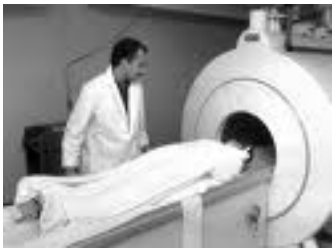
Therapeutic Products Directorate

Medical Devices Bureau
Annual Performance Report

April 1, 2016 through March 31, 2017



Canada

Table of Contents

OVERVIEW

This yearly Performance Report reflects activities of the Medical Devices Bureau (MDB) of the Therapeutic Products Directorate (TPD) of Health Canada over the last five consecutive Fiscal Years.

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 MDB activities and include the number of applications received, workload, and recommended decisions.

The updated Cost Recovery Fee Categories[1] introduced on April 1st 2011 have been included in the report. Performance is measured against the performance standards for Submission Type/Submission Class/ Status combinations as set out in Attachment 1 of the Management of Applications for Medical Device Licences and Investigational Testing Authorizations[2].

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.

[1] For further clarification refer to the Fees in Respect of Human Drugs and Medical Devices at http://www.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php.

[2]This is not to be confused with the 'UF Review 1(iteration 1)' performance standards that will be employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR)

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.

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

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

MDB processes Class II device licence applications and evaluates the safety and effectiveness data for Class III and IV device licence applications. Close to 1.4 million different medical devices are currently on the Canadian market.

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[3].

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, MDB 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

[3] 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 Health Products and Foods Branch Inspectorate.

required to report annually on costs, fee revenue and performance against service standards as well as feedback received from stakeholders. When performance subject to the *User Fee Act* in a particular fiscal year does not meet the established standards, the corresponding fee may be reduced proportionately by up to 50% of the fee level for the next fiscal year.

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 submission requirements are satisfied.

Cost Recovered Applications

The fees for Cost Recovered applications under Part 1 of the Regulations are increased at the start of each fiscal year with a 2% inflationary adjustment. If an application category fails to meet its performance standard based on the Average Number of days to 1st decision for all applications completed in the fiscal year, by more than 10%, the applicable fee will be reduced by an equivalent amount to a maximum of 50%. For example if the fiscal year performance for an individual fee line such as Class IV licence application for devices that contain human or animal tissue applications is 100 days, it will have exceeded the maximum target of 82.5 days (10% over the target of 75 days). The average of 100 days is 25 days over the target or 33% over, therefore the fees for the following fiscal year would be reduced by this percentage, setting a fee of $7641 for the following fiscal year. If in the following year the average meets the 75 day target the fees will be reset to the original amount (plus the 2% yearly increase).

For 2015-2016, the medical devices licensing fees are detailed below.

Fee for the Review of Class II Medical Device Licence Applications	
Category	**Fee**
Licence application	$381

Fee for the Review of Class III Medical Device Licence Applications	
Category	**Fee**
Licence application	$5,469
Licence application for a near patient in vitro diagnostic device	$9,310
Licence amendment application - a significant change that relates to manufacturing	$1,376
Licence amendment application - a significant change or a change that would affect the class of the device that is not related to manufacturing	$5,122

Fee for the Review of Class IV Medical Device Licence Applications	
Category	**Fee**
Licence application	$12,720
Licence application for devices that contain human or animal tissue	$11,866
Licence application for a near patient in vitro diagnostic device	$21,683
Licence amendment application - a significant change that relates to manufacturing	$1,376
Licence amendment application - a significant change or a change that would affect the class of the device that is not related to manufacturing	$5,836

Acronyms

HPFBI	Health Products and Food Branch Inspectorate
ITA	Investigational Testing Authorization
MDB	Medical Devices Bureau
MDR	Medical Devices Regulations
PL	Private Label
SAP	Special Access Program
TPD	Therapeutic Products Directorate
UFA	User Fee Act (Cost Recovery)

Definitions

Applications Received refers to the number of submissions received during the Fiscal Year.

