Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada
Canada

Evaluation of Health Canada's Administration of Licensing of Producers of Cannabis for Medical Purposes

Prepared by
Office of Audit and Evaluation
Health Canada and the Public Health Agency of Canada

May 2018

Table of Contents

List of Tables

List of Acronyms

ACMPR	Access to Cannabis for Medical Purpose Regulations
CLRB	Cannabis Legalization and Regulation Branch (Health Canada)
FTEs	Full-Time Equivalent (Employees)
LP	Licensed Producer (of Cannabis for Medical Purposes)
MMAR	Marihuana Medical Access Regulations
MMPR	Marihuana for Medical Purposes Regulations
O&M	Operating and Maintenance
OMC	Office of Medical Cannabis
RCMP	Royal Canadian Mounted Police
RORB	Regulatory Operations and Regions Branch (Health Canada)
SOPs	Standard Operating Procedures

Executive summary

This evaluation covers Health Canada's administration of the licensing of producers of cannabis for medical purposes by the Office of Medical Cannabis, for the period of September 1, 2014 to June 30, 2017. The evaluation was undertaken in fulfillment of the requirements of the Treasury Board of Canada's *Policy on Results* (2016).

Evaluation purpose and scope

The purpose of the evaluation was to assess the design and delivery of Health Canada's licensing of producers of cannabis for medical purposes program under the *Access to Cannabis for Medical Purposes Regulations* (ACMPR) and the prior version of these regulations for the period of September 1, 2014 to June 30, 2017. Additional information on important developments occurring after the end of the scoping period were provided by the program in early 2018. This information has been included in the report to provide further context on findings, conclusions and recommendations.

The evaluation was designed to assess activities to date in the implementation of the licensing of producers of cannabis for medical purposes program in support of the achievement of intended results. The evaluation covered the following issues: Licensing Program Design and Delivery, Achievement of Immediate Outcomes, and Alternative Design.

Health Canada's new activities as of August 2016 associated with the registration of individuals authorized to produce a limited amount of cannabis for their own medical purposes or to designate someone to produce it for them was not included in the scope of the evaluation.

Program description

The Office of Medical Cannabis (OMC) is situated within Health Canada's Cannabis Legalization and Regulation Branch (CLRB). OMC provides policy, regulatory, operational and litigation support to the regulation of cannabis for medical purposes. OMC, with support from the Regulatory Operations and Regions Branch (RORB, Health Canada) and the Royal Canadian Mounted Police, administers the licensing of producers of cannabis for medical purposes in Canada, in accordance with applicable laws and regulations, to facilitate reasonable access by eligible Canadians to quality-controlled cannabis for medical purposes.

Licensing Program Design and Delivery

- OMC succeeded in implementing a program to license producers of cannabis for medical purposes within a context of high public interest and ongoing refinements to the regulatory framework. The program experienced very rapid development both leading up to and following the coming into force of the enabling regulations, as well as significant funding and program infrastructure constraints, while supporting a nascent industry. These factors contributed to inefficiencies during implementation, such as

long processing times for some licence applications. Despite these constraints, the program delivered on its intended outputs of issuing licences, producing inspection reports and publishing guidance materials.

- The program recently introduced a number of improvements to the process of issuing licences to produce cannabis for medical purposes. These changes were identified based on a risk-based review of existing practices, and came into effect in May 2017. There are, however, additional opportunities to better support day-to-day operations, for example by introducing an integrated case management system.
- OMC has worked collaboratively with its delivery partners and has been successful in maintaining control over the movement of cannabis produced by licensed producers (LPs) in a manner consistent with its obligations under the regulatory framework and international conventions.
- OMC's actual expenditures were regularly three times higher than its budget appropriations from Parliament for the timeframe covered by this evaluation. This was due in large measure to the fact that the program's parliamentary appropriations were not adjusted in consideration of additional regulatory authority and workload until Fall 2017's Supplementary Estimates.

Achievement of Immediate Outcomes

- LPs and applicants generally have access to information supporting an overall understanding of the licensing requirements and the regulations. There are unmet information needs with regard to the interpretation of some regulatory requirements and the status of licence application review, which can limit LPs and applicants' ability to make informed business decisions.

Risk Management

- Health Canada has adopted a prudent approach to administering the initial roll-out of the licensing program. The program's risk mitigation activities in support of delivery have generally been successful given that there have been sufficient quantities of quality-controlled legal cannabis available to eligible Canadians, with high LP compliance with the regulations and without instances of diversion or significant risks to health and safety. Health Canada has also taken risk-based steps to improve efficiency and effectiveness in the area of compliance monitoring, and as the program continues to evolve and mature, there will remain potential opportunities for further efficiencies as it relates to inspection and compliance monitoring. There remain, however, aspects of the program's delivery, which could benefit from the introduction of an integrated electronic case management system so as to reduce the risks presented to program operations. OMC reports that a system is in development and will be implemented in Summer 2018.

Alternative Design

- Service standards and fees, which are common design elements implemented by other licensing programs in Canada, are viewed positively by OMC stakeholders.
- Canada is a world leader in the domestic regulation of the licensing of production of cannabis for medical purposes. Canada differs from other international jurisdictions in that Canada does not charge application fees for applicants that wish to become LPs of cannabis for medical purposes, nor does it place a maximum on the number of LPs.

Recommendations

Recommendation 1

Examine opportunities for modernizing the licensing process through a consolidated data system (such as a case management system), including an online interface, in support of increased efficiency and effectiveness of the licensing program.

Considering the sheer volume of information associated with each application (in both paper and electronic format), the current application management tools employed by OMC are of limited efficiency, and cannot easily generate reliable and sophisticated licensing activity data or reports. Furthermore, the use of the generic email account as the principal information management tool for the program creates risks related to information management. A consolidated data system could better support OMC's ability to help current and future applicants make informed business decisions while also supporting monitoring and reporting on the application process.

Recommendation 2

Develop internal and external communication processes, tools and materials with the intent of increasing access by Licensed Producers and applicants to the information necessary to support informed business decision-making.

LPs and applicants have unmet information needs related to interpretation of some regulatory requirements and application processing (including status) which can limit their ability to make informed business decisions. Updated Standard Operating Procedures (SOPs) reflecting the requirements of the ACMPR would support OMC and Regulatory Operations and Regions Branch (RORB) staff in consistently discharging their responsibilities and help them better engage with applicants and existing LPs.

Recommendation 3

Engage in risk-based reviews of compliance and enforcement activities as a means of increasing the efficiency and effectiveness of the licensing program.

As part of improvements to the licensing of producers of cannabis for medical purposes in late May 2017, Health Canada has taken risk-based steps to improve efficiency and effectiveness in some areas; however, there remain potential opportunities for further efficiencies. As such, the risk-based approach to determining the frequency and the areas of focus of inspections could be regularly reviewed to ensure alignment to the relative risks to the system and harms of non-compliance.

Recommendation 4

Study options to allow for collection of fees and the introduction of service standards for the issuance of new and renewed licences, as well as import and export permits, in support of the timely provision of outputs and increased economy.

Service standards and fees are common elements of licensing programs in Canada and internationally for regulated private goods. OMC stakeholders have expressed support for both as mechanisms for improving the timeliness of the application experience. Cost recovery may present an opportunity for addressing long-term funding concerns and provide stability, as well as improve the experience of applicants and producers.

Management Response and Action Plan

Evaluation of Health Canada's Administration of Licensing of Producers of Cannabis for Medical Purposes

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation as stated in the evaluation report	Identify whether program management agrees, agrees with conditions, or disagrees with the recommendation, and why	Identify what action(s) program management will take to address the recommendation	Identify key deliverables	Identify timeline for implementation of each deliverable	Identify Senior Management and Executive (DG and ADM level) accountable for the implementation of each deliverable	Describe the human and/or financial resources required to complete recommendation, including the source of resources (additional vs. existing budget)
Examine opportunities for modernizing the licensing process through a consolidated data system (such as a case management system), including an online interface, in support of increased efficiency and effectiveness of the licensing program.	Agree	Examine options for a consolidated data system (such as a case management system). Decide upon option(s) and develop business requirements. Develop and execute implementation plan. Phase I system implementation.	List of business requirements for the case management system. A chosen solution that will modernize the licensing and security process that has been approved by the responsible project authorities. Implementation plan. Delivery of the system. User documentation. Training.	Completed Completed Completed Q1 – 2018/19	CLRB – ADM Director General, Policy Directorate Director General, Licensing and Medical Access Directorate CLRB – ADM & Corporate Service Branch – ADM CLRB – ADM	Existing resources in the Cannabis Legalization and Regulation Branch, and Regulatory Operations and Regions Branch – Cannabis Directorate (Office of Secondary Interest) Case Management System (CMS) - new financial resources will need to be allocated for the development, consultation and implementation of the system.

