Regulatory Rapporteur

Overview of medical device regulations in Canada

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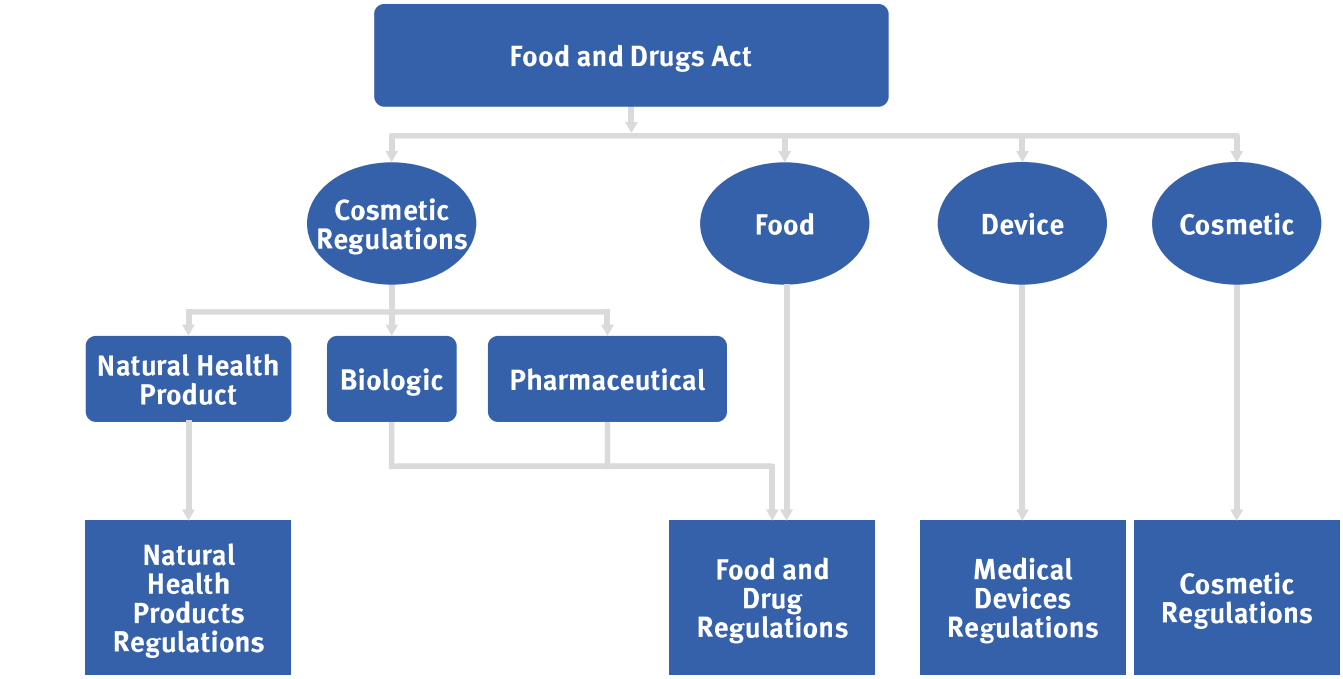
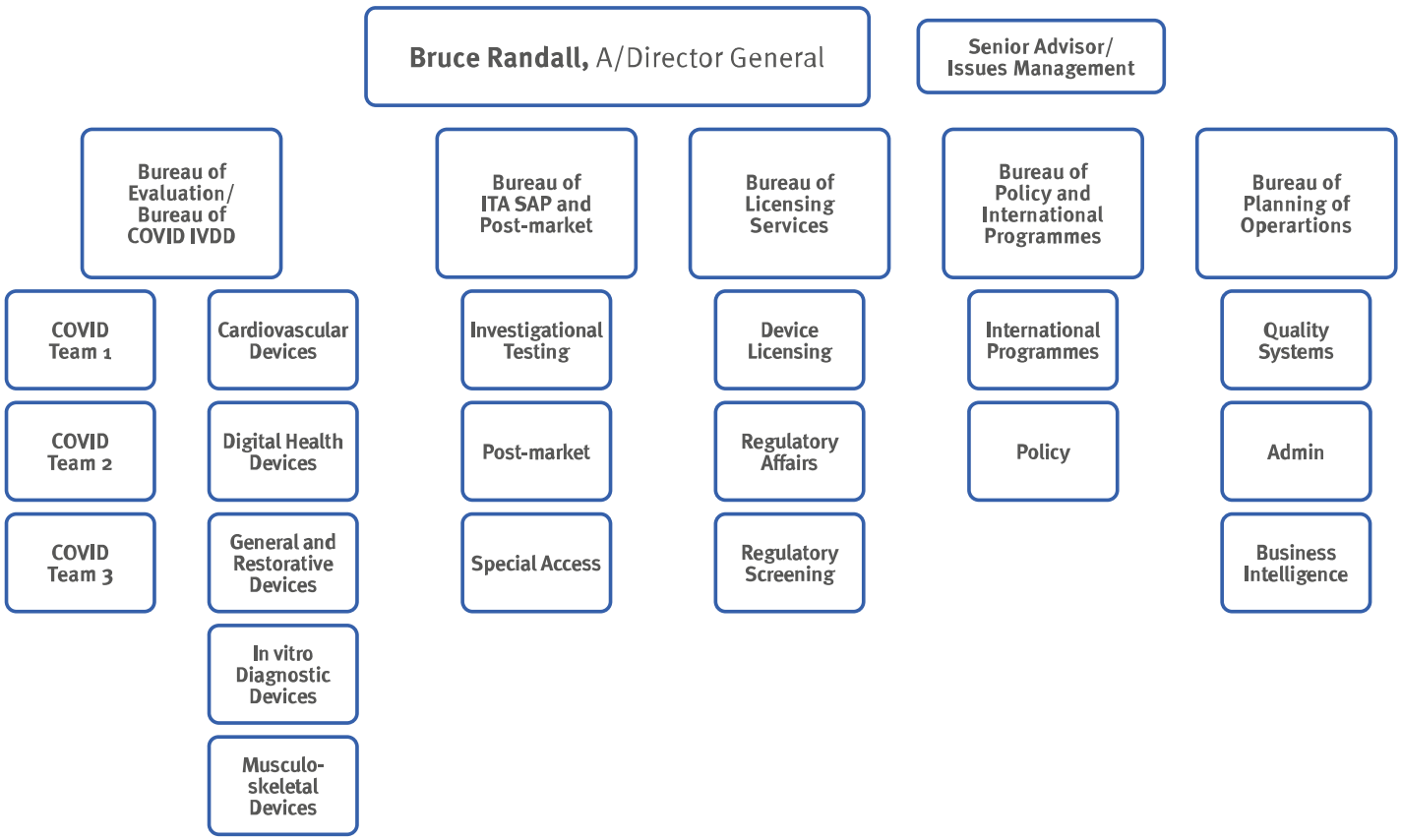
Abstract

