mHealth
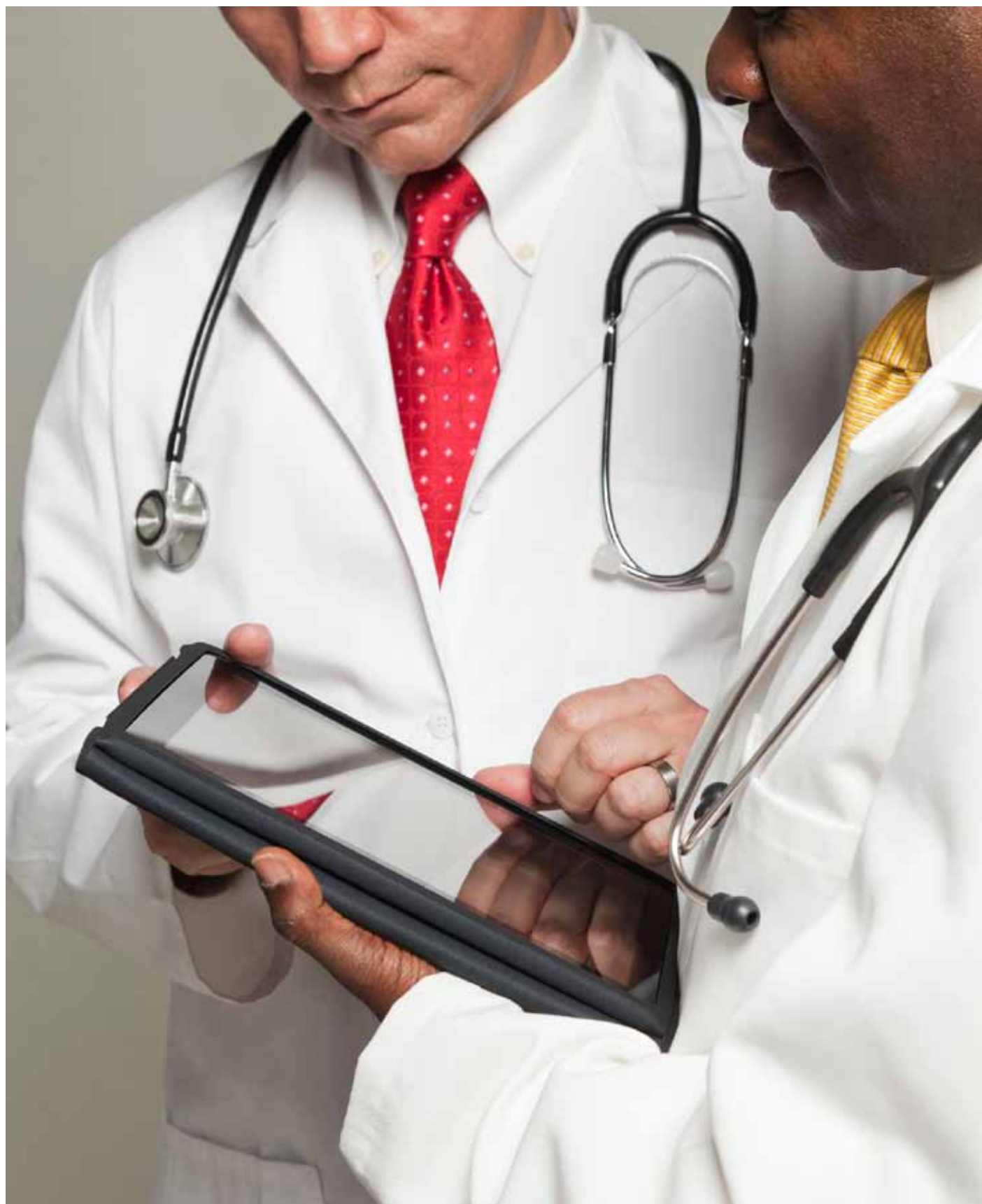
mHealth and the EU regulatory framework
for medical devices

