mHealth: Harnessing Growth and Innovation

As the mHealth market experiences unprecedented growth, it is time to harness its potential and extract tangible value for EU healthcare systems and ultimately its citizens.

Investment in healthcare technology has never been higher: between 2013 and 2014, venture capital investments alone in digital health doubled from $2.2 to $4.7 billion globally. With an expected compound annual growth rate (CAGR) of 33.5% between now and 2020, the potential for market innovation and development is vast. The impetus for growth in mHealth is, in part, driven by rapid technological innovation and increasing consumer demand. Furthermore, as healthcare systems continue to scrutinise their cost structure and identify ways to drive efficiencies, there is a growing interest in unlocking the potential of healthcare technology. Through mHealth, Member States can deliver more patient-focused healthcare, putting responsibility on citizens for better managing their own health and well-being. The opportunity is accurately captured in the European Commission’s Green Paper on Mobile Health, which highlights efficiencies such as a reduced number of patient consultations. On a larger scale, developed countries are expected to save up to $400 billion in annual healthcare costs by 2017 as a result of innovation in mHealth.

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The definition of mHealth is broad: it covers the medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), as well as lifestyle and well-being apps that can connect to medical devices or sensors. The challenge now for both industry and policy makers is to segment the market effectively and ensure that there is a robust legal and market framework in place to capture the opportunities, ensure growth and sustainability, whilst at the same time affording patients the highest protection. The European Commission is seeking to address this under the banner of the Digital Society, one of the key pillars of the Digital Agenda for Europe 2020. We analyse below the progress to date.

1. HTI, Health IT VC Funding More Than Doubles in 2014, January 2015
3. GSMA, The Rise of Connected Devices Will Drive Mobile Operator Data Revenues Past Voice Revenues Globally by 2018
The Issues
Recent estimates show there are approximately 97,000 mHealth apps available; 70% of these target consumer fitness and 30% target health professionals. However, there is a lack of clinical evidence to support their safety, reliability and accuracy. One study in 2013 found that three out of four skin cancer apps incorrectly classified 30% of melammas. The issue of ensuring reliability and accuracy is exacerbated by the absence of regulation of healthcare apps, as these are not classified as a medical device and therefore do not adhere to the same regulatory standards.

As Member States continue to look for ways to integrate personal data with electronic health care records, another issue rising up to the top of the list is how to ensure effective interoperability. There is an excessive range of terminology required to code health data, which, combined with the diversity in healthcare information systems across the EU, makes it a highly complex and lengthy process to assimilate personal data with electronic health records.

To add to the problem, the reliability of mHealth apps could be jeopardised when internet connectivity is weak. In communities where connectivity is intermittent and access to hospitals and healthcare professionals is limited, users will struggle to receive consistent and effective healthcare advice and treatment.

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Perhaps the most prominent issue so far, the lack of consumer trust in data protection and privacy is threatening to jeopardise the broader uptake of mHealth, in particular, the lack of transparency in the accountability of data processing, notably for lifestyle and well-being apps. Indeed, mHealth apps collect and process large quantities of data and concerns arise when unwanted sharing of information with third parties occurs.

Data and cloud security is also of high concern. There have been an alarming number of data breaches in healthcare, with almost 96 million personal records stolen last year. Given the sensitive nature of personal health data, strong security safeguards are needed to protect EU citizens against data theft and security risks. A solution could be to introduce the automatic encryption of personal and patient data to mitigate security risks. This would give users the confidence that their data is not being used for commercial gain or non-medical purposes.

The potential value that big data can create for healthcare is vast. The challenge is to ensure that EU citizens put their trust into the electronic processing of their health data by digital and mobile health systems.