Despite being a relatively small jurisdiction, Canada's Medical Device Directorate (MDD) plays a dynamic role in shaping global regulations and taking a leadership role in regulatory harmonisation and convergence. From close collaborations with the US FDA to consortiums with major regulators from Brazil to Australia, the MDD works hard to ensure no interruption to health product supply and provides support for innovation and trust building with patients. Health Canada has a culture of inclusiveness, dialogue, pragmatism and global vision which are necessary values in today's ever more stringent regulatory environment. This article introduces the regulatory framework for medical devices and discusses some key initiatives undertaken by Health Canada.

The Canadian regulatory framework

Health Canada is the federal department of the Government of Canada responsible for the national health policy. As the country's federal health authority, it has the mandate of developing, implementing and enforcing health policies, regulations and programmes. Medical devices are regulated under the Food and Drugs Act which is enforced by the Health Products and Food Branch (see **Figure 1**). Additionally, Health Canada is also accountable for matters related to public health issues and emergencies. The Environmental and Workplace Health Branch assesses and manages risks related to environmental factors affecting health.





SOURCE: *Health Canada (2022) Government of Canada, Canada.ca. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/classification-products-food-drugs-act.html (Accessed: 25 December 2023)*

Figure 1:
Classification of products under the Food and Drugs Act (F&DA)[1]

Overall, Health Canada's primary mission is to protect and support the wellbeing of Canadians by regulating health products, monitoring public health trends and collaborating with provincial and territorial partners to enhance the nation's health outcomes.**[2]** The regulatory agency has always strived to play an active role in global harmonisation efforts through contributing to committees including the International Medical Device Regulators Forum (IMDRF) and the Global Harmonization Task Force (GHTF). Health Canada also works very closely with the US Food and Drug Administration (FDA), the UK's Medicines and Health Products Regulatory Agency (MHRA) and Australia's Therapeutic Goods Administration (TGA) to develop partnerships. One such partnership includes the eSTAR pilot programme, an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission following the table of contents (ToC) format, initially developed by the International Medical Device Regulatory Forum (IMDRF) and made mandatory in Canada in April 2019**.[3][4]**

Mutual recognition agreements (MRAs) are agreements between countries or regions where specific evidence and documentation, issued by specific overseas regulators and assessment bodies, may be considered by participating regulators to allow for full recognition of the market approval or conformity assessment process abridgement for applications for the licensing of medical devices. For example, in Australia, Canadian approvals, licences and Medical Device Single Audit Programme (MDSAP) reports that cover Australian regulations, and ISO 13485 certifications by an auditing organisation accredited by the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA), are accepted and can be leveraged to gain access to the Australian market.**[5]** Most Association of Southeast Asian Nations (ASEAN) competent authorities have a clear definition of a reference country whereby device licences issued by these jurisdictions qualify manufacturers for abridged, expedited and sometimes immediate evaluation routes.**[6]** Health Canada is recognised in the ASEAN jurisdiction as a reference regulator and approvals by the agency can be used to leverage abridged registrations in the region.

In addition to the agency's commitment to global harmonisation, recent scandals around medical device safety, specifically breast implants and related data dumps unveiled by investigative journalists, have pushed Canadian regulators to strengthen their post-market compliance and data transparency. The agency is also involved in the development of regulatory principles for emerging technologies such as the Artificial Intelligence and Data Act (AIDA), a horizontal act that is expected to impact the ways that medical devices are assessed for approval.**[7][8]**

In summary, while Canadian medical device regulations remained relatively stable, the Canadian medical device regulatory framework continues to evolve in service of medical device innovation, with a genuine commitment to international collaboration, continuous supply of devices and patient safety.

Medical device licensing in Canada

In Canada, the licensing of medical devices is regulated by Health Canada through the Medical Devices Regulations (SOR/98-282) under the Food and Drugs Act.[9]

Health Canada categorises medical devices into four classes (Class I, II, III, and IV) based on the level of risk associated with their use. The classification determines the regulatory requirements and the type of evidence needed for licensing. The regulation defines 16 rules and the risk classification for each one of them. These rules are organised by device type as shown in **Figure 2**. Rule 16 applies to breast implants and tissue expanders for breast reconstruction and augmentation which, despite rules 1 to 15, are classified as Class IV devices in Canada.