Introduction

European healthcare systems face major challenges, including ageing populations and the growing incidence of chronic diseases, while budgets are becoming tighter. In addition, technological developments have introduced important new dimensions in healthcare, with the Internet playing a key role in enabling online access to information, services and products to a large part of the global population: by 2016, there will be an estimated three billion Internet users. Moreover, in low and middle income countries in particular, most consumers are more familiar with mobile phones than with landline phones. By 2016, mobile devices will account for about 80% of all broadband connections in the G-20 nations.[1]

Given the 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 in the centre and provide a continuum of care. More specifically, mobile health (mHealth) solutions can help healthcare providers deliver better, more consistent, coordinated and more efficient healthcare, where and how it is needed, increase access to health services to remote or under-served communities and empower individuals to manage their own health more proactively and effectively. This will help to make the needed shift from acute, reactive and hospital-based care to long term, proactive and home-based care, integrating both health and social settings – underpinned by health promotion, disease prevention, independent living and integrated health, social, community and self-care.[2]

However, in order to unlock the full potential of mHealth in Europe, the importance of innovation in healthcare needs to be recognised and some key challenges need to be addressed. Some of these challenges, for example reimbursement, will be discussed mainly at national or regional level, but other key issues touch upon a range of EU policy and legislative initiatives, such as data protection and privacy, patient mobility or skills needs for health professionals. In addition, mHealth solutions, based on rapidly developing innovative technologies, increasingly cross different regulatory frameworks. Clarity with respect to the application of different regulations is therefore urgently needed, in order to protect user safety, build trust and maximise effectiveness, while encouraging innovation and stimulating new deployment on the market.

In view of the current revision of the EU regulatory framework on medical devices and the increasing importance of this regulation for mHealth solutions, this paper will focus in particular on EU medical devices regulation and how this applies in the area of mHealth. Awaiting an in-depth analysis of the European Commission's proposals for a revised regulatory framework for medical devices, this paper aims to highlight some general key questions and to provide the views of the GSMA where appropriate.

The GSMA represents the interests of the worldwide mobile communications industry and has a strong representation in the Europe Union, including more than 100 mobile network operators providing over 600 million subscriber connections across the region. GSMA welcomes a constructive dialogue with key stakeholders in order to address some of the key challenges as well as opportunities for mHealth in Europe.

"Promoting good health is an integral part of the smart and inclusive growth objectives for Europe 2020. Keeping people healthy and active for longer has a positive impact on productivity and competitiveness. Innovation in healthcare helps take up the challenge of sustainability in the sector in the context of demographic change"

Proposal for a Regulation of the European Parliament and Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020, COM (2011) 709 final

"mHealth can enable new models of care: because it is consumer focused, mobile communications technology is ideal for empowering patients, allowing them to manage their own well-being and health. That means it can be used to drive important changes, such as a shift towards prevention, rather than cure".

GSMA and PA Consulting Group, Policy and regulation for innovation in mobile health

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1   The Digital Dimension of Heathcare, Report of the Digital Innovation in Healthcare Working Group 2012

2   Strategic Implementation Plan for the European Innovation Partnership on Active and Healthy Ageing, Steering Group Working Document adopted on 17 November 2011

About Mobile Health

The World Health Organisation considers mHealth as a component of eHealth and defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".[3]

Applications in mHealth can be described in different ways. The GSMA generally categorises mHealth solutions into two broad areas: solutions across the patient pathway and healthcare systems strengthening. Solutions across the patient pathway include wellness, prevention, diagnosis, treatment and monitoring and entail direct touch points with patients. Healthcare systems strengthening solutions include emergency response, healthcare practitioner support, healthcare surveillance and healthcare administration and do not involve direct interactions with patients, but are primarily aimed at improving the efficiency of healthcare providers in delivering patient care.

