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Review Article

Regulation of the Mobile Medical Apps in India: Need of the Hour

Anirudh Kotlo, Pradeep M Muragundi*, Virendra S Ligade, N Udupa.

Dept. of Pharmacy Management, MCOPS, Manipal University, Manipal-576104

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Abstract

The Mobile devices and its software applications are in great demand in this era of 21st century due to diverse and manifold perks which it provides to the consumer. In 2012 the number of Medical Application users reached 247 million and the global revenue from mHealth Apps grew possibly to USD 1.3Billion and growing on an upward curve. Medical Apps have emerged as a new tool in the healthcare arena. Medical Apps are nowadays replacing the sedentary techniques for example Patients can schedule appointment with a doctor just with a click from the smartphone by possessing the App instead of going all the way to the clinic and contacting the staff. According to WHO many medical and healthcare professionals the availability of medical apps in mobile context has paved way to new dimensions in health care. Changing landscape and cut throat competition between the app developers and the desire to stay ahead of the curve has created many challenges for the App developers across the globe. Indian App developers should also be proficient in handling Issues related to Content Development. The Indian and European markets are good markets to look at. The underserved rural healthcare market in India is still challenged by healthcare affordability and availability and thus is a strong market for mobile medical applications, especially with the recent penetration of mobile across rural India. Further, the regulatory authority in India is open to mobile medical apps. A framework helps manufacturers focus on implementing a risk-management process beginning with the design function and moving all the way through to the end-of-life phase for a global application.

Keywords: Mobile medical aap, smartphone.

1. Introduction

The Mobile devices and its software applications are in great demand in this era of 21st century due to diverse and manifold perks which it provides to the consumer. . In 2012 the number of Medical Application users reached 247 million and the global revenue from mHealth Apps grew possibly to USD 1.3Billion and growing on an upward curve[(1)] .The market of Medical Apps is estimated to reach $26 billion by 2017.By 2015, some estimated 500million smartphone users will use some type of medical App.

There are now closely 1, 00,000 medical and health related Apps for every kind of smartphone. Apps are sold via an application distribution platform, commonly known as an Google Play Store. The development of the App is measured by the number of downloads which in turn generates the Revenue. This paper elaborates an overview of mHealth and comparative evaluation of regulatory guidelines within India and various countries with an emphasis on the current challenges faced by the various App developers.

Medical Apps have emerged as a new tool in the healthcare arena. Medical Apps are nowadays replacing the sedentary techniques for Ex: Patients can schedule appointment with a doctor just with a click from the smartphone by possessing the App instead of going all the way to the clinic and contacting the staff.

Corresponding author
E-mail address: muragundi@hotmail.com
(Pradeep M Muragundi)

According to WHO many medical and healthcare professionals the availability of medical apps in mobile context has paved way to new dimensions in health care. Changing landscape and cut throat competition between the app developers and the desire to stay ahead of the curve has created many challenges for the App developers across the globe.

The health Apps are downloaded in most of the categories such as weight loss which topped with (>50 million Apps), Exercises (>26.5 million Apps) and others (18 million Apps). Healthcare App Statistics states that 85%of the population use social media for health (Facebook, LinkedIn), 87% of the people use an smartphone and the population using smartphones are generally using Medical and healthcare Apps i.e. 76% to take the prescription. Studies also revealed that 25% of the consumers wanted to use free health Apps and 51% of the Consumers wanted to use Pay Apps and 24% of the Consumers wanted to use Apps which ranged between$ 1.00 and $5.99

According to a survey [(2)], 58% of respondents said they wanted to use a health App to help manage disease medications and 48% of respondents said they wanted to use the software to keep the track of the Health Information. The Mobile Apps on a regular smartphone are easily converted into an effective healthcare platform that patients rely like in case of a Sickness, pain or discomfort Patients could browse via comprehensive FAQ database to see available medications and options before physically consulting a practitioner. There are boundless possibilities as the medical Apps can be used to curate knowledge from diverse information sources and provide structured access to healthcare consumers when needed. Pharmaceutical Companies could use mobile channels to disseminate information, organize webinars and work directly with patients. Due to the following factors and tremendous potential for Apps, with simultaneous alarming lack of knowledge about risks, these Apps pose Strict Regulation and guidance is the need of the hour.

The healthcare industry is moving from a system that delivers remedial care to one that focuses more on delivering preventive and pervasive care. Traditionally, a patient visited a caregiver only upon spotting health abnormalities. Today, patients want their caregivers to deliver quality care by remote monitoring—regularly—and patients want prompt warnings and alerts on wellness negligence. They also demand remote patient monitoring solutions powered by mobile devices (such as smartphones, tablets, etc.) and with applications (such as apps that connect to their physical health records, applications that diagnose a disease remotely, or those that promote wellness, etc.).

