Mobile Applications in Healthcare – Trends and Legal Considerations

Life Sciences Group Seminar
Wednesday, October 30, 2013

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Mobile Technology and mHealth

Why is everyone talking about mobile today?

A new world

Digital Disruption.
What is Post digital?

The Post digital Enterprise™ is a business that organizes and operates in a (future) “new normal”

That is, a time in which the 5 forces of Analytics, Mobile, Social, Cloud and Cyber are all mature, implemented and integrated – baked-in vs. bolted-on

Through these forces, IT can deliver engagement and empowerment to business customers – innovating up the IT layers, and industrializing down
So – How Broad is Mobility?

Enterprise Mobility extends from the edge to the core, and across all corporate functionalities.

Mobility is changing the world in fundamental ways

Anybody remember these?
The growth of Mobile

1) **Network Speeds** – LTE is faster than most office copper lines
2) **Device Capability** – dual and quad core phones/tablets are better computing devices than our laptops just 5 years ago
3) **Application Ecosystem** – an absolute “gold-rush” of application builds and the growth of app ecosystems
4) **Demand for Data** – the growth of data, specifically real time/complex content

*Mobile data will be 10x+ of all current data use in just 4 more years*

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**Mobile only and beyond**

**What’s different today?**

- Every THING can be on the net
- Every PERSON can interact when-, where- and however
- Smart phones and tablets expand to augmented reality for tasks, information interaction, and environment control
- Device ubiquity and convergence and new generation of devices enable new interaction mechanisms
- Point-click-type → touch-swipe-talk → gesture-talk-environment
A new world

The DNA of today’s landscape is in the midst of a fundamental shift. Digital technology is dramatically changing the way that we interact with the world around us. Business operates in a new normal, a time in which the five forces of analytics, mobility, social, cloud and cyber are all mature and fully integrated; think baked in vs. bolted on.

Devices are infiltrating the enterprise at an exponential growth rate

Technology Adoption Drivers

- Lower Prices
- Increased Mobility
- Enhanced Usability
- Evolved Connectivity

Technology Adoption: Number of Days to Reach 1MM Units Sold

- iPod
- BlackBerry
- Netbooks
- iPhone
- iPad
- Next Big Thing

Inflection Point:
In 2012, for the first time, the number of smartphones shipped globally exceed the number of PCs.
These changes are necessitating new approaches

A new business experience
- Digital experience
- Mobile
- Anywhere
- Personalized
- Social

And a different way to work
- Iterative
- Agile
- Design thinking
- Rapid prototypes

That requires new capabilities
- Creative
- UX
- Agile
Even our culture is changing significantly

Deloitte Digital is its people: an eclectic mix of creatives, digital visionaries, and technology experts.

Modern Mobile Applications = Industrial Design Principles

- Observe
- Iterate
- Prototype
- Measure
- Innovate
- Monitor
- Experiment
- Create
Creating great user journeys

Start by understanding user personas and needs to create rich yet efficient customer journeys.

Understanding
Contextual and user research to understand user needs and constraints

Envisioning
Definition of user goals, personas and profiles. Articulation of user stories, journeys and task descriptions

Creating
Proof of concept execution and validation of design and usability

Approach
Frameworks

UX Principles
Guiding principles

Methodology
Embed UX principles to deliver user-centric designs

Things are getting more personal…
Things are getting more personal…

What this means to you…

1. Think like a designer
2. Adopt highly iterative approaches to delivery
3. Seek client involvement and feedback throughout the process
4. Condensed/faster process
5. Get things faster to market
6. Be proactive to client needs
7. Focus on prototyping and constant client feedback
Deloitte.
Digital
MOBILE MEDICAL APPLICATIONS
LEGAL AND REGULATORY CONSIDERATIONS

Timothy Squire
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Co-Chair International Life Sciences Group