Examples of mHealth Services in Europe

	Mobile operators	Description
Wellness	Moldcell	Practical tips about immune system strengthening, measures to protect from and prevent seasonal diseases, unconventional therapy to treat seasonal diseases, tips on how to use dietary supplements and healthy eating habits.
Prevention	MyAsthma	Free personalised health application for iPhone and Android users designed to help people over the age of 12 take greater control of their asthma. The MyAsthma app keeps users posted on local information about asthma triggers, including pollen count, pollution, and weather. It also helps users track symptoms and their ACT scores over time to see trends that they can share with care providers.
Monitoring	Business Services SORIN GROUP SmartView	Using the SMARTVIEW remote monitoring solution, healthcare providers can now access valuable cardiac data and alert messages from Sorin's devices, while the patient is at home. Combined with remote data transmission, the intelligent proprietary features embedded in Sorin's CRM devices offer advanced diagnostic capabilities and early detection of cardiac disease progression for enhanced patient management.

Recent studies have shown that the use of technology as a remote intervention can make a considerable difference, both at individual and societal level. Early indications from a study undertaken by the Department of Health in the UK show that if used correctly, remote care can deliver a 20% reduction in emergency admissions, 14% reduction in bed days and most strikingly, a 45% reduction in mortality rates.[4]

Essentially, mHealth solutions can comprise one or more of the following core elements:

- Medical Device Technologies

- Communications Technologies

- Network Infrastructure, including access to the Internet

- Software Technologies

Basic mHealth services may simply be using the standard capabilities of a mobile handset to access health related information, for example via SMS messaging or internet connection, or perhaps by linking back to an electronic medical record application. Mobile technology also enables more advanced services, e.g. connected services that incorporate medical devices. These extend the capabilities of the mobile by carrying data directly from the medical devices across the mobile network through to a data platform where users can access the information in a relevant format.


"The use of mobile and wireless technologies to support the achievement of health objectives (mHealth) has the potential to transform the face of health service delivery across the globe".

WHO, Global Observatory for eHealth series – Volume 3 "mHealth: New horizons for health through mobile technologies: second global survey on eHealth"

3 WHO, Global Observatory for eHealth series – Volume 3 "mHealth: New horizons for health through mobile technologies: second global survey on eHealth"

4 Department of Health, Whole System Demonstrator Programme, Headline Findings, December 2011
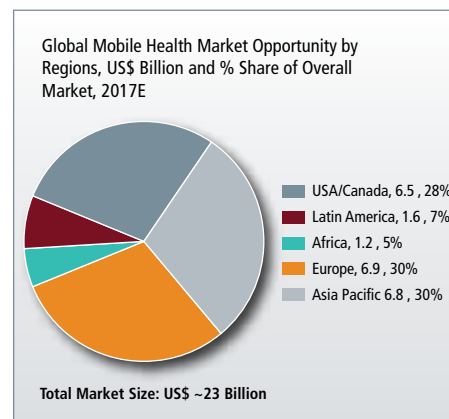
Figure 1: Policy and regulation that could apply to remote monitoring solutions
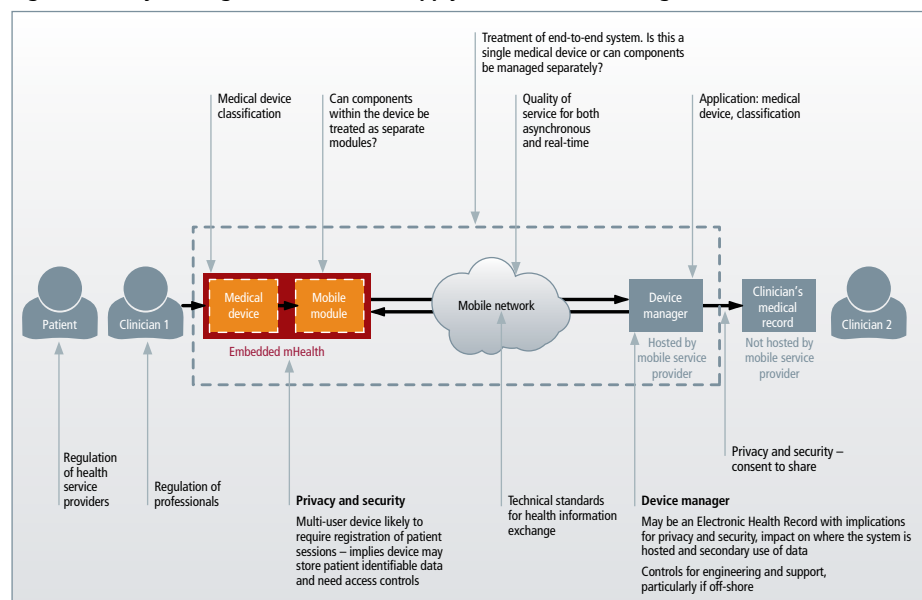
The potential of mHealth

