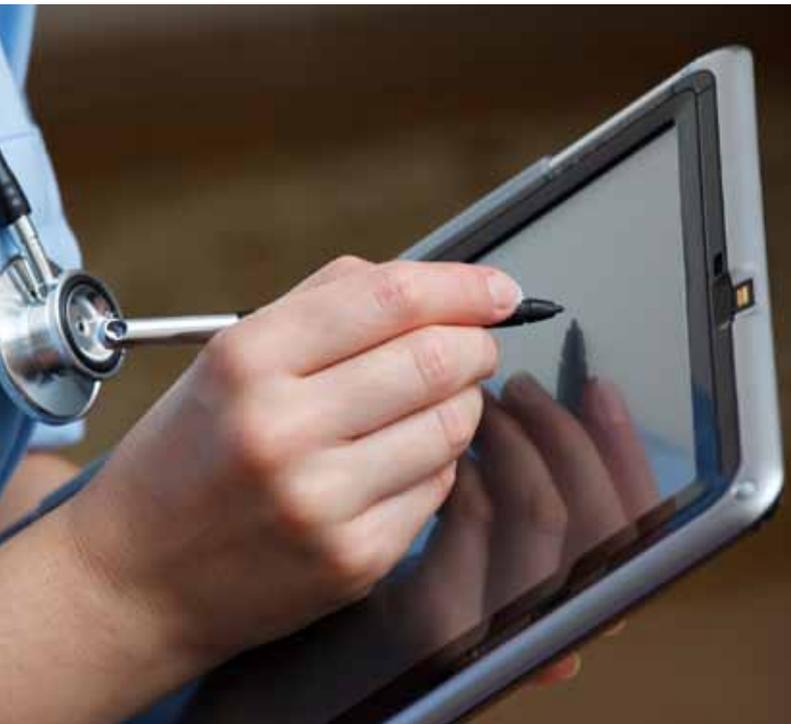




mHealth

Medical Device Regulation mHealth Policy and Position

Ensuring continued patient safety whilst enabling
medical device innovation in mobile health



Continua[®]
HEALTH ALLIANCE

Foreword

Mobile technologies are poised to make a significant contribution to addressing the enormous challenges of healthcare provision worldwide. Healthcare systems are under pressure, with significant lack of healthcare resources in developing markets, steep increases in healthcare expenditures in developed markets, and emerging economies facing the combined challenges of both infectious and chronic diseases.

Mobile health solutions provide a real opportunity to help healthcare providers deliver better, more consistent and more efficient healthcare, where and how it is needed, to increase access to health services to remote or under-served communities, and to empower individuals to manage their own health more effectively.

Early efforts in mobile health saw many trials funded by Operators, governments, NGOs and other interested bodies. We are now in a transition phase in the development of this market. Many mobile health propositions have gained acceptance and are being more widely adopted. The market is developing and this growth is accompanied by a rapid increase in the number of software solutions; Apps that potentially offer new modalities of care.

Industry is seeking guidance as to how medical device regulations apply to these new mobile health solutions. These regulations are vital in ensuring patient safety and trust in solutions. However, it is important to ensure that these regulations are well-understood and do not inadvertently hold back new deployments reaching the market.

This medical device regulatory position statement for mHealth, developed by GSMA and fully endorsed by the Continua Alliance, aims to contribute to this debate by clarifying views on the implications of medical device regulation from a mobile industry perspective. We also lay out the key policy principles that provide the appropriate balance between ensuring patient safety, whilst providing an environment for innovation and growth.

With the appropriate application of medical device regulation by regulators around the world, we foresee significant growth in many new mobile devices, applications and solutions reaching the market, providing real benefits to all.



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Introduction

As the market for mobile medical devices reaches the next stage in its development, greater consideration is being given to the regulatory frameworks that will govern their promotion and use. In contrast to models for regulation in the telecommunications industry, to those unfamiliar, medical device regulations can appear complex and burdensome.