Toronto, October 30, 2013

OVERVIEW

• Health Canada Regulation of Mobile Medical Apps as Medical Devices
• Current Regulatory Landscape
• Is it a Medical Device?
• If so, what does that mean for:
  • Manufacturers
  • Distributors
  • Users
• Mobile Medical Apps and User/Patient Privacy
Current Regulatory Landscape

• Medical Devices are regulated under the Medical Devices Regulations made pursuant to the Canadian Food and Drugs Act.
• The Regulations impose legal obligations on manufacturers, importers and distributors of Medical Devices related to:
  • Safety and Efficacy
  • Licensing
  • Labelling
  • Quality Management
  • Record Keeping
  • Problem Reporting & Recalls

Current Regulatory Landscape

• Two types of Licenses are prescribed by the Regulations:
  • Medical Device Licence (MDL) - (product specific)
  • Medical Device Establishment License (MDEL) - (activity specific)

• Medical Devices and stakeholders are under the jurisdiction of Health Canada
• Subject to broad inspection and enforcement powers
Is it a Medical Device?

- Definition of “Medical Device” - s.1 of the Regulations & s.2 of the Act:

- ANY ARTICLE OR CONTRIVANCE INTENDED FOR USE IN THE DIAGNOSIS, TREATMENT, MITIGATION OR PREVENTION OF A DISEASE, DISORDER OR ABNORMAL PHYSICAL STATE IN HUMANS

Is it a Medical Device?

- Intended use is determinative
- This definition casts a very wide net
- The medical user can be peripheral to the primary means of treatment, diagnosis, mitigation or prevention
- Users can be healthcare professionals, patients and/or consumers
Is it a Medical Device?

- Examples – Are they Medical Devices?
  - Mobile Apps that are connected to an external device (device system)
  - Mobile Apps that utilize a built-in mobile device function (camera, microphone, speaker, motion sensor, GPS)
  - Mobile Apps that process inputted data and provide a specific analysis, diagnosis or recommendation
  - Resource Apps

The U.S. Situation

- On September 25, 2013, the FDA published “Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff”
- Outlines FDA’s view of what is, and what is not, a Medical Device under U.S. law
- Identifies Mobile Medical Apps for which the FDA intends to exercise “enforcement discretion” (i.e. will not enforce)
- No similar guidance from Health Canada is currently planned
It’s a Medical Device – What Next?

- Devices are classified under the Regulations according to risk profile – Class I – IV
- Classification determines level of regulatory oversight
- Class I devices do not require an MDL
- Class II to IV devices require an MDL

Classifying Mobile Medical Apps

- Classification involves a case-by-case assessment using the classification rules in the Regulations
- General guidelines:
  - Mobile Medical Apps that are an accessory to a device system are classified according to the risk profile of the system
  - Stand-alone Mobile Medical Apps that image or monitor a physiological process for a diagnostic purpose are Class II devices (and require a MDL)
  - All other Mobile Medical Apps are Class I devices (and do not require an MDL)
What does this mean for Manufacturers, Distributors and Users?

• The Manufacturer of a Mobile Medical App has primary regulatory responsibility for the Device

• The Manufacturer is the person who sells the device under their own name or brand (or one controlled by them) and is responsible for its design or specifications

• Not necessarily the App Developer

What does this mean for Manufacturers, Distributors and Users?

• Under the Regulations, the Manufacturer of a Mobile Medical App (regardless of risk classification) is required to:

  • Ensure the App meets the safety and effectiveness requirements (including software validation)
  • Label the App according to labelling requirements
  • Maintain distribution records
  • Record and investigate product complaints
  • Report adverse events
  • Initiate and report recalls when required
What does this mean for Manufacturers, Distributors and Users?

• Manufacturers of Class II to IV Mobile Medical Apps must also:
  • Obtain an MDL for the Mobile Medical App
  • Hold an ISO 13458 QMS certificate from a recognized registrar
  • Class II MDL application is a standard form (30 day processing target - $365 fee).
  • Class III and IV MDL applications involve the submission of data (120 and 135 day processing targets - $5,255 - $20,840 fee).
  • It is an offence to advertise or sell and unlicensed Class II, III or IV Medical Device.

