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Evaluation of Health Canada's Medical Devices Program (2020-2021 to 2025)

Final Report – February 2025

Prepared by the Office of Audit and Evaluation



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List of Acronyms

AI	Artificial Intelligence
ARIS-G	Adverse Reaction Information System – Global
CMDSNet	Canadian Medical Devices Sentinel Network
DTB	Digital Transformation Branch
HPFB	Health Products and Food Branch
IT	Information Technology
MDCCD	Medical Devices and Clinical Compliance Directorate
MDD	Medical Devices Directorate
MDEL	Medical Device Establishment Licence
MDI	Medical Device Incident
MDL	Medical Device Licence
MDP	Medical Devices Program
MDR	Medical Devices Regulations
MDS	Medical Device System
MHPD	Marketing Health Products Directorate
OAE	Office of Audit and Evaluation
ROEB	Regulatory Operations and Enforcement Branch
SGBA Plus	Sex- and Gender-Based Analysis Plus

Executive Summary

Program Background and Context

Health Canada's Medical Devices Program is responsible for ensuring that medical devices licenced for sale in Canada meet applicable safety, effectiveness, and quality requirements. The Program's mandate is delivered under the authority of the *Food and Drugs Act* and its accompanying *Medical Devices Regulations*.

The implementation of the Program is a shared responsibility between Health Canada's Health Products and Food Branch (HPFB) and its Regulatory Operations and Enforcement Branch (ROEB). To fulfill this mandate, the Program conducts pre-market reviews of device applications, monitors products in the post-market phase, and carries out compliance and enforcement activities. It also engages a wide range of stakeholders and plays a vital role in informing health care professionals and the public to support the safe and effective use of medical devices.

Evaluation Approach and Scope

The Office of Audit and Evaluation (OAE) conducted this evaluation to assess the performance of the Medical Devices Program from April 2020 to March 2025. Multiple lines of evidence were used for this assessment, including:

- document and performance data reviews;
- interviews with internal and external stakeholders;
- financial analyses;
- case studies; and
- an online survey with external stakeholders.

The purpose of the evaluation was to examine the Program's effectiveness and efficiency across its core functions: pre-market review, post-market surveillance, and compliance and enforcement. The assessment focused on the Program's ability to inform the medical device industry and ensure regulatory compliance, communicate risks and benefits to stakeholders, and coordinate and collaborate effectively with partners. It also reviewed the Program's operational efficiency, focusing on the clarity of its roles and responsibilities, whether the level of resources allocated was appropriate to meet the mandate, the suitability of tools to support Program activities, and its ability to adapt to emerging challenges.

Findings

Effectiveness

The Program has helped ensure Canadians have access to medical devices that meet safety, effectiveness, and quality and regulatory requirements, while also facing some challenges and opportunities for improvement.

The Program effectively communicates with the medical devices industry and ensures its compliance with regulations. Using various channels, including guidance documents, consultations, and direct engagement, the Program informs the industry of its obligations. As a result of these efforts, compliance with regulatory requirements consistently met or surpassed target levels. At the same time, suggested improvements for industry outreach included increasing engagement with smaller companies, conducting more frequent outreach through webinars and training, making guidance documents easier to find online, and providing a single point of contact at Health Canada.

In fulfilling its regulatory role, the Program considers risk in its pre-market reviews and communicates its regulatory decisions through various tools (e.g., Regulatory Decision Summaries). In the post-market phase, it informs stakeholders and the public about device risks through channels like public advisories, recall notices, Health Product Risk Communications, and Health Product InfoWatch. However, the evaluation identified a need to improve the timeliness, clarity, accessibility, and consistent integration of Sex-and Gender-Based Analysis Plus (SGBA Plus) in some of these communications.

Collaboration with external partners emerged as a key strength, demonstrated by the Program maintaining strong relationships with various domestic partners through multiple formal channels. In addition, Health Canada worked closely with international regulators on priority issues like software as a medical device and the COVID-19 pandemic response.

Efficiency

The Program has not clearly defined, documented, or consistently communicated roles and responsibilities, particularly for cross-branch activities like surveillance and device classification issues that arise post-market, such as products being originally classified at one level, but further monitoring and compliance activities raise questions about the appropriateness of that classification. These issues underscore the need for coordinated decision making and clearer accountability across branches. Of note, the Program has begun addressing some of these issues, most significantly by developing a new device

classification framework for ROEB and HPFB officials that outlines clear roles and responsibilities for classification issues arising post market.

Internal coordination and collaboration were found to be inconsistent and often reactive. This is largely due to siloed teams, which has led to a reliance on informal networks rather than established processes, governance bodies, and regular communications. Formal committees, like the Trilaterals at Manager and DG levels, and Medical Devices Program (MDP) Committee have not been used as much as possible as forums for strategic collaboration and decision making. Coordination challenges between the Program and the Digital Transformation Branch (DTB) have further affected the management and integration of the Program's information technology (IT) systems. However, the Program and DTB have recently taken steps to improve collaboration.

Although the Program has met its regulatory mandate and generally meets cost-recovery targets, the evaluation noted capacity pressures in other areas, such as post-market surveillance and incident reporting, which can delay incident response and risk mitigation efforts.

The evaluation found that the Program's information technology (IT) infrastructure is fragmented, with directorates operating separate, non-integrated tools, including the Adverse Reaction Information System – Global (ARIS-G), which is not suited for medical devices, and the Medical Device System (MDS), which was developed in-house. These weaknesses create data silos, require extensive manual data entry, and lead to backlogs and duplicated work.

The Program demonstrated agility in its response to the COVID-19 pandemic and emerging risks like software as a medical device, artificial intelligence, and cybersecurity. Health Canada introduced measures, including Interim Orders and Agile Licensing, to expedite approvals, reduce burden, and enhance responsiveness. This adaptability was sustained through regulatory amendments and initiatives showcased in Health Canada's 2025 report on red tape reduction. However, challenges with IT systems and slow regulatory updates constrain the Program's ability to stay flexible in the face of evolving risks and changes.

Recommendations

The evaluation findings point to challenges in role clarity, internal coordination, and IT systems and tools. The following recommendations address these issues.

Recommendation 1: Clarify and communicate internal roles and responsibilities across the Program, especially for ongoing device classification issues post market.

The evaluation found that, in the absence of clear and consistently communicated documentation, roles and responsibilities were not always well understood, especially for cross-branch activities like post-market surveillance and device classification challenges that arose post market due to ambiguous or non-existent pre-market classification statuses. This ambiguity contributed to operational inefficiency, including duplicated work and delays. Clarifying and formally documenting these responsibilities would help streamline processes, strengthen collaboration between branches, and reinforce the Program's ability to respond to incidents in a timely and effective manner.

Recommendation 2: Strengthen internal coordination, collaboration, and communication across all Program partners.

The evaluation observed that collaboration within the Program, and with DTB, could benefit from a more proactive and structured engagement. This would help to alleviate operational silos and the limited use of formal governance bodies, which can hinder transparent and strategic decision making. Coordination issues between parties have also affected the efficiency and effectiveness of IT tools, further complicating Program operations. Strengthening internal coordination, collaboration, and communication through a more structured approach would help foster a unified and program-wide perspective, and ensure key partners are effectively engaged.

Recommendation 3: Explore opportunities to modernize tools to improve efficiency, enhance data integration across directorates, and adopt artificial intelligence and other innovative technologies.

The evaluation identified that the Program's IT infrastructure is fragmented and relies on some tools not designed specifically for medical device oversight. This contributes to significant operational challenges, including data silos, backlogs from manual entry, and duplicated processes, which can delay incident processing and hinder coordinated regulatory decisions. Exploring opportunities to modernize these tools, streamline data integration, and adopt artificial intelligence and other innovative technologies would improve overall efficiency, accelerate incident processing, strengthen surveillance capacity, and support more effective regulatory analytics.

Management Response and Action Plan

Recommendation 1: Clarify and communicate internal roles and responsibilities across the Program, especially for ongoing device classification issues post-market.