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

Any questions or comments on this report should be forwarded to:

Medical Devices Bureau
2934 Baseline Road
Ottawa, Ontario, K1A 1B9

Telephone: 613-954-4587

Email: mdb_enquiries@hc-sc.gc.ca

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

Figure 1: Class II Applications Received and Licences Issued

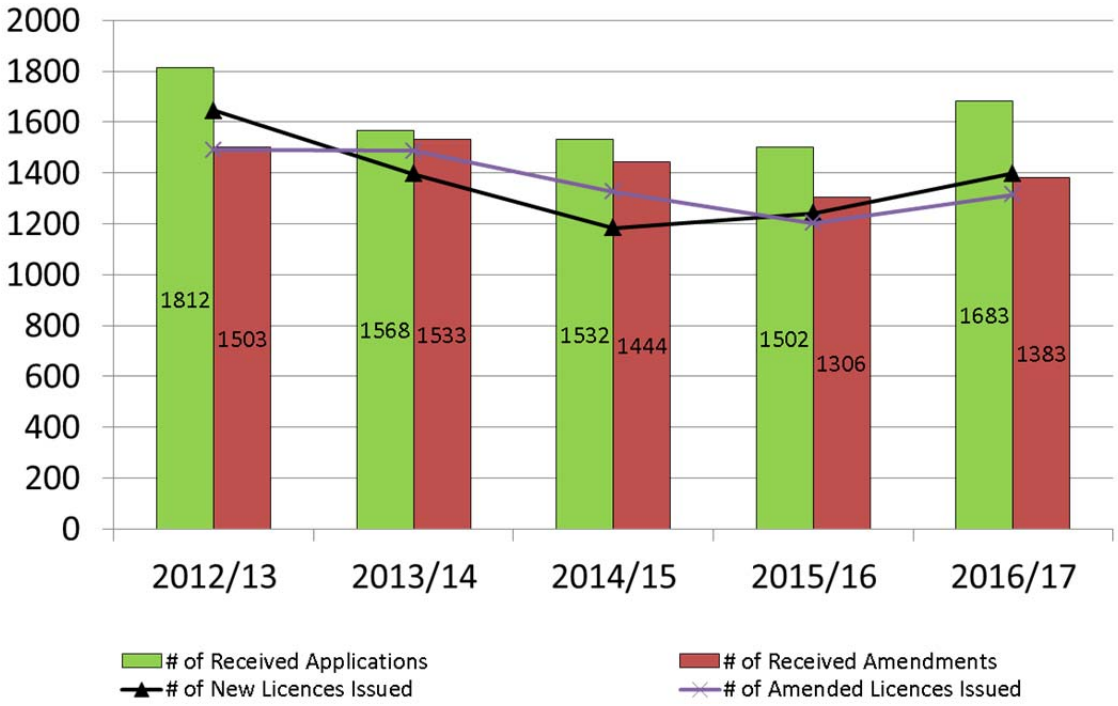