What does this mean for Manufacturers, Distributors and Users?

• Distributors of Mobile Medical Apps have certain post-market regulatory responsibilities
  • A Distributor is a person who sells or distributes the Device in Canada (with or without consideration)
  • Subject to several exemptions, Distributors must hold an MDEL
  • MDEL Application is a standard form document:
    • Attestation from a senior officer
    • $7,500 fee (approx)
    • 120 target turn-around
    • Subject to inspection
What does this mean for Manufacturers, Distributors and Users?

- MDEL exemptions:
  - Retailers
  - Healthcare Facilities
  - Manufacturers of Class II to IV Devices
  - Manufacturers of Class I Devices if they distribute solely through a person who holds an MDEL
  - Manufacturers of Class I Mobile Medical Apps require an MDEL if they distribute directly through a retailer (e.g. App Store)

What does this mean for Manufacturers, Distributors and Users?

- Subject to several exemptions, Distributors are required to:
  - Maintain distribution records (to facilitate rapid recall)
  - Record and investigate product complaints

- Exemptions:
  - Retailers
  - Healthcare Facilities

- All Distributors must ensure that Mobile Medical Apps are properly labelled
What does this mean for Manufacturers, Distributors and Users?

- Users of Mobile Medical Apps are not directly governed by the Regulations or the Act
- Users are still potentially impacted by stop sale orders or recalls
- Health Canada warned Healthcare Facilities in December 2009 and again in September 2013

What does this mean for Manufacturers, Distributors and Users?

- The borderless nature of Mobile Medical App availability raises several interesting regulatory issues:
  - Who is the Importer?
  - Personal Use exemption
  - Health Canada enforcement
  - Ex-Canada liabilities
Mobile Medical Apps and User/Patient Privacy

- Connectivity of Mobile Medical Apps raises many user/patient privacy issues
- Manufacturers and Distributors are subject to Federal Personal Information Protection and Electronic Documents Act ("PIPEDA")
- Healthcare Professionals (and in some cases Manufacturers and Distributors) are subject to Ontario Personal Health Information Protection Act ("PHIPA")

Mobile Medical Apps and Patient Privacy

- Manufacturers and Distributors of Mobile Medical Apps collect User information for many purposes:
  - Customize or enhance functions
  - Compilation of data
  - Marketing
Mobile Medical Apps and Patient Privacy

• If the information is about an identifiable individual, PIPEDA requires (among other things) that:
  • The purpose for which the information is collected is clearly disclosed
  • The consent of the User is obtained (express consent required for sensitive information such as personal health information)
  • The information is only used or disclosed for the stated purpose

Mobile Medical Apps and Patient Privacy

• PHIPA imposes a wide range of restrictions on Health information Custodians (e.g. Healthcare Professionals and Facilities), including:
  • Establishing Information Practices in a Privacy Policy regarding collection, use disclosure and disposal of personal health information
  • Maintaining accuracy and security of personal health information
  • Obtaining patient consent to the collection, use and disclosure of personal health information when required
Mobile Medical Apps and Patient Privacy

• PHIPA (Regs) also imposes restrictions on those who supply services to enable the collection and use of personal health information by Health Information Custodians
• Can apply to Mobile Medical App Manufacturers and Distributors
• If the service provider has access to personal health information:
  • It cannot be used except as necessary to provide the service
  • It cannot be disclosed
  • It is only made accessible to employees who agree to comply with these restrictions

Mobile Medical Apps and Patient Privacy

• Mobile Medical App functionality is replacing conventional means of handling personal health information
• Health Information Custodians should:
  • Address Mobile Medical Apps in their required Privacy Policies
  • Source Mobile Medical Apps that will ensure PHIPA compliance
  • Include functionality specifications for PHIPA compliance in RFP’s
  • Ensure contracts with Mobile Medical App Manufacturers and Distributors contain privacy provisions
BIOGRAPHIES
Andrew Szabo, MBA, Senior Manager, Canadian Mobility and Digital Lead