Key facts and figures:

- Today, mobile services are ubiquitously available with a population coverage rate of nearly 100% and a mobile penetration rate of 128% in Europe. This represents 656 million individual subscriptions held by an estimated 456 million European (89% of the population).[5]

- Mobile services are being used across all age groups and socio-economic segments of the population.[5]

- By 2016, mobile devices will account for about 80% of all broadband connections in the G-20 nations.[6]

- Smartphones, which are forecast to grow at 33% per year, and more recently tablets, which are forecast to grow at 57% per year, are further driving an explosion in mobile data traffic.[5]

- It is estimated that some 30% of smartphone users are likely to use wellness apps by 2015.[6]

- In the US, more than 80% of physicians are now using smartphones for personal and general use, and increasingly, doctors will use their smartphones – as well as other devices such as tablets – as digital assistants.[6]

- By speeding up processes, reducing the possibility for human error, and avoiding duplication, remote access to centralised electronic health records can reduce administrative burdens by 20 to 30%.[6]

- Early indications of the Whole System Demonstrator Programme in the UK show that if used correctly, the use of technology as a remote intervention can lead to: a 20% reduction in emergency admissions, a 14% reduction in bed days and a 45% reduction in mortality rates.[8]

- Trials in Nordic countries show that mHealth could generate a 50-60% reduction in hospital nights and rehospitalisation for patients with COPD.[6]

- Taking data collected from pilots and projects in Scotland and Norway, it is estimated that mHealth could reduce overall elderly care expenditure by 25%.[6]

- Europe will be one the largest markets for mHealth globally, representing roughly 30% of global revenues by 2017.[8]

- Currently, there are over 800 mHealth deployments worldwide, of which 119 in Europe.[9]

Global Mobile Health Market Opportunity by Regions, US$ Billion and % Share of Overall Market, 2017E

- USA/Canada, 6.5 , 28%
- Latin America, 1.6 , 7%
- Africa, 1.2 , 5%
- Europe, 6.9 , 30%
- Asia Pacific 6.8 , 30%

Total Market Size: US$ ~23 Billion

Source: PwC analysis

5   GSMA, European Mobile Industry Observatory 2011

6   The Boston Consulting Group and the Telenor group, The Socio-Economic Impact of Mobile Health, April 2012

7   Department of Health, Whole System Demonstrator Programme, Headline Findings,

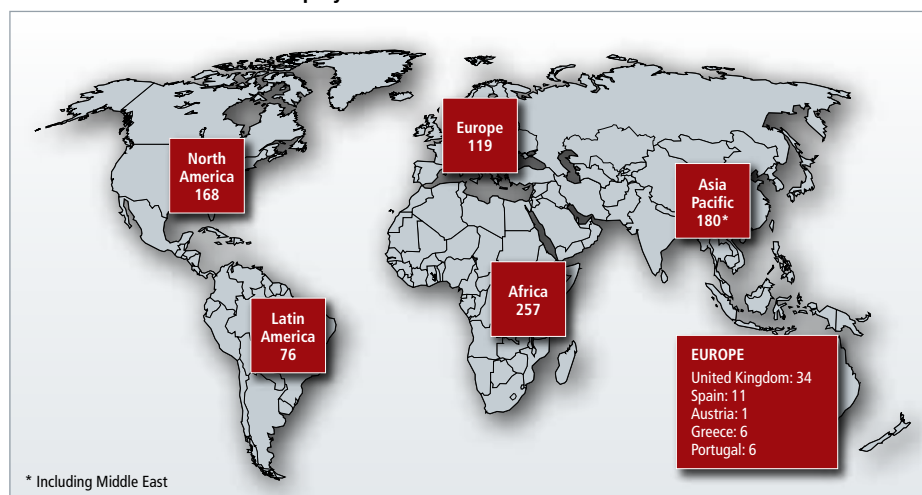8   Touching Lives: Assessment of the Global Mobile HealthMarket, PWC and GSMA, 2012