And yet, despite this apparent complexity, it is estimated that there are over 1.5 million different medical devices available on the market worldwide. With the rapid pace of technology advancement and innovation, medical devices comprise one of the fastest growing and vibrant industries, with a global market value today of around US\$250 billion.

This document serves as a set of policy and position statements to guide interested parties in this dynamic evolving environment of mobile healthcare regulation. It is prepared from the perspective of the mobile industry, and is intended as a tool to share views with our members and wider regulatory and industry stakeholders. Each position statement contained herein is supported by a short-form rationale.

In this opening section, we introduce and clarify some of the key guiding principles and terminology within the context of medical device regulations.

“Intended Use” is a cornerstone of device regulation

Medical device regulations, whilst broadly similar, do vary from country to country. However, a governing principle in medical device regulation in both EU and US is that of “Intended Use”. Any determination regarding applicability of medical device regulations to a product or service will be based on the intended purpose of the product and its mode of action.

Considering a product’s intended use in conjunction with the regulators definition of what constitutes a medical device (discussed later) enables manufacturers to decide with reasonable clarity, whether the product will fall within the scope of the regulations where there are no claims made regarding the suitability of a network or a mobile device for medical purposes, then this principle should generally relieve both mobile network operators and vendors of mobile communications equipment of any burden in medical device regulation.

Risk Assessment and Medical Device Classification

Medical devices by their very nature have the potential to present a hazard – to be a source of harm in normal use, and more so if misused. Regulations are therefore a necessary instrument to safeguard users from undue and unnecessary risks and are based on the principle of mitigating, to an acceptable level, the potential of a device to cause harm.

Determination of the potential to cause harm (risk assessment) and implementation of appropriate risk reduction measures through the design and development process is an essential requirement under the regulations.

Regulators recognize that there are many different types of medical devices with a correspondingly wide range of associated risk. Medical devices are therefore assigned to a particular class (National regulations typically identify three or four device classes).

Regulations place obligations on manufacturers, but also provide a supporting framework for product development, facilitating design and development of products that are fit for purpose and that provide an acceptable risk-benefit balance.

Standards

The use of standards has been a key element in establishing medical device regulations. The International Organization 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”.

Standards can establish a wide range of specifications for products, processes and services:

- Prescriptive specifications obligate product characteristics, e.g. device dimensions, biomaterials, test or calibration procedures, as well as definitions of terms and terminologies.
- Design specifications set out the specific design or technical characteristics of a product, e.g. operating room facilities or medical gas systems.
- Performance specifications ensure that a product meets a prescribed test, e.g. strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy.
- Management specifications set out requirements for the processes and procedures companies put in place, e.g. quality systems for manufacturing or environmental management systems.

Prescriptive design and performance specifications have been commonplace in standards for some time and management specifications have also rapidly gained prominence.

The Role of the Manufacturer

The term 'Manufacturer' has specific meaning within medical device regulations, namely the legal company with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under the company name, regardless of whether these operations are carried out by that company itself, or on their behalf by a third party.

Put simply, if you or your company place a medical device on the market, you or your company are the legal manufacturer and you are thus responsible for compliance with the applicable medical device regulations. This is true, irrespective of what your route to market is – the distributor, for example, has no responsibility here, and nor does the component manufacturer. In addition, as the manufacturer, you are responsible for post-market surveillance; monitoring and acting upon any adverse events or complaints in the field. It must be clear to the consumer therefore, how they can contact the manufacturer (again, not the distributor) in order to report such events.

Device, Accessory and Component

Beyond intended use, regulators make a distinction between a medical device, an accessory and a component; each of which is regarded and managed differently in the regulations. The elements of a mobile health solution may include sensors, software, a mobile phone and an associated network infrastructure, each of which could be classified as a device, accessory or component, depending on the construction of the specific product and the intended use. Understanding the distinction is key to navigating the healthcare regulations.