Management response

Management agrees with Recommendation 1. Health Canada recognizes that clearly defined and documented roles and responsibilities with regards to pre-market and post-market activities, including cross-branch activities, will enhance efficiency and strengthen the Program's capacity to address risks, classification challenges, and other regulatory obligations throughout the product life cycle.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Review and update the RACI (Responsible, Accountable, Consulted, or Informed) framework developed in 2021 by HPFB and ROEB to clarify and document roles and responsibilities across the Medical Devices Program (MDP).	Conduct a comprehensive assessment of the RACI framework to identify gaps and required updates, ensuring roles and responsibilities remain accurate and aligned with current processes. Document in the form of a briefing note to MDP's DGs.	September 30, 2026	OPI: HPFB – MDD DG OSI: ROEB – MDCCD DG	Within existing resources
	Develop an updated RACI framework that reflects current roles, responsibilities, and processes for the MDP.	March 31, 2027	OPI: HPFB – MDD DG	Within existing resources

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Review and update the Standard Operating Procedure on Directing Medical Devices enquiries.	Update the 2023 Standard Operating Procedure (SOP) on Directing Enquiries to reflect organisational changes, current roles and responsibilities and validate contact information. This SOP will be updated as necessary. Email SOP to staff.	September 30, 2026	OPI: HPFB – MDD DG HPFB – MHPD DG OSI: ROEB – MDCCD DG	Within existing resources
Communicate MDP's RACI framework.	Present the finalized RACI framework to HPFB and ROEB Directorate Management Committees for endorsement and alignment. Meeting agenda and summary of discussion will be submitted.	March 31, 2027	OPI: HPFB – MDD DG HPFB – MHPD DG ROEB – MDCCD DG	Within existing resources
	Communicate and explain the updated RACI framework to all HPFB and ROEB staff involved in the MDP to ensure clarity of roles and responsibilities. This RACI will be updated as necessary. Email to staff.	June 30, 2027	OPI: HPFB – MDD DG HPFB – MHPD DG ROEB – MDCCD DG	Within existing resources

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Develop framework for the classification of medical devices in the context of compliance & enforcement (i.e. post-market); supporting program-wide consistency in post-market device classification, and strengthening the program's capacity to address risks more efficiently.	ROEB Post-Market Classification Framework, including: inspector training, classification SOP (including defining responsibilities for program partners) and repository of decisions.	December 30, 2026	OPI: ROEB – MDCCD DG OSI: HPFB – MDD DG	Within existing resources

Recommendation 2: Strengthen internal coordination, collaboration, and communication across all Program partners.

Management response

Management agrees with Recommendation 2. Health Canada will continue to work towards the use of common information management databases and tools. Information management in one common system will enhance access to pre and post market medical device information by program partners throughout the device lifecycle, allow for increased process automation and enable a coordinated approach across the Program. By consolidating data into one common technical platform, we eliminate systems silos within the medical devices program and help ensure that all program partners have timely, consistent access to critical medical device information throughout the entire lifecycle.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Building on respective Branch planning processes, program partners will share plans and priorities.	Priority planning documents are shared amongst program partners via emails from Program Directors General.	June 30, 2026	OPI: HPFB – MDD DG HPFB – MHPD DG ROEB – MDCCD DG OSI: DTB – DPDDM DG	Within existing resources
Plan and implement IP1102.	A Benefits Realization Plan that defines the specific benefits this initiative aims to deliver (e.g., improved integration, information sharing).	August 31, 2026	OPI: HPFB – MHPD DG OSI: HPFB – BFMD DG DTB – DPDDM DG	Within existing resources

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
	Business User sign off document to confirm completion of the specified requirements (see above).	August 31, 2026	OPI: HPFB – MHPD DG OSI: HPFB – BFMD DG DTB – DPDDM DG	Within existing resources
	Project Closeout Report to signal overall completion of IP1102.	March 31, 2027	OPI: HPFB – MHPD DG OSI: HPFB – BFMD DG DTB – DPDDM DG	Within existing resources

Recommendation 3: Explore opportunities to modernize tools to improve efficiency, enhance data integration across directorates, and adopt artificial intelligence and other innovative technologies.

Management response

Management agrees with Recommendation 3. There are plans underway at the Department and Branch levels to adopt and leverage artificial intelligence. This work will inform future actions meanwhile; IP1102 will integrate pre-market medical device data with post-market medical device data in a single IT system. This eliminate silos between areas of the program and integrates data into a single system and has been identified as a potential solution to address data management throughout the life cycle.

Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Explore opportunities to adopt artificial intelligence within Branch processes.	Present HPFB AI plan to Branch Executive Committee and share this plan with program partners.	April 30, 2026	OPI: HPFB – BFMD DG	Within existing resources
Explore opportunities for enhanced data integration within the Medical Devices Program IT systems.	Present IP1102 Project Management Plan to DG-Investment Plan governance.	May 31, 2026	OPI: HPFB – BFMD DG OSI: DTB – DPDDM DG HPFB – MHPD DG	Within existing resources

Program Description

The term “medical devices”, as defined under the *Food and Drugs Act* (FDA), refers to a broad category of health or medical instruments used in the treatment, mitigation, diagnosis, or prevention of diseases or abnormal physical conditions. These devices range widely in type and complexity, from simple tools like thermometers to advanced technologies like pacemakers and diagnostic imaging systems. The *Medical Devices Regulations* (MDR) were established in 1998 under the FDA.

Health Canada's Medical Devices Program (MDP) is tasked with ensuring that all medical devices sold in Canada meet the safety, effectiveness, and quality requirements outlined in the MDR. To fulfill its mandate, the MDP conducts pre-market reviews of device applications, evaluates risk-benefit profiles, monitors products after they reach the market, and carries out compliance and enforcement activities. It also plays an important role in providing information to Canadians and health care professionals to support the safe and effective use of medical devices.

Medical devices in Canada are grouped into four classes based on risk: Class I (lowest risk), Class II, Class III, and Class IV (highest risk). For example, simple devices like bandages are Class I, while complex devices like pacemakers are Class IV. This system allows Health Canada to establish appropriate regulatory controls, licensing, and oversight for each device to ensure devices meet appropriate safety standards before they are sold in Canada.

The Program engages a wide range of stakeholders, including medical device manufacturers, market authorization holders, and licenced establishments, as well as health professionals and the public. Regulated parties are responsible for complying with regulatory requirements, promoting appropriate device use, and reporting adverse incidents to Health Canada.

Program activities are a shared responsibility between the Health Products and Food Branch (HPFB) and the Regulatory Operations and Enforcement Branch (ROEB).

Evaluation Scope and Approach

This evaluation assessed the effectiveness and efficiency of Health Canada's Medical Devices Program, including how well the Program allocated resources to fulfill its mandate. It used multiple lines of evidence, including a bilingual online stakeholder survey that received 774 complete responses, mainly from industry representatives. Details of the evaluation questions, evaluation methodology, and all lines of evidence are provided in [Appendix A: Methodology](#).

The evaluation focused on the Program's pre-market, post-market, and compliance and enforcement activities undertaken by the Medical Devices Directorate (MDD) and the Marketed Health Products Directorate (MHPD) within HPFB, as well as the Medical Devices and Clinical Compliance Directorate (MDCCD) within ROEB, between April 2020 and March 2025.

Activities related to medical device shortages are now managed by the Health Product Shortages Directorate within ROEB, and were excluded from this evaluation. As this new unit was established in 2024, it had limited data available during the evaluation period and was also previously examined as part of a recent audit on drug shortages.

Findings

Effectiveness

Access to Safe, Effective, and Quality Medical Devices

The evaluation found that the Medical Devices Program helped ensure Canadians have access to medical devices that meet applicable safety, effectiveness, and quality requirements through its core regulatory activities, while also having some challenges and areas for potential improvement. These findings are supported by multiple lines of evidence, including a document review, internal and external interviews, and survey results. Of note, in the OAE's 2025 external stakeholder survey, a strong majority of respondents (83%) reported satisfaction with Health Canada's efforts to ensure that medical devices in Canada meet safety, quality, and effectiveness requirements.

The following sections discuss the Program's various efforts to ensure Canadians have access to medical devices that meet safety, effectiveness, and quality requirements, including working with industry stakeholders to make them aware of, and compliant with regulatory requirements, communicating risks, and coordinating efforts with partners and stakeholders.

Industry Stakeholders Informed of, and Compliant with Regulatory Requirements

Key Takeaways: The Program keeps industry stakeholders informed and compliant with regulatory requirements; however, opportunities exist to enhance engagement with small companies, increase outreach through webinars and training sessions, make guidance materials easier to find online, and simplify industry interactions by using a single Health Canada contact.

Communication and stakeholder engagement

The Program kept industry stakeholders informed and engaged through multiple communication channels. It disseminated regulatory requirements via guidance documents, online bulletins, notices, refusal decision letters, licence recommendation memoranda, and renewal packages. Over the past five years, staff have also provided one-on-one feedback on device applications by email or phone, demonstrating responsiveness to stakeholder questions. For example, an external interviewee shared that, while developing a cancer genomic testing device, they received direct guidance on screening indications within an hour of contacting Health Canada, while another stakeholder confirmed similar telephone support when new guidance emerged. However, internal interviewees noted that providing individualized support required considerable resources and was not sustainable. As a result, the Program shifted toward directing stakeholders to published guidance. External interviewees valued the earlier one-on-one support and found the new reliance on online documents less effective for resolving specific or complex inquiries.

