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Medical Devices Directorate Performance Quarterly Report

Q2-2022/23 July through September

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Overview

This Quarterly Performance Report reflects activities of the Medical Devices Directorate (MDD) of Health Canada over the last five consecutive Quarters.

MDD is required to meet performance targets so that decisions are made in a timely manner

The report is broken into three sections reflecting the three Parts of the *Medical Devices Regulations (MDR)*. The following statistical tables provide a snapshot of MDD activities and include the number of applications received, workload, and recommended decisions.

The updated Cost Recovery Fee Categories[1] introduced on April 1st 2011, and updated on April 1, 2020, have been included in the report. Performance is measured against the performance standards for Submission Type/Class/Status combinations as set out in the Management of Applications for Medical Device Licences.

General Information

The term “medical devices” encompasses a wide range of medical, surgical, and dental products and instruments and diagnostics to diagnose, treat and prevent diseases and other physical ailments. They range from basic items, such as bandages, to increasingly complex devices such blood donor screening tests, diagnostic ultrasound, pacemakers and other implanted technologies.

Medical devices play an important role in the health and well-being of patients by helping to prevent, diagnose, and treat disease, to reduce pain and suffering, and to extend and save lives. Medical devices are increasing in number and complexity due to technological advances.

As required under the *Food and Drugs Act*, Health Canada regulates the safety and effectiveness of all medical devices marketed in Canada. It does this through a combination of scientific review before devices are authorized for sale, monitoring, as well as compliance and enforcement activities after the devices reach the Canadian market place.

Medical devices in Canada are categorized into four Classes (I, II, III and IV) on the basis of the risks associated with their use and the controls necessary to provide reasonable assurance that they are safe and effective.

The *Medical Devices Regulations* provide three means by which manufacturers can sell devices in Canada: under the general provisions (Part 1), which include licensing for Class II, III and IV devices; by individual authorization for emergency use of an unlicensed device (Part 2 - referred to as Special Access or SAP); or by means of an Investigational Testing Authorization (ITA) to conduct a clinical trial with a device (Part

[1] For further clarification refer to the Fees in Respect of Human Drugs and Medical Devices at https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/fees-respect-human-drugs-medical-devices.html.

3). For most licence applications under Part 1, MDD is required to meet performance targets for review.

MDD processes Class II device licence applications and evaluates the safety and effectiveness data for Class III and IV device licence applications. Close to 1.3 million different medical devices are currently on the Canadian market.

As of March 18 2020, the Minister of Health issued an Interim Order[2] under the *Food and Drugs Act* to authorize the importation and sale of medical devices in relation to COVID-19. As of March 1 2021, the first Interim Order has been replaced by Interim Order No. 2[3]. As a result, MDD also processes and evaluates Interim Order applications for Class I, II, III and IV COVID-19 medical devices.

The Application Review Process

The *Medical Devices Regulations* require that manufacturers who are seeking a licence for a Class II, III or IV device must first demonstrate to Health Canada that they meet quality standards in the design and manufacturing of their medical devices[4].

There are several steps involved in the medical device review and approval process which includes administrative processing, regulatory and scientific screening, in-depth scientific review, and management approval.

Before issuing a device licence, MDD evaluates information provided by manufacturers in support of their claim that the devices meet the safety and effectiveness requirements of the *MDR*. The nature of the information required increases with the class of the device under review. Health Canada charges manufacturers fees for the review of new Class II, III and IV licence applications, as well as licence amendments for changes to the design or manufacturing process of devices that are already licensed. SAP and ITA application review and decisions have no associated fees and are subject to an internal service standard.

The Cost Recovery Framework links service standards with fees charged and collected by a program or department. Under the *User Fee Act*, Health Canada is required to report annually on costs, fee revenue and performance against service standards as well as feedback received from stakeholders. In a case where an applicable performance standard has not been met, Health Canada is required to remit 25% of the applicable fee.
Health Canada joint and parallel reviews with other regulatory agencies are exempt from the application of the performance standard remissions. Medical device combination reviews where the medical device includes a drug component and a decision has been made to issue or amend (or refuse to issue or amend) a medical

[2] Interim order respecting the importation and sale of medical devices for use in relation to COVID-19
[3] Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19
[4] Health Canada requires manufacturers of Class I devices who do not sell through an establishment already holding a licence, as well as importers and distributors of any medical devices for human use, to obtain an establishment licence to sell their products in Canada. This requirement applies to organizations located in Canada and abroad. Establishment licences attest that the organizations holding them comply with regulatory requirements. Establishment licenses are managed by the Regulatory Operations and Enforcement Branch.

device licence are also exempt from the application of performance standard remissions. Publicly funded health care institutions and branches or agencies of the Government of Canada or of a provincial or territorial government are exempt from the payment of fees.

The mitigation measures for small businesses with fewer than 100 employees or income between $30,000 and $5 million (CAD) in annual gross revenues, include the following: a full remission for a first pre-market application, a 50% remission for all pre-market evaluation fees, a 25% remission for all fees for right to sell and a 25% remission for all establishment licence fees[5].

Data presented in this report includes review and evaluation activities based on the three Parts of the *Medical Devices Regulations*. The performance target is 15 days for Class II licence applications, 60 days for Class III and 75 days for Class IV applications once the screening requirements are satisfied. Health Canada reviews all COVID-19-related applications as quickly as possible without compromising patient safety.