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation as stated in the evaluation report	Identify whether program management agrees, agrees with conditions, or disagrees with the recommendation, and why	Identify what action(s) program management will take to address the recommendation	Identify key deliverables	Identify timeline for implementation of each deliverable	Identify Senior Management and Executive (DG and ADM level) accountable for the implementation of each deliverable	Describe the human and/or financial resources required to complete recommendation, including the source of resources (additional vs. existing budget)
						Additional human resources will be sought for the development, consultation and implementation phases.
Develop internal and external communication processes, tools and materials with the intent of increasing access by Licensed Producers and applicants to the information necessary to support informed business decision making.	Agree	In addition to the ongoing, regular communications with licensed producers and applicants, develop a strategic approach to communication and engagement with regulated parties, including enhancements to information sharing with licensed producers and applicants. Internal communication processes, tools and materials aimed at Health Canada regional inspectors, as they play a key role in communications with licensed producers.	Stakeholder Engagement Strategy for the Cannabis Legalization and Regulation Branch Updated and new external guidance documents, to be posted on the Canada.ca website Internal guidance (e.g. standard operating procedures)	Q1 FY 2018-2019 Q1 and Q2 FY 2018-2019 (stages) Q2 FY 2018-2019	CLRB – ADM Director General, Policy Directorate Director General, Licensing and Medical Access Directorate	Existing resources in the Cannabis Legalization and Regulation Branch, and Regulatory Operations and Regions Branch – Cannabis Directorate (Office of Secondary Interest)

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation as stated in the evaluation report	Identify whether program management agrees, agrees with conditions, or disagrees with the recommendation, and why	Identify what action(s) program management will take to address the recommendation	Identify key deliverables	Identify timeline for implementation of each deliverable	Identify Senior Management and Executive (DG and ADM level) accountable for the implementation of each deliverable	Describe the human and/or financial resources required to complete recommendation, including the source of resources (additional vs. existing budget)
Engage in risk-based reviews of compliance and enforcement activities as a means of increasing the efficiency and effectiveness of the licensing program.	Agree	For licensed producers as a group: - Continue ongoing risk-based review of regulatory requirements (e.g. physical security measures, good production practices) to confirm risk calibration based on latest evidence. For individual licensed producers: - Continue to update the risk rating criteria, and examine the possibility of assigning risk levels to activities. - Reassess risk ratings assigned to licensed producers following each annual inspection (or other inspection, if warranted) based on compliance history and emerging issues.	Enhanced approach to conducting risk-based reviews of regulatory requirements. Updated risk rating standard operating procedure. Implementation of risk rating standard operating procedure. Report on number of annual inspections conducted in the fiscal year and number of risk ratings that were revised based on the annual inspections conducted in the fiscal year.	FY 2018-2019 FY 2018-2019 FY 2018-2019 April 30, 2019	CLRB – ADM Director General, Compliance Directorate	Existing resources in the Cannabis Legalization and Regulation Branch, and Regulatory Operations and Regions Branch – Cannabis Directorate (Office of Secondary Interest)

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation as stated in the evaluation report	Identify whether program management agrees, agrees with conditions, or disagrees with the recommendation, and why	Identify what action(s) program management will take to address the recommendation	Identify key deliverables	Identify timeline for implementation of each deliverable	Identify Senior Management and Executive (DG and ADM level) accountable for the implementation of each deliverable	Describe the human and/or financial resources required to complete recommendation, including the source of resources (additional vs. existing budget)
Study options to allow for collection of fees and the introduction of service standards for the issuance of new and renewed licences, as well as import and export permits, in support of the timely provision of outputs and increased economy.	Agree	Implementation of a cost recovery regime for regulating cannabis production in FY 18-19.	Consultations with stakeholders on a proposed approach to cost recovery for the regulation of cannabis Review feedback and adjust fee proposal where appropriate Drafting of ministerial order Minister of Health signs the order Final publication in *Canada Gazette*, Part II	Spring 2018 Spring 2018 Spring/Summer 2018 Summer 2018 Summer 2018	Cannabis Legalization and Regulation Branch – Assistant Deputy Minister Director General, Policy Directorate	Existing resources in the Cannabis Legalization and Regulation Branch, and Regulatory Operations and Regions Branch – Cannabis Directorate (Office of Secondary Interest)

1.0 Evaluation Purpose

The purpose of the evaluation was to assess the design and delivery as well as immediate outcomes of Health Canada's administration of the licensing of producers of cannabis for medical purposes program by the Office of Medical Cannabis (OMC), for the period of September 1, 2014 to June 30, 2017.Additional information on important developments occurring after the end of the scoping period has been included in the report to provide further context on findings, conclusions and recommendations.

The evaluation was conducted by the Health Canada and Public Health Agency of Canada's Office of Audit and Evaluation in accordance with the Five-Year Evaluation Plan 2017-18 to 2021-22. This was the first time that the licensing activities of OMC were evaluated.

2.0 Program Description

2.1 Office of Medical Cannabis Profile and Context

Cannabis (also frequently referred to as marihuana or marijuana) is a plant from which a variety of products can be derived, including dried or fresh material and oil. While cannabis has been used historically for medical purposes, it is not presently an authorized therapeutic product in Canada and remains a Schedule II drug under the *Controlled Drugs and Substances Act*[1]. The current regulatory framework (the *Access to Cannabis for Medical Purposes Regulations*[2]*)* enables individuals (authorized by their health care practitioner to access cannabis for medical purposes) to have the option of accessing cannabis in one of three ways. They can purchase quality-controlled cannabis from producers licensed by Health Canada, produce a limited amount of cannabis for their own use, or designate someone to produce it for them.

Canada has had a system of access to cannabis for medical purposes in some form since the late 1990s. The regulatory regime was put in place following a court decision that determined that the Government of Canada must provide some lawful means for Canadians to access and possess cannabis for medical purposes.

The regulatory framework has evolved over time as the Government has introduced improvements and responded to a number of court decisions. These changes have included introducing a system of regulated production and distribution of cannabis for medical purposes.

OMC is situated in Health Canada's Cannabis Legalization and Regulation Branch (CLRB) and provides policy, regulatory, operational and litigation support related to the regulation of cannabis for medical purposes. OMC is responsible for the following activities with regard to the licensing of producers of cannabis for medical purposes in Canada:

- reviewing applications for new licences, renewals, amendments and applications for import and export permits;
- issuing new licences, renewals, amendments, and import and export permits;
- monitoring and verifying compliance with legal and regulatory requirements through inspections and other activities, and initiating enforcement action as required to address instances of non-compliance;
- monitoring the availability of cannabis through data collection; and
- developing and providing policies, regulatory interpretations and guidance.

In administering the program for licensing of producers of cannabis for medical purposes, OMC works in collaboration with Heath Canada's Regulatory Operations and Regions Branch (RORB). RORB is responsible for conducting inspections (including determining the inspection schedule) and providing inspection reports to OMC in support of its licensing and compliance functions, per agreed-upon timelines. OMC also works in collaboration with the Royal Canadian Mounted Police (RCMP), as all licence applicants and other key personnel in a facility must undergo criminal record and law enforcement record checks as part of the licensing process.