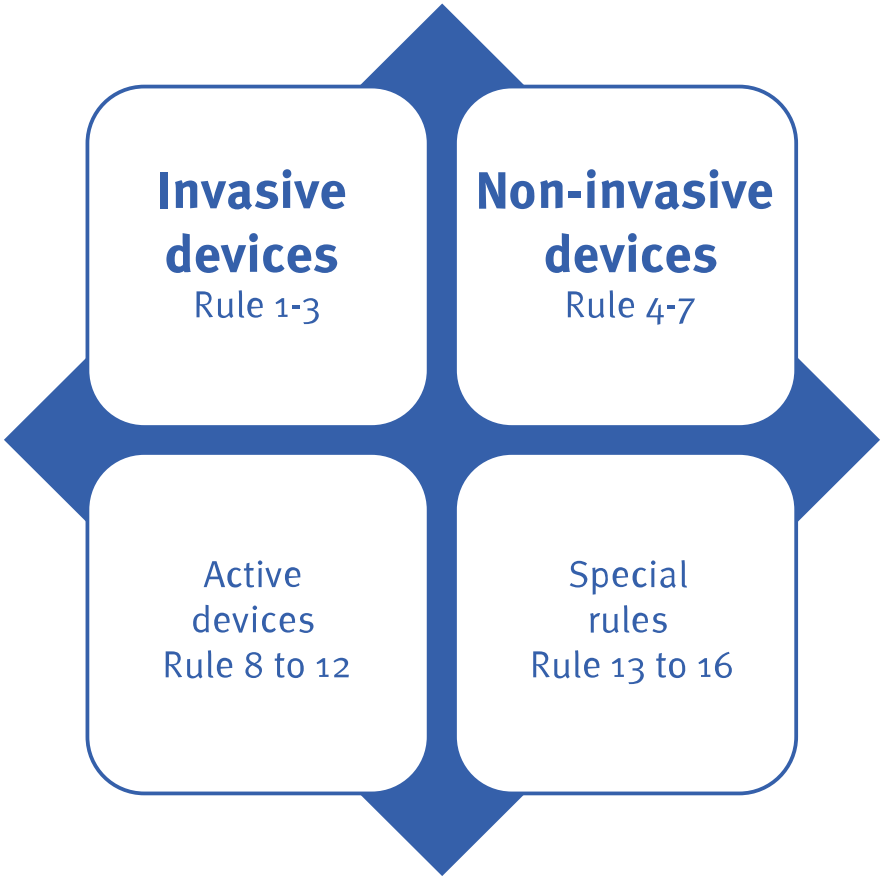


Figure 2:
Canadian Medical Device Regulation (SOR98/282) medical device risk class groups

In addition to these rules, Health Canada also issued the 'Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices'.**[10]** This index is intended to assist manufacturers in confirming the classification of medical device products after application of the Classification Rules for Medical Devices set out in *Schedule 1* of the medical device regulations. However, during its annual regulatory and quality conference in June 2023, Health Canada admitted that the keyword index is 'officially outdated'. The agency is working on new classification guidance that will also incorporate the global medical device nomenclature (GMDN) codes to align with global nomenclature. The agency is also planning to add the intended use and GMDN code to the Medical Device Active Licence List (MDALL) database.**[11]**

Beyond its mandate to establish, promote and ensure the safety, efficacy and quality of health products and services, the department also has the responsibility of specifying the Safety and Effectiveness Requirements (Sections 10 to 20) and Labelling Requirements (Sections 21-23) which all medical devices must meet. Because these requirements are stated in general terms in the regulations, both manufacturers and Health Canada must set clearly defined criteria for determining whether a device meets these requirements.

One way to provide such criteria is to make use of standards issued by national or international standards writing organisations, such as the International Standards Organization (ISO) or the Association for the Advancement of Medical Instrumentation (AAMI). Like the EU harmonised standards, Health Canada accepts conformance with a recognised medical device standard to be a presumption to comply to the regulation, and therefore an assurance of safety and effectiveness for those aspects of medical devices addressed by the standard. However, not all devices or elements of device safety and effectiveness may be addressed by recognised standards, especially for new types of devices and emerging technologies.

The use of recognised standards can improve consistency in the interpretation of the regulations. Specifically, if an application for a medical device licence or authorisation contains a declaration of conformity to a recognised standard, this will in many cases eliminate the need to review the actual test data for those aspects of the device addressed by the standard. In some cases, conformance with recognised standards may not always be a sufficient basis for regulatory decisions.**[12]**

Efforts are continuously made to harmonise Canada's requirements with those of other countries. Such efforts include using international standards wherever possible to reduce regulatory burden and enable safe, effective quality products to enter the Canadian markets more quickly.

Pre-market review and licencing pathways

Most medical devices in Canada require pre-market review and approval before they can be sold.

Class I devices are of lower risk and generally subject to the least regulatory control. Manufacturers must simply notify Health Canada before selling the device by submitting a medical device establishment licence application form. Class II, III, and IV devices require a medical device licence (MDL) from Health Canada and typically undergo a more rigorous review process of scientific and clinical evidence supporting the device's safety and efficacy. This evidence may include clinical trial data, performance testing, manufacturing information and other relevant documentation. There are different licensing pathways based on the risk class of the medical device (**Figure 3**).