Cost Recovered Applications

Beginning on April 1, 2021, the fees for Cost Recovered applications under Part 1 of the Regulations are adjusted each fiscal year on April 1 by the percentage change over 12 months in the April All-items Consumer Price Index for Canada, as published by Statistics Canada under the *Statistics Act*, for the previous fiscal year and rounded up to the nearest dollar. For 2022-2023, the medical device licence application fees are detailed below.

Fee for the Review of Class II Medical Device Licence Applications	
Category	**Fee**
Licence application	$522
Licence amendment application	$282
Fee for the Review of Class II, III or IV Private Label Medical Device Licence Applications	
Category	**Fee**
Licence application or licence amendment application	$152
Fee for the Review of Class III Medical Device Licence Applications	
Category	**Fee**
Licence application	$10,679
Licence application for a near patient in vitro diagnostic device	$20,723
Licence amendment application - a significant change that relates to manufacturing	$3,070
Licence amendment application - a significant change or a change that would affect the class of the device that is not related to manufacturing	$8,780
Fee for the Review of Class IV Medical Device Licence Applications	
Category	**Fee**
Licence application	$25,955
Licence amendment application - a significant change that relates to manufacturing	$3,070
Licence amendment application - a significant change or a change that would affect the class of the device that is not related to manufacturing	$12,128

[5] Fees in Respect of Drugs and Medical Devices Order: SOR/2019-124

Acronyms

ITA	Investigational Testing Authorization
MDD	Medical Devices Directorate
MDR	Medical Devices Regulations
PL	Private Label
ROEB	Regulatory Operations and Enforcement Branch
SAP	Special Access Program
UFA	User Fee Act (Cost Recovery)

Definitions

Applications Received refers to the number of submissions received during the Quarter.

Workload is the number of submissions “under active review” on a given day.

Backlog is the proportion of submissions under active review that are past their target date for a first decision.

Decisions are recommendations to license, reject, refuse, or request additional information, in regard to the application. The first decision is measured from acceptance for review to the issuance of a licence or a request for further information (AI). The second decision is measured from receipt of a response to a request for additional information (AI) to a decision to license or issuance of a subsequent AI.

Contacts

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Part 1: Applications for Class II, III, and IV licences