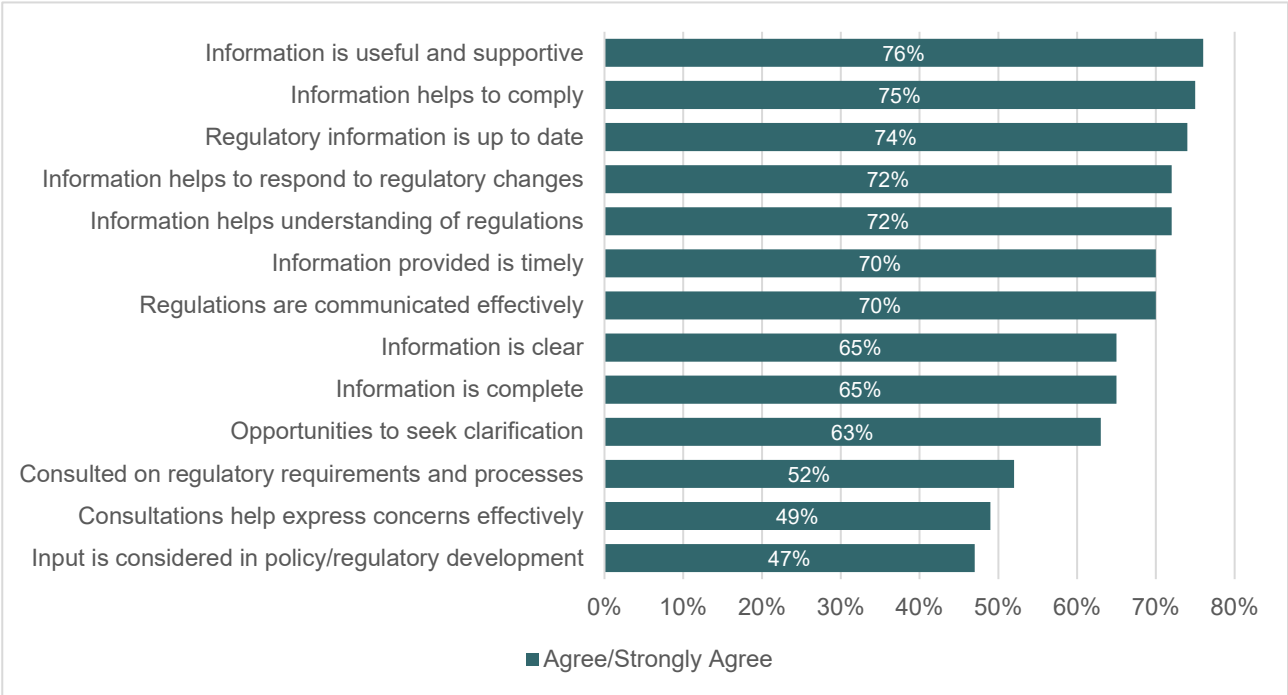
To reach wider audiences, the Program distributed monthly email updates with information on regulations, guidance, and notices. For breast implants and vaginal surgical mesh, it offered an opt-in subscription service that flagged new or updated publications, including safety or recall notices, and in the case of breast implants, Breast Implant-Associated Anaplastic Large Cell Lymphoma data blog updates. Health Canada also updated its website to communicate safety information, such as those involving therapeutic and cosmetic energy-based devices. In addition, the Program created a GCwiki site to disseminate additional information and documents to external stakeholders.

In addition, between 2020-2021 and 2024-2025, MDD's Bureau of Policy and International Programs produced three regulatory documents, three policy documents, 20 guidance documents, and 14 notices. While uptake data specific to these new documents was not available, web analytics indicated that medical device industry pages containing regulatory guidance and policy materials had received more than 200,000 PDF downloads between April 2022 and March 2025. During this same period, the Program conducted five public consultations to inform regulatory and policy development and address stakeholder concerns. Furthermore, it engaged industry stakeholders through dialogues during inspections, compliance, and enforcement activities. Each fiscal year, the Program also held bilateral meetings with major industry stakeholders and participated in the Medtech Canada Regulatory Conference.

These efforts have led to a percentage of Class III and IV medical device applications meeting regulatory requirements, remaining consistently near or above the 90% target,

ranging from 88% to 96%, likely supported by the Program’s diverse communication channels. Furthermore, OAE’s 2025 stakeholder survey clearly demonstrated that stakeholders, a vast majority of whom were from industry, were quite positive about all these efforts. For example, 95% of respondents felt informed about medical device regulatory requirements (44% somewhat, 51% fully), and two-thirds (67%) reported satisfaction with Health Canada’s engagement with their organization. As can be seen in Figure 1, they viewed Health Canada’s efforts as having a positive impact on their level of understanding and ability to comply with applicable regulatory requirements.

Figure 1: 2025 stakeholder survey results on being informed



Challenges and opportunities for improvement with industry communication

Despite these positive outcomes, stakeholders and staff have identified some challenges limiting the Program’s ability to inform industry stakeholders and recommended areas for improvement. Health Canada faces difficulties in reaching and informing all businesses, particularly smaller companies. These organizations often lack the capacity to monitor regulatory updates and typically learn of new requirements only during inspections, which underscores the need to strengthen targeted outreach to this segment of the medical device industry.

Both internal and external interviewees have stated that Health Canada's medical devices website is difficult to navigate and lacks clear and current information. A review confirmed that 81% of the 53 posted guidance documents predate 2020. A few external stakeholders also found the "What's new: Medical devices" page ineffective as an information tool, since it typically displays a new date without clearly summarizing substantive updates. Stakeholders recommended that Health Canada improve its website navigability, upgrade search tools, and eliminate outdated content.

A few internal interviewees reported that communication silos within the Program have created a fragmented and inefficient experience for the industry, requiring companies to contact multiple branches for information. This structure can lead to inconsistent messaging and delayed responses, limiting the Program's ability to provide clear, coordinated, and timely updates. To streamline communication, external interviewees and survey respondents recommended establishing a single, clearer, and more accessible point of contact within Health Canada, such as a dedicated intake system to redirect inquiries, or an assigned case manager for each inquiry, to ensure consistent follow up.

External interviewees expressed confusion and frustration about differences between Canadian and U.S. regulations, and between federal and provincial regulations. A few external interviewees suggested that clearer communication to industry stakeholders could help reduce these misunderstandings.

A case study on energy-based cosmetic devices, such as therapeutic lasers and light-emitting diodes used for treatments like hair removal and skin rejuvenation, showed further communication issues. Some internal and external stakeholders reported that Health Canada's messages on these devices were often generic, delayed, or insufficiently specific, making it difficult for industry members to understand classification decisions and requirements. Using simpler language was suggested to address this issue.

Survey respondents had varied perspectives on Health Canada's engagement efforts, with about half agreeing that Health Canada had adequately consulted external stakeholders over the past five years (52%) or considered stakeholder input during policy and regulatory development (49%). Of note, roughly 40% either expressed no opinion or responded neutrally to these statements about Health Canada's engagement actions. Suggestions to enhance the Program's external stakeholder engagement included offering more frequent opportunities for dialogue (e.g., roadshows, meetings, webinars), responding more quickly to stakeholder input, and clearly communicating how feedback would be addressed.

Ensuring compliance

Overall, it appears that the Program's communication and outreach activities helped foster industry compliance. As shown in Table 1, post-market activities such as inspections and compliance verification consistently found high levels of compliance by industry, demonstrating that medical devices on the market continue to meet safety requirements. Overall, performance data showed that the Program generally met or exceeded compliance targets during the evaluation period.

Table 1: Performance on medical device compliance indicators by fiscal year

Indicator	Target	2020-2021	2021-2022	2022-2023	2023-2024	2024-2025
1) % of regulated medical devices establishments inspected and found compliant	95%	80%	N/A	100%	99%	99%
2) % of high-risk compliance verification cases resolved with compliance achieved	95%	100%	100%	100%	100%	100%

Sources: Indicator 1: Post-Market Surveillance Activity Tracking System, Indicator 2: Medical Device System

According to performance data, in 2024-2025, the Program issued 1,965 active Medical Device Establishment Licences (MDELs) and completed 296 regular inspections. Health Canada inspects companies in Canada and abroad using on-site and remote methods. While all risk classes are subject to inspection, several internal interviewees reported that the Program is developing a Site Risk Profile tool that uses machine learning and artificial intelligence (AI) to create risk scores for each company, based on 20 to 30 different pieces of information like compliance history and incident reports from various internal and international sources. The Program prioritizes inspections for companies with higher risk scores.

Informing Stakeholders about Risks and Benefits

Key Takeaways: Health Canada's role as a regulator is primarily focused on communicating medical device risks rather than benefits. Some challenges remain with timeliness, clarity, accessibility, and consistent integration of Sex- and Gender-Based Analysis Plus (SGBA Plus).

