mHealthinsights

January 2013

How supportive is the regulatory framework for mobile health applications?

Highlights

- Regulatory bodies in the United States and the European Union are beginning to increase scrutiny over mHealth solutions but over 150 countries have yet to develop regulatory frameworks or guidance
- However, while the regulatory environment and healthcare systems vary from region to region, current healthcare industry players or new entrants can still follow certain principles when developing or adopting mHealth solutions

Mobile health (mHealth) is having a significant impact globally on the delivery of care but most regulators around the world are still uncertain how to address this phenomenon. While regulatory bodies in the United States (US) and the European Union (EU) are beginning to increase scrutiny over mobile health (mHealth) solutions, over 150 countries have yet to develop regulatory frameworks or guidance. Some countries appear to be following a 'one-size-fits-all' approach where the rigorous standards of healthcare are being applied to non-intrusive, non-critical mHealth services and applications.[1] In other instances, other regulations, such as telecommunication requirements, are being applied to mHealth solutions even though phone device manufacturers and network operators have entirely different risk factors from mHealth providers.

Uncertainty in regulatory requirements would likely dampen the growth of mHealth, one of the most powerful emerging tools available to enable greater access to more affordable quality care. According to the PwC-commissioned Economist Intelligence Unit report, ***Emerging mHealth: Paths for growth***, 45% of payers and doctors believe that the application of inappropriate regulations from earlier technologies are hindering the innovation of mHealth. Regulatory support to facilitate the approval of devices and medical apps, and the development of an interoperability standard, is a key factor in gaining the trust and confidence of healthcare providers, patients and payers of mHealth solutions.

Yet there is some progress. The Global Harmonization Task Force (GHTF) and its successor the International Medical Device Regulators Forum, whose membership includes GHTF delegates such as the US, EU, Canada, Japan, Australia and Brazil, have made progress in harmonising and simplifying medical device regulation. A key challenge for regulators as they continue to devise regulatory frameworks will be fostering innovation without sacrificing

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[1] PwC, GSMA, "Touching lives through mobile health: Assessment of the global market opportunity", February 2012, p. 31.

safety, complementing data privacy and security rules in accordance to the laws of the land, and aligning regional approaches to create a uniform system.

A global snapshot of current mHealth regulations

In the US

The US is advancing regulatory policy and legislation for mobile health. On 9 July, 2012, President Barack Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA) that provides the Food and Drug Administration (FDA) with the authority to continue developing mHealth regulations. The Act also enables the FDA to accelerate the approval process for mHealth solutions that function as devices.

Past proposed legislation in this area could see renewed efforts in the new Congress. Representative Mike Honda (D-CA) introduced the "Healthcare Innovation and Marketplace Technologies Act" ("HIMTA" H.R. 6626) on 3 December, 2012 in the 112th Congress to clarify existing regulations and provide support for entrepreneurs. The bill would establish an mHealth developer support program at the Department of Health and Human Services to help mobile application developers build their devices in compliance with current privacy regulations. It would also establish a national hotline, an educational website and an annual report that would translate privacy guidelines into common English. The legislation would include the creation of a small business loan program for clinics and physician offices to purchase new health information technologies. Tax incentives and grant programs are also envisioned to accelerate the adoption of health information technology. However, for this Act to move forward, Rep. Honda would have to introduce it to the 113th Congress, which was sworn in on 3 January, 2013.

In the EU

Although the European Medicines Agency has issued guidance on how they intend to regulate the mHealth application market, the final guidance[2] on stand-alone software has a smaller scope than proposed FDA regulations.[3] For example, the FDA regulation on Medical Data Device Systems, which displays, stores or transmits medical device data in its original format does not have a counterpart in EU regulation.

Furthermore, in the EU most medical apps usually qualify for the lowest risk class of medical devices (class 1), which involves only a small number of regulatory requirements. Applicants receive a European Conformity (CE)[4]-mark for a class 1 device by registering at the competent national authority based on a self-declaration. They must also ensure that the device or app complies with national data and security laws.

Other territories including Africa, Asia-Pacific and Latin America

Despite the emergence of regulatory frameworks in the EU and the US, other countries face major gaps in the regulation of mobile medical applications. They either follow a model similar to the US and the EU's or some, such as China and India, do not have specific mHealth guidelines at all.

Navigating the changing regulatory landscape

While the regulatory environment and healthcare systems vary from region to region, current healthcare industry players or new entrants can still abide by certain principles when developing or adopting mHealth solutions, especially when making an assessment in the context of the global market.

The following checklist outlines basic recommendations manufacturers (e.g., medical device companies), healthcare providers and payers and developers (e.g., software and hardware manufacturers and telecommunication companies) could consider when working with regulators. This could be a developer or manufacturer obtaining market clearance for an app, or a provider or payer considering the viability of an approved mHealth solution for their market.

[2] EMA, MEDDEV 2.1/6, "Guidelines on the Qualification and Classification of Stand Alone Software Used in Healthcare within the Regulatory Framework of Medical Devices", 2012.

[3] FDA (2011): Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications

[4] CE-mark is the mandatory conformity mark for products placed on European markets and shows manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives

mHealth regulatory checklist

- ☐ Assess which regulatory market best conforms to the stakeholder's business interests.
- ☐ Ensure that the solution enhances the existing physician and hospital infrastructure.
- ☐ Develop a plan for greatest penetration of mobile adoption with stakeholders.
- ☐ Ensure that the solution is easy to use by patients and physicians.
- ☐ Establish a reimbursement model that benefits all stakeholders and encourages patient and practitioner usage to improve outcomes.
- ☐ Confirm that the mHealth solution integrates with current technology platforms and is compatible with other types of relevant devices/software.
- ☐ Develop a strategy for the app to be compatible with other online retailers or ecommerce solutions such as banking.
- ☐ Ensure that the app follows the six principles of interoperability, integration, intelligence, socialisation, outcomes and engagement (see sidebar).
- ☐ Confirm that the app can securely transmit sensitive information, such as health patient records, and transactions e.g., several mHealth apps help patients manage diabetes, allowing patients to log in their glucose and other self-care data while providing their physicians with access to monitor progress.
- ☐ Also ensure that the app complies with the region's security and privacy laws.
- ☐ For US applicants, confirm if the solution or device is in scope of the FDA's Medical Device Regulation. If so, submit the app to the FDA using the 510k for apps that either assists in the development of clinical decisions for health issues or causes the app to be used as a medical device.
- ☐ For EU applicants, submit the medical device to the national regulator using the CE-Declaration of Conformity. Also determine the risk class of the app or medical device.

Six principles for successful mHealth solutions

PwC research has found that mHealth solutions that embrace the following six principles have a higher likelihood of success:

Interoperability - interoperable with other mobile/non-mobile devices to capture data and has the ability to share that data other applications, such as electronic health records.

Integration - integrated into existing activities of patients and workflows of providers.

Intelligence - use the data collected and analytics to provide real-time, qualitative solutions.

Socialisation - share information with designated or appropriate parties to provide support, coaching, recommendations and other forms of assistance.

Outcomes - support the collection of relevant information for outcomes based on reimbursement models.

Engagement - enable and encourage patient and provider usage to provide feedback and realise better care outcomes.

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