Figure 1: Class II Applications Received and Licences Issued

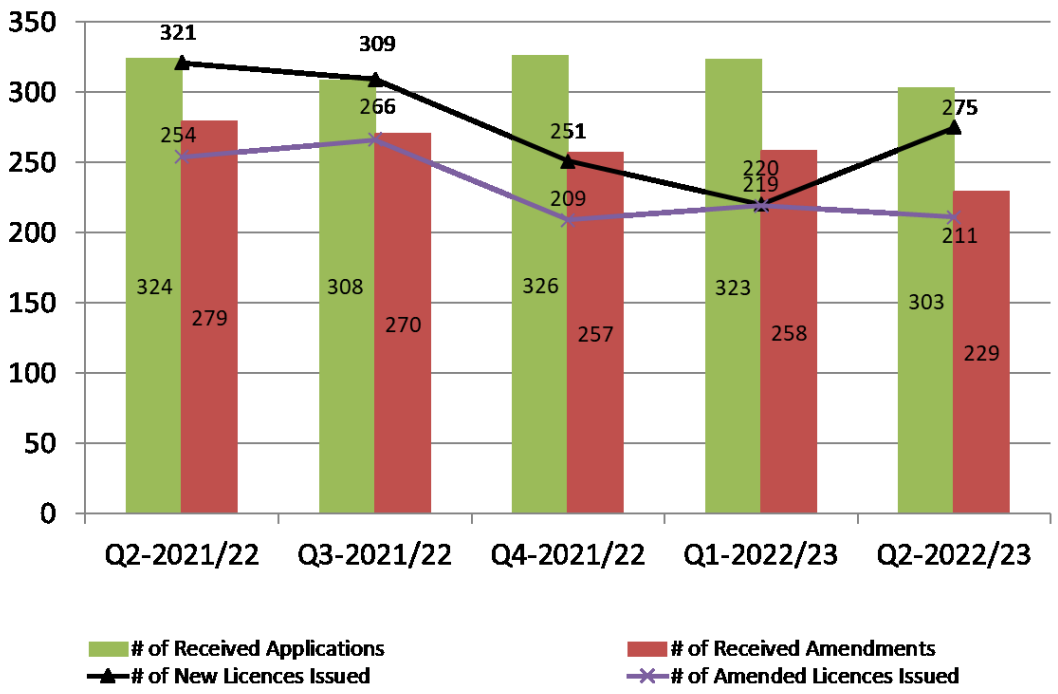


Figure 2: Class III Applications Received and Licences Issued

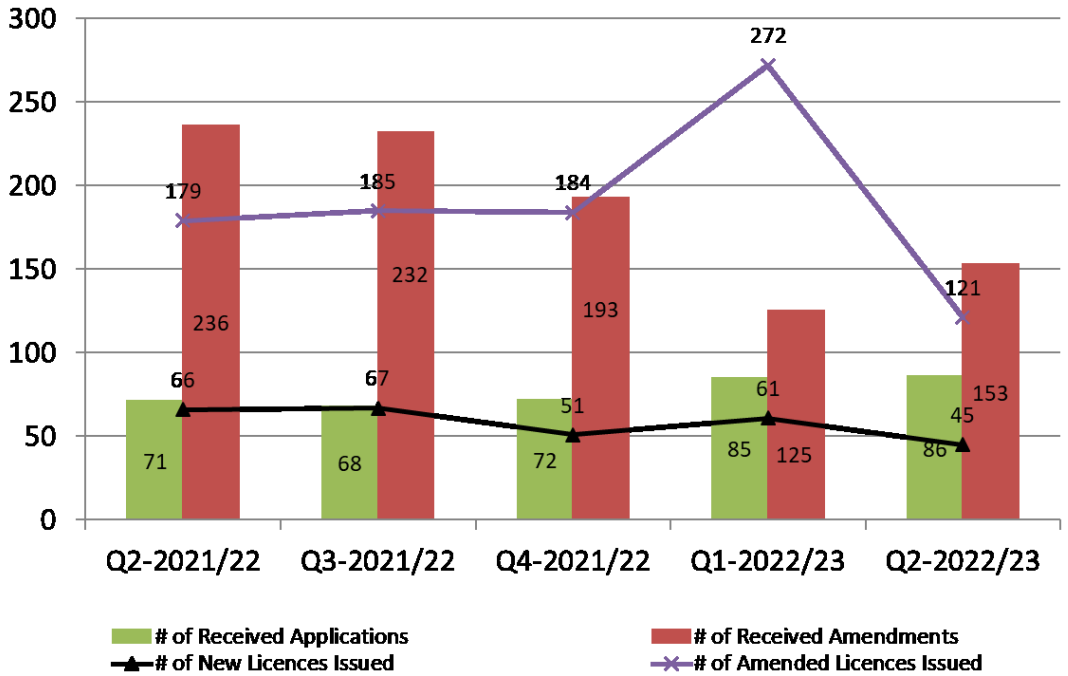


Figure 3: Class IV Applications Received and Licences Issued

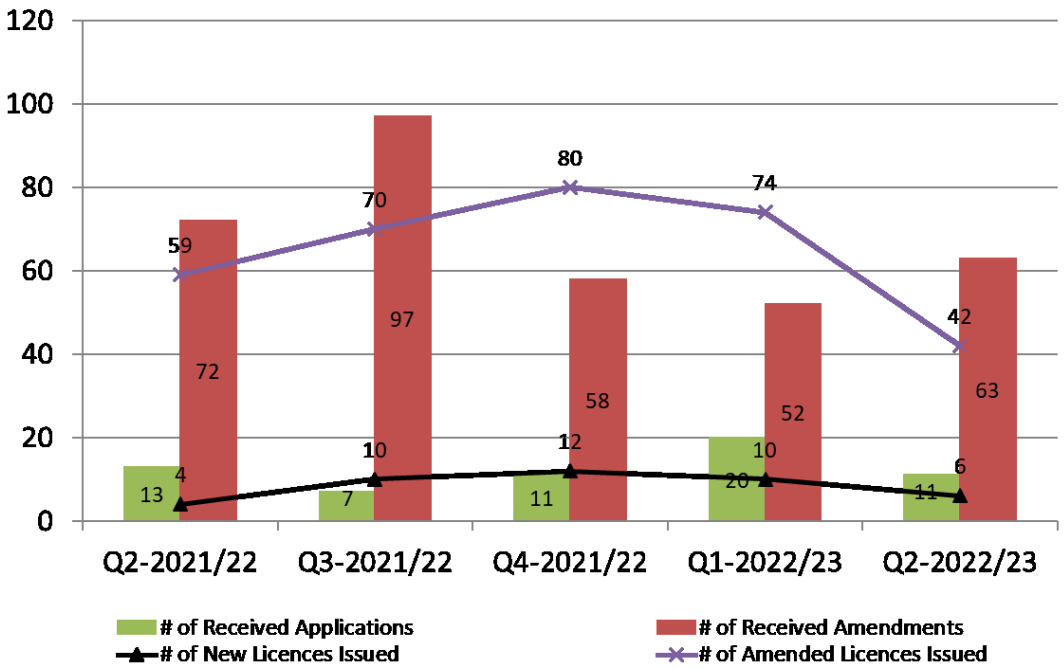


Figure 4: Private Label Applications Received

Medical devices licensed by a company that does not manufacture the product, but sells it under its own name or trademark