Risk communication activities

During the pre-market phase, the Program considers risks in its licensing decisions and communicates the outcomes of its regulatory decisions through Regulatory Decision Summaries (RDS), Summary Bases of Decisions (SBD), Public Release of Clinical Information (PRCI), as well as through physical and electronic labelling of Class III and IV medical devices. In the post-market phase, the Program communicates on risks when incidents occur. It informs stakeholders, partners, and the public of emerging risks through a range of tools like recalls, public advisories, and email updates from MedEffect e-Notice. For example, approximately 26,000 subscribers received email updates from MedEffect e-Notice and RSS feeds, providing consumers, patients, and health care professionals timely access to safety and alert information. See [Appendix B](#) for a more complete list of tools.

Performance data indicated that, over the past three fiscal years, 100% of risk communications targeted to health professionals were disseminated within service standards. Furthermore, according to the OAE's 2025 stakeholder survey results, 62% of respondents agreed that Health Canada provides adequate information on both the risks and benefits of medical devices, and 85% reported using the Program's risk information to make informed decisions, representing a 14 percentage point increase from 2022.

Internal interviewees noted that, given Health Canada's regulatory role, the benefits of medical devices were not typically promoted since they are assessed during licensing.

However, Health Canada’s communications group actively informed the public about the benefits of personal protective equipment and testing kits during the COVID-19 pandemic.

Risk communication challenges

At the same time, the evaluation found that there are gaps in sharing and publishing some risk information, which limit stakeholders’ access to timely and complete information for informed decision making. Between 2020-2021 to 2023-2024, the Program published very few summaries of its regulatory decisions for new Class III and IV devices, well below its targets, resulting in limited access to information on the risks and benefits considered in licensing decisions. The evaluation also found that a backlog of mandatory incident reports may delay scientific assessment, potentially creating information gaps that could reduce the effectiveness of post-market surveillance and slow incident responses.

Both Program documents and a few internal officials indicated that some risk is mitigated by triaging hospital reports before industry submissions. The Program also ensures that high-risk cases involving death or serious harm are being effectively triaged and actioned for immediate assessment, risk communication, and enforcement. Vanessa’s Law came into force in December 2019, mandating hospitals to report all medical device incidents (MDIs). However, the Program has since been unable to meet its MDI report processing targets, as shown in Table 2. The backlog of mandatory MDI reports reached 28,000 reports in 2020-2021, dropped to 11,000 with temporary staffing, but has since increased again and is projected to reach approximately 50,000 reports by the end of 2025-2026.

Table 2: MDI processing backlog by fiscal year

Indicator	Target	2022-2023	2023-2024	2024-2025
% of manual and semi-automated medical device incident (MDI) reports processed within service standards	90%	31%	29%	15%

Outdated tools have further compromised transparency and access to risk information. Although some Program documents reference the MDI database as a publicly available resource for incident reports from industry, hospitals, and health care professionals, a

2023-2024 internal administrative planning document found that both external stakeholders and Health Canada staff considered the MDI public database difficult to use, non-functional, unintuitive, and failing to meet user needs. Similarly, both internal and external interviewees contended that the MDI database on the Health Canada website was ineffective because it contains outdated and incomplete data, suffers from poor maintenance and low usage, and features a non-intuitive design. The absence of current information in the database prevents stakeholders from accessing some safety information, which can result in the continued use of problematic devices. It also compromises reporting accuracy and discourages database use, prompting some non-governmental organization stakeholders to turn to external sources, such as the U.S. Food and Drug Administration's MAUDE database or other non-profit sites for reliable information.

Complex language also reduces accessibility. For example, internal interviewees noted public confusion around the term "recall", which may refer to product withdrawal, label changes, or monitoring. Similarly, according to a few internal officials, the Public Release of Clinical Information can be difficult for the public to interpret because it presents highly technical and scientific data without plain language explanations. As a result, many people cannot easily use this information to make informed decisions.

SGBA Plus communication

An internal 2021 report drafted by a consultant found that Health Canada's medical device regulatory documents and public materials used by Health Canada staff, health care providers, industry, and patients often lacked information related to SGBA Plus, even for devices that affect women more than men. The review emphasized the need for clearer and more consistent integration of SGBA Plus data across all materials. This reinforced the recommendation first highlighted in the 2019 Joint Audit and Evaluation of Medical Devices¹ to systematically embed SGBA Plus considerations throughout the medical device life cycle.

In response, the Program improved SGBA Plus integration in medical device risk communications. For example, it now requires manufacturers to include safety data and testing that addresses risks for all skin tones when applying for a licence for Class III and IV energy-based devices, and it has issued targeted risk communications for devices like breast implants and vaginal mesh^{2,3}. The Program developed an SGBA Plus implementation plan to integrate equity considerations into regulatory forms and public risk communication tools. There was no available documentation of the progress on this work at the time of the evaluation.

Coordinated Approach with Partners and Stakeholders

Key Takeaways: The Program effectively collaborated with external partners and stakeholders through formal structures and active engagement.

Collaboration with domestic partners and stakeholders

While some stakeholder survey respondents reported less positive feelings regarding being adequately consulted on regulatory policy over the past five years, the evaluation found that the Program had maintained strong relationships with various domestic partners. The Program engaged domestic partners through multiple formal channels, including:

- scientific advisory committees, such as the Scientific Advisory Committee on Digital Health Technologies, the Scientific Advisory Committee on Medical Devices Used in the Cardiovascular System, and the Scientific Advisory Committee on Health Products for Women;
- bilateral meetings with industry associations, including with MedTech Canada, the Canadian Council of Innovators, and the Dental Industry Association of Canada; and
- regular engagement with the Canadian Medical Devices Sentinel Network (CMDNet).

External interviewees praised CMDNet for its strong coordination, effective engagement, and prompt, clear, and helpful responses. Stakeholders also viewed frequent engagement with MedTech Canada positively and observed that input from the advisory committees had informed published guidance.

To improve coordination and collaboration, stakeholders recommended strengthening mechanisms to solicit input from a more diverse range of partners, including non-traditional industry partners, health care professionals, buyers, and non-profit organizations.

International coordination and collaboration

Canada's strong relationships with international regulators enhanced regulatory alignment and supported Program objectives. Program documents and both internal and external interviewees revealed that Canada had participated in major forums, including the International Medical Device Regulators Forum (IMDRF), the Australia-Canada-Singapore-Switzerland-UK Consortium, and International Medical Device Safety meetings. For example, interviews and documents from the software as a medical device case study highlighted that Canada collaborated with the United Kingdom and the United States to

develop and publish three joint documents related to guiding principles for machine learning-enabled medical devices, to help promote safe, effective, and high-quality medical devices that use AI and machine learning.

As a founding member of the Medical Device Single Audit Program (MDSAP), Canada has partnered with the United States, Australia, Brazil, and Japan. This work-sharing agreement allows a single regulatory audit to satisfy the requirements of all five member countries, thus reducing duplication, maximizing resource efficiency, and increasing international harmonization.

According to Program documents and internal and external interviewees, Canada strengthened global coordination during the COVID-19 pandemic, participating in bi-weekly meetings with trusted regulators like the United States, United Kingdom, and Australia. These meetings enabled rapid information sharing on common challenges in the management of medical devices and shortages, as well as safety, performance, and quality issues for medical devices used in response to the pandemic. This supported a harmonized approach for guidance and communication to stakeholders.

Efficiency

Clarity of Roles and Responsibilities

Key Takeaways: The Program lacks clear and current documentation defining internal roles and responsibilities, and existing documents are not consistently communicated or used in practice.

Clear roles within specific groups

A few internal interviewees noted that roles and responsibilities were clear within certain groups. For example, teams within MDCCD had distinct, process-based roles, while staff in MHPD described distinct roles between the data management and assessment teams.

Documentation of roles and responsibilities

The Program possesses some governance documents that outline roles and responsibilities; however, a review of program documents and internal interviews found that many of these tools are outdated and do not reflect current organizational structures or operational processes. Key documents have not been subject to regular updates, including the Responsible, Accountable, Consulted, or Informed (RACI) chart for Post-Market Risk Management of Medical Devices and Standard Operating Procedures (SOPs), such as those for managing the two scientific advisory committees, processing

Special Access Program applications, and handling post-market requests concerning health risks.

For example, the RACI chart, which was developed after the 2019 joint audit and evaluation to address the Program's gaps in roles and responsibilities, was meant to be an "evergreen document" and provide ongoing clarity. However, it has not been updated to reflect organizational changes, such as the dissolution of the Compliance and Risk Management Unit and that two teams have since taken over those functions. Similarly, a review of eight SOPs showed that only two have been updated within the past five years, highlighting the need for regular maintenance of core documents.

