

# The Medical Devices Directorate

## *Focused - Agile – World Class*

### **Medical Devices - The Changing Landscape**

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The landscape for medical devices in Canada’s health care system has evolved substantially over the last several years. Advanced technologies such as microelectronics, biotechnology, and software now feature routinely in medical devices and innovation cycles are becoming increasingly rapid.

Consumers are also more empowered than ever before: along with industry and clinicians, they are looking to Health Canada to provide more information, access, and transparency. Market trends such as data analytics, real world data, artificial intelligence, and the “Internet of Medical Things” are enabling the shift from reactive to proactive medicine. New tools and information sources are becoming available to consumers, including the first generation of wearable devices that allow consumers to monitor aspects of their health, such as vital signs and blood glucose. These tools continue to evolve, from simple to increasingly more sophisticated medical devices. This will ultimately enable new care delivery models.

All this change is driving Health Canada and its international regulatory counterparts to increase the focus on medical devices, their regulation, and the new risks posed by this pace of innovation. The federal government has responded with policy initiatives such as the Regulatory Review of Drugs and Devices (R2D2), the Medical Devices Action Plan (MDAP), and Treasury Board’s Regulatory Review (RR). These demonstrate that there is a desire for a continued evolution in the management of medical devices across their life cycles.

### **Consolidation, Integration and Growth – Creating a New Organization**

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The Health Products and Food Branch (HPFB) is responding to the many challenges and opportunities of medical devices development by creating a new, stand-alone Medical Devices Directorate (MDD). The new Directorate will take a life cycle approach to regulating medical devices, by bringing together specific post-market functions now led by the Marketed Health Products Directorate, with the pre-market functions of the Therapeutic Products Directorate. This will create an organization that is dedicated to the regulation of medical devices.

The new organization will enhance scientific and policy capacity, modernize processes to respond to rapid innovation cycles, and increase resources to support transparency and stakeholder engagement activities across the medical device life cycle.

It will bring together medical device experts from both the pre- and post-market, forge relationships, and exchange knowledge.

Life cycle management of medical devices is an international best practice that will better align us with our international counterparts. The new organization will continue to optimize collaboration with internal,

national, and international medical device stakeholders through outreach activities and policy and regulatory initiatives.

It will also strive to further enhance client services and quality in operations, and respond rapidly and efficiently to the needs of the medical devices sector and the health care system as they change and evolve.

All of this will enable us to continue to ensure that medical devices in Canada are safe, effective and of high quality, both when they are first sold and throughout their life cycles.

## The Medical Devices Directorate – Organizational focus

The MDD will include 165 positions and a budget of \$15.85M funded through resource transfers and re-allocation within HPFB.

It will align with international best practices, maximize existing resources, and expand the Department’s medical device operations in the following areas:

- scientific expertise
- regulatory excellence
- planning, business intelligence, IT and reporting
- policy, stakeholder engagement, and international alignment
- quality assurance, training and continuous improvement
- post-market surveillance