Figure 2: Class III Applications Received and Licences Issued

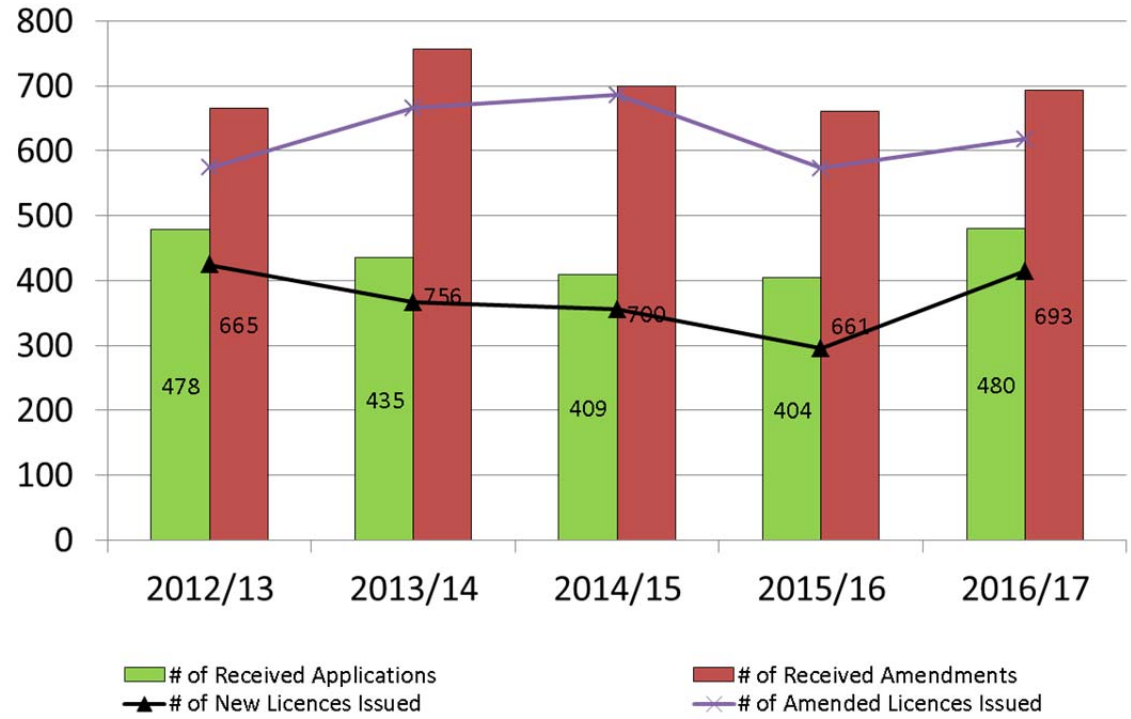


Figure 3: Class IV Applications Received and Licences Issued

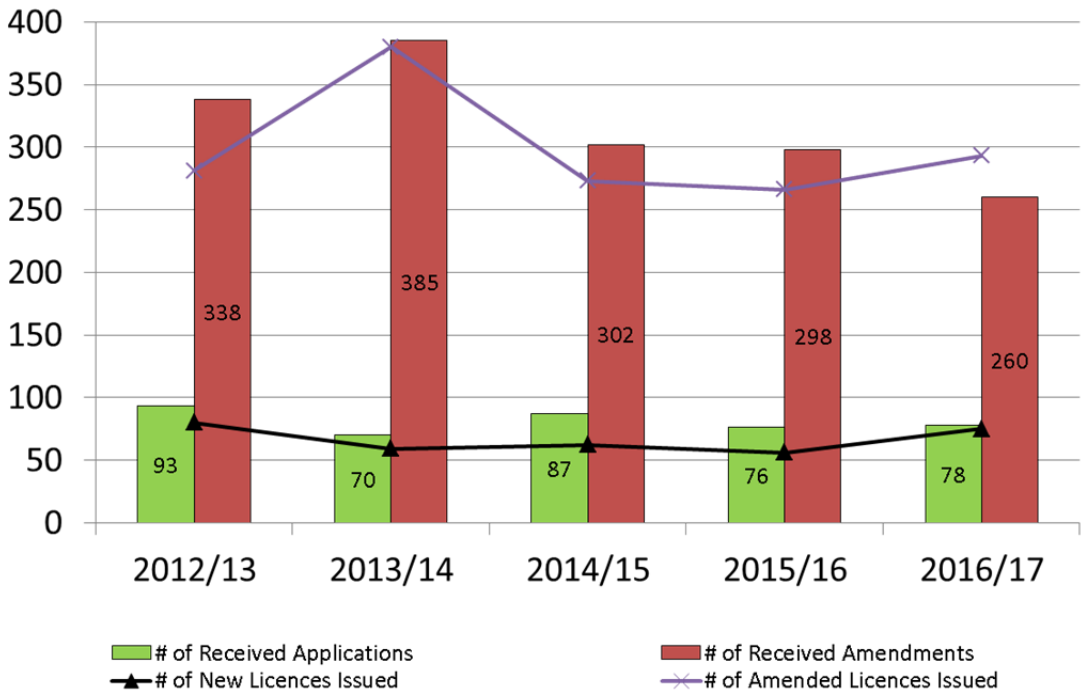


Figure 4: Private Label Applications - Medical devices licensed by a company that does not manufacture the product, but sells it under its own name or trademark