Despite the existence of this documentation, many internal officials reported limited awareness and use of these documents. Moreover, the Program has no formal process to regularly maintain or update governance tools, reducing their relevance and effectiveness.

Examples of unclear and poorly communicated roles and responsibilities

A review of the Program's documents and internal interviews found that, in some instances, the Program has not formally documented or consistently communicated internal cross-branch roles and responsibilities. For example, following the 2020 transfer of some post-market surveillance responsibilities from MHPD to MDD, functions were divided across groups: MDD took on signal analysis, MHPD retained management of the surveillance database and processing of mandatory incident reports, and MDCCD continued to manage voluntary incident reports. However, internal interviewees provided differing accounts of which group held overall responsibility for surveillance, with some pointing to any one of these directorates. Unclear roles and accountabilities left staff uncertain about processes and leadership for this core function.

Similar challenges have occurred in defining and communicating roles and responsibilities for device classification issues that arise post market. For example, MDCCD inspectors rely on device classification information (Classes I to IV) to conduct compliance and enforcement activities. According to some internal interviewees, issues can arise when inspectors encounter devices that lack documented classification, appear to be incorrectly classified based on their features or intended use, or have been modified after licensing in ways that may affect their risk class. In cases where uncertainty exists about device classification, inspectors refer cases to MDD for guidance before proceeding with regulatory actions. However, MDD assigns classifications only during device licence application reviews, meaning no single authority manages classification decisions after market entry. The Program also does not have a centralized process or established timelines for reviewing and issuing classification decisions in these situations. Without a

defined process, inspectors often lack timely guidance and rely on informal communication to make classification decisions. The intraoral camera case study provides an example of how unclear roles and expectations prolonged back-and-forth discussions. Although no health or safety incidents were identified in this particular case, it highlighted a regulatory impasse that delayed decision making and required senior management involvement to resolve classification disagreements between the Program and industry stakeholders.

Program officials acknowledged these challenges and flagged this as an important area that they have begun to address. For example, they have started developing a tiered classification framework to clarify the respective roles of MDCCD and MDD, specifically as they relate to classification issues that arise post market. This framework aims to empower inspectors, strengthen compliance, and promote consistent and transparent decision making.

Internal Coordination and Collaboration

Key Takeaways: Coordination among Program partners is inconsistent and often reactive due to siloed teams and a lack of touch points.

Internal coordination strengths and challenges

During the COVID-19 response, the Program demonstrated effective internal coordination by rapidly implementing emergency regulatory tools and frameworks. Staff worked across multiple teams, reprioritized workloads, paused non-essential tasks, and supported swift decision making.

Beyond the pandemic, many internal interviewees described internal coordination as ad hoc and reactive, often driven by urgent issues or isolated projects, rather than by sustained and strategic planning. These coordination challenges affect the Program as a whole and have had consequences across every stage of the medical device life cycle. At the working level, staff reported relying on informal relationships that provided some effective coordination, but these channels offered limited opportunities for consistent and proactive collaboration across the Program. A few governance bodies are documented (i.e., two Trilaterals and the MDP Committee), but internal interviewees reported they were largely ineffective, in part because meetings were so infrequent that some questioned whether the committees were active.

Internal coordination challenges were also evident in day-to-day operations. For example, two branches managing two separate incident reporting systems largely in isolation from one another has resulted in information-sharing challenges and duplication of effort.

The case study on the classification of intraoral cameras also identified coordination and collaboration challenges. Different Health Canada units independently contacted the same Program partners and industry stakeholders about identical compliance issues without knowing about each other's activities. In addition, classification decisions were changed but not shared with the relevant teams. These uncoordinated actions confused industry stakeholders.

Digital governance challenges

Collaboration between the Program and the Digital Transformation Branch (DTB) has also been limited and, in some cases, the Program has independently developed some IT tools. DTB's digital oversight role is designed to ensure IT tool synchronization, integration, and evidence-based decision making. However, at times, DTB felt they were brought in late, primarily to fix problems, rather than being engaged early enough to jointly develop solutions. This has affected the effectiveness of various IT tools; see section on Appropriateness of Tools for more details. These challenges have arisen from differing perspectives on IT governance, wherein the Program prioritizes operational agility for its specialized work, while DTB is mandated to enforce compliance with enterprise-wide standards. Governance is a central focus of the ongoing OAE Audit of Governance and Strategic Planning of IT. Recognizing these issues, both groups have recently taken steps to improve collaboration by establishing clearer IT governance structures, increasing meeting frequency, and designating dedicated DTB points of contact.

Suggested improvements

Several internal interviewees identified opportunities for the Program to improve internal coordination through a more integrated and formalized approach. They recommended reinstating regular and strategic inter-directorate meetings at all levels to discuss program-wide issues, anticipate risks, align priorities, and prevent siloed decision making. Interviewees also suggested implementing brief and recurring stand-up meetings to facilitate timely information sharing and collaborative resolution of emerging issues. One internal official summarized it as follows: "The Medical Devices Program should strive to work as a program, ensuring that all activities, including authorization, surveillance, and compliance and enforcement are fully aligned".

Activity and Resource Allocation

Key Takeaways: By focusing its resources on certain activities, the Program has met its regulatory mandate and cost recovery targets; however, this has contributed to capacity pressures in other areas.

Alignment between Program activities and regulatory responsibilities

Documentary evidence and internal interviews found that HPFB and ROEB have aligned pre-market and post-market activities with their mandates and regulatory responsibilities. The internal Project Compass allowed HPFB to systematically align all Program activities to regulatory requirements and levels of risk, confirming coverage across core, mandated, high-risk, and legislatively required functions. Most internal interviewees agreed that these activities accurately reflected the Program mandate. However, a few internal interviewees identified gaps in Health Canada's oversight of Class I medical devices. Although these devices make up a large portion of the Canadian market, Health Canada does not maintain a complete or centralized list of them, nor does it require manufacturers to register them. As a result, the Program cannot reliably define, track, or take timely action on safety signals involving Class I devices, despite having a regulatory responsibility to oversee them under the MDR, sections 10 through 20 and 25.

Financial allocations

Appendix C shows the Program spent 90% of its planned budget over the last five fiscal years. Of note, 57% of the planned operations and maintenance (O&M) budget was used due to factors like COVID-19 pandemic-related travel restrictions impeding compliance verification activities and causing procurement delays. Salary spending was close to planned budgets across branches, with HPFB spending a little under its initial salary budget (94%), primarily because it received temporary COVID funding that increased salary budgets above what could be spent. ROEB slightly exceeded its planned salary budget (105%) to manage increased operational demands during the pandemic, particularly processing, issuing, and managing an increased number of Medical Device Establishment Licence (MDEL) applications, as well as monitoring compliance.

Cost-recovery performance and fee structure

Most internal interviewees noted that cost recovery performance targets are the primary drivers for resource allocation. The Program consistently met service standards for MDEL applications and for Review 1 decisions on cost-recovered Class II, III, IV, and Private Label Medical Device Licence (MDL) applications from 2020-2021 to 2024-2025. Because missed service standards require partial refunds, the Program prioritizes activities associated with cost recovery. In five years, HPFB issued less than \$44,000 in remissions for missed deadlines. While ROEB remitted a significant \$2.4 million in 2022-2023, nearly all of this was due to a one-time COVID-19 pandemic remission order, with only about \$2,000 related to missed service standards that year. This cost-recovery structure incentivizes the Program to prioritize cost-recoverable tasks, leaving some non-recoverable activities with ongoing capacity pressures.

Current cost recovery fees cover 53% of actual Program expenditures. Many internal interviewees questioned the sustainability of the fee structure, which is based on 2014 to 2017 costing data and was only indexed to the Canadian Price Index in 2022. They noted that fees have not kept pace with inflation, and fee exemptions and reductions create further challenges. Internal officials estimated that updating the fee schedule would take 24 to 36 months, but no plan is currently in place to do so.

Capacity challenges in post-market activities

Many internal interviewees perceived a disparity in resources between pre-market and post-market functions. They described pre-market activities as lean but adequately resourced, largely due to the stability of the cost-recovery funding model. In contrast, interviewees stated that post-market teams are struggling to meet demand. Officials attribute this capacity challenge to an increased workload, which is compounded by an increased complexity of issues and files, inefficient IT tools, and manual data entry. For example, the growing backlog of mandatory MDI reports, discussed previously under the section on Informing Stakeholders about Risks and Benefits, is both a financial and technological problem. It represents a liability because addressing the backlog will require additional investments.

At the same time, the financial data in Table 3 below shows that, contrary to interviewee perceptions, the total spending for post-market functions was comparable to pre-market allocations and surpassed them in the last two fiscal years. Despite these figures, internal interviewees raised concerns about available resources, and financial data shows that ROEB significantly exceeded its budget in the last two years (131% and 126%), as overall available resources declined.