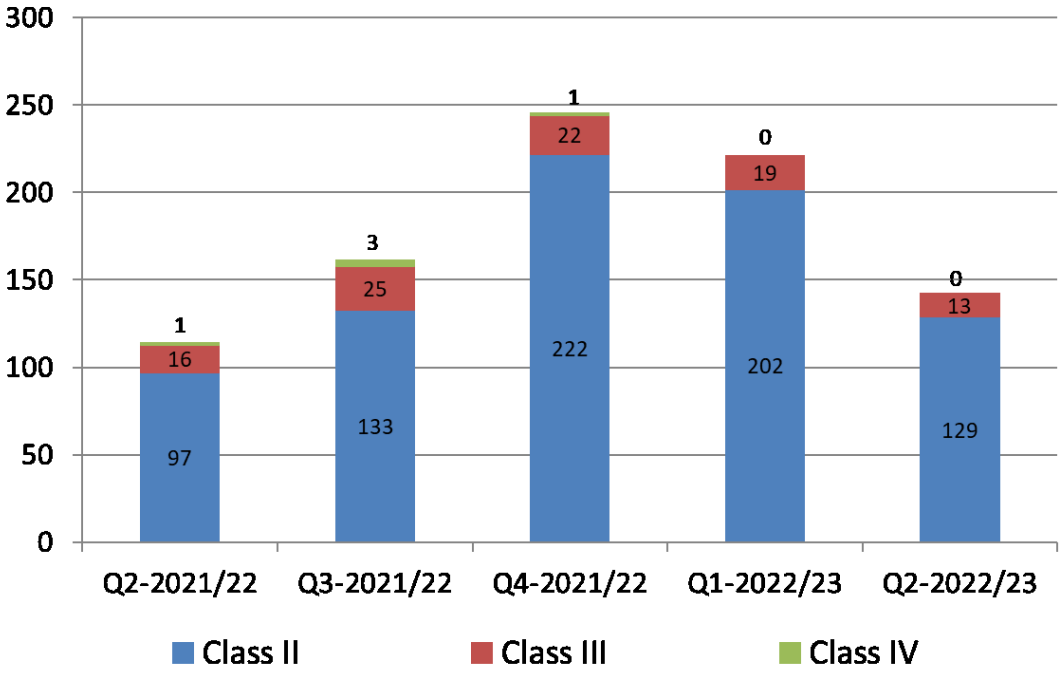
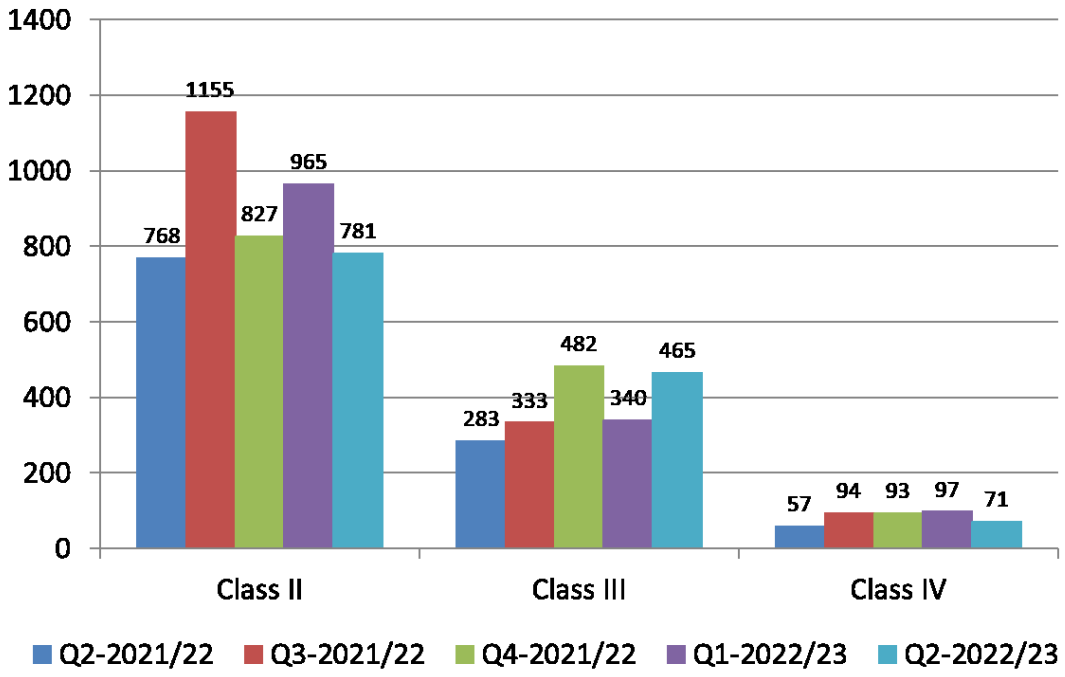


Figure 5: Minor Changes Applications Received

Amendments where the change consists of the addition or deletion of new catalogue or model number that represents non-significant change.



Decisions Made on Time

Includes first decisions, second decisions and final decisions to issue, request additional information, or refuse a licence application. These performance targets are a measure of the percentage of all decisions made on-time or late, within a class of devices.

