mHealth Regulatory Coalition

Strategic Plan for Policy Development and Advocacy in the European Union

Introduction

1. **EU regulation of health information technologies will impact many different industries, and established EU trade groups and companies should cooperate to build strong advocacy partnerships at the intersection of health and information technologies.**

As the European Union (EU) policymakers move more actively into regulating health information technologies (Health IT), including mobile medical apps and clinical decision support (CDS) software, those regulations will impact many different industries including information technology and telecommunication companies that are expanding into healthcare, as well as traditional healthcare technology companies. More specifically, the new regulatory framework will affect traditional medical device manufacturers adopting mobile platforms for their devices, mobile medical apps developers, cellular handset manufacturers, information technology and network operators developing software applied in the health industry, backend software service providers and data storage providers, and pharmaceutical companies using mobile apps to aid patients in treatment management and personalized medicine.

The EU has a well-established network of professional organizations, trade groups and associations representing those various sectors. These associations have a legitimate interest in the regulatory framework governing Health IT.

Although most EU associations and their members have traditionally operated in separate industry sectors, Health IT is now blurring the lines between health information technology telecommunications. Now these organizations have a joint and overlapping interest to define the common Health IT issues that will impact their members, and the way they do business. Cooperation on Health IT policymaking will offer these organizations the opportunity to build partnerships in new areas, share their expertise, and build a unified policy and advocacy agenda that crosses the boundaries of health and information technologies.

Moreover, international governmental groups such as International Medical Device Regulators Forum (IMDRF) are working on the regulatory harmonization for medical devices. In March 2013, the IMDRF created a new work group tasked with defining a harmonized regulatory framework for standalone medical device software that would fit into the regulatory systems in the EU, US, and other parts of the world. That is either a tremendous opportunity or a tremendous risk, depending on whether you are an optimist or pessimist. But it certainly is significant. This year the presidency of IMDRF rotates to Europe – the Directorate General for Health and Consumers (DG SANCO) will administrate it. This will offer EU stakeholders the opportunity to play a prominent role in the medical devices regulatory harmonization of Health

IT.

Currently operating in the United States (US), the mHealth Regulatory Coalition (MRC) is focused on the specific set of issues that directly impact standalone medical software, including mobile health and CDS. MRC has engaged in policy development on the core issues pharmaceutical and medical device manufacturers and information and communication companies have traditionally dealt with. We have built our expertise in Health IT products including mobile health technologies, CDS software and other standalone software used by healthcare professionals, patients and consumers to access and use healthcare information. Wherever possible, MRC would like to assist the established EU associations to come together and collaborate in proposing a balanced regulatory framework for Health IT.

2. **MRC proposes industry associations across health care, IT and telecommunications join forces on Health IT policy development and advocacy.**

MRC would like to invite EU associations and companies with interest in Health IT to form an EU centered coalition focused on these technologies. Members would come together to develop a common policy position, and would jointly advocate their position with the relevant policymakers and stakeholders. In light of the effort of international regulators to come up with a harmonized approach, we believe that this EU center group could work with its US counterparts to help ensure harmonized policy development on the industry side.

MRC envisions implementing this approach in a two-step process:

Step 1: Policymaking phase: Companies and associations interested in EU healthcare would collaborate on consensus policymaking, working in relation with their American counterparts.

Step 2: Advocacy phase, including both:

- EU associations and companies would individually weave the consensus policy positions into their individual advocacy strategies.
- MRC EU would pursue joint advocacy in addition to the individual EU association advocacy.

3. How will EU associations benefit from joining MRC EU?

Simply put, the benefits will come in two ways:

a. MRC has a focused expertise on Health IT regulation. We obviously understand that the EU has its own unique regulatory framework. We simply wish to offer our experience as a resource, and convene a practical forum for EU stakeholders to collectively develop an EU specific regulatory proposal.
b. By working together we can offer international regulators a harmonized approach. Since many companies with an interest in this discussion have significant regulatory interests both in the EU and the US, we believe that a transatlantic approach will lead to significant benefits. It's important to note that the IMDRF is looking for ways to harmonize

the regulation of Health IT globally, so we believe that if we can make helpful recommendations, we will find a sympathetic audience.

c. Experience in coordinated advocacy. After developing a harmonized international regulatory approach, we will offer our assistance in coordinating the advocacy phase as we share the policy proposals with regulators.

4. How will companies benefit from joining MRC EU?

While companies in the medical device, pharmaceutical, information technology, and telecommunications industries have historically been involved in policy development and advocacy on many issues affecting the core of their business, MRC is proposing a dedicated team of experts focused on Health IT. By participating in the MRC EU, companies can have an impact on the Health IT policy environment in which they operate.