Program Operating Context

In 2001, Health Canada introduced a regulatory framework for cannabis for medical purposes with the implementation of the *Marihuana Medical Access Regulations* (MMAR). The regulations allowed individuals who were authorized by their health care practitioner, or their designated person, to produce cannabis for their own medical use. The program operated with budget appropriations from Parliament of $5.7M a year and included 21 full-time equivalent employees (FTEs). As patient numbers grew from 500 registered (or designated) individuals in 2001 to over 37,000 in 2013, public safety concerns arose. To address these concerns, Health Canada introduced the *Marihuana for Medical Purposes Regulations* (MMPR).[3] The MMPR was introduced in June 2013 and fully implemented by April 2014.

The MMPR created the conditions necessary for the licensing of production and distribution of cannabis for medical purposes. Under the MMPR, individuals with the authorization of their health care practitioner could access quality-controlled dried legal cannabis produced under secure and sanitary conditions. With the implementation of the MMPR, OMC was tasked with several additional responsibilities, including creating and implementing a licensing program, developing guidance materials for applicants and licensed producers (LPs), preparing standard operating procedures (SOPs), processing licence applications, and issuing licences, renewals and amendments as well as export and import permits.

The budget appropriations from Parliament for OMC for the first year of the MMPR implementation (2013-14) remained the same as under the MMAR, meaning $5.7M with 21 FTEs. However, this budget did not take into consideration the additional responsibilities associated with the implementation of the licensing of producers of cannabis for medical purposes associated with the MMPR. Thus, Health Canada had to

internally re-allocate funds on a temporary basis to the program to better equip OMC in implementing the new licensing program. Even though the OMC's new licensing activities under the MMPR were not fully funded in terms of budget appropriations from Parliament, the program's appropriations budget had to be revised downward in 2014-15, as part of a government-wide strategic and operating review[4]. Thus, the program's parliamentary appropriations decreased 61% from 2013-14 to 2014-15, going from $5.7M to $2.2M and from 21 FTEs to eight FTEs.

Since the licensing program has been operating in a context where it is not fully funded, Health Canada has had to internally re-allocate funding to the program on a temporary basis to allow it to deliver on its outputs and outcomes. One of the consequences of this high reliance on temporary funding is that, over the last four years, OMC has had to rely on a temporary workforce and experienced high employee turnover.

The current regulatory framework, the *Access to Cannabis for Medical Purpose Regulations* (ACMPR), was implemented in August 2016. In addition to the licensing of producers, OMC assumed additional responsibility for reviewing applications from, and issuing registration certificates to, individuals (or their designate) who have the authorization of their health care practitioner to produce a limited amount of cannabis for their own use[5]. No permanent adjustment to OMC's budget appropriations from Parliament was made following the ACMPR implementation. As of June 2017, OMC was still operating with a $2.2M budget appropriations that included eight FTEs. Since then, the Government of Canada has announced, through its Fall Economic Statement 2017, additional funding for the cannabis program.

In May 2017, OMC introduced improvements to the process for licensing producers of cannabis for medical purposes. These improvements are intended to better position HC in administering the licensing framework while addressing some industry concerns (see detailed discussion in the following section of the report).

Evolution of the Licensing Program

From 2013 to May 2017, the process to become a LP has eight consecutive steps[6]. The process included (1) application receipt, (2) preliminary screening for completeness and (3) enhanced screening to determine if enough information is present to establish whether the requirements of the ACMPR are addressed. If the application was deemed compliant at the Enhanced Screening stage, (4) security clearance was undertaken. If an application successfully completed a security clearance, it advanced to (5) the review stage, in which OMC completed a full assessment of all requirements of the relevant regulations to determine whether the proposal met them including: Security Measures, Storage Area Security, Good Production Practices and Record Keeping. Once stage 5 was completed, an inspection was initiated, using (6) a "confirmation of readiness" request sent to the applicant to seek confirmation of readiness to proceed with the pre-licence inspection. The (7) pre-licence inspection was undertaken when applicants indicated that they were ready. The final step was (8) the licence issuance for a successful applicant. Notification of refusal could occur at any stage of the assessment process if the reviewer deemed there were sufficient grounds to do so.

In May 2017, OMC introduced several changes aimed at streamlining the licensing of producers of cannabis for medical purposes and enabling increased production of cannabis[7]. These changes drew upon the lessons learned from nearly four years of experience administering the cannabis for medical purpose licensing program. The changes reduced the processing of LP applications from eight to six steps. The new approach included additional features:

- allocation of additional resources to OMC to review and process applications;
- process changes that allow OMC to undertake some stages of the review of the application concurrently;
- measures that permit LPs to manage production on the basis of their vault capacity;
- longer validity periods for licences and security clearances in accordance with the regulations; and
- streamlined review and approval processes for applications to modify or expand a production facility for LPs with a record of good compliance with the ACMPR.

Measures were also taken to streamline inspections[8]. RORB conducts inspections of LPs to assess and monitor their compliance with the regulations and other applicable legislation. Prior to May 2017, RORB conducted the following four types of inspections:

- Pre-licence inspection – Conducted to assess whether the information submitted to Health Canada in a licence application or amendment is accurate.
- Initial inspection – Conducted when cannabis is ready for sale and testing is completed to assess whether the facilities, activities, and products are in compliance with the good production practices and record keeping requirements.
- Targeted inspection – Conducted to verify compliance with particular areas of the ACMPR.
- Regular inspection – Conducted to monitor and verify compliance with all the requirements of the ACMPR, *Controlled Drugs and Substances Act* (CDSA) and *Food and Drugs Act* (FDA) prior to licence renewal.

As part of improvements to the licensing of production of cannabis for medical purposes in May 2017, RORB now conducts the following four types of inspections:

- Introductory inspection – Conducted to verify that the LP is meeting the requirements of the ACMPR and to confirm that the activities being conducted by the LP correspond to those indicated on their licence.
- Pre-sale inspection – Conducted prior to the issuance of a sales licence to verify that the LP is meeting the requirements of the ACMPR prior to the issuance of a licence for the activity of sale.
- Targeted inspection – Conducted to verify compliance with particular areas of the ACMPR.

- Annual inspection – Conducted to monitor and verify compliance with all the requirements of the ACMPR, CDSA and FDA.

Stakeholders

OMC administers the licensing program in collaboration with the stakeholders listed in Table 1.

Table 1: Stakeholders

Stakeholder Groups	Roles and Responsibilities
Industry associations	Represent the interests of the LP community
Health care practitioner associations	Represent the views of physicians in all provinces and territories, and nurse practitioners in certain provinces and territories with respect to authorizing Canadians to possess marijuana for medical purposes
Health care regulatory authorities	Monitor the practices of members by collecting information from LPs on the medical documents signed by their members that authorize Canadians to register with LPs to access and possess marijuana for medical purposes
Patient advocacy groups	Represent the interests of individuals who access cannabis for medical purposes
Law enforcement and public safety authorities	Enforce the statutes of Canada as they relate to the status of cannabis as a controlled substance
Provincial, Territorial and municipal governments	Establish laws and by-laws that apply to LPs
International governments and bodies	Issue import and export permits Contribute to information sharing and lessons learned, given that a number of other jurisdictions have established or are contemplating establishing regulatory frameworks related to the use of cannabis for medical purposes
Scientific and research community	Participate in studying the benefits and harms of cannabis for medical purposes

Source: Office of Medical Cannabis

2.2 OMC Narrative

The logic model developed for OMC identifies three main activity areas (see Appendix 1):

- review applications (for LPs: review of new licence applications, applications for renewal of existing licences, and import/export permit applications; for individuals: review of applications for personal and/or designated production);
- play a leadership and coordination role with RORB in relation to the inspection and compliance and enforcement program; and
- provide information to LPs, LP applicants and other stakeholders.

The immediate outcome expected to materialize from these activities is: LPs, LP applicants, registered persons and other stakeholders have access to the information they need to make informed decisions.

It is expected that positive results for the immediate outcomes will contribute to: LPs and registered persons are compliant with the regulations; and Canadians register with LPs to access cannabis for medical purposes.

The long-term outcome is: quality-controlled, legal supply of cannabis for medical purposes is available in the Canadian market in accordance with the regulations.

2.3 OMC Alignment and Resources

The OMC is part of the Cannabis Legalization and Regulation Branch (CLRB). Prior to 2016, it was part of the Healthy Environments and Consumer Safety Branch. Within RORB, the cannabis inspectors are part of the Controlled Substances Program.