Table 3: Combined salary and O&M actual spending to pre- and post-market activities by fiscal year

Fiscal Year	Total Pre-Market (\$)	HPFB Post-Market (\$)	ROEB Post-Market (\$)	Total Post-Market (\$)	Comparison (Pre vs. Post)
2020-2021	25,121,149	3,840,451	20,718,512	24,558,963	51% vs 49%
2021-2022	28,671,395	4,711,086	23,566,815	28,277,901	50% vs 50%

2022-2023	28,617,346	3,585,271	23,737,720	27,322,991	51% vs 49%
2023-2024	26,711,289	4,581,360	26,314,096	30,895,456	46% vs 54%
2024-2025	24,143,463	3,711,454	26,001,764	29,713,218	45% vs 55%

Appropriateness of Tools

Key Takeaways: Issues with various in-house, enterprise, or vendor-supplied IT tools, combined with a fragmented IT environment have challenged program efficiency.

IT tool challenges

Internal interviewees and Program documents identified several in-house intelligence tools as valuable for managing and storing documents, reporting information, and automating tasks. Staff rely heavily on shared drives and email. The Program streamlines licence submissions with a partner-interface gateway like eSTAR or the Regulatory Enrolment Process (REP), but lacks a unified online portal for incident report submissions. Without automation and pre-coded fields, staff must often re-enter data from spreadsheets and non-functional submission forms, which increases workload and reduces efficiency.

The Program faces difficulties with IT system limitations and poor integration. For example, MDCCD and MDD use the Medical Device System (MDS), an in-house database that, due to its aging architecture, would require future investment. MHPD uses the vendor-supplied Adverse Reaction Information System – Global (ARIS-G), a system originally designed for drug safety monitoring, which makes it challenging for medical device reporting. Program officials widely reported that ARIS-G's lack of automation and reliance on manual data entry slowed report processing and led to significant backlogs. These critical systems do not share data, which prevents a complete understanding of the medical device life cycle and allows inefficiency in managing approvals, incident reporting, and compliance activities. In addition, staff use multiple and separate reporting and analytics tools, which further complicates data sharing and creates inconsistent reporting across the Program.

Both Program and DTB officials noted that staff had developed their own unofficial workarounds to bridge system gaps, but these are not formally supported and may fail after system updates. As mentioned previously, the lack of coordination between the Program and DTB has also affected the efficiency of some IT tools.

Modernization and suggested improvements

The Program has started addressing key IT challenges. MHPD is phasing out ARIS-G and consolidating operations into MDS, with completion anticipated in July 2026, while exploring alternative tools for medical device reporting. The Program introduced AI to automate the translation of licensing decisions, raising the percentage of applications with published rationales from below the 85% target to 99% in 2024-2025.

To further improve IT tool efficiency, DTB officials emphasized the need for their early and continuous engagement in any IT discussions, as well as adherence to departmental IT governance frameworks. Program officials called for the development of an integrated IT roadmap for the entire Program, and the broader application of AI to automate document processing. The Program may also benefit from collaborating with other branches (e.g., Strategic Policy Branch) that are innovating to expand and accelerate AI adoption and use.

Adapting to Changing Environments, Risks, and Challenges

Key Takeaways: The Program demonstrated significant agility in its pandemic response and collaborative planning for new technologies that use software as a medical device. However, this kind of agility is at risk due to IT issues and challenges in updating regulations.

Agile regulatory response to emerging risks

During the evaluation period, Health Canada proactively addressed various emerging issues, including those related to software as a medical device, AI, and cybersecurity. The Program established a dedicated digital health team to provide expertise on, and oversight of evolving technologies, analyze trends, identify regulatory gaps, and develop new guidance. International coordination undertaken to advance work in these areas is described earlier in this report in the Coordinated Approach with Partners and Stakeholders section.

The Program also demonstrated strong regulatory agility during the COVID-19 pandemic, issuing seven Interim Orders (IOs) that expedited the approval of more than 650 medical devices and authorizing 11 clinical trials for COVID-19 medical devices. These responses reduced administrative burdens for the industry and allowed a timely pandemic response.

The Program sustained the regulatory agility developed during the pandemic by enacting amendments and new regulatory measures, including introducing Part 1.1 of the MDR, which established flexibilities to better support future public health emergencies without relying on temporary measures like interim orders. The broad scope of existing regulations

also supported the development of new guidance and interpretations for emerging technologies, such as machine learning-enabled medical devices. For example, the Program was able to respond swiftly to innovations in software-based and AI-driven medical devices. Health Canada also highlighted these initiatives in its September 2025 report on red tape reduction⁴. In addition, 75% of external stakeholder survey respondents indicated that current regulations effectively support responses to emerging health and safety issues.

Challenges to flexibility

Systemic challenges undermine the Program's agility. As previously discussed, fragmented IT issues and reliance on manual processes restrict the Program's flexibility to respond quickly to evolving needs.

Both internal and external interviewees identified challenges in updating medical device regulations. They observed that certain aspects of existing regulations are rigid and slow to change, limiting Health Canada's ability to respond quickly to emerging technologies and complicating classification decisions. While broad regulatory frameworks may provide some benefits, they also hinder the consistent classification of innovations like software as a medical device, leading to delays in licensing and responses to industry inquiries. Internal interviewees further emphasized that the process to update regulations itself is lengthy and resource intensive, further limiting the Program's ability to adapt to technological advances and meet evolving stakeholder needs. Health Canada's red tape reduction report⁴ recognizes the challenges described by interviewees, specifically the barriers to timely innovation and regulatory responsiveness. The report highlighted new initiatives, such as guidance for machine learning-enabled medical devices, which aim to make regulation more agile and risk-based, however it also noted that further regulatory modernization is still needed to address these challenges.

Suggested improvements

Several internal and external interviewees suggested modernizing IT infrastructure to reduce manual processes, such as implementing electronic portals for incident reporting and checking application statuses. External interviewees proposed introducing regulatory sandboxes to test innovative medical devices under Health Canada oversight, to stimulate innovation, keep pace with evolving technologies, and inform permanent regulatory changes. A regulatory sandbox is a tool that can help federal regulators keep pace with changing technologies and reflect current business realities, challenges, and opportunities⁵. From the case study on software as a medical device, stakeholders also suggested developing new regulatory pathways to accommodate novel technologies that

are not covered by existing regulations. Others suggested further developing the Program's capacity to adapt by providing targeted skills training in areas like AI, digital health, or cybersecurity.

Conclusions and Recommendations

Conclusions

The Medical Devices Program effectively fulfills its mandate of ensuring Canadians have access to medical devices that meet safety, effectiveness, and quality requirements, while also facing some challenges and opportunities for improvement. It delivers risk-based pre-market reviews, communicates regulatory requirements through a clear multi-channel outreach that supports compliance and informs stakeholders of risks across both pre-market and post-market phases. The Program works actively with domestic and international partners to align practices, address emerging issues, and strengthen regulatory coherence. During the COVID-19 pandemic, it demonstrated both innovation and agility by accelerating access to more than 650 essential devices, and it continues to show foresight by proactively advancing guidance, expertise, and partnerships in areas like digital health.

Despite these strengths, the evaluation identified challenges that limit the Program's overall effectiveness and efficiency. The Program could improve its industry outreach and engagement by doing more to support small businesses, providing more accessible guidance online, conducting more frequent outreach through webinars and training, and offering a clear point of contact for industry members. Communication of risks is challenged by publication delays, complex language, outdated tools, and inconsistent integration of SGBA Plus. Internally, coordination suffers from siloed practices and a lack of touch points. Unclear roles and responsibilities cause confusion and duplication of effort. A focus on cost-recovery priorities leads to capacity pressures in areas like post-market surveillance and incident reporting, which can delay risk mitigation efforts. Reliance on aging, poorly suited, or non-integrated IT systems leads to greater inefficiency. Collectively, these issues challenge the Program's ability to operate as effectively and efficiently as possible.

Encouragingly, some improvement efforts are already underway. The Program has successfully implemented AI to improve efficiency in some areas, developed adaptive frameworks for emerging technologies, is working on developing frameworks to clarify roles and responsibilities in key areas like classification issues, and is trying to improve collaboration with DTB. These initiatives provide a strong foundation to address identified challenges; however, further action is needed to clarify roles, strengthen collaboration, and

modernize tools to sustain effectiveness in an evolving technological and regulatory environment.

Recommendations

Building on the findings of this evaluation, the following three recommendations are designed to address the most critical issues identified.

Recommendation 1: Clarify and communicate internal roles and responsibilities across the Program, especially for ongoing device classification issues post market.