5. Why should you join?

Beyond having an impact on the policy environment in which you operate, join the Coalition will allow you to:

- Gain a solid understanding of the global regulatory environment for mHealth
- Stay up-to-date with developments in the EU and other major markets
- Have access to regulatory experts who staff the coalition and can answer brief questions at no cost and help you understand key regulators and their roles
- Work with other mHealth technology stakeholders to assess regulatory impacts and shape solutions as needed
- Expand your network of mHealth leaders by participating in MRC meetings and educational sessions.
- Work directly with government officials on regulatory policymaking

Substantive Policy Development

Health IT offers many innovative solutions to improve health and healthcare delivery and include, among others, simple display or data storage software, standalone software that might function as a mobile app, CDS software, or electronic patient records.

Some of these technologies perform simple functionalities such as display or data storage, and are not considered medical devices. According to the European Commission guidelines on standalone software, if software does not perform an action on data, or performs an action limited to storage, archival, communication, "simple search" (e.g. library functions, but not interpretative search results, e.g. to identify medical findings in health records) on medical images or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.[1] Altering the representation of data for embellishment purposes does not make the software a medical device.

In other cases, however, including where the software alters the representation of data for a

medical purpose, it could be a medical device.

While there are numerous issues regarding software and hardware Health IT, based on input from companies established or now moving into the healthcare sector, there are four important topics that MRC would like to focus on in the EU:

1. The wellness v. disease dichotomy, with disease use cases being regulated and wellness not
The European Commission eHealth Action Plan 2012-2020 acknowledged the growth in wellness or wellbeing apps. Such applications potentially offer information, diagnostic tools, possibilities to 'self-quantify' as well as new modalities of care. They are blurring the distinction between the traditional provision of clinical care by physicians, and the self-administration of care and wellbeing. Network operators, equipment suppliers, software developers and healthcare professionals are all seeking clarity on the roles they could play in the value chain for mobile health. The European Commission is currently working on a Green Paper to clarify the dichotomy in the space of eHealth and mHealth.

2. The accessory issues
The September 2012 EU Proposed Regulations on Medical Devices and In Vitro Diagnostics have expanded the definition of "accessory":

"an article which, whilst not being a medical device, is intended to be used bit is manufacturer to be used together with one or several particular medical device(s) to specifically enable or assist the device(s) to be used in accordance with its/their intended purpose(s)".

In that language, the very general wording of "assist" suggests an expansive view of what could be considered an accessory. But that will result in tremendous overregulation, as a mere cable that connects a blood glucose meter to a cell phone, and thus assists the blood glucose meter, becomes regulated as a medical device.

3. Standalone software that aids in clinical decision-making

Standalone CDS software is software that is not connected to any medical device but provides information used in the treatment or diagnosis of disease.
Manufacturers need to determine whether software that performs decision-making support will be regulated as a medical device. Software is a medical device when it is "specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device."

The medical purposes set out in the definition of a medical device are:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process; and
- Control of conception.

Beyond the initial question of scope, if the software falls within the scope of the Medical Device

Directive, the manufacturer must take another step to determine specifically how the software is regulated – as a general medical device or as an in vitro diagnostic device. The latter category is regulated under yet another EU directive, the In-Vitro Diagnostic Devices Directive (IVDD). Software is regulated under the IVDD if it meets the definition of a medical device, as stated above, and is, moreover, intended to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state;
- concerning a congenital abnormality;
- to determine the safety and compatibility with potential recipients; or
- to monitor therapeutic measures.

With CDS specifically in mind, software that is intended to create or modify medical information might qualify as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by healthcare professionals when reviewing medical information (for example, when searching a medical image for findings that support a clinical hypothesis involving diagnosis or evolution of a therapy) the software could be a medical device.

CDS software, if it is provided as a stand-alone product, would normally fall within Class I, as the default classification rule in the Medical Devices Directive defines stand-alone software as an "active medical device."

Software that is outside the scope of the Medical Devices Directive is not regulated as medical device. This typically concerns "software for general purposes when used in a healthcare setting."

There is difference in approach to the scope of the concept of 'medical device' and software, which is likely not remedied by the proposed new Medical Devices and In Vitro Diagnostics Regulations. The EU is currently in the process of overhauling its initial guidance on standalone software under the Medical Devices Directive and is working on a Green Paper on health and wellness to explore the borderline in that respect.
In a nutshell, we need to be involved in order to make sure that the division the EU comes up with between regulated CDS and unregulated software is a sensible one, and for that software that is regulated, the burdens are as modest as they can be and still assure the safety and effectiveness of the software.

4. Regulation of pharmaceutical software – medication reminders, drug dosage calculators, tracking and compliance logs

Health IT is becoming a major offering of pharmaceutical companies. Such software might simply function as electronic copies of drug labeling. Further, software can also remind patients to take their medication and help them create a historical log of adherence. It can also provide patients and healthcare professionals drug-drug interaction formulae, or personalized chemotherapy drug dosing.

Although pharmaceutical software can be used on a desktop computer, patients and healthcare professionals are adopting convenient pharmaceutical mobile apps.