Table 2 presents the budget appropriations from Parliament for OMC since the creation of the licensing program for producers of cannabis for medical purposes in 2013-14 until June 2017. OMC was first allocated an annual appropriations budget of $5.7M. This was the funding associated with the cannabis for medical purposes program first created in 2001. However, in 2014-15 following a government-wide strategic and operating review, this parliamentary appropriations budget was revised downwards by 61% to $2.2M. Note that the OMC appropriations budget below is for the entire office and not just for the licensing division; it also includes RORB activities, which are funded through a budget transfer from OMC.

Table 2: OMC Budget Appropriations from Parliament ($)

Year	Salary[a]	O&M	Total
2013-14	1,494,000	4,269,469	5,763,469
2014-15	1,280,534	966,949	2,247,483
2015-16	1,280,534	966,949	2,247,483
2016-17	1,280,534	966,949	2,247,483
2017-18[b]	1,280,534	966,949	2,247,483
Total	**6,616,136**	**8,137,265**	**14,753,401**

Source: Office of Chief Financial Officer
[a] Salary includes Employee Benefit Plan.
[b] Number reported for 2017-2018 do not account for the additional funding announced through the 2017 Fall Economic Statement

Table 3 presents the budget specific to RORB's activities as they relate to the cannabis for medical purposes program. As indicated earlier, RORB's budget is funded through a transfer from OMC's budget appropriations from Parliament. This transfer averaged $1.7 M per year over the last three years, which represents about 75% of OMC's annual parliamentary appropriations budget.

Table 3: RORB (for Cannabis for Medical Purpose Activities Only) Budget ($)

Year	Salary[a]	O&M	Total
2014-15	927,601	171,001	1,098,602
2015-16	1,740,220	283,432	2,023,652
2016-17	1,663,270	270,000	1,933,270
2017-18	1,476,000	270,000	1,746,000
Total	**5,807,090**	**994,433**	**6,801,523**

Source: Office of Chief Financial Officer
[a] Salary includes Employee Benefit Plan.

3.0 Evaluation Description

3.1 Evaluation Scope and Approach

The scope of the evaluation covered the licensing of producers of cannabis for medical purposes program for the period from September 1, 2014 to June 30, 2017. It included licensing activities conducted under the MMPR (from September 1, 2014 to August 23, 2016), and licensing activities conducted under the current ACMPR (from August 24, 2016 to June 30, 2017). Additional information on important developments occurring after the end of the scoping period were provided by the program in early 2018. This information has been included in the report to provide further context on findings, conclusions and recommendations.

Health Canada's new activities as of August 2016 associated with the registration of individuals authorized to produce a limited amount of cannabis for their own medical purposes or to designate someone to produce it for them were not included in the scope of the evaluation.

As per the Treasury Board of Canada *Policy on Results* (2016), it was determined that a design and delivery evaluation would be the most beneficial in assisting management to adjust the course of implementation activities and, where applicable, to improve the achievement of results. Three evaluation areas were identified to address the design and delivery element. These areas were: Licensing Program Design and Delivery, Achievement of Immediate Outcome, and Alternative Design. Corresponding to these areas, specific questions were developed based on management considerations and these guided the evaluation process.

Data for the evaluation was collected using various methods, which consisted of: a document review, key informant interviews, a survey of LPs, financial data review, international comparison analysis, licensing program comparison analysis, performance measurement data review, and licensing application file review. More specific details on the data collection and analysis methods are included in Appendix 2.

Data were analyzed by triangulating information gathered from the different methods listed above. The use of multiple lines of evidence and triangulation were intended to increase the reliability and credibility of the evaluation findings and conclusions.

3.2 Limitations and Mitigation Strategies

Most evaluations face constraints that may have implications for the validity and reliability of evaluation findings and conclusions. Table 4 outlines the limitations encountered during the implementation of the selected methods for this evaluation. Also noted are the mitigation strategies put in place to ensure that the evaluation findings can be used with confidence to guide operational planning and decision-making.

Table 4: Limitations and Mitigation Strategies

Limitation	Impact	Mitigation Strategy
Key informant interviews are retrospective in nature.	Interviews are retrospective in nature, providing recent perspective on past events. This can impact validity of assessing activities or results.	Triangulated other lines of evidence to substantiate or provide further information on data captured in interviews. Document review provided corporate knowledge.
The licensing process changed during the time period of the evaluation scope (in late May 2017).	The findings may not reflect the current system or approach.	Where possible, the impact of the changes was addressed in interviews.
Inconsistent data entry for performance measurement and file tracking.	Due to inconsistent methods of data entry for performance measurement tracking tools, key data were not available for a large number of application files.	Analysis was done with the available data, and caution was used in extrapolating to the full sample. Where possible, information was triangulated with other lines of evidence.
A small sample of existing applicants was selected for file review and interviews.	The experiences of these interviewees may not be generalizable to the applicant community at large.	A random sample of applicants was chosen. Findings from applicant interviews are presented as the opinions and experiences of a sample.
The breakdown of OMC's financial data associated with the licensing program was not available.	Specific analysis between spending levels of the licensing functions and their performance level cannot be done across the years.	The evaluation used OMC global financial data for years 2013-14 to 2016-17. Although OMC's global financial data encompassed more than just the licensing activities, the data still allowed for a general understanding of the financial context in which the licensing program has been operating since its creation.
Limited data on physical and personnel security requirements for licensed producers in other jurisdictions.	This limited the comparison with other jurisdiction in terms of physical and personnel security requirements.	Physical and personnel security requirements were compared only to those of other Canadian programs, such as controlled substances or other regulated products.

4.0 Findings

4.1 Issue #1 – Licensing Program Design and Delivery

4.1.1 Intended outputs

The program has generally delivered on its intended outputs of issuing licences, producing inspection reports and publishing guidance materials.

Outputs: Issuance of licences and permits to conduct regulated activities with cannabis.

Licensing producers

The licensing of producers of cannabis for medical purposes began with the implementation of the licensing program in June 2013. Between June 2013 and June 2017, OMC received a total of 1,680 applications to become an LP. Table 5 reports the number of application received, closed, carried over and in progress as of June 30, 2017.

Table 5: Application Processing by Fiscal Year, 2013-14 to 2017-18

	2013-14	2014-15	2015-16	2016-17	2017-18 (as of June 30, 2017)
Number of applications carried over from previous year as of April 1st	N/A	297	323	425	414
Number of applications received during the year	651	633	237	109	50
Total active applications per year	651	929	561	524	464
Number of applications closed in the year	354	606	146	110	36
% of applications closed in the year	54%	65%	26%	21%	N/A
Total applications still active at Year End	297	323	425	414	N/A

Source: Office of Medical Cannabis
N/A = Not Available

At the end of the scoping period for the present evaluation (June 30, 2017), OMC had closed about 75% of the application files it received over the years (1252 out of 1680). Of the 1,252 files closed since 2013, 69% (866) were closed because they were incomplete, 21% (267) were refused, 6% (69) were withdrawn and 4% (50) received a licence. These results however, do not account for performance improvements associated with the changes to the licensing process introduced by OMC in late May 2017 and discussed earlier in this report. Early results associated with these changes show that between July 1, 2017 and December 27, 2017, the program had licensed an additional 34 producers of cannabis, bringing the total number of LPs to 84.

Licence renewals and amendments to licences

The OMC licensing division is responsible for processing renewals of, and amendments to, existing licences. Prior to May 2017, licences had to be renewed every year. However, with the implementation of improvements to the licensing process for producers of cannabis for medical purposes, licences can now be granted for up to three years as per the regulations, for LPs with a good compliance record, which decreases the number of renewal applications received each year.

LPs interested in conducting a broader range of activities and/or increasing their production amounts must submit an application to amend their licence which, if approved, results in the issuance of a new licence. Table 6 below presents the number of amended licences issued for 2016 and 2017. For the year 2016, the average number of amended licences by LP was six, with the actual numbers ranging from 0 to 27 amended licences per LP.