9   GSMA mHealth Tracker, October 2012

Unlocking the potential of mHealth

In contrast to healthcare access, mobile access is increasingly widespread: almost all developed markets, including EU Member States, already have mobile penetration greater than 100%. Also, the increasing penetration of smartphones, as well as the 3G and 4G networks, provides a significant boost to the use of mobile platforms for providing healthcare services.[10]

We are currently in a transition phase in the development of the mHealth sector. Early efforts in mobile health saw many trials funded by operators, governments, NGOs and other interested bodies. Many mobile health propositions have gained acceptance and are generally being more widely adopted, although in some regions faster than others. Currently, there over 800 mHealth deployments worldwide, of which 119 in Europe.[11] The sector is developing and this growth is accompanied by a rapid increase in the number of software solutions, including Apps that potentially offer new modalities of care.

Mobile Health is Here – 800 deployments worldwide

North America 168

Europe 119

Asia Pacific 180*

Latin America 76

Africa 257

EUROPE
United Kingdom: 34
Spain: 11
Austria: 1
Greece: 6
Portugal: 6

* Including Middle East

Source: The GSMA mHealth Tracker, October 2012

"Remaining barriers for entrepreneurs to bring "ideas to market" must be removed: better access to finance, particularly for SMEs, affordable Intellectual Property Rights, **smarter and more ambitious regulation and targets,** faster setting of interoperable standards and strategic use of our massive procurement budgets. As an immediate step, agreement should be reached on the EU patent before the end of the year."

Europe 2020 Flagship Initiative Innovation Union COM 2010 546 final

However, an important challenge for the full deployment of mobile solutions, in Europe in particular, is regulation. For example, new mHealth devices are increasingly covered by two regulatory frameworks: the Radio Equipment and Telecommunications Terminal Equipment (RTTE) and the EU Medical Devices Directives (MDD). Amongst other concerns, this leads to questions regarding the application and coordination between these different regulations.

Guidance with respect to the application of regulation in the area of mHealth is therefore urgently needed, in order to protect user safety, while ensuring that the potential of mHealth with respect to the health sector, but also growth, jobs and trade, is realised. As highlighted in the EU's Flagship initiative "Innovation Union", Europe's future economic growth and jobs will increasingly have to come from innovation in products, services and business models.[12] In this respect, innovation also plays a key role in the healthcare sector[13] and should be stimulated, rather than limited by regulatory barriers.

10 GSMA, PWC, Touching lives through mobile health – assessment of the global market opportunity, February 2012

11 Mobile Health Service Deployment tracker, October 2012

12 Europe 2020 Flagship Initiative Innovation Union COM 2010 546 final

13 Proposal for a Regulation of the European Parliament and Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020, COM (2011) 709 final

The EU regulatory framework for medical devices and mHealth

EU medical device regulation and patient safety

EU medical device regulation is essential in assuring patients' and users' safety. Safety for end-users is and should be at the centre of mHealth solutions and is essential in creating the foundations to ensure trust in services.

GSMA members have working processes and quality systems in place that facilitate rapid and efficient introduction of safe and effective new products to a fiercely competitive market. In this respect, the mobile communications industry itself works within a highly regulated environment. We believe that our members are therefore well-placed to also work in a healthcare regulatory environment and engage effectively in its processes and with authorities.