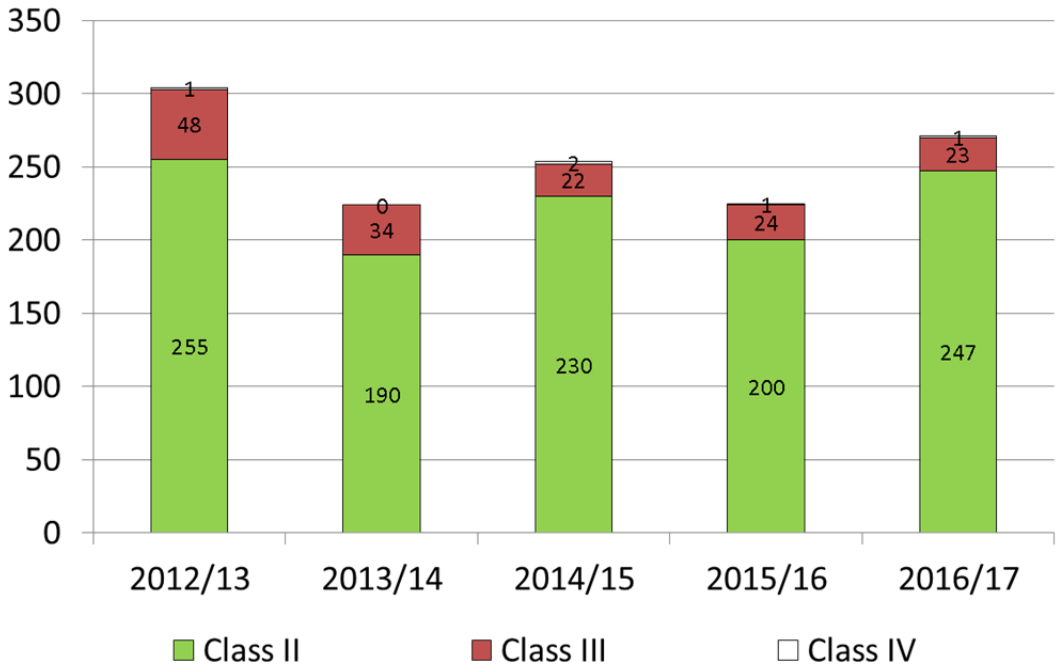
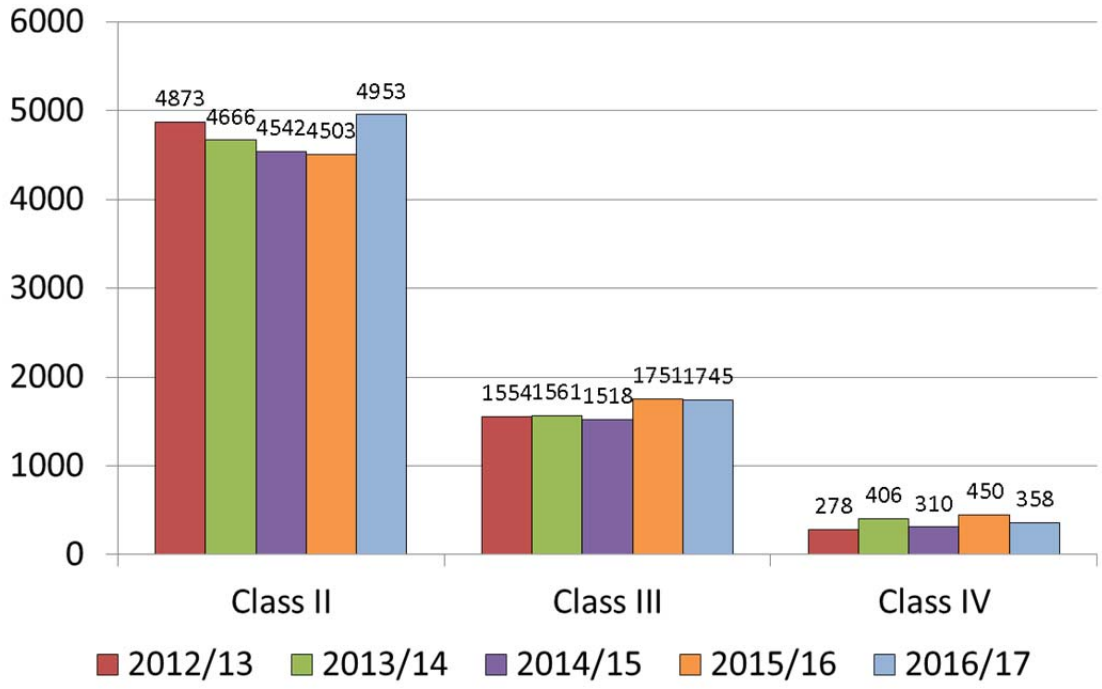


Figure 5: Administrative Faxback Submissions Received - Amendments where the change consists of the addition or deletion of new catalogue or model number that represents non-significant change



Decisions Made on Time – Includes first decisions, second decisions and final decisions to issue, request additional information, or refuse a licence. These are performance targets established under TAS (Therapeutic Access Strategy) and are a measure of the percentage of all decisions made on-time or late, within a Class of devices (they are not associated with performance penalties).

