

# Canada's Experience in Regulatory Cooperation in the Medical Devices Sector February 25, 2019

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# Global Context and Drivers

- Rising health care costs and budget constraints
- Fast paced technological development
  - R&D generates competitive edge for device companies, as in other industries
  - Rate of innovation, shorter review timelines and greater diversity/complexity of technologies pose increasing regulatory challenges
- International regulatory cooperation

# International Collaboration

Key international activities for the Medical Devices Program:

- Participation in the International Medical Device Regulators Forum (IMDRF)
- Medical Device Single Audit Program (MDSAP)

# International Medical Devices Regulator Forum (IMDRF)

- Goals are to:
  - Accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force (GHTF)
  - Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies
  - Accelerate innovation by clear and practical regulatory expectations

# Current IMDRF Working Groups

- **Adverse Event Terminology**
  - Develop harmonized terminology and systems being used to code information relating to medical device adverse events
- **Good Regulatory Review Practices**
  - Develop harmonized requirements for assessing conformity to safety and performance regulatory requirements for new medical devices
- **Regulated Product Submission (RPS)**
  - Develop standard system for the electronic exchange of information related to premarket medical device submissions and a common 'Table of Contents' for medical device regulatory submissions

# Current IMDRF Working Groups

- **Standards**

- Improve the utility of standards for regulatory use

- **Unique Device Identification (UDI)**

- Establish guidance for the positive identification of medical devices

- **Patient Specific Devices**

- Develop a harmonized approach to defining medical devices that are manufactured for a particular individual

- **Clinical Evaluation**

- Develop a harmonized approach and requirements for leveraging and evaluating clinical evidence

- **Cybersecurity**

- Develop a globally harmonized approach to medical device cybersecurity that ensures the safety and performance of medical devices while encouraging innovation

# Implementation of Guidance Documents Leads to Regulatory Convergence

- **Common Table of Contents for Medical Device Regulatory Submissions**
  - Health Canada published guidance in 2019 to accept the IMDRF Table of Contents as a preferred format. Other countries have since announced their implementation of this format to lead to efficiencies in re-using submission content for multi-jurisdictions.
- **Software as a Medical Device (SaMD)**
  - Health Canada recently published guidance in 2020 that used definitions and risk categorization criteria developed by IMDRF. Other countries such as US FDA, Australia's TGA, Singapore have published similar guidances.

# Implementation of Guidance Documents Leads to Regulatory Convergence

- **Adverse Event Terminology**

- Health Canada will be using the IMDRF code information relating to medical device adverse events. Other jurisdictions are in the process of implementing this terminology and will enable to internationally track and trend this adverse events.

# Medical Device Single Audit Program (MDSAP)

## How Was It Developed

- The concept of a third party medical device auditing program that would enable recognized auditing organizations (AOs) to perform a quality systems audit that would satisfy the regulatory requirements of multiple jurisdictions developed through bilateral discussions with the US.
- FDA approached Health Canada several years ago to explore developing a pilot Multi-Purpose Audit Program (pMAP).
- The pMAP was launched in 2006 and concluded in 2010 after the completion of eleven joint audits.
- Results confirmed that such audits could satisfy the requirements of both countries and represented a reduction in overall time spent at a device manufacturer compared with separate audits/inspections, an advantage to industry.
- This led to discussions on the development of a new single audit program, with a proposed expansion in membership to include Australia (TGA), Brazil (ANVISA) and Japan (MHLW/PMDA).

# Medical Device Single Audit Program (MDSAP) – How Was it Developed?

- Innovative approach to collaborative regulation that positions regulators for a more global efficient model of third party auditing of medical device manufacturers. This global approach is dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale
- MDSAP builds upon ten years of experience that Canada had with operating an a with the existing Canadian Medical Devices Conformity Assessment System (CMDCAS) program as well as the experience of other regulatory partners to produce a program that better defines regulatory expectations and oversight in the planning, conduct and reporting of third party audits.
- Medical device manufacturers will benefit from MDSAP through the introduction of a single audit that meets the requirements of multiple countries – reduction in the number of audits faced by medical device manufacturers.

# Final Points

- Challenges as a regulator to embrace innovation, with the agile review and evaluation of novel devices and the increasingly reduced innovation and version cycles
- Need for international collaboration and solutions to encourage market interest while regulating in the best interest of Canadians