We appreciate the differences in medical device and mobile platform risk assessment and product life cycles and would like to help bring clarity around the potential impact of EU medical device regulation on the development of mobile health solutions and the boundaries between medical devices and consumer products.

We believe that the exciting expansion of mobile capabilities in healthcare provision must be conducted in partnership with regulatory bodies both at EU and national level and that mutual understanding can be achieved by such proactive engagement. We therefore encourage constructive discussion between our members and EU and national regulators to help realisation of new technologies that can better serve consumers safely and provide a positive benefit in the provision of healthcare.

In view of the upcoming debate on the revision of the EU Medical Devices Directives, we would like to raise some initial questions that we would like to gain clarity on, working together with EU regulators and other key stakeholders. The questions and views expressed focus on mHealth solutions.

Mobile medical device definitions and classification

We are confident that the existing definition and classification of Device and Accessory can embrace the large spectrum of technological and scientific advances being incorporated in new mobile health systems. As the technologies involved in creating such new systems are developing rapidly and are varied in both their technical aspects and types of service provided, we welcome the on-going dialogue with regulatory bodies both at EU and national level, to further refine current definitions and boundaries. **We believe there is no requirement for additional new device regulation, but rather a clarification of existing regulation. The current revision of the EU regulatory framework on medical devices offers an important opportunity in this respect.**

"Intended use" and boundaries between Wellness and Medical solutions

Determination with respect to applicability of medical device regulation to a product or service is based on the intended purpose of the product and its mode of action. Considering a product's intended use in conjunction with the regulator's definition of what constitutes a medical device enables manufacturers to decide with reasonable clarity, whether the product will fall within the scope of the regulation. In this respect, where there are no claims made regarding the suitability of a network or a mobile device for medical purposes, medical device regulation should normally not apply.

However, one significant area of uncertainty that has risen in the definition of the boundary between general wellness and diagnosis or treatment of a disease or health condition: under what circumstances might a product intended to support self-awareness and well-being become subject to the medical device regulation? For example, the distinction between Mobile Medical Apps and Mobile Wellness Apps can become unclear as healthcare models become more patient-centric. Today, the impact on quality of life or health outcomes may be significantly improved through preventive and self-monitoring activities. Some mHealth solutions, such as health and fitness Apps, intended to support general consumer wellness could arguably, if integrated in a diagnosis and treatment regimen, be classified as a medical device.

In order to provide guidance in this area, the US Food and Drug Administration (FDA) has recently proposed that App distributors as a sales channel have no responsibility under medical device regulations. Similarly, the manufacturer of the phone that a medical App runs on has no responsibility as the phone is not intended for use as a medical device. The medical App writer is clearly identified as the manufacturer under the regulation and hence carries the burden of compliance based on "intended use".

Given the speed of technological developments and the development of mobile solutions in a health context, we would welcome similar clarity and guidance with respect to regulatory implications at EU level.

Risk assessment

Determination of the potential to cause harm through risk assessment is key to medical device or system classification and hence the degree of regulatory burden. It is the responsibility of the manufacturer to conduct effective risk-based analysis and to engage with the regulator in agreeing device classification. However, the GSMA would welcome guidance and an exchange of views with EU regulators on the application of risk analysis techniques to assess device risk in the context of mHealth solutions. We support and encourage our members to engage with EU and national regulators to define and examine safety risks related to new mobile medical technologies. We believe that this engagement will enhance manufacturers' understanding of medical device safety risks. Similarly, as regulators engage with mobile technology providers, innovative mitigating strategies may emerge. It is therefore in the best interests of both parties to be involved in an on-going risk evaluation process. Classification rules can be adapted as new technological advances occur, providing means to reduce safety risks to patients.

We acknowledge that in the light of the rapid rate of change of mobile technologies, such a review process may need to take place more frequently than is required or assumed in the broader medical device arena. In this respect, a risk-based approach to regulating medical devices and more particularly software will foster innovation while preventing potentially harmful devices from reaching consumers. For example, it is essential for medical Apps to be evaluated on the principle of potential severity of injury that the "device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use".