For doctors and other healthcare professionals, pharmaceutical apps can contain prescribing information (i.e., product labeling or a package insert) providing instructions for use. Pharmaceutical apps can also contain a promotional labeling to help sell the drug.

Importantly, in addition to labeling, pharmaceutical apps can also contain more sophisticated software that operates as CDS for treatment or alleviation of a disease or may even be considered a companion diagnostic. As such, the software might fall under the definition of a medical device. For example, software can help people decide whether they need medications for certain common and chronic diseases such as high cholesterol or high blood pressure. Software can also calculate a drug dose based on a patient's height, weight, mass, and other patient-specific information. Manufacturers will need to carefully monitor the regulatory framework for this type of software, and it will be important to have clear criteria to distinguish unregulated from regulated products.

If MRC gathers sufficient support from pharmaceutical companies interested in pharmaceutical apps, MRC in collaboration with company members and relevant EU associations would develop policies for a balanced risk-based regulatory framework to ensure that such apps do not get overregulated

Advocacy Strategy

EU associations and their members have solid advocacy experience with the relevant policymakers. As representatives of their members' common positions, and through concerted policy making and advocacy, EU associations have established themselves as important stakeholders in the dialogue with the European Commission and other European bodies. In addition, individual company members' directly engage in advocacy on specific issues arising in the daily operations of their business.

MRC would like to assist EU associations and their members in their advocacy efforts. EU associations and their members would continue their advocacy through their traditional relationships and opportunities, using consensus policy positions developed in the coalition. MRC would engage in very moderate advocacy, and would mainly operate as a resource EU associations and company members can tap into on Health IT-related subjects. As the case may be, if the EU associations and their members recommend Health IT-specific advocacy actions, MRC could engage in supplemental advocacy on behalf of the whole group.

To summarize:

- EU associations and company members will continue to be the drivers of advocacy strategies;
- MRC would serve as a resource for the EU associations and company members advocacy for policy development and refinement;
- Based on the interest and needs of the moment, MRC can engage in supplemental advocacy on Health IT-related topics on behalf of interested associations and companies. Such supplemental advocacy might focus on the activities of the IMDRF.

The MRC EU, either on its own or through the member associations, will seek ways to offer input to the IMDRF. This year the presidency of IMDRF and the directorate rotates to the EU

and the meeting will take place in Brussels on 12-14 November 2013

Cost Structure

To cover the MRC EU costs, each company member will be charged a monthly fee, based on the following chart. **Membership is maintained on a month-to-month basis; members can discontinue membership and dues at any time.**

MEMBERSHIP DUES for companies that are joining MRC EU - EUROS

Member Category	Annual Gross Revenue	MRC EU Monthly Dues*
Advocacy Organization	N/A	Free
Trade Association	N/A	Free
Small Company	<€50 Million	€300
Medium Company	€50 Million to €1 Billion	€1,000
Large Company	>€1 Billion	€2,000

* Membership in the mHealth Regulatory Coalition and Clinical Decision Support Coalition (United States) entitles an organization to a discount on the MRC EU. Membership in just the MRC EU does not require membership in the US Coalitions.

DISCOUNTED DUES for companies that are already members of the MRC and CDS Coalitions in the US

Member Category	Annual Gross Revenue	Discounted MRC EU Monthly Dues
Advocacy Organization	N/A	Free
Trade Association	N/A	Free
Small Company	<€50 Million	€200
Medium Company	€50 Million to €1 Billion	€750
Large Company	>€1 Billion	€1,500

MEMBERSHIP DUES for companies that are joining MRC EU – US DOLLARS

Member Category	Annual Gross Revenue	MRC EU Monthly Dues*
Advocacy Organization	N/A	Free
Trade Association	N/A	Free
Small Company	<$50 Million	$400
Medium Company	$50 Million to $1 Billion	$1,300
Large Company	>$1 Billion	$2,500

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Member Category	Annual Gross Revenue	Discounted MRC EU Monthly Dues
Advocacy Organization	N/A	Free
Trade Association	N/A	Free
Small Company	<$50 Million	$300
Medium Company	$50 Million to $1 Billion	$1,000
Large Company	>$1 Billion	$1,900

Staff, Operations and Timelines:

Staff:

The MRC will have the support of a team that brings a wide variety of skills:

- Epstein Becker Green's Bradley Merrill Thompson, a respected attorney with experience in medical device regulatory policy, serves as general counsel and assists with policy development.
- Dana Pirvu, a French/US attorney in EBG's Washington, DC office will act as administrator and coordinator of the group.

Operations:

The MRC EU will hold a one-hour conference call every two weeks, on Wednesdays at 5 PM (Central European Time), 11 AM (US Eastern Time). MRC EU would communicate policy documents a couple of days prior to each call, to give members sufficient time to review them.

Timeline:

Given all of the activity in this space, MRC estimates that a coalition of associations and companies would be in existence for at least three years.