcare.orange.com/eng/discover-e-health/all-use-cases/How-can-we-improve-the-treatment-of-diabetic-patients-using-telemedicine

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

In order to contribute to providing evidence of the benefits of mHealth in Europe, the GSMA commissioned a study conducted by PwC on the socio-economic impact of mHealth in the EU. The study was published in 2013 and indicates that the use of mHealth could save 99 billion EUR in healthcare costs in the EU and add 93 billion EUR to the EU GDP in 2017 if its adoption is encouraged.



Moreover, mHealth solutions could help 185 million potential users lead healthier lives and gain 158,000 years of life. mHealth could enable 11.2 million people with chronic diseases and 6.9 people at risk of developing a chronic disease, to extend their professional lives and improve their productivity. This would add 93 billion EUR to the EU GDP in 2017. [17]

In addition, the GSMA has supported literature research aiming to create an overview of studies on the added value of mHealth, as well as reports on the evidence for mHealth.[18]

GSMA recommendation:

- The GSMA would recommend the European Commission, with the support of other key stakeholders, to facilitate and centralise the further collection of evidence with respect to the overall impact of mHealth on healthcare costs in the EU.

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

Given the widespread use of mobile phones and the reach of mobile networks, mHealth can support equal access to healthcare and help reduce health inequalities in the EU. However, measures should be taken in in different (policy) areas and at different levels (EU, national and local) in order for healthcare professionals and patients to be able to access and use mHealth solutions.

GSMA recommendations:

- In order to facilitate widespread access to mHealth, innovative and sustainable funding and reimbursement schemes that reward health outcomes and efficiency improvements need to be

[17] Socio-economic impact of mHealth – An assessment report for the European Union, PWC, May 2013
[18] http://www.gsma.com/connectedliving/resources/?project=mHealth

developed and implemented. Exchange of examples and good practices in this area needs to be promoted and facilitated at EU level.

- mHealth awareness campaigns as well as mHealth education and training programmes for healthcare professionals and patients need to developed both at EU and national level.
- An overview of mHealth services, their regulatory status and accessibility should be established and made available to EU citizens.
- The GSMA would also like to highlight the importance of recognising 'inclusion' in any follow up action to the Green Paper, taking into account that there over 80 million people in Europe with a disability who could benefit from mobile solutions, but may not have access to them.

Interoperability

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?

One of the major factors to make mHealth a success, is to put in place the foundations that will enable the technology to reach scale. In this regard, the success of the mobile industry has been built on the use of common interoperable standards that allow the scaling of solutions at minimal cost.

Although standards are used within healthcare, the systems developed are traditionally closed and bespoke, provided by a single manufacturer with minimal use of interoperable standards. Not only would the use of interoperable standards potentially reduce device/platform costs, it would also have a significant impact on the costs relating to design and development. In a recent PwC study, it was identified that the use of standards could save an estimated US$40,000 to US$50,000 in design costs. In addition, it was estimated that integration of an interoperable device into a mobile health solution or an electronic medical record (EMR) would take only one to three weeks instead of about three months (the time it typically takes to develop and test the code), when standards are used.[19]

Therefore, a set of core interoperable standards that would enable the mass market deployments of mHealth solutions is urgently needed. Currently the fragmented nature of the healthcare ICT sector is leading to an environment that stifles innovation and leads to the development of closed proprietary solutions.

GSMA recommendations:

- The adoption of core interoperable standards needs to be stimulated: the use of common standards will not only ensure that e.g. apps being developed are secure, robust and meet the end-users' needs and safety requirements, it will also reduce the cost and complexity of developing apps for healthcare.
- We would like to refer to and call upon the EU to recognise the important work of the Continua Health Alliance in this area, in particular ITU recognised standard (ITU-T H.810) for end-to-end interoperability.
- In addition, exchange of experiences with other sectors could be explored: lessons could be learned from other sectors and areas where mobile technology is applied, such as the financial sector (mobile money and mPayments technologies).

[19] http://www.pwc.com/gx/en/healthcare/mhealth/mhealth-insights/mhealth-interoperability.jhtml

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?

Work in this area should be encouraged through EU and national initiatives resulting from the Green Paper. Ultimately mHealth and patient generated health data will become a powerful source of health information of an individual. To truly leverage this, it is important to ensure Electronic Health Records are interoperable with mHealth solutions. In this respect the Continua guidelines (also ITU-T H.810 standards)[20] for end-to-end interoperability should be referred to.

mHealth solutions often collect data through medical devices. The way data are transported from the medical device to the mHealth app must occur in a standardised way. From the app, the mobile device data are often transferred to a third party (e.g. hospital, doctor's office, health cloud). Also this transfer must occur in a standardised form.