Figure 6: Class II Application Decisions

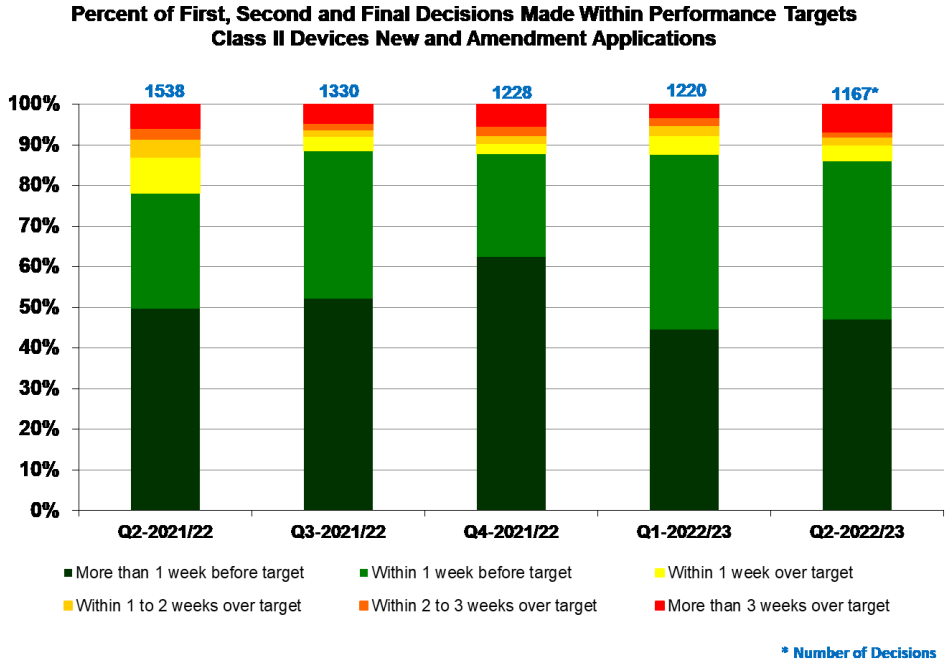


Figure 7: Class III Application Review Decisions

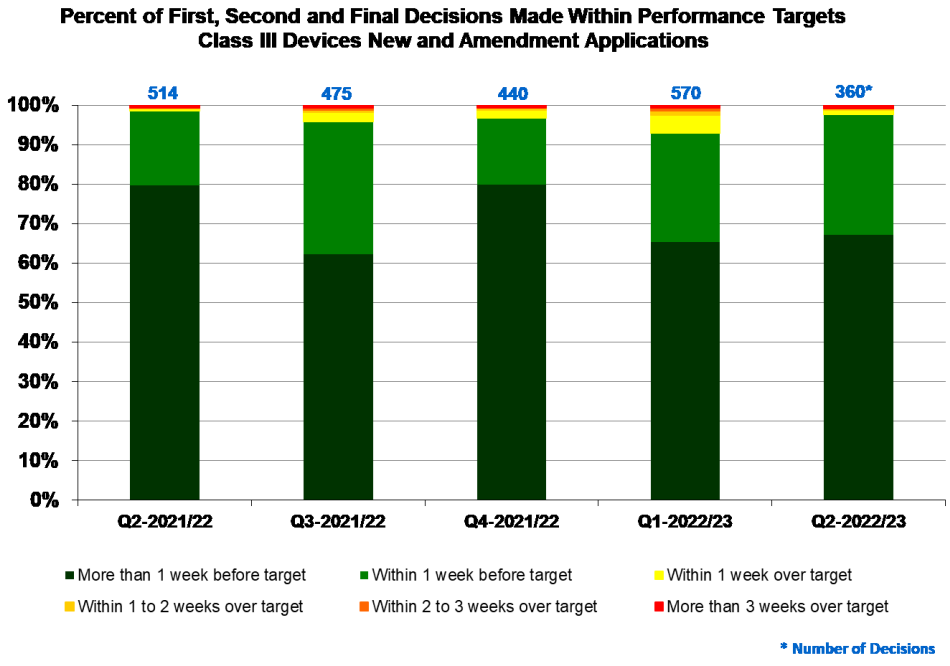


Figure 8: Class IV Application Review Decisions

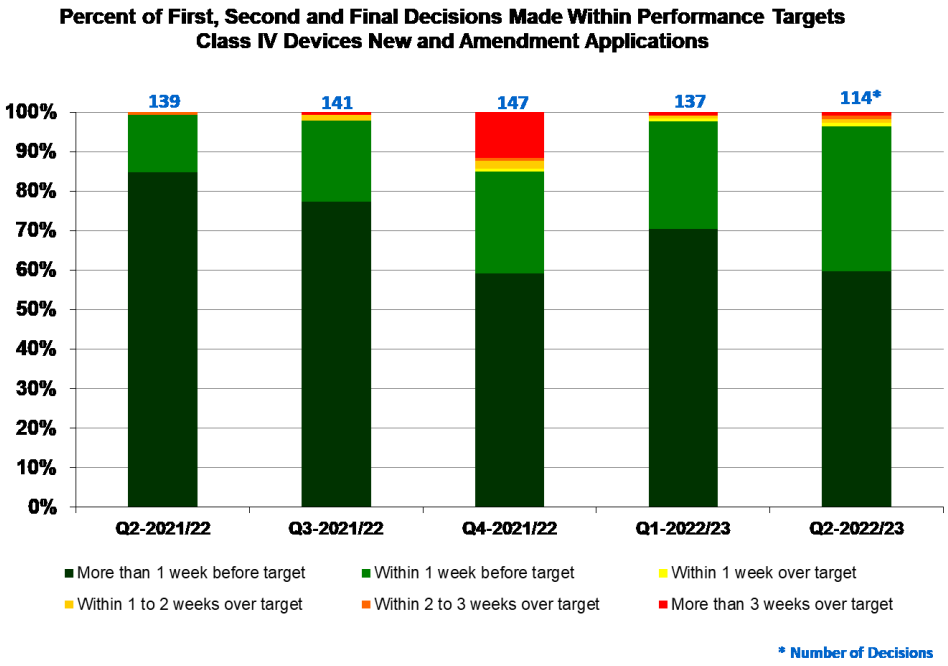


Figure 9: Class II, III and IV Cost Recovery Application Performance Against Target

Includes 1st decisions made for each application fee line. These targets are associated with fee penalties as detailed on page 7, “Cost Recovered Applications”. This performance target uses “decisions on time” calculation which has only two results, on-time or beyond target.