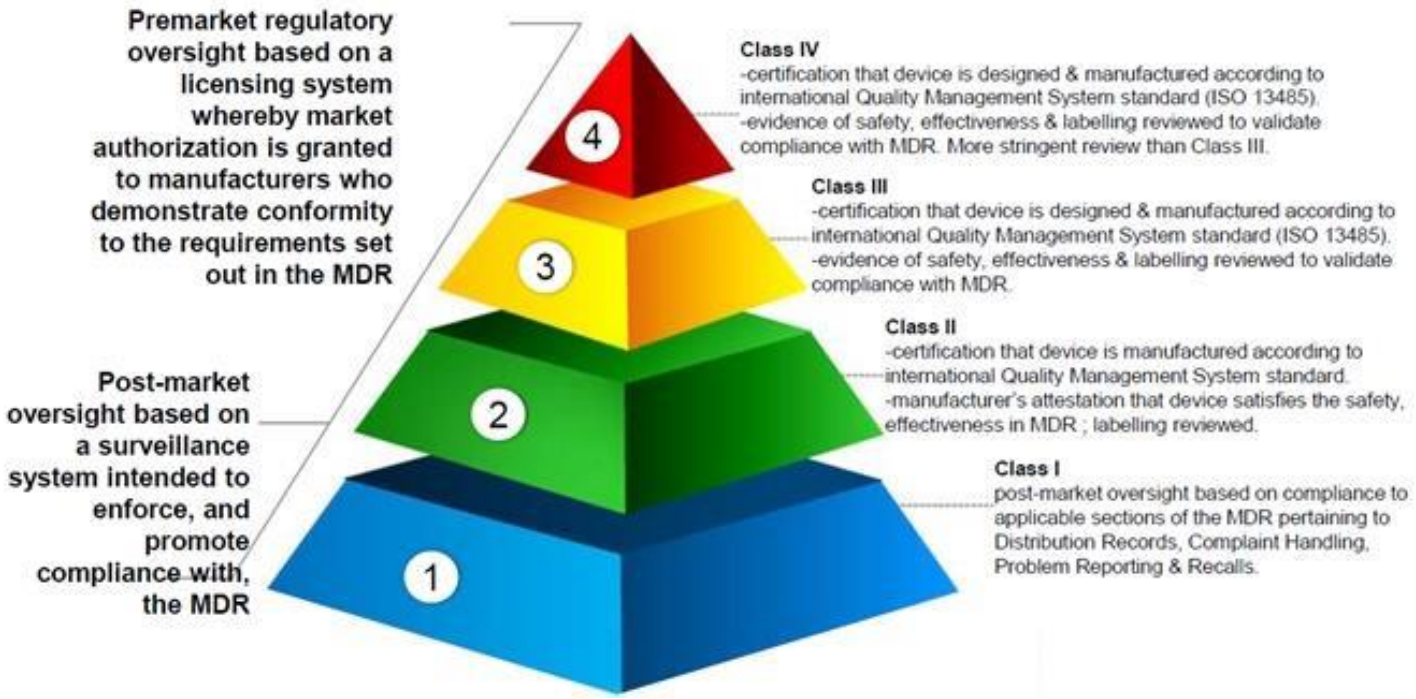


Figure 3.
Health Canada regulatory requirements per medical device risk class

Manufacturers submit a detailed application to Health Canada, including all necessary documentation and evidence (**Table 1**). The submission undergoes a thorough review by Health Canada's Medical Devices Bureau and should follow the IMDRF ToC format. If Health Canada determines that the

device meets the regulatory requirements, a MDL is issued. The licence allows the manufacturer to sell the device in the Canadian market.

Required Submission Documents					Regulatory Requirements				
Responsible Parties	Manufacturer			All parties engaged in importation or sales activities	Manufacturer Importer Distributor			Manufacturer Importer	
Documentation	Medical device licence application and fee form	Objective evidence for safety & effectiveness	Quality Management System (QMS) Certificate	Compliant label	Complaint Handling Record	Distribution Records	Must hold an active establishment licence	Recall Notice	Mandatory Problem Preliminary and Final Report
Class I	Requires Medical Device Establishment Licence			✔	✔	✔	✔	✔	✔
Class II	✔	Provide attestation	✔	✔	✔	✔	Exempt if holding an active medical device licence	✔	✔
Class III / IV	✔	✔	✔	✔	✔	✔	Exempt if holding an active medical device licence	✔	✔

Table 1: Health Canada submission requirements per device risk class[13]

Medical device establishment licence

Typically, establishments that import, distribute, or sell medical devices in Canada need to obtain a medical device establishment licence (MDEL) from Health Canada. All active medical device establishment licences can be found on Health Canada's website which lists all manufacturers on the database.**[14]** The process to obtain an MDEL starts with determining the eligibility of the applicant.

The application for an MDEL is achieved through form FRM-0292 and can take up to 120 days for Health Canada to review and approve.**[15]** The MDEL must also be renewed every year before 1 April. Information required to submit an MDEL application includes details about the establishment, the types of medical devices involved and the quality management system (QMS) in place. In Canada, manufacturers of devices of Class II and above must have a QMS in place to ensure the consistency and quality of their processes and products. Like all reference regulators, manufacturers are often required to comply with ISO 13485:2016, an international standard for medical device quality management.