Figure 6: Class II Application Decisions

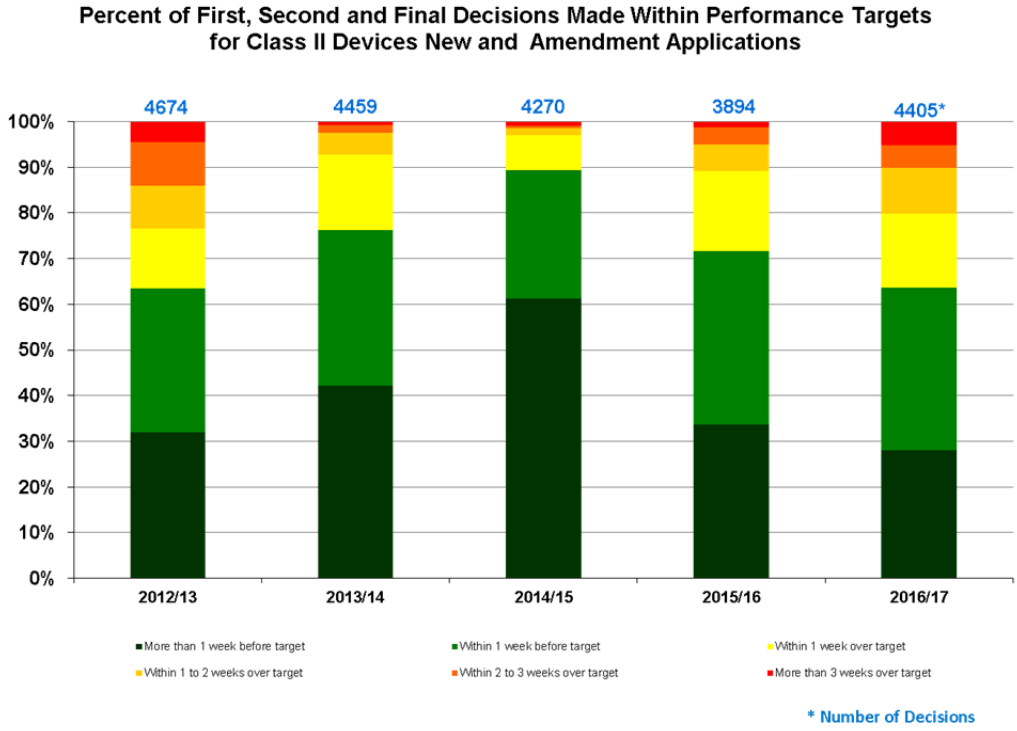


Figure 7: Class III Application Review Decisions

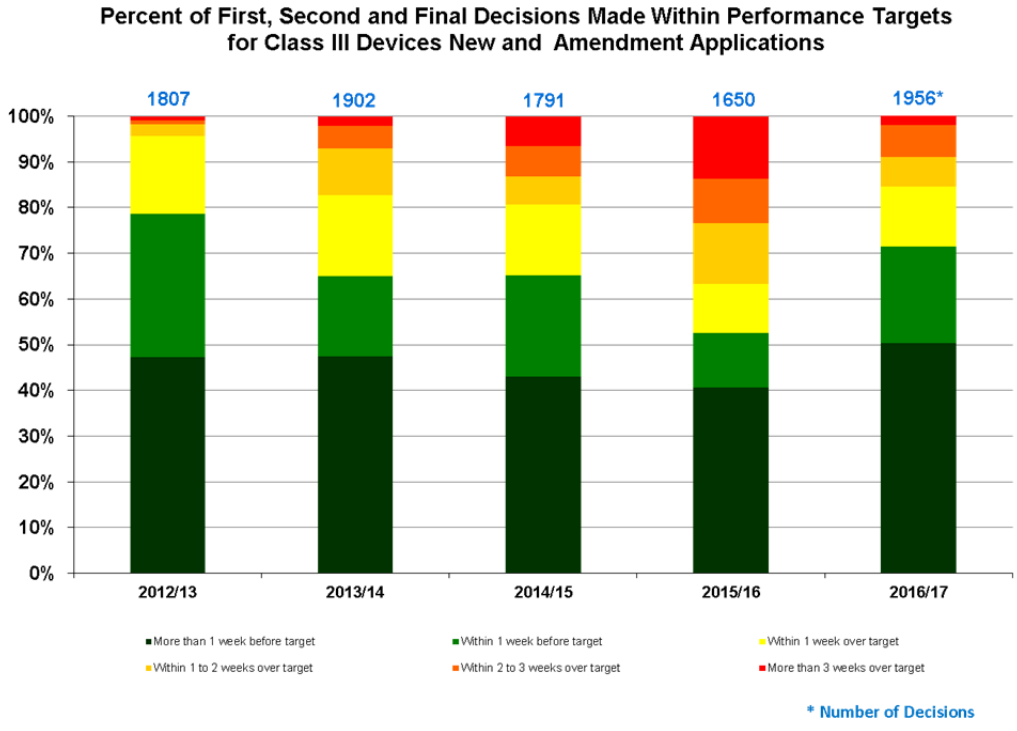


Figure 8: Class IV Application Review Decisions

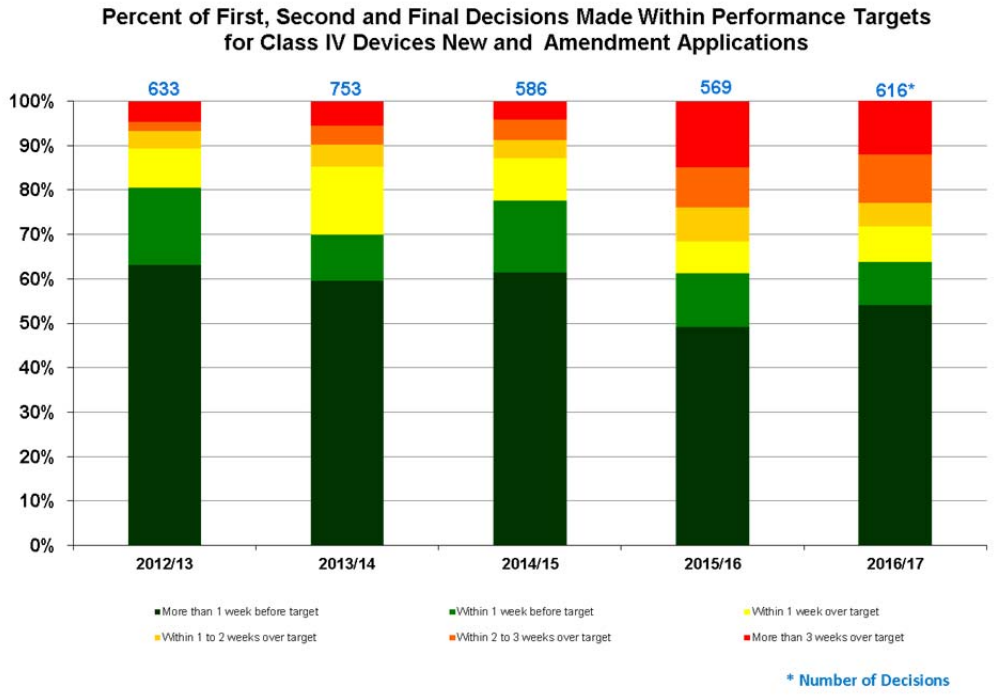


Figure 9: Class II, III and IV Cost Recovery Application Performance Against Target - Includes 1st decisions made for each application fee line. The time is measured from date of acceptance to review until the 1st decision to licence or request for additional information is made, and is an average of those days for all decisions within the fee line. These targets are associated with fee penalties as detailed on page 6, “Cost Recovered Applications”. This performance target uses “average days” and is therefore different than the “decisions on time” calculation which has only two results, on-time or beyond target.