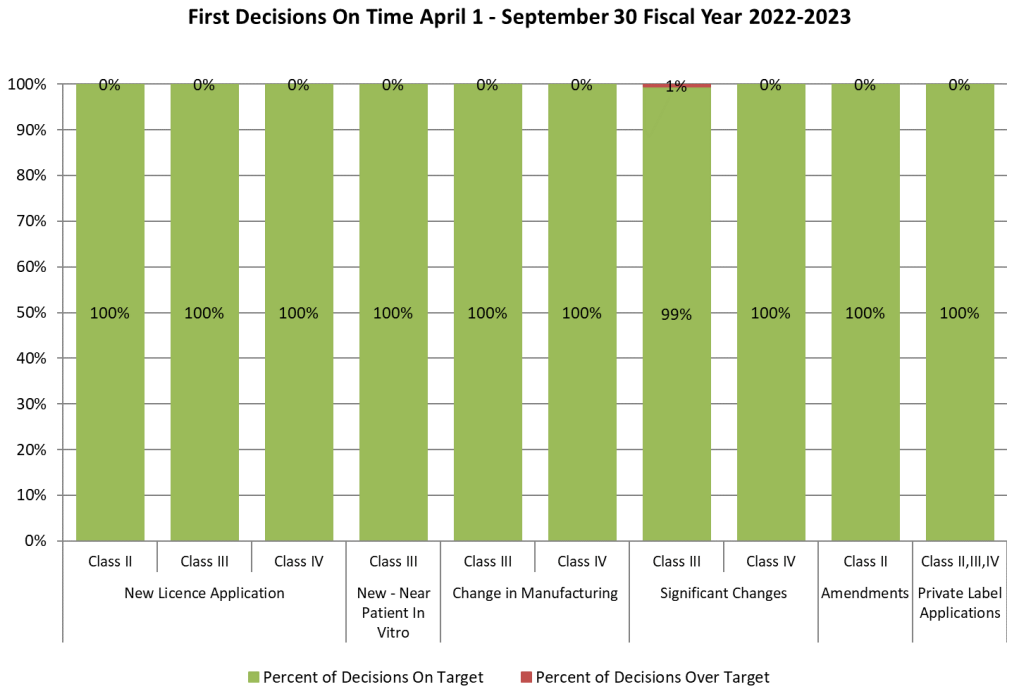
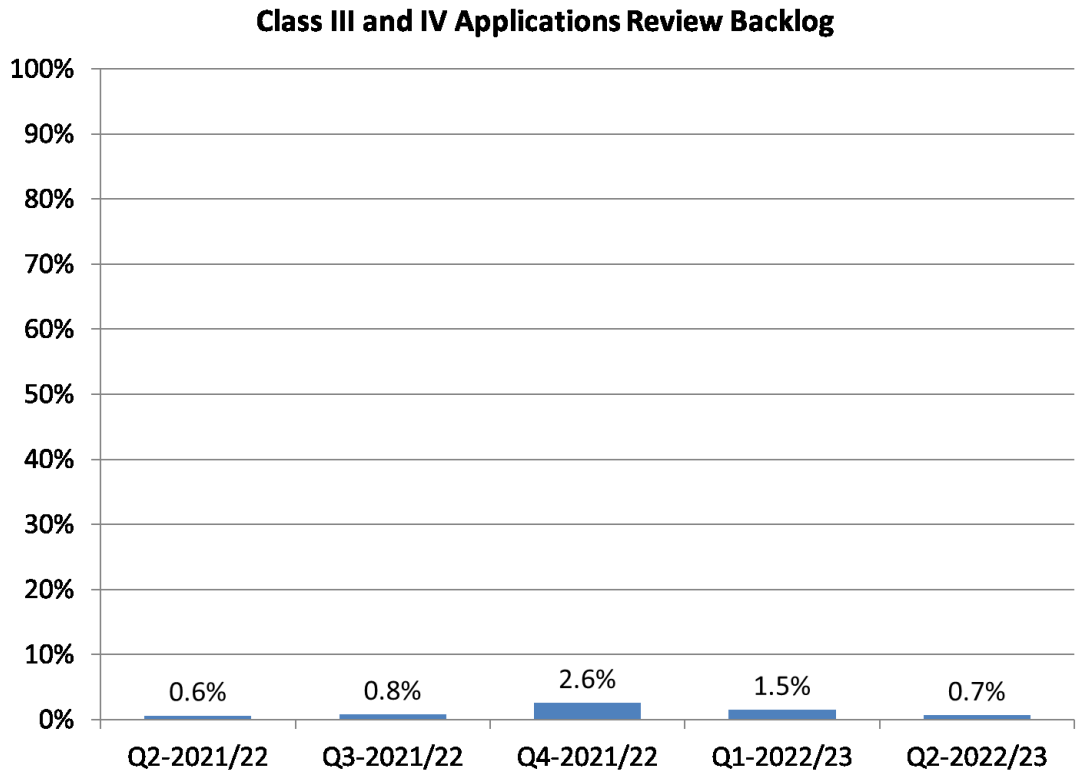


