Health Canada’s Digital Health Division: A Year in Review and Future Directions

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Agenda

1. Intro to Medical Devices Bureau and Digital Health Division
2. Current Activities in Digital Health
3. Future Directions and Next Steps
REGULATING MEDICAL DEVICES
Ensuring the safety, quality, and effectiveness of medical devices in Canada

MEDICAL DEVICES REGULATIONS (MDR)

PART I
LICENSING
Requirements to meet Canadian safety and effectiveness requirements

PART II
SPECIAL ACCESS
Requirements to access to custom-made devices or unlicensed devices if conventional therapies have failed or are unavailable/unsuitable

PART III
INVESTIGATIONAL TESTING
Requirements to access a device for clinical trials involving human subjects

MEDICAL DEVICES PROGRAM

REGULATORY AND OPERATIONS AND ENFORCEMENT BRANCH (ROEB)
Compliance & enforcement of The Regulations with the manufacturers/importers/distributers

MARKETED HEALTH PRODUCTS DIRECTORATE (MHPD)
Monitoring incidents once medical devices are on the Canadian market

RISK-BASED MEDICAL DEVICES CLASSIFICATION

Classification Indicators
Duration of contact • Potential for transmission of infection • Impact of results on the person/public • Invasiveness • Importance of information for diagnosis • Energy exposure • etc.

CLASS I
Wheelchair
Hospital bed
Gauze bandage
Surgical/dental instrument

CLASS II
TENS unit
Contact lens
Surgical glove
Digital thermometer
Powered toothbrush

CLASS III
Surgical Robotics
Orthopedic implant
Insulin pump
CT Scanner
Surgical Navigation SW
Neonatal HR monitor

CLASS IV
HIV test kit
Pacemaker
Heart valve
Neurovascular stent
Deep brain stimulator

RISK and OVERSIGHT
Digital Health - Resources and Objectives

**OBJECTIVE:** To advance and adapt regulatory approach to respond to system needs by:

- Building expert review capacity in Digital Health
- Developing a targeted review process for large volumes of digital health products
- Aligning and engaging with other regulatory agencies, HTAs, and other stakeholders
- Being better positioned for innovative and disruptive technologies (e.g. AI)
- Continue to be a key international player in regulating digital health devices

**RESOURCES**

For the Digital Health project only: $4.6 M over five years (2017-2022)

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Digital Health-enabled Medical Devices

Digital Health is intended to:

- Make health information more accessible
- Improve and facilitate more timely diagnosis
- Provide access to care for patients at home, at other health care facilities, and in rural and remote communities

Key areas of focus:

1. Mobile Medical Apps
2. Medical Device Interoperability
3. 3D Printing
4. Software as a Medical Device (SaMD)
5. Artificial Intelligence/Machine Learning
6. Cybersecurity
Digital Health: A year in review…

Notables from the last 12 months…

Workload
- Over 250 Class III and Class IV applications completed primarily in diagnostic imaging, radiotherapy, and cosmetic devices

Key Engagements
- Scientific Advisory Committee – Cyber
- Best Brains Exchange – AI
- Scientific Advisory Committee - AI

Support
- Supported classification, review, industry meetings, and investigational testing activities in software, cybersecurity, and AI

Guidance Documents
- Involved in 4 guidance documents
Current Activities

**Cybersecurity**
- Guidance Finalization
- Co-chair IMDRF WG with FDA
- Collaboration with NRC and Canadian Centre for Cybersecurity
- Participation in cybersecurity standards development

**3D Printing**
- Guidance Finalization
- Participating in regulatory review activities on point-of-care manufacturing
- Participating in policy development on software for 3D printing

**Software**
- Guidance Finalization
- Continued classification on SaMD
- Continue to develop a targeted review process

**AI / Machine Learning**
- Training
- Scientific Advisory Committee: May 9
- Generating Report from Best Brains Exchange
- Continue to review devices that employ machine learning
3D PRINTING
Medical Applications of 3D Printing

- Implants
- Anatomic models, surgical tools
- Casts, splints, prosthetics
3D Printing Guidance Document: Timeline

- **AUGUST 2018**
  - Publication of the online notice for 3D Printing

- **FALL 2018**
  - Draft publication of guidance document posted for comment

- **APRIL 2019**
  - Final publication of guidance document posted

*Notice: Upcoming Guidance Development on the Licensing Requirements for 3D-Printed Devices*
August 28, 2018
Our file number: 18-110417-534
Health Canada is pleased to announce that it is currently developing a draft guidance document to assist medical device manufacturers seeking to license 3D-printed devices.
3D Printing Guidance Document: Key Messages

• The document provides guidance for manufacturers regarding specific evidence required to support pre-market Class III and Class IV licence applications for implantable medical devices manufactured by 3D printing processes.

• Considerations related to the design and manufacturing process, material controls, device testing, and labelling of 3D printed devices are included in this document, including considerations for patient-matched devices.