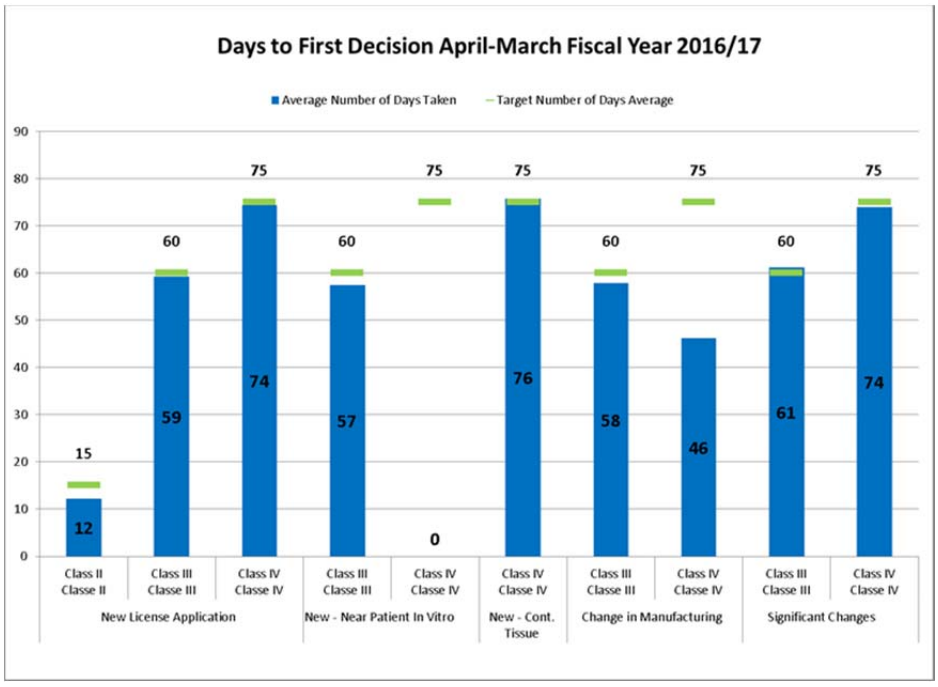
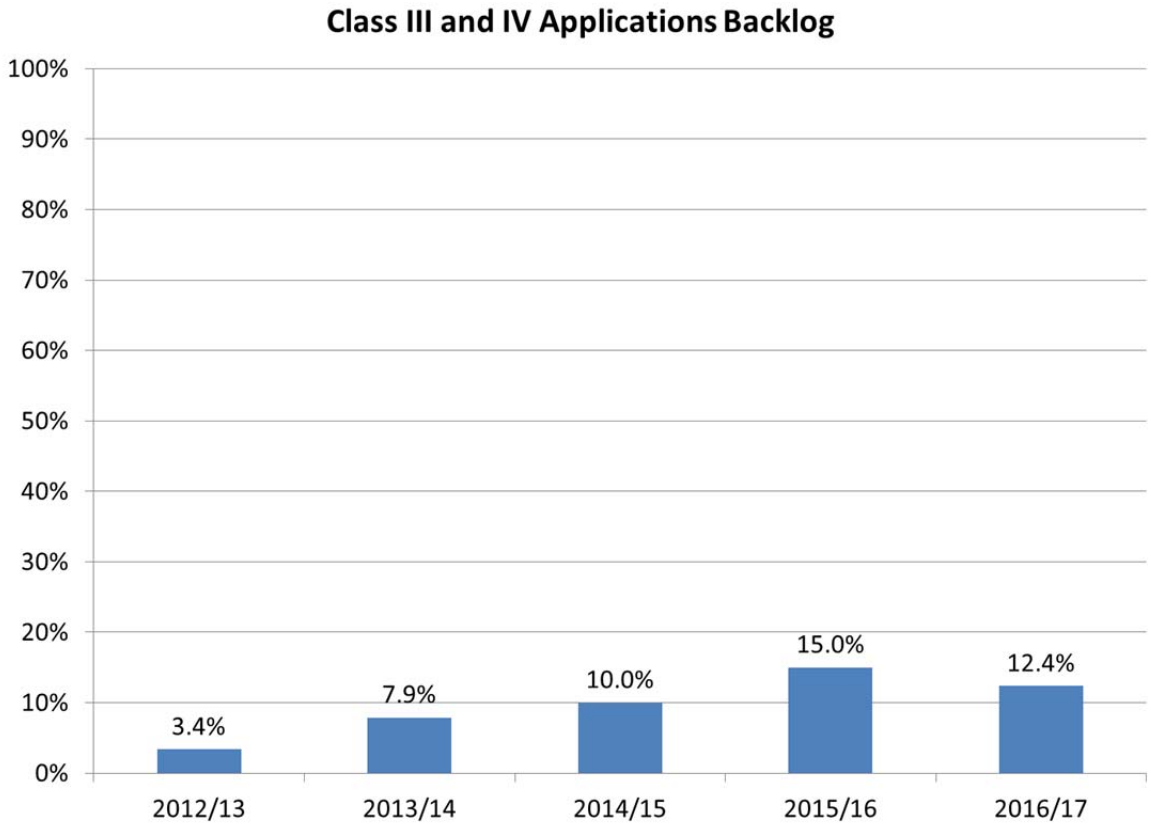


Figure 10*: Backlog - This is the average for the fiscal year of the weekly Class III & IV applications in review. The value is calculated as the number of applications past their due date divided by the number of applications in review.



*This chart was updated and changed in FY 2013/14 to remove screening queue and to reflect review backlog only