Medical device OEMs hold the principal responsibility for solution security, reliability, and safety of mobile medical applications. For the US markets, the recent FDA draft guidance, “Mobile Medical Applications,”1 is the regulatory bible for all medical-related mobile applications. As per the guidance, which was issued in July 2011, any mobile application that is used as an extension of one or more medical devices for the purpose of controlling patient-specific data, transforms the mobile platform into a device using similar functionalities, or allows the user to input patient-specific information and use processing algorithms, is treated as a medical device and must comply with the regulatory requirements as per 21 CFR 807, which includes submitting a premarket notification under 510(k). This guidance expands the definition of a medical device OEMs to include healthcare service providers who have their own mobile medical device applications for remote patient monitoring and communications providers who develop applications that make the mobile device a medical device. These providers, who are not normally regulated by FDA, form a nascent medical device OEM layer. As such, most don’t have a regulatory roadmap or plan.

Regulatory landscape- a brief overview:

There are different regulatory bodies around the globe which are dealing with the regulations with respect to mobile medical Apps. Studies have been done and various numbers of articles and studies have emphasized on the dangers and the irrelevant data in the medical and healthcare Apps and

concern was focused on the safety of the medical Apps aimed at the general public

USFDA:

FDA released its first guidelines way back in 2011 under section 510(k) and has defined as "a small subset of mobile medical apps that may impact on the performance or functionality of currently regulated medical devices and will have FDA oversight" [3, 4].Acc to USFDA such medical Apps could provoke risk to the patients if the App doesn't work properly. Hence FDA has presented a list of mobile medical Apps [5] that can be used as an accessory to an FDA regulated medical device or turns a platform into regulated medical device.

UKMHRA:

According to MHRA, A medical App is not considered a medical device if it achieves the record systems and included as an electronic health record and if it includes some tools for calculation and interpretation of the data, then it is considered as an medical App. Apps which illustrates simple calculations such as BMI should not be treated as a medical device but a dosage calculator which recommends an dose based on patient records should be included.

In Europe, too, the existence of clear guidance (including practical guidance) on the issue of health app regulation, openness of the regulatory authorities toward providing approvals, and the close affinity with regulatory process of other European nations due to harmonization by the EU Medical Devices Directive makes it a viable market for launching mobile medical applications. The first registration of an app (Mersey Burns) 2 in the UK (with the MHRA classifying it as a Class I medical device) is a testament to the openness of Europe toward mobile medical applications. However, to achieve the most out of this approach, one needs to adopt a global regulatory compliant product development approach.

EUROPEAN COUNTRIES:

Medical Apps which registered as medical devices should have received CE [6]certification (Conformite Europenne) which is an indication of product compliance with the European union legislation developed in 2013 and this CE mark should be displayed on the welcome screen [6, 7].European medical device directive MDD 93/42/EEC includes software such as medical Apps included in its definition of medical device. App developers wanting to have the CE mark on their Apps need to inform the MHRA in the UK to produce a declaration of conformity which includes detailed technical documentation of how their App would conform to the Medical Device Directive MDD 9342/EEC. App developers would be also needed to undergo an assessment and risk test which would suggest them any improvements for the Function.

AUSTRALIAN TGA:

Australian TGA has also regulated Mobile medical Apps included with all the other medical devices. Firstly App developers should review their Apps in accordance to the Australian Register of Therapeutic Goods [8] and should be compliant with the Australian healthcare professionals and public. Medical Apps should obtain a conformity assessment certification and then are expected to meet the essential principles for safety and performance. These regulations are unique and make no distinction between all forms of software.

HEALTH CANADA:

In Canada, medical Apps are not directly governed under the Medical device regulations or under Canadian food and drugs Act [9].Health Canada classifies medical devices from class 1 to class 4. Risk classification determines the level of regulatory oversight, including whether market authorization is mandatory and hence has framed the following guidelines:

Mobile medical apps that are components of a medical device system are classified according to the risk profile of the system (MDR Section 7 & 28). For example, an imaging app that is part of a portable ultrasound system comprising a pocket transducer connected to a mobile platform will be classified as part of the ultrasound device system (ultrasound systems are typically Class III devices).

2. Mobile medical apps intended to control, monitor or directly influence the performance of a device which emits ionizing radiation are Class III devices (MDR Schedule 1, Part 1, Rule 8). For example, an after-market mobile app intended to control a mammography

system would be a Class III device under this rule.

