

HEALTH CANADA'S ACTION PLAN ON MEDICAL DEVICES



Continuously improving safety,
effectiveness and quality



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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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BACKGROUND

Health Canada's Regulatory System

Health Canada's *Medical Devices Regulations* contain some of the most stringent requirements in the world for the licensing of medical devices. The Regulations were founded on the approach that the safety and effectiveness of medical devices can best be assessed through pre-market scrutiny, post-market surveillance, and compliance and enforcement activities (e.g., inspections).

Canada takes a risk-based approach to the regulation of medical devices, where the level of review before approval depends on the potential risk that the use of the device presents. This approach balances the need to provide the healthcare system with timely access to new and innovative technology, with the appropriate level of oversight and time required to assess safety and effectiveness.

In Canada, medical devices are categorized into four classes based on the risk associated with their use, with Class I devices presenting the lowest potential risk (e.g. a tongue depressor) and Class IV devices presenting the greatest potential risk (e.g. a pacemaker). Class II, III and IV medical devices must have a Medical Device Licence to be sold in Canada. Companies selling Class I medical devices in Canada are required to have a Medical Device Establishment Licence.

ACTION PLAN

Despite the strong foundation of Canada's existing Regulations, more can be done to improve the safety and effectiveness of medical devices and to optimize health outcomes for patients. This Action Plan lays out a three-part strategy, which will be achieved through improving how devices get on the market; strengthening, monitoring and follow-up of devices once they are being used by Canadians; and providing more information to Canadians about the medical devices they use. Collaboration with provinces and territories, and other healthcare system partners will be fundamental to delivering results. Health Canada will strengthen and expand existing outreach and information activities, as appropriate, to reinforce these important partnerships.

Health Canada will promote open communication and engagement with Canadians throughout the implementation of the Action Plan to ensure that all perspectives, particularly those of the people who use medical devices, are taken into account when developing policies and regulations. It will also keep Canadians up to date with progress on the Action Plan so that they know what the Department is doing to enhance the safety and effectiveness of the devices they use.



PART I: IMPROVE HOW DEVICES GET ON THE MARKET

1. Increase research by medical professionals and increase patient protection – Starting early 2019

Investigational testing of medical devices involves studying unlicensed devices or devices that are being assessed for new uses or in new populations. Many regulatory provisions in the clinical trials framework involving similar studies for pharmaceuticals are not available for investigational testing of medical devices. For example, currently only manufacturers (not independent researchers or healthcare professionals) are able to apply to undertake investigational testing. In addition, that testing does not have the same oversight requirements that are in place for drugs.

The proposed changes will allow health care professionals and researchers to file an application for authorization to conduct investigational tests. These actions will improve safeguards for Canadian participants of medical device testing, align Canadian approaches with international best practices, and expand the scope of Canadian research.

MILESTONES:

- Notice of Intent – June 2019
- What we Heard Report – September 2019

2. Review evidence requirements and expand scientific expertise – Starting January 2019

Health Canada evaluates a wide variety of scientific and technical information and expertise. To ensure that we have access to independent scientific opinions, we also engage with external experts who are leaders in the field. Currently, Health Canada has two scientific advisory committees dedicated to medical devices: one on digital health and the other on cardiovascular devices such as pacemakers. Health Canada will also be forming a new expert advisory committee on women's health issues for drugs and medical devices, in collaboration with the Canadian Institutes of Health Research. Patient participation and perspectives will be an important component of these committee discussions. The first meeting of the new expert advisory committee will focus on medical devices.

Health Canada has created a new division to review medical devices that involve digital health technologies such as complex software systems. This division, made up of engineers and scientists from various disciplines, will focus on addressing safety issues related to digital health technologies, such as securing private health information and preventing hacking and cyber security threats.

Under the current process for reviewing and approving medical devices, there is flexibility on the type of clinical evidence that can be provided to demonstrate medical device safety and effectiveness. For example, an application for a new medical device can be supported by demonstrating similarities in design and performance of an earlier version of the same device. Health Canada will review its evidence requirements related to higher-risk medical devices with a view to strengthening the evidence requirements for devices based on previously authorized versions. In conducting this review, Health Canada will also ensure alignment with international practices.

MILESTONES:

- Call for members for the new Expert Advisory Committee on Women's Health – January 2019
- Meeting of Scientific Advisory Committees – March and May 2019
- Draft guidance document on evidence requirements – November 2019





PART II: STRENGTHEN MONITORING AND FOLLOW-UP

1. Implement mandatory reporting and expand the Canadian Medical Devices Sentinel Network – Starting February 2019

Health Canada has a mandatory requirement for manufacturers and importers to submit medical device incident reports and encourages reporting from healthcare practitioners, hospitals and patients/consumers. There is, however, under-reporting of incidents from the healthcare system. With regulations being developed under *Vanessa's Law*, Canadian hospitals will be required to report medical device incidents. This will bring mandatory reporting to Health Canada from zero to 776 hospitals. The data from these hospital reports will complement the reports from manufacturers and will result in increased capabilities for surveillance and signal detection. Health Canada is also developing an educational approach and content to help healthcare professionals and hospitals identify and report medical device incidents.