Standards

The use of standards has been a key element in establishing medical device regulations. The International Organisation for Standardization (ISO) defines a standard in the medical device domain as follows: "Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose".

The GSMA strongly embraces the adoption of global, consensual standards. Markets for mHealth are increasingly global and interdependent. Global standards are therefore key to ensure economies of scale can be achieved and innovation can flourish. We acknowledge that a wealth of knowledge governing best-practice in the development of medical devices already exists. We believe that the mobile industry will benefit from further contribution to such standards and acknowledgment by regulators of emerging standards[14] that are aimed specifically at harmonising the exploitation of mobile medical devices.

We encourage adoption of current medical device and software standards when developing mobile medical products. We believe that the establishment and use of international standards can have a high impact on the ability of the industry to create innovative and safe products and that existing standards are broadly fit-for-purpose as they relate to mobile systems. We also support initiatives aimed at identifying potential gaps in consensual standards relating specifically to the mobile health industry.

Clarity on regulatory status, post-market surveillance and traceability

It is important for users (medical professionals or lay persons) to be clearly aware of the regulatory status of a mobile health solution and its different components. Therefore, end users should be aware of the level of scrutiny these components have been subject to in order to assess its fitness for use. For example, a large number of Apps are already available on App distribution sites, which are classified as "medical" or "wellness" regardless of their legal classification as medical devices or not. The responsibility of ensuring this clarity on regulatory status lies with the manufacturer, who should provide clear labelling of its product.

We would like to highlight the requirement, within the current EU regulatory framework on medical devices, for products to have an appropriate level of traceability and post market surveillance to ensure safety is maintained through the product lifecycle. The same should apply for all mobile health solutions.

Relation between EU regulatory frameworks for medical devices and telecoms

The Radio and Telecommunications Terminal Equipment (RTTE) Directive, is the main route to compliance for Radio and Telecoms equipment that is marketed in the EU. Compliance with this Directive is required in order to place a CE Mark on these products. The requirements of this Directive are rather different from those of the EU Medical Devices Directives (MDD) which may place a higher burden of design control, testing and pre-market clearance. In addition, the quality assurance requirements for each Directive, whilst similar, lead to the application of different harmonised standards (ISO 9001 and ISO 13485).

We would welcome the opportunity to discuss and work with other key stakeholders to clarify the interaction and distinction between these two Directives when developing and manufacturing mobile health solutions. A recent "mHealth Task Force", initiated by the US Federal Communications Commission (FCC) and involving leading wireless healthcare technology experts from industry, Government and academia, put forward a set of concrete recommendations to accelerate the adoption of mHealth technologies. One key recommendation highlights the need for increased collaboration between federal agencies, such as the FCC and the FDA, to promote innovation, protect patient safety and avoid regulatory duplication.[15] A similar initiative involving key Directorates of the European Commission, Member States and other key stakeholders could perhaps be considered at EU level.

In the same context, clarity is also needed with respect to the Quality System requirements, the need for compliance with the appropriate ISO standard and the requirement for Notified Bodies to approve both or either type of quality system for telecoms manufacturers under given medical device classification statuses.

Mobile health expertise when applying the EU regulatory framework on medical devices

In order for medical devices to access the market and reach patients and users, and to ensure that the product is safe and performing as designed, manufacturers must accomplish a conformity assessment and – with the exception of low risk class I devices – undergo an inspection and certification procedure carried out by Notified Bodies. Components of mobile health solutions which fall under the EU regulatory framework for medical devices can be of a very different and new nature compared to medical devices (for example Apps). **It is therefore essential that Notified Bodies or other expert committees playing a role in the certification of (components of) mobile health solutions, include solid knowledge and expertise in the area of mobile health.**

15 mHealth Task Force, Findings and Recommendations: improving care delivery through enhanced communications among providers, patients and payers, Pre-Publication Public Draft, 24 September 2012

Conclusion

mHealth is a rapidly evolving sector offering great promise for healthcare in the EU. There still are barriers to unlock the potential of mHealth and the application of EU regulation is a key point to address. We believe that these questions can be solved through dialogue and engagement with key stakeholders.