3. Stand-alone mobile medical apps that image or monitor a physiological process for a diagnostic purpose are Class II devices, unless an erroneous reading could result in immediate danger, in which case they are Class III devices (MDR Schedule 1, Part 1, Rule 10). For example, a mobile medical app that converts the mobile platform into a spirometer using the built-in microphone to measure lung capacity would be a Class II medical device under this rule.

4. Mobile apps intended to detect a transmissible agent in blood, tissues or organs (i.e. an in-vitro diagnostic device) are classified according to the transmissible agent being detected (Class II to IV) (MDR Schedule 1, Part 2). For example, a mobile app that utilizes the built-in camera (or other function) to detect the presence of a transmissible agent that causes a highly contagious life threatening disease would be a Class IV medical device under this rule.

5. All other mobile medical apps are Class I medical devices

Comparative evaluation of regulation in medical Apps:

The regulation of medical Apps has undergone phenomenal changes in the few years due to the fact that development of medical Apps for mobile devices has received wide encouragement and support and also to the fact that the 21st century is mostly technology naïve and newer generation including students are enthusiastic to adopt to the use of mobile devices in their future professional practice. Various countries have developed many guidelines and rules with respect to Mobile medical Apps and the Table no.1 deals with the various parameters and their guidelines in different countries

Approval Procedure:

The Approval procedure listed for USFDA is that The App developer should bring it to the notice of the agency of the conformity assessment should educate about the possible risk factors and followed by a screening by the officials and validating and registering in the class of devices and ultimately paying the registration fees and hence subsequent confirmation.

UKMHRA also similarly follows the same procedure with a little expensive registration fees but the only variation is the medical devices should be given a CE mark compulsorily on the welcome screen on the App.

Australian TGA clearly defines a specific set of guidelines for the Regulatory guidelines covering under Medical Devices which covers the Medical Apps wherein a Table no.2 depicts the Regulation of the medical Apps [(11)]

Health Canada also has separate regulatory guidelines in which the whole process is the same but reporting and registration of the device is done by the minister of health

Fees:

The Fees for USFDA for the medical Apps is 1694 USD wherein the Fees include from the assessment and paid on the whole including registration Fees which is to be submitted to USFDA by the App developers

The Fees for UKMHRA is 70 GBP which involves the assessment conformity test and subsequent registration of the Device

The Fees for Australian TGA is 1350 AUD which includes software for the initial low registration Type and for high registration type it would not include the Application Fee and an Processing Fees of 410 AUD

The Fees for Health Canada also includes 373 CAD which includes on the whole process from registration to approval inclusive of the Advertising Fees

Complaint Handling Procedure:

General Public and App developers could file a complaint against the specific App could be complained through following ways in case of USFDA [(12)]:

- Telephone report: 1-800-1088
- Online report form
- Form 3500 A and mail it to authority
- Med watcher mobile Application , a mobile Application that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smartphone or tablet

General public can complaint through UKMHRA by complaining to the Central Complaints Officer or sending an email to info@mhra.gsi.gov.uk or telephone to 020-30806000

Australian TGA records the complaints according to the openings and closings of the inspections with the TGA quality and marked to the complaints resolution Panel where it is reviewed under the supervision of quality systems manager

Health Canada mainly records the complaints by documenting, implementing the complaints in the form of mandatory reporting to the health inspectorate by Emailing to insp-dgo-bdg-insp@hc-sc.gc.ca or call toll free number to 1-800-267-9675

Content Prohibition:

In view of content prohibition USFDA amalgamates section 519 acc. to which manufacturer or App developer need to state a reason for the submission and report it accordingly UKMHRA conducts the risk assessment and then is forwarded to devices.compliance@mhra.gsi.gov.uk if still persistent in the market.

Australian TGA also has the same above guidelines as UKMHRA but should be forwarded to complaints resolution panel where the secretary considers the content prohibition.

Health Canada also has guidelines which should be reported to Recalls and safety alerts Databases which includes Health Canada, Transport Canada and Canadian Food inspection Agency.

App developer Guidelines:

App developer guidelines are specifically for Australian country wherein a practice guide has been developed for Australian App developers under the guidance of the office of the Australian Information commission.