Table 6: Number of amended licences issued by calendar year

	2016	2017 (to June 30,2017)
Number of amended licences issued	224	71

Source: Office of Medical Cannabis
Note: Complete data for 2014 and 2015 are unavailable.

Issuance of import and export permits

The cannabis for medical purposes program is neither intended to make Canada an exporter of cannabis, nor to enable importation as an alternative to domestic production. Still, Subdivision G of the ACMPR sets out a framework for LPs to obtain import and/or export permits. Review of these permit applications and issuance of permits falls under the responsibility of the licensing division of OMC. Table 7 provides the number of import and export permits issued by OMC since 2014.

Table 7: Number of import and export permits issued by OMC per calendar year

Type of product	2014		2015		2016		2017 (to June 30, 2017)	
	Import	Export	Import	Export	Import	Export	Import	Export
Dried cannabis	23	0	15	0	0	6	0	11
Cannabis plant	1	0	4	0	0	0	0	0
Cannabis seeds	8	0	14	0	3	3	5	0
Total	32	0	33	0	3	9	5	11

Source: Office of Medical Cannabis
Note: Import and export permits for cannabis oil are not processed by OMC.

Outputs: Inspection reports, warning letters and product seizures

RORB conducts inspections of LPs to assess and monitor their compliance with the regulations and other applicable legislation. Table 8 presents the number of inspections conducted and their associated compliance rate for the last three fiscal years. The average number of inspections per LP was 10 in 2014-15, 11 in 2015-16 and 7 in 2016-17.

Table 8: Number of inspections and associated compliance rate

Type of inspection	2014-15		2015-16		2016-17	
	Number	Compliance rate	Number	Compliance rate	Number	Compliance rate
Pre-licence	22	N/A[a]	47	N/A[a]	50	N/A[a]
Initial	27	92%	16	100%	29	N/A[b]
Targeted	171	93%	227	97%	165	99%
Regular	20	100%	27	100%	30	93%
Total Inspections (#LP)	240 (25)		317 (30)		274 (41)	

Source: RORB

[a] Pre-licence inspections do not have a compliance rate as they are conducted to verify that the information submitted to Health Canada in a licence application is accurate prior to licence approval.

[b] For FY 2016-17 initial inspections have no compliance rate, as they are now conducted under the ACMPR (implemented in 2016) to verify that the products ready for sale meet the Good Production Practices requirements under the ACMPR prior to granting the activity of sale.

Table 8 also illustrates that the total number of inspections decreased between 2015-16 and 2016-17, particularly in the case of targeted inspections. As of April 2016, RORB adopted a new individual risk-based rating approach for determining the number of targeted inspections for each LP (further details on this approach are discussed in the Output and Outcome Risk Management section of this report) which led to fewer total inspections in 2016-17, despite an increase in the number of LPs.

Lower inspection numbers can also be explained by an initiative undertaken by RORB in September and October 2016, following the implementation of the new ACMPR. For these two months RORB, instead of conducting targeted inspections, did a series of compliance promotion visits aimed at helping LPs understand the new regulations. A total of 34 compliance promotion visits were completed in place of targeted inspections. During compliance promotion visits, no observations, risk rating or compliance actions were undertaken.

Corrective measures resulting from inspection activities conducted since the beginning of the licensing program include 25 warning letters and seven product seizures. Inspection activities also led to 12 product recalls done by the industry since 2014.

Outputs: Production of Guidance, Information Bulletins, Reports and Market Data

Since 2014, OMC produced and published a considerable amount of guidance material on a variety of subjects including internal operations, building and production security requirements, advertising prohibitions on cannabis for medical purposes, compliance with local laws, and testing of cannabis for medical purposes. Market Data reports have also been made publicly available on the Health Canada website since 2014-15; the data provided publicly continues to expand in response to demand. As of 2015-16, the Market Data report is being updated quarterly (dependent on the availability of data). At the time of the evaluation, OMC was developing guidance on good production practices and mandatory pesticide testing, as well as a guide to recalls, in consultation with regulated parties.

4.1.2 Efficiency of delivery methods and program compliance

OMC succeeded in implementing and delivering a licensing program for producers of cannabis for medical purposes. OMC has responded to a need for a more efficient approach to issuing licences with the introduction in late May 2017 of improvements to the licensing process. Outstanding needs to better support the efficiency of day-to-day operations remain however, such as the need for an integrated case management system.

OMC has worked collaboratively with its delivery partners, and has been successful at maintaining control over the movement of cannabis produced by LPs and at monitoring their compliance.

Efficiency

The following section discusses the efficiency of the licence application process managed by OMC, as well as efficiency associated with the two stages of the process delivered in collaboration with partners, which are: inspections, delivered by RORB, and personnel security clearances, undertaken by the RCMP.

Licence application process

The licence application process is composed of multiple steps requiring the input of many contributors. There are external factors reported by the program which can influence the time it takes to process a licence. These include the overall volume of applications, the quality and completeness of these applications, the responsiveness of the applicant to requests for additional information or evidence to support the application, and the time required to conduct law enforcement record checks. The evaluation found that there is no standard timeframe against which to benchmark the application and licensing process given that each LP applicant's situation is unique (for example, some applicants choose to build new facilities, while others convert existing buildings into production facilities). The evaluation found that OMC employees who were in charge of reviewing application files could rely on clear checklists to guide their

work. The program, however, had not yet established internal service standards for the elements of the licensing process for which it was solely responsible.

For licences issued up to June 30, 2017 (a total of 50 LPs), the average time for an application to be reviewed for compliance with the regulations, for the necessary security checks to be completed, for an applicant to be ready for a pre-licence inspection, and for an applicant to receive their initial production licence was 15 months. The time taken for all these steps to be completed ranged from 1 to 33 months following Health Canada's receipt of an application.

The evaluation found that approximately half (52%) of LPs surveyed believed that the length of time between their submission of an initial application and the issuance of licences was unreasonable. However, as a result of a number of improvements introduced in late May 2017 to the processing of applications to become a licensed producer, there is evidence of increased efficiency. Early results associated with these improvements show that a total of 40 licences were issued between late May and December 2017, which is more licences than were issued in the previous three years combined.

OMC has been reviewing and processing applications to become LPs without the benefit of having an electronic case management system to help them manage their files and accurately track processing time, instead relying on an extensive system of paper files and a database. While the database in use by the program is useful to keep track of the volume of applications in progress and/or closed, it does not allow for the extraction of precise information on the time spent on each step of the application process in order to analyze where important delays are encountered and identify the causes.

Within the context of having recently updated their application process, there are additional opportunities for OMC to start to collect data on processing time for each step of the new licensing process for which it is responsible. (e.g., application screening, review of applications for import/export permits). Such data would help inform OMC in setting future internal service standards for processing applications. Furthermore, setting service standards would support the program in managing expectations from applicants as it relates to the application process time.

A high level of correspondence between parties was to be expected, as the ACMPR are comprehensive regulations that include an important number of rigorous criteria. The evaluation found that there were opportunities for the program to increase efficiency as it relates to communication, as there was an average of 115 emails per file reviewed. As a result of the improved licensing program (introduced in May 2017), steps were being taken to address these issues. The evaluation found that each application file is now being assigned to a single officer overseeing its review from beginning to end with the intention of increasing continuity and consistency of the application process, as well as improving communication.

The move to single-officer oversight addresses one of the main improvements suggested in interviews across stakeholder groups, which was that applicants would like to have a single person assigned to their file instead of using the OMC's generic email account. It also addresses a finding of the evaluation's file review, which noted that all of the application files reviewed had been assigned to successive, multiple reviewers over the course of its assessment. Interviews conducted with applicants after May 2017 confirmed that the new file assignment approach was being implemented and was seen as an important improvement. Furthermore, some stages of the application process are now conducted concurrently instead of consecutively, as was the case before May 2017. Applicants interviewed after May 2017 welcomed the change as this should lower overall processing time for applications.

Inspections

RORB has service standards related to the pre-licence inspection stage of the application process. The Branch must conduct the inspection within 20 days of receiving the request from OMC, and has 10 days to provide OMC with their inspection report. The evaluation found that these service standards were systematically met. The evaluation also found that OMC and RORB have been able to develop an efficient working relationship.