Licensed establishments are expected to maintain ongoing compliance with the regulations and report any changes to Health Canada, such as changes in key personnel, addresses or modifications to the QMS. It is worth mentioning that the specific requirements and processes may vary depending on the nature of the medical devices and the activities of the establishment.

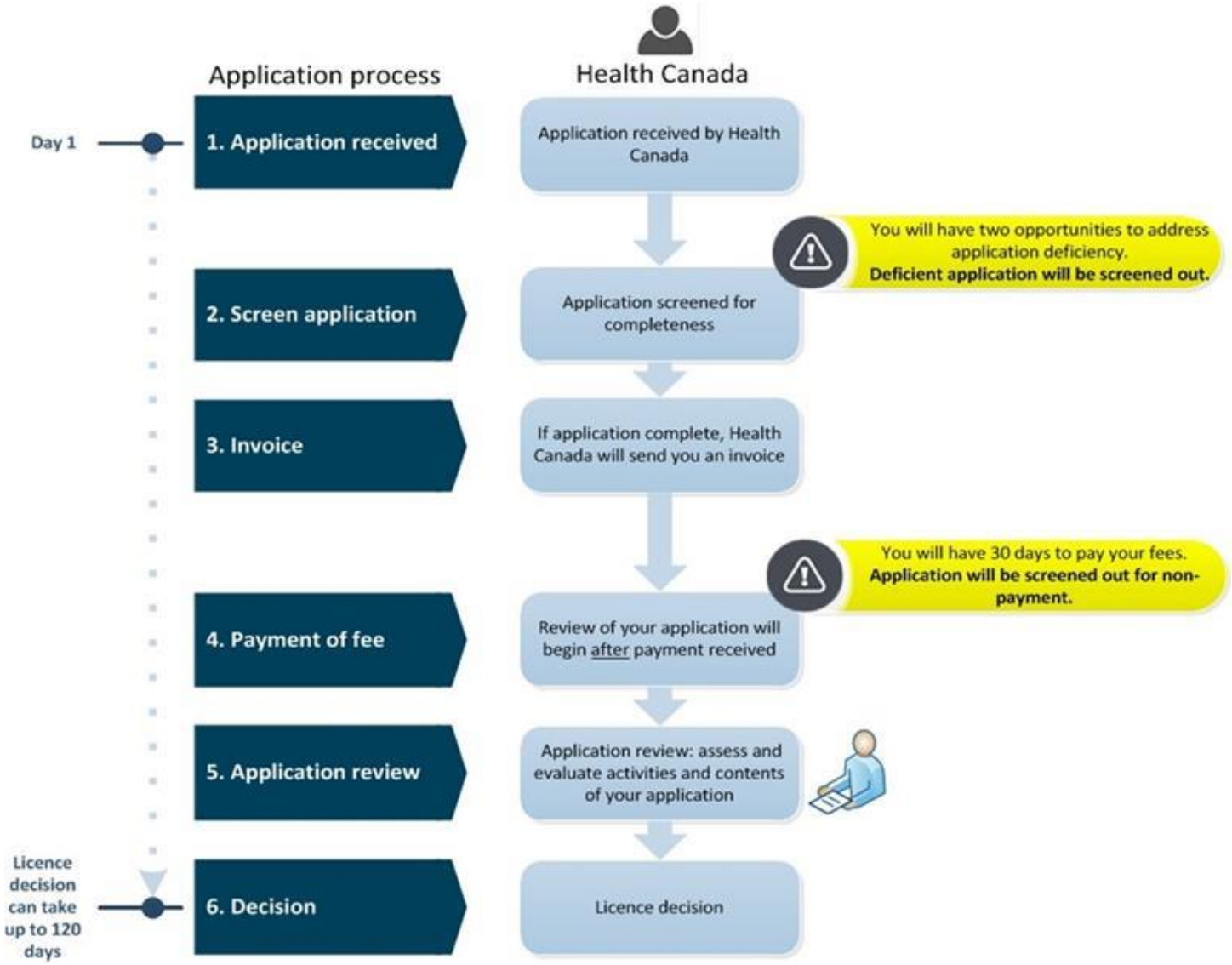


Figure 4:
Medical device establishment licence (MDEL) application process[16]