Outdated, poorly communicated, or missing documentation on roles and responsibilities has led to role confusion, delays, duplicated work, and fragmented coordination, especially in device classification issues that arise post-market and in incident reporting. Clearly defining and consistently communicating roles and responsibilities would help streamline processes, strengthen cross-branch collaboration, and enhance the Program's responsiveness and effectiveness in managing incidents.

Recommendation 2: Strengthen internal coordination, collaboration, and communication across all Program partners.

Collaboration within the Program often relies on inconsistent, ad hoc practices rather than proactive, structured engagement. Siloed teams within and across Program partners have led to a reliance on informal networks instead of established processes, governance bodies, and regular communication. Governance bodies such as the MDP Trilateral and MDP Committee exist but remain underused or poorly understood, limiting their value as strategic decision-making forums. Collaboration between the Program and DTB has presented some challenges for managing and integrating the Program's IT tools. Improving coordination, collaboration, and communication would promote unified, program-wide operations and ensure consistent, transparent, and strategic decision-making.

Recommendation 3: Explore opportunities to modernize tools to improve efficiency; enhance data integration across directorates; and adopt AI and other innovative technologies.

The Program's fragmented and poorly integrated IT systems, particularly ARIS-G and MDS, contribute to backlogs, data silos, and duplicated work that delay incident processing and hinder coordinated regulatory decisions. Efficiency is restricted by ARIS-G's design, which is intended for drugs rather than devices, and by the MDS, whose aging

architecture requires future investment. Siloed reporting tools like Cognos and Tableau prevent a unified view of medical device risks and activities. Implementing an incremental modernization approach to tools, better data integration, and the adoption of emerging technologies like AI would enable faster incident processing, stronger surveillance, enhanced compliance monitoring, and greater regulatory analytic capabilities.

Appendix A: Methodology

Evaluation Questions

The evaluation addressed the following questions:

Effectiveness: How have the Medical Devices Program's main activities helped ensure Canadians have access to safe, effective, and quality medical devices?

- a) To what extent was the industry informed of and compliant with regulatory requirements?
- b) Were partners, stakeholders, and Canadians informed of the risks and benefits of medical devices, and were they using this information to inform their decisions?
- c) Did the Program take a coordinated approach with partners and stakeholders?

Efficiency: How efficient were the Program's design and its implementation?

- a) Were the roles and responsibilities of Program partners clear? What governance structures and other measures were in place to ensure a coordinated effort by HPFB, ROEB, and key stakeholders?
- b) Were activities and the level of resources allocated appropriately for the Program to meet its mandate across pre- and post-market and compliance and enforcement activities?
- c) Were appropriate tools available to support Program activities?
- d) How nimble and flexible was the Program in adapting to changing environments, risks, and challenges?

Data Collection Sources and Methods

The evaluation draws on multiple lines of evidence to support the assessment of the effectiveness and efficiency of Health Canada's Medical Devices Program from April 2020 to March 2025.

Document and Performance Information Review

We reviewed approximately 550 internal documents, including:

- Planning and monitoring tools like monthly dashboards, operational plans, and engagement plans;

- Governance and meeting records, including committee terms of reference and Records of Decision;
- Corporate and performance reporting like Departmental Results Reports, mid-year updates, and status reports;
- Training and procedural documents, including training modules and Standard Operating Procedures (SOPs);
- Internal communications, including presentations, briefing notes, speaking points, and memos;
- Policy and regulatory documents, such as guidance documents, Canada Gazette submissions, and consultation drafts; and
- Public-facing resources, including the Health Canada website.

Internal and external interviews

We conducted 37 interviews with 55 interviewees from the following groups:

- Health Canada officials from HPFB, ROEB, DTB, and Communications and Public Affairs (CPAB) (27 interviews with 39 staff);
- Medical Devices Industry (5 interviews with 6 representatives);
- Non-governmental organizations (4 interviews with 9 representatives); and
- Foreign governments (1 interview with 1 representative).

Case studies

We conducted three case studies. The first case study examined the extent to which industry stakeholders were informed of, and compliant with regulatory requirements, with a focus on highlighting challenges in the qualification and classification of energy-based cosmetic medical devices like therapeutic lasers, intense pulsed light devices, and light-emitting diodes. These devices use targeted energy to perform non-surgical cosmetic procedures, including hair removal, skin rejuvenation, and acne treatment. Most are considered non-invasive and classified as Class II medical devices, though higher-powered or deeper-tissue devices may be considered Class III due to increased risk. The second case study assessed how the clarity of roles and responsibilities had shaped decisions around the classification of intraoral cameras. The third case study explored the

Program's ability to be responsive and keep pace with emerging technologies, including Software as a Medical Device (SaMD) and AI-based diagnostic software.

- **Documents:** For these case studies, we reviewed approximately 60 internal and publicly available program documents, including:
 - Guidance and policy documents;
 - Regulatory and compliance records, including refusal letters, classification reports, and evaluation reports;
 - Communications, including email correspondence, internal memoranda, and presentations;
 - Reports and reference lists, including summaries of international collaborations, incident lists, and error reports;
 - Meeting records, including notes from internal and external meetings; and
 - Public-facing resources, including the Health Canada website and international standards.
- **Interviews**

As part of the case study line of evidence for this evaluation, we conducted 15 interviews with 21 participants from the following groups:

- Health Canada officials from HPFB and ROEB (9 interviews with 14 staff);
- Medical device industry (5 interviews with 6 representatives); and
- Experts (1 interview with 1 representative).

Stakeholder survey

In summer 2025, we conducted a bilingual online survey of Program stakeholders. The survey was distributed to 11,344 email addresses. Potential respondents included active MDEL and MDL holders, investigators, advisory committee members, industry and professional associations, CMDNet members, and organizations that submit post-market reports. After removing duplicates and invalid addresses, the survey reached 9,449 unique recipients. Between May 26 and June 16, 2025, we received 774 complete responses, resulting in a response rate of 8.19%.

Among respondents, 79% represented industry, including manufacturers, importers, distributors, and suppliers, while 8% represented medical or health care professional organizations. Just over half (52%) represented small organizations (1 to 50 employees), while 27% represented large organizations (200+ employees) and 21% from medium-sized organizations (51 to 200 employees). In terms of location, 43% of respondents were based outside of Canada. Within Canada, the most represented provinces were Ontario (37%) and Quebec (16%). The survey gathered feedback on key aspects of the Program, including regulatory communication, understanding and compliance, risk and benefit communication, the use and effectiveness of regulatory tools, and the Program’s overall performance.

Performance data review

We reviewed data from the Program’s Performance Information Profile and other internal sources, including web analytics data.

Financial data review

We reviewed planned and actual expenditures for both HPFB and ROEB from fiscal years 2020-2021 to 2024-2025 that were provided by Chief Financial Officer Branch officials assigned to each branch.

Limitations

The following table identifies limitations and mitigation strategies adopted for this evaluation.

Table 4: Limitations, impacts and approach for addressing them

Limitations	Impact on evaluation	Approach for addressing the limitation
Internal stakeholders are overrepresented in the interviews, while external stakeholders are underrepresented.	Findings may overemphasize internal perspectives and downplay external stakeholders' concerns.	Case study interviews and an online survey with 774 respondents captured additional external perspectives.
The evaluation relied heavily on program documents.	Some findings may reflect the Program's intent more than actual implementation.	Interviews and performance data were used to triangulate the document review results to ensure a broad understanding of the issues.
For the survey, OAE did not have full demographic information (e.g., stakeholder type, region, organization size) on the various distribution lists.	Without demographic data on the full distribution list, the evaluation cannot verify the representativeness of survey respondents.	While complete demographic distribution information was unavailable, comparing the respondent sample to available distribution list data revealed reasonable alignment overall. Furthermore, triangulation of the survey results with case studies, and external interviews provided evidence to support key survey findings.

The evaluation applied a Sex- and Gender-Based Analysis Plus (SGBA Plus) lens to Program activities to determine the extent to which equity issues were considered and applied by the Program. It found no concerns regarding official languages, as the Program provides all materials on Health Canada's website in both official languages and works with stakeholders and partners in their official language of choice. The evaluation determined that the Truth and Reconciliation Commission's Calls to Action were not directly applicable because the Medical Devices Program regulates medical device safety,

quality, and access for all Canadians, without direct engagement in Indigenous-specific initiatives.

The evaluation confirmed that Goal 3: Good Health and Well-Being of the United Nations Sustainable Development Goals applies directly to the Medical Devices Program. Specifically, target 3.8, which aims to achieve universal health coverage, including access to quality essential health care services and medicines or devices, aligns with the Program's objective to ensure access to safe, effective, and high-quality medical devices for all Canadians.