Personnel Security Clearances

As required by Subdivision H of the ACMPR, Health Canada has adopted a security clearance standard for the cannabis industry that allows the program to mitigate against the involvement of persons associated with organized crime and minimize the chances of product diversion. The standard adopted by Health Canada is comparable to the one adopted by Transport Canada for airport employees. OMC liaised with Transport Canada to learn and benefit from that department's years of experience with a security clearance process for airport employees requiring restricted area access.

Each application received by OMC requires the security clearance of four people at a minimum; however this number can be significantly higher for a corporation, as each officer and director of the corporation also need a security clearance. The security clearance stage of the licensing process is undertaken in collaboration with the RCMP. As of January 2017, there were 158 applications (including renewals) at the Security Clearance stage and over 850 active security clearances. Obtaining a security clearance can take between six to 12 months from the day the security file is opened.

The evaluation found that OMC has improved the way it internally manages the security clearance process in recent years by bringing security experts on staff to manage the security clearance process, replacing the former practice of engaging Health Canada's corporate service to administer the process. This has enabled OMC to reduce its own administrative process relating to security clearances by several weeks. In addition, as a result of improvements announced in late May 2017, the security clearance process is now undertaken concurrent with the review of the rest of the application (rather than consecutively), increasing efficiency of the process as a whole. All new and renewed

security clearances for key personnel can now be issued with a validity period of up to five years in accordance with the regulations (and subject to Health Canada not receiving new information that could result in a security clearance being suspended or revoked). Prior to May 2017, the security clearances had a validity period of one year.

Interviews and file reviews conducted as part of the evaluation, however, found some operational practices that may have lessened the efficiency of the administration of the security clearance process. For example, the use of paper forms was reported as linked to increased chances of errors and delays associated with having to return the form to an applicant before it can be further processed. OMC reports that it will be implementing an electronic case management system in Summer 2018 which will enable the electronic submission of applications for a security clearance.

Compliance of the program and of LPs

The licensing of producers of cannabis for medical purposes program must operate in compliance with the *Single Convention on Narcotic Drugs* (1961) as amended by the 1972 *Protocol*, the *Convention on Psychotropic Substances* (1971), and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (1988). These conventions strictly limit trade in cannabis to medical and scientific purposes to the confirmed estimates set by the International Narcotics Control Board. Health Canada maintains a system of control for the movement of cannabis in a manner consistent with international drug control conventions.

Health Canada has put in place a system to monitor the compliance of LPs of cannabis for medical purposes. Since the beginning of the licensing program, no case of product diversion from LPs of cannabis for medical purposes has been reported to or documented by Health Canada. Furthermore, the overall level of compliance of LPs licensed for the production of cannabis for medical purposes resulting from inspections was 95% for 2014-2015, 97% for 2015-16 and 98% for 2016-2017 (see Table 8 presented earlier in this report for the detailed compliance rate by type of inspection).

4.1.3 Economy

OMC actual expenditures were regularly three times higher than its budget appropriations from Parliament for the period under review by the evaluation. This is due to the budget appropriations not having been adjusted to take into account the 2013 creation of a licensing program for producers of cannabis for medical purposes.

Since the financial data specific to the licensing program were not available, the evaluation used OMC global financial data. Although OMC's global financial data encompassed more than just the licensing activities, the data still allowed for a general understanding of the financial context in which the licensing program has been operating since its creation.

Table 9 highlights the variance between OMC's budget appropriations from Parliament and its actual expenditures, since the creation of the licensing of producers of cannabis for medical purposes program in June 2013 until the end of fiscal-year 2016-2017. For this period, OMC reported spending between 342% and 440% (with an average of 374%) of its budget appropriations. OMC has been operating, since the introduction of the licensing program, in a context where it was not fully funded. As a result, Health Canada had to internally re-allocate funding to the program on a temporary basis to allow it to deliver on its intended outputs and outcomes for the period covered by this evaluation. Note that shortly after the end of the scope period used for this evaluation, the Government of Canada announced additional funding for the cannabis program through its Fall Economic Statement 2017. This funding was confirmed through tabling of Supplementary Estimates C, 2017-18.

Table 9: Variance between Budget Appropriations and Expenditures – OMC

Year	Budget Appropriations ($)			Expenditures ($)			Variance ($)	% Budget Spent
	Salary	O&M	TOTAL	Salary	O&M	TOTAL		
2013-14	1,494,000	4,269,469	5,763,469	7,659,520	12,051,213	19,710,733	13,947,264	342%
2014-15	1,280,534	966,949	2,247,483	5,970,724	3,021,773	8,992,497	6,745,014	400%
2015-16	1,280,534	966,949	2,247,483	6,163,292	2,022,365	8,185,657	5,938,174	364%
2016-17	1,280,534	966,949	2,247,483	6,667,927	3,222,522	9,890,449	7,642,966	440%
TOTAL	5,335,602	7,170,316	12,505,918	26,461,463	20,317,873	46,779,336	34,273,418	374%

Source: Office of Chief Financial Officer

Table 10 presents the variance between the budget and actual expenditures of RORB as it related to cannabis for medical purposes activities. RORB has reported spending between 83% and 103% (with an average of 89%) of its planned budget.

Table 10: Variance between Budget and Expenditures – RORB (for Cannabis for Medical Purpose Activities Only)

Year	Budget ($)			Expenditures ($)			Variance ($)	% Budget Spent
	Salary	O&M	TOTAL	Salary	O&M	TOTAL		
2014-15	927,601	171,001	1,098,602	750,949	158,471	909,419	-189,183	83%
2015-16	1,740,220	283,432	2,023,652	1,344,154	278,542	1,622,695	-400,956	80%
2016-17	1,663,270	270,000	1,933,270	1,748,260	237,245	1,985,505	52,235	103%
TOTAL	4,331,091	724,433	5,055,524	3,843,363	674,258	4,517,619	-537,904	89%

Source: Office of Chief Financial Officer

4.2 Issue #2 – Achievement of Immediate Outcomes

Outcomes: Licensed producers and other stakeholders have access to the information they need to make informed decisions

Licensed producers and applicants generally have access to information supporting an overall understanding of the cannabis for medical purposes licensing process and regulations, but have unmet information needs in some areas which are limiting their ability to make informed business decisions.

Applicants to become LP and representatives of industry associations interviewed stated that participating in a predictable licensing process and obtaining timely information has a direct impact on their ability to plan and finance their projects. While 52% of LPs surveyed agreed that the application process for an initial licence was clear, 36% disagreed and 12% neither agreed or disagreed. Interviews with applicants indicated that they found the application process difficult to understand at times, and that some had sought the services of consultants to help them prepare their application and respond to Health Canada's requests for additional information. Applicants interviewed as part of this evaluation noted early signs of improvements in the timeliness and openness of their communication with OMC after the introduction of improvements to the licensing of producers of cannabis for medical purposes announced in late May 2017.

As reported earlier in this report, OMC has, since 2014, produced and published considerable amount of guidance material on various subjects filling several information gaps. On that level, the evaluation found that 88% of LPs surveyed agreed that their company was aware of the required Good Production Practices. The evaluation also found that 85% of LPs surveyed agreed that their company had sufficient information regarding the transition between the MMPR and the ACMPR to operate effectively. Meanwhile 69% of LPs surveyed agreed that their company had access to enough information regarding the ACMPR to operate effectively. However, many applicants interviewed and LPs surveyed were of the view that there are still areas of ambiguity related to parts of the ACMPR and expressed a need for more guidance in interpreting and applying the requirements of the ACMPR in relation to their application process or their ongoing operations.

4.3 Risk Management

Health Canada has adopted a prudent approach to administering the initial roll-out of the licensing program. The program's risk tolerance approach and mitigation activities have been successful given that there have been sufficient quantities of quality-controlled legal cannabis available to eligible Canadians without instances of diversion. As part of improvements to the licensing of producers of cannabis for medical purposes introduced in late May 2017, Health Canada has taken risk-based steps to improve efficiency and effectiveness in

some areas. There remain a few elements of the licensing program's design and processes, which could benefit from further risk-based reviews as the model matures.