The European Commission’s Green Paper on mHealth

The Green Paper on mHealth was published by the Commission’s Directorate General for Communications Networks, Content and Technology (DG CNCT) under the banner of the Digital Agenda for Europe in April 2014 and alongside a Staff Working Document. A public consultation later that summer sought opinions on the identified barriers to the uptake of mHealth in the EU. The European Commission continues to address these issues during stakeholder meetings and most recently at its mHealth stakeholder forum, a full-day event on 6 July which convened 43 stakeholders, with the medical professionals and industry representing 21% each and public authorities representing 19%. There are three points worth highlighting.

Firstly, the European Commission acknowledged the need to develop guidelines to improve the quality of health, lifestyle and well-being apps and announced its intention to facilitate an EU-wide standard. To achieve this, it suggested a strong collaboration between Member States and public authorities to develop a common assessment methodology for health apps. The Commission to that effect has announced last week to form a Working Group on EU guidelines with the objective of assessing the validity of data for the purposes of linking apps to electronic health records; the group is expected to start work in the autumn.

Secondly, the European Commission is in the early stages of preparing a pro-innovation legal framework to clarify the legal status of health and well-being apps. The MEDDEV guidelines, entitled ‘Guidelines on the qualification and classification of stand-alone software used in healthcare with the regulatory framework of medical devices’ will provide a clearer framework to classify mHealth apps.

Thirdly, the European Commission announced it is taking action to tackle the issues of data privacy and security in order to build trust within the market. The first initiative to get off the ground is an industry-led Code of Conduct on mobile health apps, the development of which is being overseen by the European Commission. Its aim is to foster trust with EU citizens and raise awareness among app developers of the EU’s data protection rules and requirements. The Code of Conduct is being approved and drafted by the Article 29 Working Party with input from the industry.

Next Steps
The European Commission is taking important measures to minimise the safety, security and reliability risks associated with mHealth. The Green Paper on Mobile Health has triggered an overdue debate around the tools, systems and processes needed to ensure a sustainable and effective mHealth market.

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5 Deloitte study “mHealth in an mWorld”, 2012
6 Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection, Jama Dermatology 2013;149(4):422-426
7 Healthcare Moves To The Cloud But Is The Cloud Ready For Healthcare?, Forbes June 2015
8 European Commission – Green Paper on mHealth, 2014
Moving forward, it is critical to maintain momentum to ensure it is effectively translated into tangible outcomes. The next steps include the establishment of the above mentioned Working Group on EU guidelines for assessing the validity of data for the purposes of linking health apps to the electronic health records. The Working Group will be open to all interested stakeholders and its objective is to develop guidelines on the criteria that could be used by public authorities, healthcare providers, professional and patient associations, developers and other relevant bodies to assess the reliability of the data collected and processed by health apps. The creation of the Working Group will be proposed for discussion at the next eHealth Network6 meeting in November.

Furthermore, the MEDDEV Guidelines, to be developed by DG GROW will also provide much needed clarity on the classification of healthcare apps. The next meeting of the Working Group on Software will take place on 20 October where the draft guidelines will be discussed, with the hope of having these adopted in 2016.

Beyond this, however, our understanding is that the European Commission has no immediate plans to draft legislation, a situation that will very much hinge on the success of the aforementioned initiatives.

mHealth is now at a critical juncture, like many emerging technology markets there is a huge amount of interest and excitement over its potential. If its ambitions are to be realised, the sector needs to harness the hype and focus on measuring and articulating value in a robust way. At EU level, this means ensuring the right level of collaboration between the Commission Directorates-General, namely DG SANTE, DG CNECT and DG GROW as well as continued input and engagement from industry, healthcare providers and patient groups.

The role of the EU is evolving and the institutions now provide greater input on matters linked to the regulation of the pharmaceutical and life sciences sector in which it had hitherto little competence. Urged on by the EU Council and European Parliament, the European Commission is now moving from regulating marketing authorisations, clinical trials to influencing approaches to pricing and the procurement of health technologies. As a result, the need has never been greater for Government Affairs functions to be integrated, at EU and national level.

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