Hardware, Software and Network Infrastructure

We can only assume that computing power and functionality will continue to increase, becoming more distributed and closer to the point of service. With increasing convergence of the medical and telecommunications industries, the boundaries between all these elements becomes increasingly more difficult to define.

The pace of technological change means that revision and reissue of regulations essentially lags behind, providing challenges for all stakeholders, including regulators themselves. For example, 'downloadable Apps' on iPhones did not exist when the EU medical device regulations were originally published. Regulators are therefore actively seeking to engage in a dialogue with industry to accommodate new developments within the regulations and provide clarity on the regulatory requirements.

In light of the significance of these distinctions, this policy paper offers insight in each of these areas, and we structure our policy recommendations into general comments as well as specific remarks regarding the areas of Hardware, Software and Network Infrastructure.

Policy & Position Statements

1. General comments

1.1 Medical device regulation is essential to ensure patient safety

Medical device regulations are essential in assuring patients' and users' safety. We believe that the exciting expansion of mobile capabilities in healthcare provision must be conducted in partnership with international regulatory agencies and that mutual understanding can be achieved by such pro-active engagement. We appreciate the differences in medical device and mobile platform risk assessment and product life cycles. We therefore encourage constructive discussion between our members and international regulators to help realization of new technologies that can better serve consumers safely and provide a positive benefit in the provision of healthcare.

We are keen to help bring clarity around the potential impact of medical device regulations on development of mobile health solutions and the boundaries between medical devices and consumer products. For example, we would suggest that use of a mobile network as a conduit for medical data transmission is analogous to traditional use of a fax machine – both are intended as communication tools and neither are medical devices.

1.2 The telecoms industry is itself, a regulated industry

Our industry works within a highly regulated environment. Members therefore have working processes and quality systems in place that facilitate rapid and efficient introduction of effective new products to a fiercely competitive market. We believe that our members are therefore also well-placed to work in this new healthcare regulatory environment and engage effectively in its processes and authorities in this space.

1.3 Engagement between principal healthcare regulators and industry will help establish appropriate boundaries and guidelines for mobile medical devices

We support the FDA and EU regulators in efforts to define further the guidance surrounding mobile medical device definitions and classification. We are comfortable that the existing classification of Device, Accessory and Component 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 varied in both their technical aspects and types of service provided, we welcome the on-going dialogue with government and regulatory bodies to further refine current definitions and boundaries. We believe there is no requirement for additional new device regulation, but rather a clarification and possible extension of existing regulations.

1.4 Harmonization of regulatory systems among authorities is essential to enable interoperability and achieve required scale

Our members operate and distribute products globally, however, many nation states have not established regulations governing the introduction of medical devices to the market. We acknowledge the work conducted by the WHO Global Harmonization Task Force in promoting the adoption of existing major regulatory frameworks (essentially EU and USA) more widely and believe harmonization of regulations would be of benefit to all stakeholders.

1.5 Further clarity in defining the boundaries between Wellness and Medical solutions is required

The distinction between wellness and healthcare may have a significant impact on the industry's development in this sector. This distinction should to be more carefully defined and clarified by the regulator; and potentially more widely communicated (to the telecommunications, medical and healthcare industries) to include the consumer.

While it is not our objective to offer solutions in this position paper, we seek a model that enables consumers to make better-educated choices as they adopt mobile technologies in the management of healthcare. A public classification system that educates consumers to the degree of regulatory governance of a given mobile medical device/ application may be appropriate.

We are encouraged by the recent guidance provided by the FDA in this regard¹, although this was limited to mobile medical Apps. Examples of mobile wellness Apps have been included in the guidance document, Understanding Medical Device Regulation for mHealth - A Guide for Mobile Operators, including dietary tracking logs, appointment reminders, calorie counters, and posture and exercise examples.