Profile

- Andrew is the National Lead for Enterprise Mobility and Digital in Canada, and has spent multiple years building and delivering long-term strategic projects for networks, backend systems and client facing applications. He has spent a large part of his career in the US and Asia as well.
- Over the past fourteen years, Andrew has also worked with large banking, energy, manufacturing and defense firms, as well as federal and municipal governments in general strategy/technology consulting, process design, with a specific focus on complex project and system implementations.
- Andrew also previously lead a national consulting practice at a large carrier, where his focus was complex mobility solutions, especially how a properly designed and implemented mobility strategy can transform a firm's customer experience, bottom line and operational efficiencies.
- Andrew's work currently encompasses a large variety of activities, including strategy and governance, as well as application development and implementation of large scale enterprise mobility systems and solutions across multiple industry portfolios.
- Notable clients include Bank of America, Citi, Wells Fargo, Scotiabank, CIBC, TD, TELUS, Rogers, AT&T, Sprint, Orange, BT, Deutsche Telecom, NTT DoCoMo, Telecom Malaysia, Time Telecom, Telstra, US Federal Government, Canadian Federal Government and Government of Ontario
- Andrew also holds an MBA from the Rotman School of Management from the University of Toronto.
Timothy M. Squire
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Timothy Squire is Co-Chair of the firm’s International Life Sciences Industry Group. His practice is devoted to the regulation and commercialization of drug products, medical devices, natural health products and other types of life science innovation. Tim brings a unique perspective to the firm’s Life Sciences Group given his considerable knowledge and experience across the entire health product lifecycle. Tim has become a trusted advisor to many large and small drug and device manufacturers with operations in Canada. He also performs in-house legal functions for several U.S. and international clients without Canadian in-house legal or regulatory capabilities, and in this capacity has developed a comprehensive understanding of the business issues and pressures facing companies in the life sciences industry.

Tim’s regulatory practice covers all aspects of health product regulation, including clinical trials and good clinical practices, market authorization, special access programs, the operation and application of the Patented Medicine (Notice of Compliance) Regulations, data protection under the Food and Drug Regulations, quality management, site and establishment licensing, packaging and labeling, promotion and advertising, product recalls and adverse event reporting, pricing and mandatory price reporting, provincial drug benefit plans including formulary eligibility and listing, and interaction with regulators throughout the product lifecycle including responses to government audits and enforcement actions. Tim also crafts corporate policies which implement a wide range of regulatory requirements, as well as corporate ethics and anti-corruption policies.

In addition to his regulatory expertise, Tim’s practice also involves the commercialization of health product innovation. Tim negotiates and drafts sophisticated intellectual property agreements (including licenses, technology and material transfer agreements, joint R&D agreements, funding agreements, and employee, consultant and content specific confidentiality agreements), distribution and service agreements, and manufacturing and associated quality agreements. Tim is also called upon to quarterback intellectual property and regulatory due diligence in complex domestic and cross-border share and asset purchase transactions involving drug and device companies and product lines, and to manage the transition of market authorizations, intellectual property assets and other regulatory matters post acquisition.

Tim works closely with other specialists at Fasken including corporate, tax, intellectual property, government relations, litigation and employment lawyers to provide clients in the life sciences industry with a complete range of integrated legal services.

**Representative Experience**

- **Retained by Canadian Life Sciences start-up companies**
  Counsel to a select group of Canadian Life Sciences start-up companies

- **Retained by US based clinical-stage biopharmaceutical company in connection with investigation by Health Canada for misconduct by its 3rd party site management organization**
  Counsel to US based clinical-stage biopharmaceutical company
• Retained by a distributor of natural health products following the revocation of its Class A Precursor License
  Counsel to a distributor of natural health products

• Health Canada investigates US based global distributor of OEM medical device parts
  Counsel to a US based global distributor

• Retained by key stakeholder to assist in the review and adoption of a new mammography standard for the provincially funded Ontario Breast Screening Program
  Counsel to a key stakeholder