Regulatory enrolment process (REP)

The regulatory enrolment process (REP) is planned to be a set of web-based templates, which will be used to collect information from manufacturers on the company, dossiers, devices, regulatory activities and transactions, including a single process for all regulatory transactions and regulatory activities filed through the Common Electronic Submissions Gateway (CESG)**2**. The REP will be

available for Class II, III and IV licence applications, licence amendments, minor change amendments (faxbacks), including manufacturer name and/or address change, private label applications and private label amendments. Health Canada intends to make regulatory enrolment process mandatory within 18 months from the implementation date of July 2024. The hope is to have a more efficient and secure platform, compared to using courier and email, which will enhance accuracy, consistency and reliability of the information captured.

Health Canada summary reports

In June 2021, Health Canada implemented the summary report which is a requirement applicable to all licence holders including private labelers. Health Canada expects a concise and critical analysis generated from information such as adverse events, problem reports to the manufacturer, importer or distributor related to the device performance and safety, incidents and risks of injury received about the use of their licensed device(s).**[17]**

Manufacturers are not required to share the summary reports with Health Canada unless there was a change in the risk profile of the medical device. However, manufacturers should expect auditing organisations (AOs) to be looking into the processes and related procedures put in place to ensure the summary report requirements are fulfilled including record keeping for seven years and foreign risk notifications procedures. Finally, manufacturers present on the EU market can leverage the EU MDR periodic safety update report (PSUR) as a summary report, as long as Canadian data and requirements are also accounted for and reflected in the report.**[18]**

Medical Device Single Audit Program (MDSAP)

The Medical Device Single Audit Program (MDSAP) was initiated at the International Medical Devices Regulators Forum (IMDRF) inspired by the Canadian Medical Devices Conformity Assessment System (CAMDCAS) where Health Canada required Canadian requirements to be reviewed within the ISO13485:2003 audits. Several other jurisdictions thought it was a good approach and got together to start the MDSAP programme. So far, and despite a lot of industry pushback, Canada is the only country to make the MDSAP mandatory. This is to say, manufacturers cannot sell their devices in the Canadian market without an MDSAP certificate.**[19]** As such, MDSAP audits are not only an audit of the QMS but also include additional regulatory requirements such as registration of manufacturing sites, licensing of medical devices, reporting of adverse events and advisory notices and device tracking. There are five base consortium regulators including Australia, Brazil, Canada, the US and Japan.

It is a three-party system involving regulators, AOs and manufacturers. In this system, regulators assess the AOs and then AOs audit the manufacturers. Audit reports and AO designation status are

saved on the MDSAP IT portal hosted by the Pan-American Health Organization (PAHO). While the programme was initially not popular due to the associated cost, key regulatory agencies including the MHRA, Mexico, Taiwan, South Korea and Singapore have gained interest.**[20] [21]**

Most recently, the EU stepped out of its observer-only status and issued the MDCG 2020-14 guidance on the use of MDSAP audit reports in the context of surveillance audits carried out under the MDR and the In Vitro Diagnostic Medical Devices Regulation (IVDR).**[22]** The new UK regulatory system could make provisions to take MDSAP assessments into account, in fact it is expected that the UK approved bodies will also be AOs under MDSAP and in most cases, this should be a seamless process. However, there will be some AOs who do not have an affiliation with a UK approved body.

MDSAP accredited AOs are typically also EU designated notified bodies (NB). With the surge in requests for MDR QMS upgrade audits, the EU's refusal to allow simultaneous MDSAP and MDR QMS, manufacturers with existing devices on the Canadian market or those intending to place devices on the Canadian market must wait longer to schedule audits. Health Canada also saw its capacity impacted by significant change submissions due to changes in labelling initiated to comply with the EU MDR requirements.

Conclusion

In the absence of a fully harmonised global medical device regulation, Health Canada's MDD proactively and consistently prioritises harmonisation and the use of existing structures to regulate medical devices. The agency's efforts are recognised through its active contribution and implementation of IMDRF's recommendations and guidances, its close collaboration with key agencies and its implementation of EU best practices. Furthermore, its ability to embrace global generic descriptors such as GMDN without sacrificing local regulatory specificities by requiring MDSAP certification.

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