In contrast, mobile medical Apps are those intended for "curing, treating, seeking treatment for, mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition".² However, the distinction between mobile medical Apps and mobile wellness Apps can become less clear as healthcare models become more patient centric. Today, medical conditions can be significantly improved through preventive and self-monitoring actions. Such products thus potentially fall into a grey area as they are not intended to cure, but can have a significant positive impact on health.

We acknowledge that other sub-categories of mobile medical Apps are already considered by FDA to fall outside the regulations, (such as mobile drug reference, medical news digest and interaction checkers).

1 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm>

2 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm>

1.6 Industry would benefit from further clarity in defining the level of change necessitating regulatory re-submission, and rules defining when products can be submitted with reference to a predicate

The rapid growth in the mobile communications industry over the last two decades has been founded upon a rigorous adherence to the principles of modularity. Underlying components – be they applications, handsets, peripherals, or indeed infrastructure, have benefited from being subject to a number of predetermined standards. This modularity has allowed partners to work independently on improving technologies that can be combined later into larger products or services. Hence when improvements are introduced, the impact of regulatory and standards alignment / re-approval is limited to only the modified modules.

An analogous situation occurs in the medical device industry, where modifications to part of a multi-element system does not require resubmission for approval of the entire system, but only a limited submission – universally referred to as a 510(k). This less onerous submission is based on the principle of ‘substantial equivalence’ to an existing device.

The definition of the level of change necessary for re-submission in general, and for qualifying for a 510(k) submission instead of the more onerous premarket approval has been discussed multiple times by the regulators³.

The mobile industry could benefit from further confirmation on how this process can be directly applied to mobile technology changes. We acknowledge that this may be largely a task of education rather than a need to address fundamental problems with the current mechanisms used to re-appraise risk or to accommodate change. We are mindful, however, that the appetite for innovation within the mobile technology space is such that there will be great enthusiasm to understand how the regulatory re-submission process can be streamlined wherever possible.

1.7 Standards aimed specifically at harmonizing the exploitation of mobile medical devices are essential

Both GSMA and the Continua Health Alliance strongly embrace the adoption of global, consensual, standards. We acknowledge that a wealth of standards governing best-practice in the development of medical devices already exists. We believe that the industry will benefit from further contribution to such standards and acknowledgement by regulators of emerging standards that are aimed specifically at harmonizing 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 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. We will support groups facilitating the recognition of consensus standards relevant to this area of the industry.

³ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>

1.8 Regular review of risk associated with mobile technologies would further the understanding between mobile and medical industries

We support and encourage our members to engage with regulators to define and examine safety risks related to new mobile medical technologies. We believe that as manufacturers engage more often with regulators, their understanding of medical device safety risks deepens. 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 therefore 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.

2. Devices

2.1 Regulations facilitate the use of off-the-shelf mobile platforms in medical device systems

As product development in this area can involve multiple partnerships between technology and service providers, it would be unreasonable to expect medical device manufacturers, App writers, App distributors and phone manufacturers to be all impacted in the same way by regulations.⁴

FDA has 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'. We believe that this approach is reasonable and allows necessary flexibility between suppliers, manufacturers and distributors.

⁴ Draft guidance on Mobile Medical Applications issued on July 21, 2011, page 10 Chapter 3 "Definitions" section E "Mobile Medical App Manufacturer" states that "the fact that a mobile platform could be used to run a mobile medical app identified by this guidance does not mean that the mobile platform manufacturer is considered a medical device manufacturer. For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany with a medical device intended use, then BrandNameCompany would not be a medical device manufacturer".

3. Software

3.1 End users should receive clear guidance whether a product is classified as a medical device or not

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.

It is important for users (medical professionals or lay persons) to be clearly aware of the regulatory status of all such Apps and hence to be aware of the level of scrutiny a particular App has been subject to in order to assess its fitness for use. The responsibility of ensuring this clarity lies with the manufacturer, who should provide clear labelling of its product.

In addition, we would highlight the requirement under the regulations for mobile medical Apps to have an appropriate level of traceability and post market surveillance to ensure safety is maintained through the product lifecycle.