As part of the analysis of data collected in support of this evaluation, some risks and opportunities to the achievement of the intended outputs and outcomes of Health Canada's licensing program for cannabis for medical purposes were noted, along with information on risk mitigation strategies employed to date by Health Canada. Although the program has not developed a formal Risk Profile and Mitigation Strategies Framework, the program did a review of risks specific to the licensing program when developing the improvements to the licensing of producers of cannabis for medical purposes introduced in May 2017. The following provides a general overview of the risk context for the licensing program as it emerged through the evaluation's review of outputs production and immediate outcomes achievement. The evaluation found that OMC had been taking action to address risks and opportunities facing the program on a regular basis, if not through a formalized risk management approach.

Risk Context of the Licensing Program

As previously noted in this report, the implementation of the cannabis for medical purposes licensing program was undertaken in a context of high public interest and scrutiny. Health Canada regulations for cannabis for medical purposes have been driven by external factors, and administration of these regulations has occurred in a highly litigious context. The most recent regulatory framework ACMPR has been described by Health Canada as an immediate solution to address a court judgment, and the Government of Canada has publicly committed to maintain this separate framework for access to cannabis for medical purposes under the proposed *Cannabis Act* that is presently being considered by Parliament. It has also committed to evaluate the regulatory framework within five years of coming into force of the new Act. Heath Canada has instituted a prudent approach to its work to ensure applicants are compliant with the regulations. This is done in support of the program's longer-term outcomes, such as having a quality-controlled legal supply of cannabis for medical purposes available in the Canadian market in accordance with regulations.

While some stakeholders interviewed expressed concern with the time required to process applications to become a LP, available Market Data reports indicate that the availability of quality-controlled legal cannabis for medical purposes has been sufficient to meet the demand of registered clients between April 2014 and March 2017. As of June 30, 2017, there were 201,398 registered clients[i] in Canada. While supply meets overall demand, the evaluation found that some shortages of specific types of oil were reported in early 2017.

[i] This refers to the number of active client registrations with licensed producers at the end of June 2017. Individuals may be registered with more than one licensed producer provided an original medical document was used with each registration.

As noted in the previous section, the LP rate of compliance with regulations (as indicated through Health Canada inspections), has been high. Actions taken to date in addressing instances of non-compliance include product recalls. Health Canada employs three classes of recalls:

- Type I: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death,
- Type II: a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences, or where the probability of serious adverse health consequences is remote; and
- Type III: a situation in which the use of, or exposure to a product, is not likely to cause any adverse health consequences.

Since 2014, there have been 12 industry recalls of cannabis products. Table 11 provides the types of recall, the reason behind them, as well as the number of adverse reaction reports received by Health Canada for each recall.

Table 11: Cannabis for medical purposes product recall from April 1, 2014 to June 30, 2017

Starting date of the recall	Type of recall	Issue	Number of adverse reaction reports received by Health Canada
April 2014	N/A[a]	Good Production Practices non-compliance (including use of non-registered pesticide)	0
August 2014	N/A[a]	Contamination (mold)	0
February 2015	N/A[a]	Mislabelling (THC content)	0
March 2015	N/A[a]	Contamination (bacterial)	0
August 2016	III	Undeclared substance (pesticides)	0
November 2016	III	Undeclared substance (pesticides)	10
January 2017	II / III	Undeclared substance (pesticides)	1
January 2017	II	Undeclared substance (pesticides)	0
March 2017	III	Mislabelling (THC content)	0
April 2017	III	Mislabelling (CBD content)	0
May 2017	III	Undeclared substance (pesticides)	0
May 2017	III	Undeclared substance (pesticides)	1

Source: Recalls and safety alerts website and Access to Cannabis for Medical Purposes Regulation – Quarterly Compliance and Enforcement Report – Inspection Data Summary
[a] The type of recall is not available (N/A) for recalls that occurred prior to 2016

Since August 2016, six product recalls related to the use of unauthorized pesticides have been undertaken. As of June 30, 2017, Health Canada received 12 adverse reaction reports linked to three of these recalls. The program was able to quickly react to this emerging issue by adjusting its inspection-related activities and by providing additional guidance to the industry on the subject.

Overall, the ability of existing LPs to supply the demand for quality-controlled legal cannabis for medical purposes, combined with a high level of LP compliance with the regulations noted in Health Canada's inspections and a lack of product diversion, indicates that the licensing program's risk management has been successful. The evaluation has noted a few areas, however, where some risk-mitigation measures implemented early on by the program may have led to unexpected or undesirable impacts. For example, prior to May 2017, the licensing application review process was undertaken in a consecutive manner across the eight steps of the process. The improvements to the licensing of producers of cannabis for medical purposes introduced in May 2017 sought to address this issue when it introduced the opportunity for some steps of the process to be completed concurrently, while ensuring continued mitigation of risks.

In line with the licensing process improvements implemented in late May 2017, RORB is also implementing a new risk-based approach to the conduct of inspections for all LPs. This approach will allow RORB to better align its inspection resources to the licensing program needs in terms of activities conducted as part of the licensing of new producers and activities conducted as part of compliance monitoring or licence renewals of existing LPs. As such, the total number of inspections of each LP conducted by year is expected to go down, while the total number of LPs inspected in a year is expected to increase. Table 12 shows the expected variance between the number of inspections that were conducted under the former approach and the inspections expected following going forward.

Table 12: Variance in inspection numbers from the previous licensing program to the May 2017 licensing program

		Former program	May 2017 Program	Variance
New LP – First year of licence		1 pre-licence inspection[a] 1 pre-sale inspection* 5 targeted inspections 1 annual inspection	1 introductory inspection[a] 1 pre-sales inspection[a] 2 targeted inspections 1 annual inspection	-3
Existing LP	**Unknown / High Risk**	5 targeted inspections 1 annual inspection 1 pre-sale inspection[a]	3 targeted inspections 1 annual inspection 1 pre-sales inspection[a]	-2
	Medium Risk	3 targeted inspections 1 annual inspection	2 targeted inspections 1 annual inspection	-1
	Low Risk	1 targeted inspection 1 annual inspection	1 annual inspection	-1

Source: RORB
[a] These inspections are only initiated following an LP's indication of readiness for inspection

Health Canada has taken risk-based steps to improve efficiency and effectiveness in the area of compliance monitoring, and as the program continues to evolve and mature, there will remain potential opportunities for further efficiencies as it relates to inspection and compliance monitoring. As such, the risk-based approach to determining the

frequency and the areas of focus of inspections could be regularly reviewed to ensure alignment to the relative risks to the system and harms of non-compliance.

The evaluation has also identified further design and delivery issues, which may be impeding the program's ability to efficiently produce outputs and effectively support the achievement of its longer-term objectives, namely finalizing Standard Operating Procedures and the use of its generic email account. The following section provides descriptions of the issues and the risks that they may pose to the program.

Standard Operating Procedures

The evaluation found that while OMC employees who were in charge of reviewing application files could rely on clear checklists, some Standard Operating Procedures (SOPs) used, however, had not been fully updated in light of the new ACMPR (which came into force in August 2016). This creates some risk of inconsistent interpretation of some requirements of the regulations. To minimize discrepancies between interpretations, OMC has put in place weekly meetings where employees from OMC and RORB (including all regions) come together and discuss files and processes. Furthermore, as of June 2017, a review of existing SOPs with the intent to finalize them according to the requirements of the ACMPR was underway.

Generic Email Use

OMC is relying on the growing contents of its generic email account as the main repository of communication with applicants. The use of the generic email account as the principal information management tool for the licensing program creates risks related to information security, availability and completeness. A formal case management system for the program may offset these risks in addition to better supporting the application review process overall. OMC reports that an electronic case management system is under development for implementation in summer 2018.

4.4 Issue #3 – Alternative Design

4.4.1 Licensing programs of controlled substances and/or regulated products in Canada

Service standards and application fees are common design elements implemented by other licensing programs in Canada, which are viewed positively by OMC stakeholders.