• This document does not provide guidance on standalone software, custom-made devices, anatomical models or products made through bio-printing which incorporate viable living cells.
Regulation of Software?

- “The authors recognize an important shift towards point-of-care manufacturing for medical models in a hospital environment.”

**Anatomical Models**
- Model printed from anatomical images

**Modified Anatomical Models**
- Digitally modified model of anatomy for enhanced surgical planning

**Virtual Surgical Planning**
- Use of models and templates during surgery

**Opportunity**
To further develop positions on:
- Anatomical Models
- Software used in 3D Printing
- Point-of-Care manufacturing in these cases of anatomical models
Only a small percentage of software products used in the healthcare industry are medical devices. Software developers are uncertain whether their products are subject to Canada’s Medical Devices Regulations (MDR).

The device risk classification system in the MDR does not clearly define how software is categorized.

Health Canada must protect Canadians from unsafe software while creating an environment that fosters innovation.
The US FDA developed certain criteria to exclude certain device functions from the medical device definition and these criteria are referenced in the Health Canada document.

The IMDRF established software labelling expectations and software risk categorization factors.

The same criteria are used in the SaMD Guidance to assist stakeholders in determining whether their SaMD is Class I, II, III or IV.
SaMD Guidance: A foundation for further work

It is Health Canada’s intention is to use the SaMD Guidance as an interim policy while appropriate legislative and regulatory amendments are developed to address:

1. The inclusion of web-based/cloud-based software products under the term “sale”,

2. The potential for new regulatory models (new classification rules, establishment oversight vs product oversight) that are more conducive to software products and their lifecycle.
ARTIFICIAL INTELLIGENCE / MACHINE LEARNING
Machine Learning – Challenges

- Artificial intelligence has the potential to revolutionize the health care sector, including advancements in diagnosis, disease onset prediction, prognosis, and more.

**FOSTERING INNOVATION**
- How to balance safety and effectiveness while facilitating market access to innovative products?

**EFFECTIVE REGULATION**
- What are the requirements for the manufacturer to get pre-market authorization?
- What does effective post-market regulation look like?

**TRAINING DATA / BIAS**
- How reliable and representative is the training data?
Challenges

VERIFICATION AND VALIDATION

• What are the best testing approaches for these software products?

PERFORMANCE METRICS

• What are the ideal performance metrics to assess performance of an AI algorithm?
• How can algorithms be shown to be generalizable between populations?

INTEROPERABILITY

• How can we ensure that AI is integrated appropriately into the end user environment without any unintended consequences?
Challenges

CONTINUOUS LEARNING

• How do we approach continuous learning algorithms where results can vary in time and between institutions?

ETHICS

• Do underlying ethics concerns impact the regulation of these medical devices?

STANDARDS

• There are no current standards for regulation of medical devices that use AI algorithms.
International Context

• United States
  – FDA's 2018 Software Precertification (Pre-Cert) Pilot Program aims to investigate the idea of regulating the manufacturer and their organizational excellence, rather than the product itself.
  – Discussion Paper: Proposed Regulatory Framework for Modifications to AI/ML-Based Software as a Medical Device (SaMD)

• European Union
  – New regulations come into effect on May 26, 2020, that will broaden the scope of the regulatory oversight of AI products.
  – The regulations address the issue of software as medical devices, including software that provides “prediction and prognosis” capabilities.
Regulatory Readiness for AI/ML

Health Canada is well-positioned to deepen its support of AI advancements in digital health by:

1. Building in-house Expertise

2. Deepening Dialogue with Industry & Key External Experts

3. Modernizing Medical Device Software Authorizations
Current Challenges in Digital Health

**DISTRIBUTION METHOD**

The definition of “sale” hinders Health Canada’s oversight in cloud-based software products.

**CLASSIFICATION**

Existing classification rules for SaMD are outdated and are increasingly not able to adequately classify novel SaMD.

**PACE OF INNOVATION**

SaMD are developed and updated at a rate inconsistent with the current regulatory process for traditional medical devices.

**NEW REGULATORY CHALLENGES**

Machine learning algorithms present new regulatory challenges (training sets, continuous learning, etc.)
Future Directions and Next Steps

Cybersecurity: Post-market
Leveraging the IMDRF WG and consultation, Digital Health is poised to actively participate in guidance development in the post-market space.

Business Process Improvements
Continue to develop a targeted review process to be able to dynamically shift technical review focus to where it is needed and contribute technical expertise to agile regulatory models.

3D Printing
Contribute to policy positions on anatomical models and software used for 3D Printing.

Machine Learning
Develop initial notice or guidance to industry of Health Canada’s requirements for pre-market submissions.

Goal
Continue to make sound, evidence-based decisions that benefit all Canadians by fostering and facilitating innovative products onto the market while maintaining our already high standard for quality, safety, and effectiveness.