• Retained by a key stakeholder to assist in the investigation and response to the diluted chemotherapy drug controversy in Ontario
  Counsel to a key stakeholder

• US based drug manufacturer to enter new prescription drug in Canada
  Counsel to a US based drug manufacturer

• Canadian medical device manufacturer recalls 7 million in vitro diagnostic devices
  Counsel to a leading Canadian medical device manufacturer

• Health Canada investigates global distributor of Class II medical device implants
  Counsel to a Canadian based global distributor of Class II medical device implants

• Canadian border detains product shipments belonging to Canadian based global distributor of Class II and III IVDD's
  Counsel to a Canadian based global distributor of Class II and III IVDD's

• US based diagnostic test kit manufacturer to enter new medical device in Canada
  Counsel to a US based diagnostic test kit manufacturer

• Ontario client proposes assignment of medical imaging devices to hospitals
  Counsel to an Ontario client

• US based drug, device and natural health product manufacturer operates in Canada
  Counsel to a US based drug, device and natural health product manufacturer

• US based medical device manufacturer to enter new Class III medical device and companion drug products
  Counsel to a US based medical device manufacturer

• Global medical device manufacturer sells unlicensed Class III medical devices
  Counsel to a global medical device manufacturer

• Health Canada investigates German based medical device manufacturer
  Counsel to a German based medical device manufacturer

• US based retailer expands operations to Canada and immediately investigated by Health Canada
  Counsel to a US based retailer

• Retained by global drug manufacturer to draft a standing challenge on interchangeability for submission to the Ontario Public Drug Program
  Counsel to a global drug manufacturer

• Medicis acquires Graceway Pharmaceuticals’ assets for US$455 million
  Canadian counsel to Medicis Pharmaceuticals

• Retained by Canadian based manufacturer of chemical and biological reagents to assist with regulatory and market analysis, including provincial laboratory licensing requirements
  Counsel to Canadian based manufacturer of chemical and biological reagents

• UK based medical device manufacturer to enter new Class II medical device in Canada
  Counsel to a UK based medical device manufacturer
BIOGRAPHY
Timothy M. Squire

Presentations

- Mobile Applications in Healthcare - Trends and Legal Considerations, Life Science Group Seminar (Fasken Martineau Institute), October 30, 2013
- Crowd Sourcing – the Ultimate Collaboration, VentureLabs MedEdge Summit 2013, June 20, 2013
- Navigating the Regulatory Environment for Market Approval, Life Sciences Ontario, June 12, 2013
- False Labelling and Advertising Claims in the Food, Beverage and Natural Health Products Industries: A Cross-Border View, Life Science Group Seminar (Fasken Martineau Institute), November 20, 2012
- The Regulation of Medical Devices in Canada - Market Authorization and Promotion, MDMA Webinar, April 19, 2012
- Focus on Medical Devices, Life Sciences Group Seminar (Fasken Martineau Institute), November 17, 2011
- Medical Devices in Canada: Hot Legal and Regulatory Issues, Life Sciences Group Seminar, April 6, 2010
- Managing Intellectual Property in a Soft Economy, November 27, 2008

Publications

- "Health Canada Loosens Restrictions on Medical Device RFPs", September 13, 2013
- "Life Line", Life Sciences Newsletter, Summer 2013
- "Life Sciences, Chapter on Canada", Getting the Deal Through, 2012 and 2013
- "Fasken Martineau’s Life Sciences Newsletter", Life Sciences Newsletter, October 2009

Memberships and Affiliations

- Member, Canadian Bar Association
- Member, Ontario Bar Association
- Member, American Bar Association
- Member, Metropolitan Toronto Lawyers Association
- Member, Toronto Intellectual Property Group
- Member, International Association for the Protection of Intellectual Property (AIPPI)
Rankings and Awards

- Winner, Canadian Regulatory Attorney of the Year Award, LMG Life Sciences, 2013
- Leading Lawyer in Life Sciences (Life Sciences Star), LMG Life Sciences, 2013