To conduct the evaluation, a single window was identified at HPFB and ROEB, with whom OAE collaborated closely throughout the process. The scoping deck was presented to Health Canada's Performance Measurement and Evaluation Committee (PMEC) on March 25, 2025, in order to review and confirm the key evaluation questions. Preliminary findings were presented to PMEC on October 28, 2025, and the final report and MRAP were presented at PMEC on January 27, 2026.

Appendix B: Examples of Post-Market Risk Communications

Stakeholders	Public
Dear Health Care Professional Letters	MedEffect e-Notice
CMDNet bulletins (e.g., MDEL licensing updates, monthly reports, and email communications)	Summary Safety Reviews (SSRs)
Health Product Risk Communications (HPRCs)	Recalls and Safety Alerts Database
Health Product InfoWatch (clinical safety information)	Social Media Outreach (e.g., X, Instagram)
Label revisions to COVID-19 medical devices (e.g., test kits)	Public Advisories

	Planned (\$)	Actual (\$)	Variance (\$)	% of Planned
HPFB				
Total Salary	158,844,187	148,760,523	10,083,664	94%
O&M	8,687,312	4,754,415	3,932,897	55%
Total	167,531,499	153,514,938	14,016,561	92%
Cost Recovery	60,571,981	56,113,135	4,458,846	93%
Net Total	106,959,518	97,401,803	9,557,715	91%
ROEB				
Total Salary	103,228,902	113,706,535	-10,477,633	110%
O&M	11,427,583	6,632,372	4,795,211	58%
Total	114,656,485	120,338,907	-5,682,422	105%
Cost Recovery	77,713,734	88,902,286	-11,188,552	114%
Net Total	36,942,751	31,436,621	5,506,130	85%
HPFB & ROEB				
Total Salary	262,073,089	262,467,058	-393,969	100%
O&M	20,114,895	11,386,787	8,728,108	57%
Total	282,187,984	273,853,845	8,334,139	97%
Cost Recovery	138,285,715	145,015,421	-6,729,706	105%
Net Total	143,902,269	128,838,424	15,063,845	90%

Financial Information – HPFB by Fiscal Year

	Planned (\$)	Actual (\$)	Variance (\$)	% of Planned
2020-2021				
FTE	208	217	-9	105%
Total Salary	27,492,090	27,824,436	-332,346	101%
O&M	1,748,336	1,137,163	611,173	65%
Total	29,240,426	28,961,599	278,827	99%
Cost Recovery	10,003,999	10,528,652	-524,653	105%
Net Total	19,236,427	18,432,947	803,480	96%
2021-2022				
FTE	240	249	-9	104%
Total Salary	38,391,228	32,664,281	5,726,947	85%
O&M	1,803,812	718,200	1,085,612	40%
Total	40,195,040	33,382,481	6,812,559	83%
Cost Recovery	11,498,324	10,366,236	1,132,088	90%
Net Total	28,696,716	23,016,245	5,680,471	80%
2022-2023				
FTE	144	231	-87	160%
Total Salary	34,846,539	30,931,041	3,915,499	89%
O&M	2,117,758	1,271,576	846,182	60%
Total	36,964,297	32,202,617	4,761,681	87%
Cost Recovery	11,128,311	10,186,217	942,094	92%
Net Total	25,835,986	22,016,400	3,819,587	85%

2023-2024				
FTE	158	204	-45	129%
Total Salary	31,155,348	30,648,855	506,493	98%
O&M	1,056,830	643,794	413,036	61%
Total	32,212,178	31,292,649	919,529	97%
Cost Recovery	13,724,079	12,153,127	1,570,952	89%
Net Total	18,488,099	19,139,522	-651,423	104%
2024-2025				
FTE	141	180	-39	128%
Total Salary	26,958,982	26,691,910	267,072	99%
O&M	1,960,576	983,682	976,894	50%
Total	28,919,558	27,675,592	1,243,966	96%
Cost Recovery	14,217,268	12,878,903	1,338,365	91%
Net Total	14,702,290	14,796,689	-94,399	101%

Financial Information – ROEB by Fiscal Year

	Planned (\$)	Actual (\$)	Variance (\$)	% of Planned
2020-2021				
FTE	160	148	12	93%
Total Salary	18,855,339	19,170,402	-315,063	102%
O&M	2,965,086	1,548,110	1,416,976	52%
Total	21,820,425	20,718,512	1,101,913	95%
Cost Recovery	14,836,526	16,124,464	-1,287,938	109%
Net Total	6,983,899	4,594,048	2,389,851	66%
2021-2022				
FTE	161	169	-7	104%
Total Salary	19,021,280	21,995,823	-2,974,543	116%
O&M	3,046,044	1,570,992	1,475,052	52%
Total	22,067,324	23,566,815	-1,499,491	107%
Cost Recovery	15,133,257	23,842,452	-8,709,195	158%
Net Total	6,934,067	-275,637	7,209,704	-4%
2022-2023				
FTE	175	167	8	95%
Total Salary	24,368,723	22,527,999	1,840,724	92%
O&M	183,324	1,209,721	-1,026,397	660%
Total	24,552,047	23,737,720	814,327	97%
Cost Recovery	15,847,750	15,049,964	797,786	95%
Net Total	8,704,297	8,687,756	16,541	100%

2023-2024				
FTE	137	162	-25	119%
Total Salary	20,158,045	25,035,032	-4,876,987	124%
O&M	2,783,901	1,279,064	1,504,837	46%
Total	22,941,946	26,314,096	-3,372,150	115%
Cost Recovery	15,952,936	17,144,225	-1,191,289	107%
Net Total	6,989,010	9,169,871	-2,180,861	131%
2024-2025				
FTE	130	167	-37	128%
Total Salary	20,825,515	24,977,279	-4,151,764	120%
O&M	2,449,228	1,024,485	1,424,743	42%
Total	23,274,743	26,001,764	-2,727,021	112%
Cost Recovery	15,943,265	16,741,181	-797,916	105%
Net Total	7,331,478	9,260,583	-1,929,105	126%

Financial Information – HPFB and ROEB by Fiscal Year

	Planned (\$)	Actual (\$)	Variance (\$)	% of Planned
2020-2021				
FTE	367	365	2	99%
Total Salary	46,347,429	46,994,838	-647,409	101%
O&M	4,713,422	2,685,273	2,028,149	57%
Total	51,060,851	49,680,111	1,380,740	97%
Cost Recovery	24,840,525	26,653,116	-1,812,591	107%
Net Total	26,220,326	23,026,995	3,193,331	88%
2021-2022				
FTE	402	418	-16	104%
Total Salary	57,412,508	54,660,104	2,752,404	95%
O&M	4,849,856	2,289,192	2,560,664	47%
Total	62,262,364	56,949,296	5,313,068	91%
Cost Recovery	26,631,581	34,208,688	-7,577,107	128%
Net Total	35,630,783	22,740,608	12,890,175	64%
2022-2023				
FTE	319	398	-79	125%
Total Salary	59,215,262	53,459,039	5,756,223	90%
O&M	2,301,082	2,481,297	-180,215	108%
Total	61,516,344	55,940,337	5,576,008	91%
Cost Recovery	26,976,061	25,236,181	1,739,880	94%
Net Total	34,540,283	30,704,156	3,836,128	89%
2023-2024				

FTE	295	366	-71	124%
Total Salary	51,313,393	55,683,888	-4,370,495	109%
O&M	3,840,731	1,922,858	1,917,873	50%
Total	55,154,124	57,606,745	-2,452,621	104%
Cost Recovery	29,677,015	29,297,352	379,663	99%
Net Total	25,477,109	28,309,393	-2,832,284	111%
2024-2025				
FTE	272	347	-76	128%
Total Salary	47,784,497	51,669,189	-3,884,692	108%
O&M	4,409,804	2,008,167	2,401,637	46%
Total	52,194,301	53,677,356	-1,483,055	103%
Cost Recovery	30,160,533	29,620,084	540,449	98%
Net Total	22,033,768	24,057,272	-2,023,504	109%

Endnotes

¹ Health Canada, Joint Audit and Evaluation of the Medical Devices Program 2013-14 to 2019-20, 2020; Available from: <https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation/joint-audit-evaluation-medical-devices-program-2013-2014-2019-2020.html>

² Health Canada, Vaginal surgical mesh: Risks, 2022; Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/vaginal-surgical-mesh/risks.html>

³ Health Canada, Ways to stay informed about medical devices, 2024; Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/subscribe.html>

⁴ Government of Canada, Health Canada and the Public Health Agency of Canada's report on red tape reduction, 2025; Available from: <https://www.canada.ca/en/services/health/publications/health-system-services/report-red-tape-reduction.html>

⁵ Government of Canada, Regulatory Sandbox, 2025; Available from: <https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/regulatory-sandbox.html>