We look forward to an ongoing and constructive dialogue with EU and national regulators, as well as end-users and other key actors in the mHealth sector, in order to ensure that the potential offered by safe and effective mobile health solutions for patients, healthcare professionals as well as healthcare systems is fully exploited.

We believe that mHealth can play a key role in addressing major health challenges in the EU and contribute to active and healthy ageing, prevention, diagnosis and management of chronic conditions and sustainability of healthcare systems.
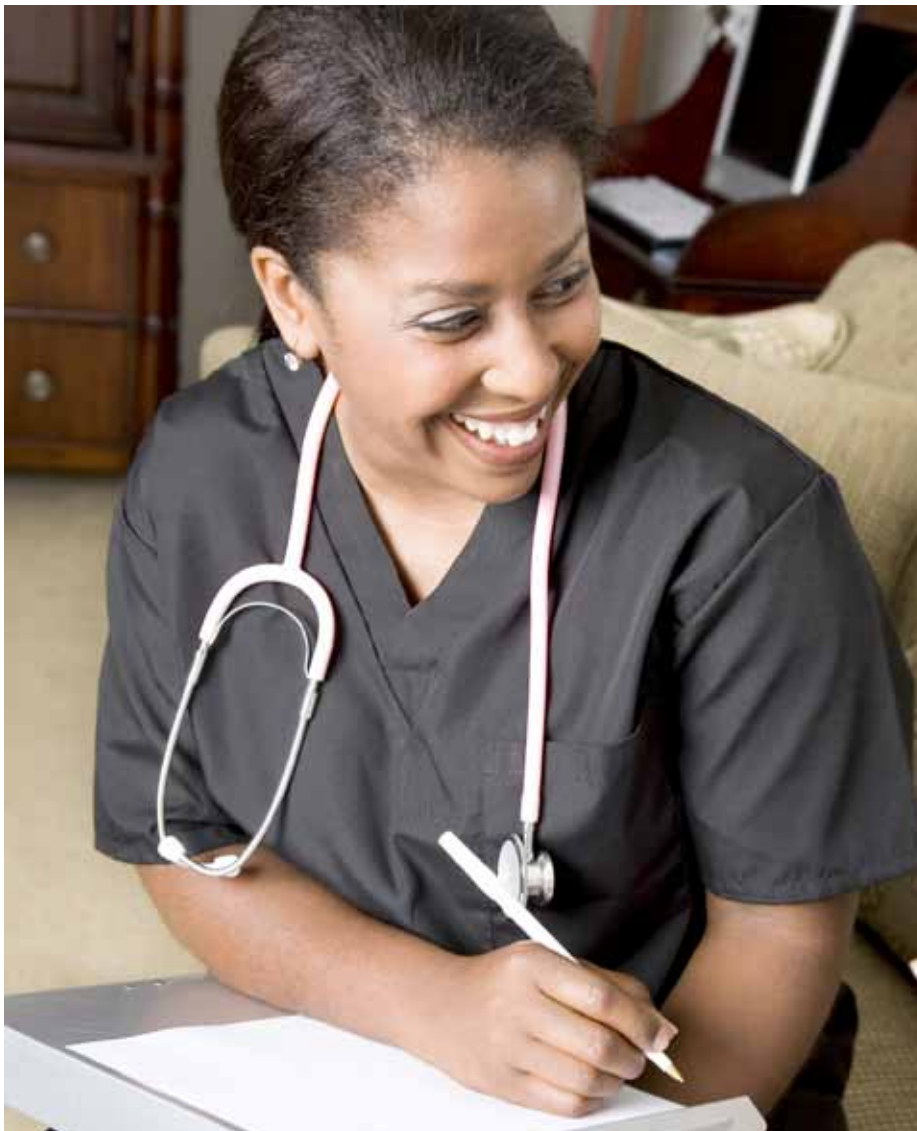
Connected Living

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