Of equal importance are the needs of the distributors of such applications – be they network operators, handset vendors, or independent vendors – to be able to establish the validity of the claims of the Manufacturer of a regulated application that they may be hosting. Whilst there may be no direct liability to such a distributor, there is a reputational risk which is sizeable.

3.2 Evaluation of medical Apps based on a risk based approach is appropriate

A risk-based approach to regulating medical devices and more particularly software will foster innovation while preventing potentially harmful devices from reaching consumers. It is therefore 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".⁵

We are encouraged to see that the FDA's basis for the application of the regulations and product classification is on the intended use of the App and potential risk to patient and users.

4. Networks

4.1 Network service providers are, in most circumstances, not considered medical device manufacturers

Just like mobile platforms, network's can be used as 'off-the-shelf' tools, mobile service providers are under no obligations to comply with medical device regulations as these are not promoted with an intended use that falls within the regulations. This is a key principle that provides a sensible and pragmatic approach that will enable mobile health to become common place in the healthcare systems of the future.

⁵ Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm#5>

Related reading

GSMA publications

Understanding Medical Device Regulation for mHealth - A Guide for Mobile Operators

An overview of the mHealth regulatory landscape in the US and EU and the implications from an operator perspective. It includes some case studies that explore the regulations and a detailed glossary of terms. Published by GSMA in February 2012 and can be read in conjunction with this Policy & Positioning Statements document.

Policy and Regulation for Innovation in Mobile Health

GSMA and PA Consulting's joint report issued in February 2011 examines where the boundary lies between a medical device and the communications infrastructure it uses and how the interface should be regulated. It identifies key policy and regulatory touch points with the greatest relevance to mobile health, and provides a set of recommendations for these.

The SIM: The Key to Better Healthcare?

In most countries healthcare ICT systems lack a common, open and secure identity management technology. The mobile industry through its SIM is unique, it has an enormous installed base of over 6 billion connections and since its inception, the SIM has provided identify, authentication, security and data storage in a one stop solution. This white paper sets out the case for the SIM being uniquely placed to satisfy a critical market need.

A High Level Reference Architecture for Mobile Health report

This report sets out the key network architectures and capabilities required to deliver secure and reliable end-to-end mobile health services. The GSMA believes that realising the full potential of mobile health will require:

- Use of a standards-based approach
- The development of open interoperable systems and devices
- Strong partnerships between mobile operators and healthcare providers

Connected Mobile Health Devices: A Reference Architecture

This report discusses the implementation options for remote monitoring solutions and the key requirements for these types of solutions are identified. From these requirements a reference architecture for mobile health connected devices is developed, along with an attempt to draw out the key assets from a mobile operator network that can be leveraged to provide enhanced mHealth solutions.

About 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, as well as more than 200 companies in the broader mobile ecosystem, including handset makers, software companies, equipment providers, Internet companies, and media and entertainment organisations. The GSMA also produces industry-leading events such as the Mobile World Congress and Mobile Asia Expo.

This year the GSMA-mHealth Alliance Mobile Health Summit will again be held in Cape Town, South Africa from May 29 to June 1 2012.

For more information, please visit the GSMA corporate website at www.gsma.com or Mobile World Live, the online portal for the mobile communications industry, at www.mobileworldlive.com. For mhealth related information please visit www.mobilehealthlive.org.

About Continua

Continua Health Alliance is an international not-for-profit industry organization dedicated to establishing guidelines for combining and applying existing standards to personal connected health products and services. Continua makes a transition from the personal connected health marketplace to a marketplace of interoperable devices that facilitate better care, possible, empowering consumers, improving outcomes and lowering overall healthcare costs. With more than 240 member companies around the world, Continua is comprised of technology, medical device and healthcare industry leaders as well as service providers dedicated to making personal connected health a reality. For more information visit: www.continuaalliance.org.



Connected Living

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