Figure 10: Backlog

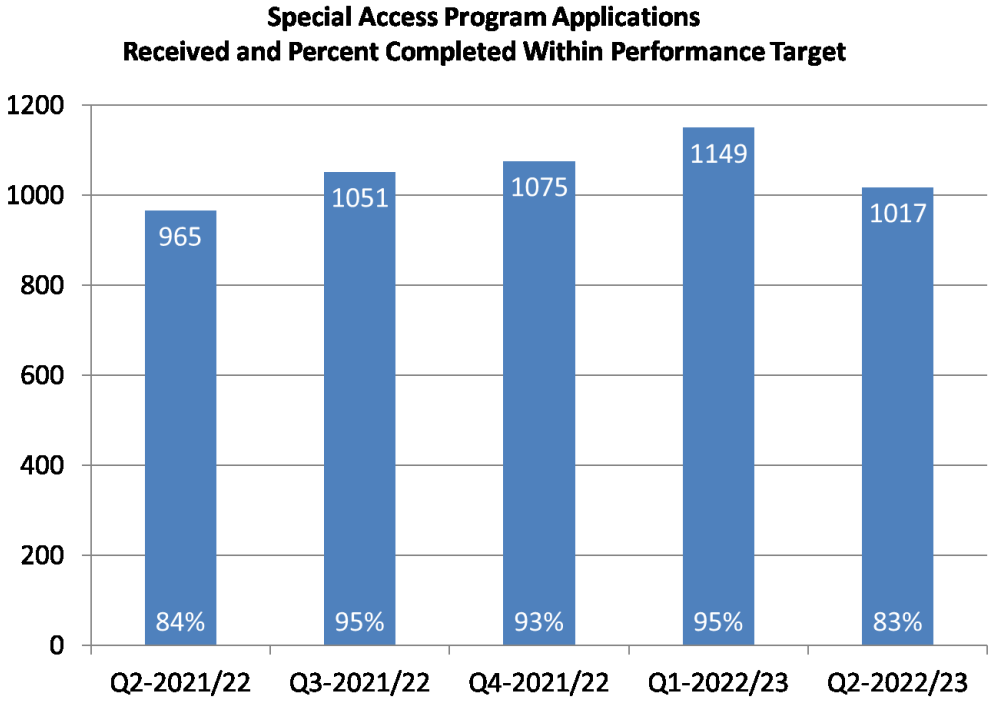
This is the average for the quarter of the weekly Class III & IV applications in review. The value is calculated as the number of applications past their due date divided by the number of applications in review.



Part 2: Special Access Program – SAP

The *Medical Devices Regulations* (MDR) provide health care professionals in Canada with the opportunity to request a special access authorization for an unlicensed medical device if they believe it is in the best interests of their patients. If a medical device is not licensed for general sale in Canada, it can only be imported or used in Canada in an approved clinical trial or with a special access authorization under Part 2 of the MDR.

Figure 11: Special Access Program Applications (72 Hour Target)



Part 3: Investigational Testing Authorization Applications

Part 3 of the *MDR* permits the importation and sale of unlicensed medical devices to qualified investigators for the purpose of conducting investigational testing (similar to clinical trials).

Figure 12: ITAs Received and Percentage Completed (30 Day Target)