Health Canada will also work to improve reporting from healthcare facilities besides hospitals (e.g., long-term care facilities, clinics, etc.). First, since 2009, Health Canada has supported the creation of, and sought medical device incident reports through, the Canadian Medical Devices Sentinel Network (CMDSNet). This network currently covers 17 healthcare organizations, representing more than 260 hospitals and facilities across the country. This year, new sites in Atlantic Canada and one

specialized in paediatrics were added. Health Canada will aim to expand this network to include facilities outside the hospital setting including long term care facilities and private clinics. Second, Health Canada will implement an education and promotion program aimed at improving reporting of medical device incidents to Health Canada from other healthcare delivery sites. This program will aim to: improve the understanding of healthcare providers working in these settings of Canada's safety regime and the critical role they play by reporting events and incidents; demonstrate the ease with which events can be reported to Health Canada; and outline how safety information gathered through this reporting system is shared back to Canada's healthcare community. If reporting frequency does not sufficiently increase with education, additional regulations for mandatory reporting from healthcare sites besides hospitals will be considered.

MILESTONES:

- Publishing of Regulations to Report Medical Device Incidents in *Canada Gazette*, Part II – June 2019
- Expansion of CMDSNet to include additional health care settings outside of hospitals, such as long term care facilities and private clinics – June 2019 and ongoing
- Launch of education program for other healthcare settings – September 2019

2. Establish ability to compel information on medical device safety and effectiveness and expand use of real world evidence – Starting early 2019

With new regulations being developed under *Vanessa's Law*, manufacturers will be required to provide a greater scope of information to Health Canada. With new authorities, Health Canada will be able to compel manufacturers to conduct assessments, tests and studies. For example, when new information such as a study or a warning issued by another regulatory agency is available, the Department will have the authority to compel manufacturers to reassess their product in light of the new information and to provide the report to Health Canada.

Health Canada will also be able to compel manufacturers to provide information to address a health risk or to monitor experience with their product. Manufacturers will be required to inform Health Canada within 72 hours if selected foreign regulatory agencies issue warnings about serious risks related to their medical device. Manufacturers will also be required to submit information regarding label changes or license suspensions.

In addition, Health Canada is exploring the expanded use of real world evidence to monitor the safety and effectiveness of a product that is used in “real world” post-market conditions. As a result of use in broader populations, for longer durations, or under different conditions of use, new information related to the benefits and risks of a medical device after-marketing can be obtained. Under Health Canada's *Regulatory Review of the Drugs and Devices initiative*, Health Canada is developing a Framework for the use of real world evidence across the medical device product life cycle. This will allow Health Canada to more quickly identify, communicate and act on new or increased medical device safety concerns.

MILESTONES:

- Publishing of Draft Regulations in *Canada Gazette*, Part I – June 2019
- Establish how real world evidence for regulatory decision-making will be used – June 2019



3. Enhance capacity in inspection and enforcement – Starting 2019

Recent investments have allowed Health Canada to strengthen key areas of its inspection and compliance verification programs for manufacturers, importers and distributors of medical devices. As a result, a greater number of inspectors is available to respond to higher-risk incidents, which will increase the frequency of inspections and compliance verifications. Health Canada has also expanded its focus to include onsite foreign inspections and has strengthened its investigation efforts in support of compliance and enforcement. These efforts will continue to increase under this Action Plan.

Health Canada will further enhance the efforts of inspectors to promote the compliance of manufacturers, importers, distributors as well as healthcare professionals with mandatory requirements to report issues with medical devices. The Department will also encourage others, including the public, to report medical device incidents.

MILESTONES:

- Hiring of an additional 8 inspectors and 2 investigational analysts – March 2019
- Increase in the number of foreign inspections from 80 to 95 – April 2019
- Increase in compliance promotion activities – fiscal year 2019/2020





PART III: PROVIDE MORE INFORMATION TO CANADIANS

1. Improve access to medical device clinical data – Finalized by early 2019

Currently the information from clinical studies provided in medical device submissions is generally made available publicly only through an Access to Information request. To improve access to the same information that Health Canada bases its decisions on, the Department will be implementing new regulations to release clinical information on medical devices. Making this information available will enable independent analysis and can offer new insights and perspectives that can benefit patients in Canada.

MILESTONES:

- Publication of regulations in *Canada Gazette*, Part II – June 2019
- Launch of searchable public web portal – Following publishing in *Canada Gazette*, Part II

2. Increase the information on device approvals and publish medical device incident data – Starting January 2019

Health Canada publishes information to help Canadians make informed choices about their health and well-being. Currently, Health Canada publishes summaries of the decisions made by the Department when it approves licence applications for new Class IV medical devices. Health Canada will be publishing these summaries for all new Class IV and Class III medical device licence applications as well as any amendments to these applications. This will increase published summaries from fewer than 100 per year to well over 1,000. More information will be provided to Canadians so that they can have confidence in the regulatory system and the medical devices they use.

Through Health Canada's participation in the International Medical Device Regulators Forum (IMDRF), there will also be opportunities to continue collaboration with other international regulators towards standardizing information related to marketed devices.

Once medical devices are on the market, individual incident reports on those devices are available only through Access to Information requests. While Health Canada has provided information on medical device incidents by publishing trend reports, some Canadians still want to have access to a searchable database for individual reports.

Health Canada will launch an accessible database that contains medical device incident reports in a user-friendly, searchable, online format. The Department is also improving its medical device inspection database to facilitate access to detailed information on inspections and results, including when Health Canada takes regulatory action, such as in the event of licence suspensions or cancellations.

MILESTONES:

- Publishing and regularly updating a de-personalized data extract file of medical device incidents, complaints and recalls – January 2019
- Launch of publishing of more review decision summaries – January 2019
- Publishing of searchable medical device incident database – December 2019



LOOKING FORWARD

The Government of Canada's priority is the health and safety of Canadians. Health Canada will continue to engage Canadians throughout the implementation of the Action Plan through open communication and consultation exercises on the specific projects. It is the combined effort of all parties involved, including provinces and territories, the healthcare community, industry and patients, which will result in the best outcomes for all Canadians.