GSMA recommendations:

- Continued EU support for organisations which can define common standards, both for the technology as the content:
    - Integrating the Healthcare Enterprise (IHE)
    - Personal Connected Health Alliance

Reimbursement models

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

In general, very few examples of implemented funding schemes or models for mHealth services exist. There are pilot projects initiated by different stakeholders, including insurers, but these seem to remain small-scale. National authorities play an important role in determining reimbursement of care. Whereas some EU Member States are more advanced in enabling the use of remote care solutions, in other Member States national law still defines medical care based on the actual physical presence of patient and doctor, preventing reimbursement of mobile and remote healthcare solutions.

As an important first step in Germany, the first health app (addressing the eye disorder amblyopia) is reimbursed since March 2014, allowing ophthalmologists in Germany to prescribe the vision therapy app. This positive example may pave the way for more reimbursement of mHealth solutions.

GSMA recommendation:

- As examples of reimbursement of mHealth services are limited and difficult to find, an initiative could be developed with the support of the European Commission, aiming to:
    - collect examples and good practices in the area of reimbursement;
    - develop recommendations for appropriate innovative incentive structures, including funding mechanisms based on health outcomes.

What good practice do you know of that supports refund of mHealth services (e.g. payer-reimbursement model, fee-for-a service model, other)? Please give evidence.

As stated above, very few examples exist. mHealth mediated health services (and eHealth in general) will become part of the range of healthcare solutions offered to citizens, if and when the overall

[20] http://www.itu.int/rec/T-REC-H.810-201312-I

approach of healthcare systems to objectives will prioritise efficacy, efficiency and outcomes based remuneration. Rewarding healthy lifestyle and prevention should also be considered in this respect.

GSMA recommendations:
The same recommendation as provided in relation to the previous question applies here. Additional points:

- Also a savings-sharing mechanism between healthcare provider and payer could incentivise the adoption of innovative technology and services. Whilst not on mHealth, the US meaningful use programme on certified EHR technology[21], by setting a carrot-and-stick approach on the financing of health services is being successful in raising the level of healthcare IT adoption.
- In addition, in particular with respect to promotion of healthy lifestyles and management of chronic conditions, initiatives including employers aiming to ensure health at the workplace, could be envisaged.

International cooperation

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

Given the global dimension of the mHealth sector, harmonisation of regulatory approaches will be important to facilitate growth and deployment. In order to achieve this, dialogue between the EU and regulatory authorities from other parts of the world needs to be enhanced, in particular discussions with the US (FDA), as many mHealth solutions originate from there.

GSMA recommendations:
As specific priority issues for international cooperation, we would like to propose:

- Regulatory convergence:
  - The International Medical Device Regulators Forum is an important platform for coordination of regulatory initiatives globally. In this respect, we welcome the Forum's work on standalone medical device software harmonisation.
  - With respect to the importance of coordination of regulatory approaches, we also would like to refer to the FDA guidance on mobile medical apps which was adopted in September 2013.[22] The FDA applies regulatory oversight only with respect to mobile apps with intended use related to diagnosis, cure, mitigation, treatment or prevention of disease. Lifestyle and wellness apps or apps for information or education purposes in this respect are not regulated.
- Interoperability adoption:
  - As mentioned, there are examples of partnerships between mobile operators and government agencies focusing on the use of mHealth data to track health and disease trends. Making full use of the potential of mHealth in this area can be encouraged through international cooperation (e.g. cooperation between the EU and WHO, ITU) and the development of cross-border public health and disease prevention programmes that leverage mHealth.
  - In addition, the GSMA would welcome international initiatives aiming to facilitate and promote the collection and exchange of good practices on the use of patient generated health data.

[21] http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/
[22] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm?utm_source=twitterfeed&utm_medium=twitter

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

There are examples of regulatory and policy developments in other countries with a positive impact on mHealth deployment:

- Use of remote monitoring in the US is gaining momentum due to a recent regulatory ruling, as part of the Affordable Care Act legislation that calls for the hospital to be charged with penalties if a patient who has been discharged from hospital is readmitted in less than 30 days. Reimbursement for eVisits is also increasing.
- A 10-year national health insurance plan has recently been adopted by the South African government, aiming to decentralise primary care and to shift away from medical knowledge and services being exclusively in hospitals, toward extending these healthcare capabilities to clinics and community care services. Pilots are being developed, including implementation of mHealth solutions.[23]
- The Brazilian government has recently passed regulation reducing taxation on machine-to-machine (M2M) devices. This move, will significantly reduce the tax burden on M2M devices, providing a stimulus for operators to develop services, including remote health monitoring.[24]

[23] http://jpubhealth.oxfordjournals.org/content/34/1/149.full
[24] http://m2mworldnews.com/2014/05/06/34989-brazil-cuts-taxes-on-m2m-services/