Many countries such as USA, UK have developed some guidelines for private App developers which includes

- California Department of Justice, Privacy on the Go: recommendations for the mobile ecosystem
- Digital Advertising Alliance, Application of self-regulatory principles to the mobile environment
- Electronic Frontier Foundation
- Future of Privacy Forum and the Center for Democracy & Technology, Best Practices for Mobile Applications Developers (July 2012) and the Future of Privacy Forum's site for app developers
- GSMA, Mobile and Privacy: Privacy Design Guidelines for Mobile Application Development

Canada specifically has guidelines for the App developers which must compulsorily pass the certification program of Happtique[13] App Certification Standards for medical, health and fitness apps

Regulatory guidelines in India:

In India regulatory guidelines are framed by the CDSCO[10] (Central drugs standards organization) which has set up specific guidelines for the medical devices imported and manufactured in India but nowhere the Area of Medical Apps has been touched and various countries have already made any specific guidelines and have included Medical Apps under the Medical Devices .

Medical devices are regulated under drugs and cosmetics Act, 1945 and the following medical devices are included in the Act

Regulation of the medical Apps in India: Need of the Hour

With reference to the above comparisons and evaluate while developing country like India lags behind in every aspect of the specific app guidelines or specific App regulations for the medical and healthcare Apps. There was an outrage among many companies stating that the medical Apps do not have any substantial Data for valid information. Indian regulation on medical devices was incorporated in 2006 but medical Apps weren't included in the sector and focus on software used in the medical devices weren't found in any of the guidelines framed by CDSCO. The guidelines if framed for medical devices mainly focused upon only on the import of the devices and n specific guidelines were framed with reference to Medical Apps.

This paper purely emphasizes that Indian regulation on medical Apps are at the ground Zero and stringent regulations should be incorporated in order to develop and protect the interests of the General Public to avoid unforeseen conditions. India needs to be also vigilant among the Medical and healthcare App developers because the Apps are assigned to third party clients where the people working in the Domain are mainly related to Non-medical

field and also Indian App developers should also privately frame an guidelines for App developers till the enforcement agencies frame the necessary guidelines.

Indian App developers should also be proficient in handling Issues related to Content Development. The Indian and European markets are good markets to look at. The underserved rural healthcare market in India is still challenged by healthcare affordability and availability and thus is a strong market for mobile medical applications, especially with the recent penetration of mobile across rural India. Further, the regulatory authority in India is open to mobile medical apps.

A homologation framework can guide a mobile medical application's introduction through multiple geographies, by taking care of the legal, environmental, quality systems, distribution cycle, and end of life cycle. Such a framework manages engineering changes that may be needed to meet various local regulatory requirements. It also acts as a vehicle to handle customer complaints and regulatory reporting, to provide field service bulletin and field modifications instructions, (FMI) and to manage the end-of-life stages of the application. It is comprised of elements of a robust assurance case framework including safety assessment, failure modes effects and criticality analysis (FMECA), fault-tree analysis (FTA), static code analysis, system verification, and risks to health, among other analyses.

A framework helps manufacturers focus on implementing a risk-management process beginning with the design function and moving all the way through to the end-of-life phase for a global application.

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Table1: Comparative Evaluation of Parameters

Parameter	**India**	**USA**	**UK**	**AUSTRALIA**	**CANADA**
Disclaimer Procedure	NA	Yes	Yes	Yes	Yes
Approval Procedure	NA	Yes	Yes	Yes	Yes
Jurisdiction of Legal Disputes	NA	Courts of United States and Hawaii	Courts of England and Wales	Courts of Australia and New Zealand	Courts of Canada
Fees	NA	1694 USD	70 GBP	1350 AUD	373 CAD
Complaint Handling Procedure	NA	Ombudsman	Central Complaint Officer	Complaint Resolution Panel	Inspectorate Health
Content Prohibition	NA	Yes	Yes	Yes	Yes
Separate App Developer Guidelines	NA	No	No	Yes	No

Table 2. Regulation of the medical Apps.

Stage	**Required regulatory Action**
Concept	Consider the essential principles
Prototype	Incorporate the essential principles for the design
Manufacturing	Apply conformity Assessment procedures and then obtain conformity assessment device
Marketing	Adhere to the therapeutic goods advertising code
Supply	• Apply to include device in the ARTG • Monitor safety and performance of the device during its lifetime • Maintain Conformity Assessment Device • Report any problems with TGA and to users of the Device • Recall/Correct Devices that have defects and flaws

Table no. 3. List of medical Apps.

Sr. no.	**Name of device**	**Sr. no.**	**Name of device**
1	Cardiac Stents	**6**	Bone Cements
2	Drug Eluting Stents	**7**	Heart Valves
3	Catheters	**8**	Scalp Vein Set
4	Intra Ocular Lenses	**9**	Orthopedic Implants
5	I.V. Cannula	**10**	Internal Prosthetic Replacements

Source of Support: Nil.

Conflict of Interest: None declared

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