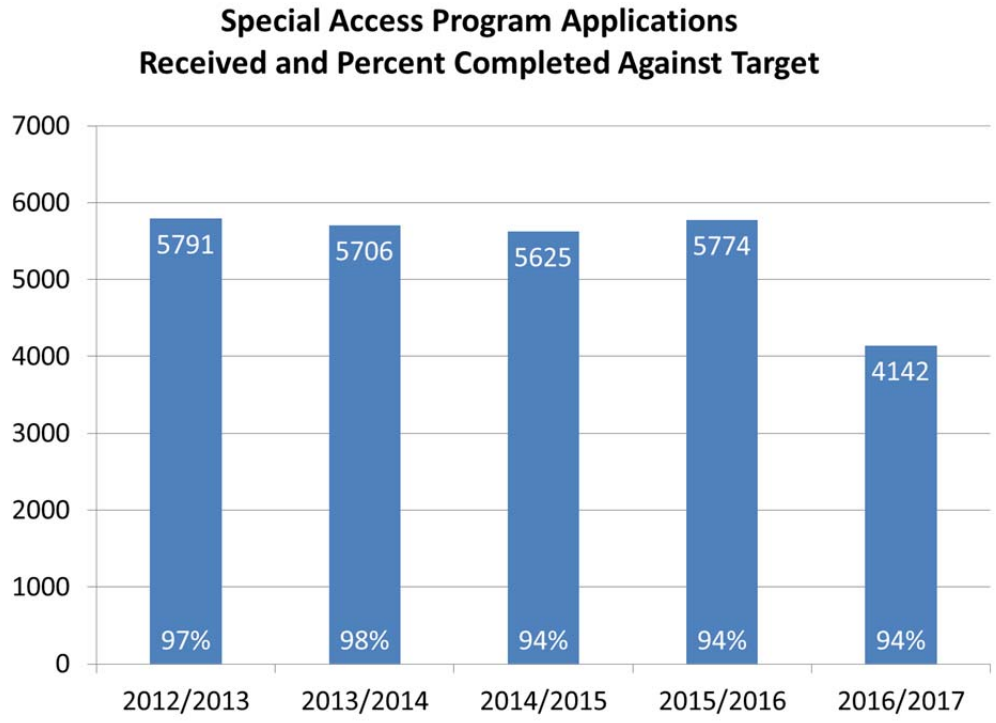
Part 2: Special Access Program – SAP

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.

Special access applications are given a high priority, and responses to an application are usually provided within 72 hour target. Provisions are available to authorize a number of devices at one time that are routinely required in urgent, life-threatening circumstances. These are considered on a case-by-case basis.

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).

The intent of the *Regulations* is to ensure that the testing is safe, is not contrary to the best interests of the study subjects, and the objectives of the testing can be achieved.

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

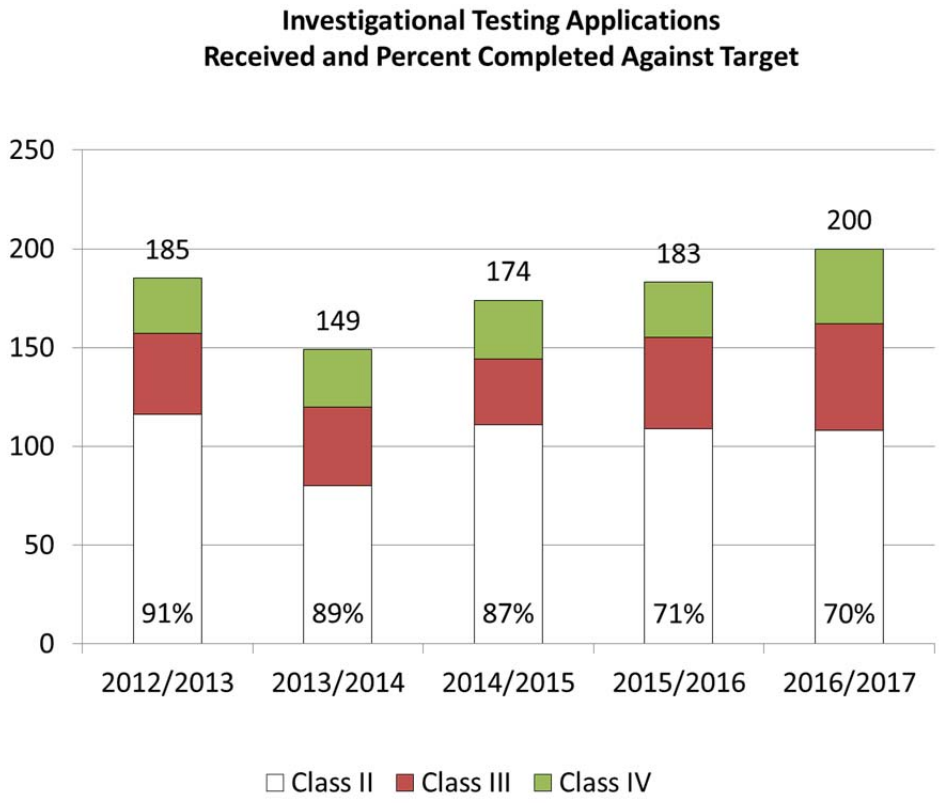


Figure 13: ITA Modifications Received and Percentage Completed (30 Day Target)