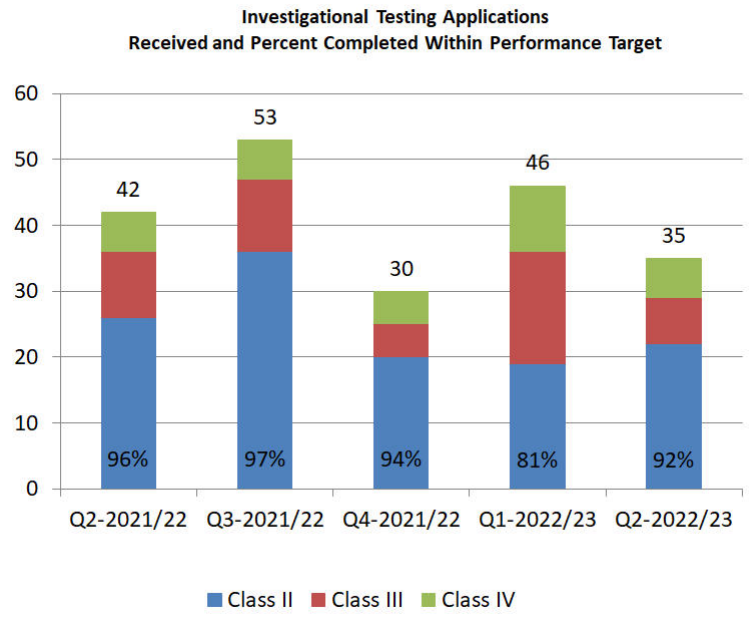
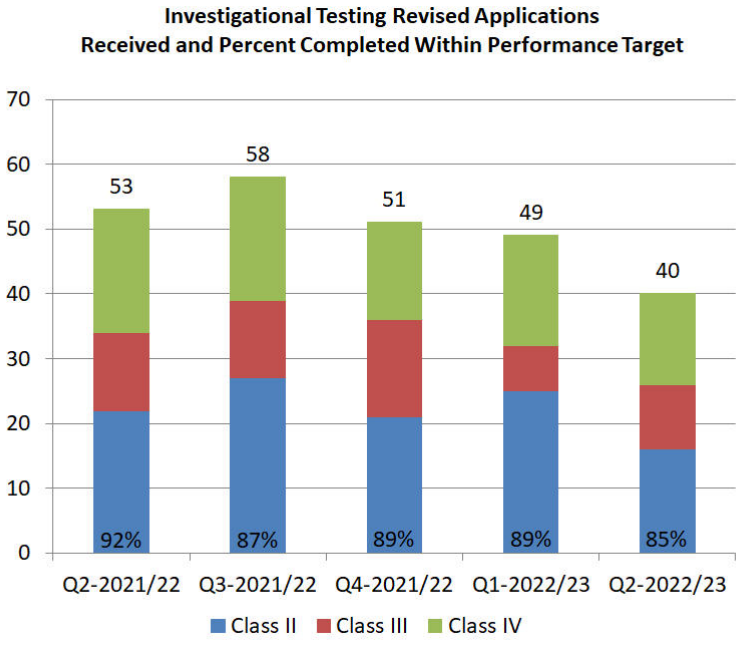
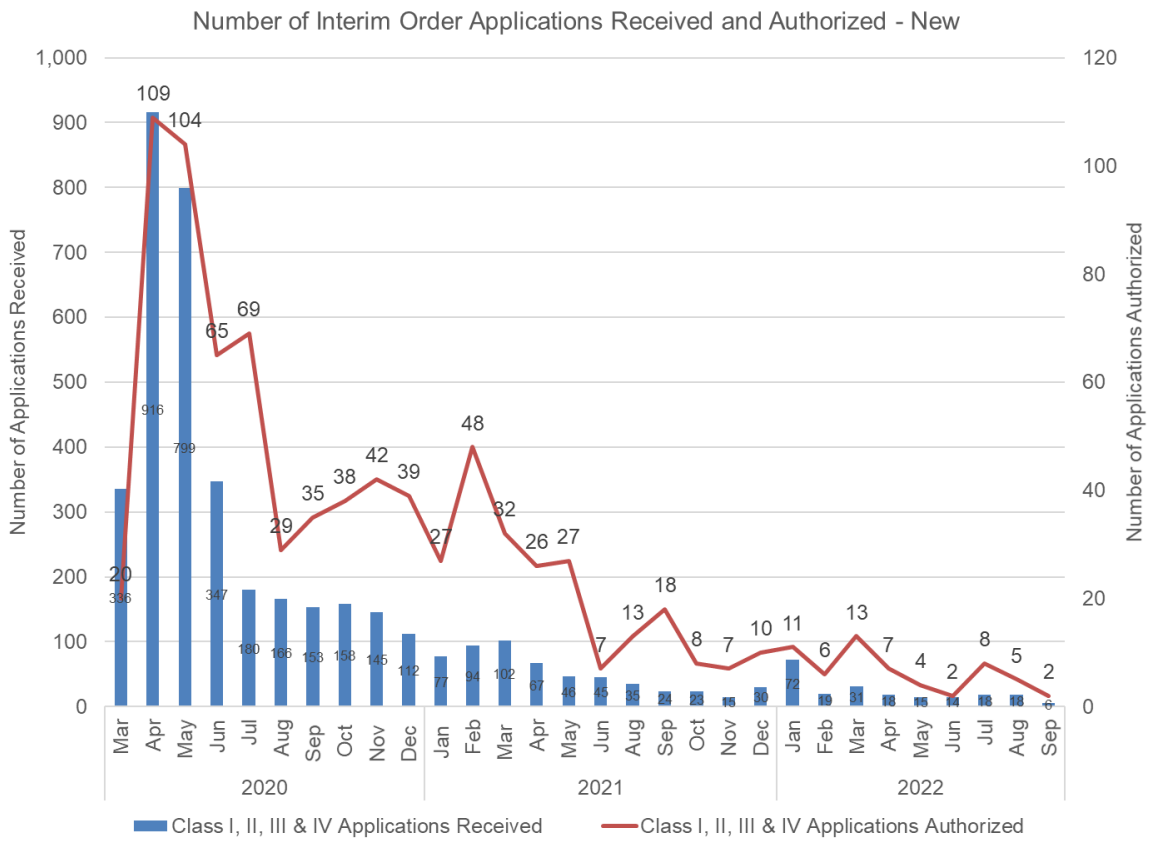


Figure 13: ITA Modifications Received and Percentage Completed (30 Day Target)



Appendix A: Volume of applications received and authorized for medical devices under the Interim Order[6] for use in relation to COVID-19

Figure 14: Interim Order Medical Device Class I, II, III and IV Applications Received and Authorized



[6] Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19