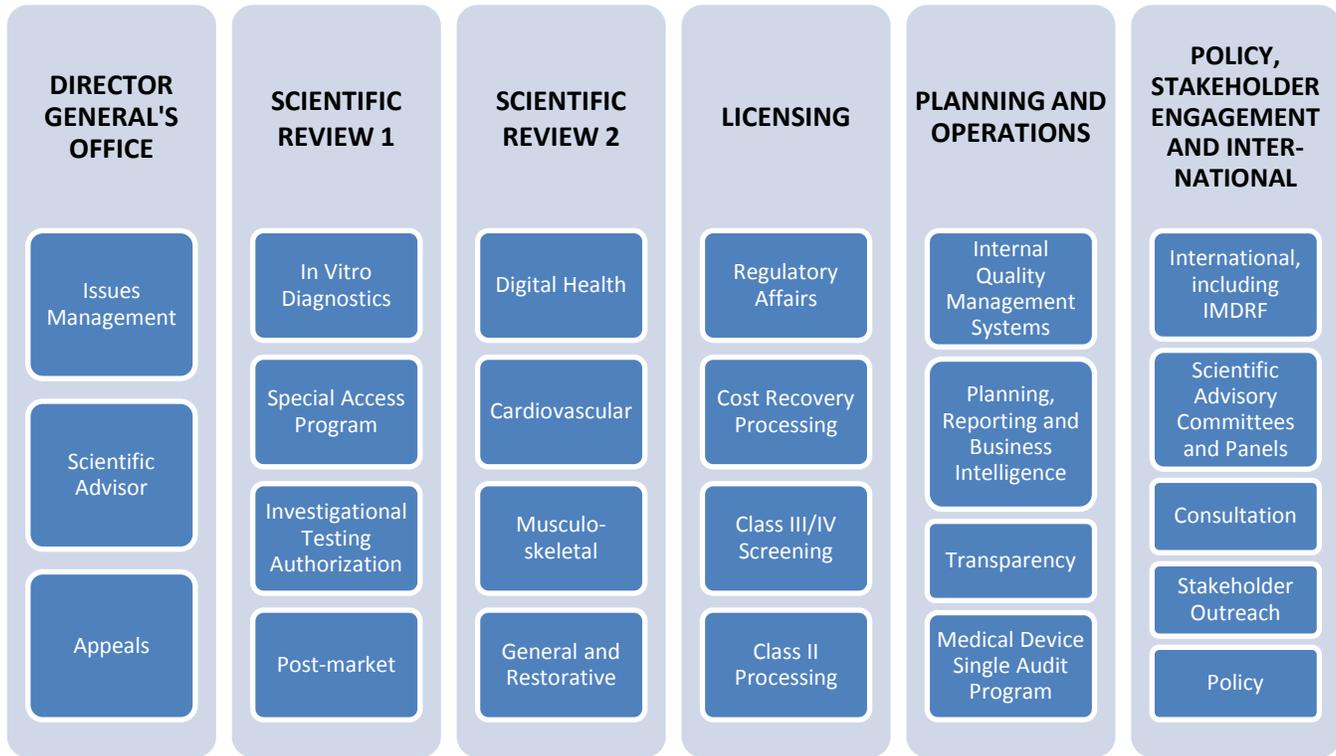
The new organization and its associated growth will create the following opportunities:

- additional capacity and focus on expanding Quality Management Systems to include both internal and external components, and the implementation of ISO 9001
- strengthened post-market and surveillance capacity
- a dedicated and expanded policy group with a focus on developing strategic policy specific to medical devices
- continuous building on the expertise and activities of the newly created Digital Health Unit
- policy, operations and guidance tailored to medical devices, including more meaningful and targeted interactions with stakeholders
- a dedicated area to maintain and grow our relationships with international partners and our role in global regulation
- more occasions to collaborate and share scientific expertise across the product life cycle

### The Vision:

- ✓ **FOCUSED:** Medical devices and pharmaceuticals are divergent in their characteristics. The new organisation will focus on this important and evolving product line, and will be better able to align with work under R2D2, MDAP, RR and other Departmental and Governmental regulatory and policy initiatives.
- ✓ **WORLD CLASS:** The growth and increased focus of this new organisation will allow it to evolve into a sustainable, world-class organisation.
- ✓ **AGILE:** Medical devices technology is an area currently experiencing rapid growth and innovation. To adapt effectively to this rapid growth, the organization will develop the competencies and classifications required to match the medical device industry.

## Overview of the Medical Devices Directorate



## Moving Forward

Canadians rely on medical devices to maintain and improve their health and well-being. Although Canada has one of the best regulatory systems in the world for medical devices with some of the most stringent requirements, the pace of change is challenging us to do better. Creating the MDD is a significant step in response to this challenge and sets up the medical devices program for a successful future.

The R2D2 and Regulatory Review initiatives present us with opportunities to update and, in some cases, overhaul the way we regulate medical devices. Large-scale initiatives are underway that are challenging us to:

- shift how we regulate investigational trials
- re-examine risk-based approaches
- find ways to regulate software that allow for rapid innovation cycles; and
- create new pathways for innovative technologies.

Having a dedicated and expanded team that has a life-cycle view of medical devices will allow the Department to invest focussed time and expertise in these important endeavours.

This organizational change, coupled with the many strategic initiatives, will set the stage for an evolving, sustainable medical devices program.