The evaluation undertook a review of five comparable Canadian licensing programs for regulated items: Prescription Drugs, Medical Devices, Industrial Hemp, Natural Health Products, and Human Pathogens and Toxins. The review aimed to examine elements of existing programs that could be of benefit to further iterations of the licensing program of producers of cannabis for medical purposes, while keeping in mind that the program

presently under evaluation is relatively new when compared to similar programs used and was created in response to court decisions, and uncertain operating context.

The review data highlighted that the number of inspections conducted as part of the cannabis for medical purposes program per licensee was well above that of the comparable programs dealing with controlled substances. It also draws attention to the fact that none of the comparable programs used was found to have the same requirement to mitigate against the involvement of persons associated with organized crime and minimize the chances of product diversion as does the licensing program of cannabis for medical purposes, thus limiting our ability to meaningfully compare requirements between programs.

The review allowed for the identification of two key design elements implemented by other licensing programs in Canada that are not elements of the existing licensing program for producers of cannabis for medical purposes: service standards and fees. Four of the five comparable programs have adopted some forms of service standards. Furthermore, the review found that the two programs with the most comprehensive service standards also have a licensing fee (prescription drugs and medical devices). The licensing fees posted by these two programs for 2016-17 ranged from $7,950 to $30,454 depending on the licence type requested. Applicants and representatives of industry associations interviewed for the evaluation indicated that they would support a fee when applying for a licence to produce cannabis for medical purposes, particularly if this would help in improving the timeliness of the process.

The evaluation team also reached out to the federal evaluation community in order to identify if recent evaluations of other federal licensing programs and/or application review and processing services had identified best practices that could be helpful to OMC in administering their licensing program. As such, it was found that a loan program administered by Agriculture and Agri-Food Canada made efficiency gains through the implementation of an online registration system[9]. The system allowed for a streamlined loan registration process while improving the transparency of the program and reducing the administrative cost of issuing loans for financial institutions. In developing the system, Agriculture and Agri-Food worked in conjunction with Industry Canada, as they also administered similar loan programs and thus were in position of also benefiting from such a system.

4.4.2 Licensing programs of cannabis for medical purposes in other jurisdictions

Canada is considered a world leader in the domestic regulation of producers of cannabis for medical purposes. Canada differs from other jurisdictions in its lack of fees for licence applications and renewals, and caps on the number of licensed producers.

Canada is considered as a global leader in the licensing of production of cannabis for medical purposes according to external stakeholders, including those in the cannabis industry. The health and safety requirements adopted by Health Canada are unmatched

in North America for either medical or non-medical cannabis systems. Increased exports of cannabis for medical purposes to other jurisdictions also supports recognition by other jurisdictions of the quality of products produced by Canadian LPs.

The international context for cannabis for medical purposes is changing quickly. Since Canada implemented the MMPR in 2013, several countries have established licensed production of cannabis for medical purposes or are in the process of implementing one. To learn more about cannabis for medical purposes licensing programs internationally, the following jurisdictions were reviewed:

- Australia (access to cannabis is legal for medical use only)
- Germany (access to cannabis is legal for medical use only)
- Israel (access to cannabis is legal for medical use only)
- United States
    - Colorado (access to cannabis is legal for medical and non-medical uses at the state level)
    - Oregon (access to cannabis is legal for medical and non-medical uses at the state level)
    - Washington (access to cannabis is legal for medical and recreation uses at the state level)
    - New York (access cannabis is legal for medical use only at the state level)

Jurisdictions with legal access to cannabis for medical purposes

Although Australia and Germany recently provided legal access to cannabis for medical purposes, their respective licensing programs were not fully implemented as of June 2017. Both countries were still relying on the importation of cannabis for medical purposes, including imports from Canada, as their locally grown production was not operational.

As of June 2017, Canada and Australia were the only two jurisdictions that did not put a maximum on the number of LPs of cannabis for medical purposes. While Australia did not adopt a maximum on the number of producer licences, its program includes an application fee. In those jurisdictions where a maximum to the number of LPs have been set, New York had five LPs (although it was in a process to license five additional producers), Israel had eight LPs, and Germany was in the process of identifying a limited number (to be determined) of producers based on set production limits.

Jurisdictions with legal access to cannabis for both medical and non-medical purposes

For the three American jurisdictions reviewed that have multiple legal uses (Colorado, Oregon and Washington), there are licensing fees for, and no caps on, multiple-use

cannabis producers. A tiered-licensing approach has been adopted in each jurisdiction. Tiered-licensing has been engaged to distinguish between the production sizes or the types of activity (i.e., production, distribution, laboratories, etc.). As of June 2017, Washington was controlling access to licences by opening and closing application periods.

In the three American jurisdictions with legal access to cannabis for medical and non-medical use, the number of producers was well over 500 as of June 2017. The American jurisdictions included in this review all use electronic plant tracking systems to keep track of cannabis production from seedling to the point of sale of plant matter as a means to mitigate the risk of diversion to other jurisdictions. The costs associated with the systems are covered by the licensing fee charged by the programs.

5.0 Conclusions

5.1 Licensing Program Design and Delivery

OMC has faced a number of challenges as it undertook the implementation of a new program of licensing of producers of cannabis for medical purposes within a context of high public interest and continual development of the regulatory framework. OMC actual expenditures have regularly exceeded 300% of its budget appropriations from Parliament. While Health Canada has internally re-allocated funds to OMC for years, the lack of permanent funding impeded OMC's ability to build and maintain necessary capacity to administer the program. The program's uncertain context and rapid implementation have contributed to inefficiencies, such as long processing times for some licence applications. Despite the limitations encountered since 2013, OMC has been able to deliver on its three key outputs (issuance of licences; inspection reports; production of guidance material), work successfully with its delivery partners, and maintain control over the movement of cannabis produced by LPs in a manner consistent with obligations under Canadian law and international conventions.

As of June 2017, the program for licensing producers of cannabis for medical purposes had:

- issued licences to 50 producers, allowing for sufficient supply overall of cannabis for medical purposes to meet the demand of registered clients, in support of having a quality-controlled legal supply of cannabis for medical purposes available in the Canadian market in accordance with regulations;
- monitored the compliance to regulations by conducting an average of 277 inspections per year from 2014-15 to 2016-17; and
- produced several guidance and information documents to better inform applicants and LPs of regulatory requirements as well as regularly publishing Market Data reports on cannabis for medical purposes.

OMC has recognized the need for a more efficient approach to the application process and has introduced a number of changes as part of improvements to the licensing of producers of cannabis for medical purposes introduced in May 2017. Outstanding needs to better support day-to-day operations remain however, such as an integrated case management system which is expected to be implemented in Summer 2018.

5.2 Achievement of Immediate Outcomes

OMC has been successful at issuing a considerable amount of guidance over the short time of the implementation of the licensing program. LPs and applicants generally have access to information supporting an overall understanding of the cannabis for medical purposes licensing process and the regulations, but have unmet information needs in some areas which are limiting their ability to make informed business decisions. There are parts of the ACMPR requirements that are still not clearly understood by the different stakeholders when relying only on the information currently available from Health Canada. There is also a need for more transparent and open communication about the status and processing of applications.

5.3 Risk Management

Health Canada has adopted a prudent approach to administering the initial roll-out of the licensing program. The program's risk mitigation activities in support of delivery have generally been successful given that there have been sufficient quantities of quality-controlled legal cannabis available to eligible Canadians, with high LP compliance with the regulations and without instances of diversion or significant risks to health and safety. Health Canada has also taken risk-based steps to improve efficiency and effectiveness in the area of compliance monitoring, and as the program continues to evolve and mature, there will remain potential opportunities for further efficiencies as it relates to inspection and compliance monitoring. There remain, however, aspects of the program's delivery, which could benefit from the introduction of an integrated electronic case management system so as to reduce the risks presented to program operations. OMC reports that a system is in development and will be implemented in Summer 2018.

5.4 Alternative Design

A comparison of the cannabis for medical purposes licensing program with similar licensing programs maintained by the Government of Canada was limited by OMC's relative newness, the establishment of regulations in response to court decisions, and an uncertain operating context. Service standards and application fees, however, were found to be common design elements implemented by other licensing programs in Canada, which could be applicable to the licensing program for producers of cannabis for medical purposes. OMC external stakeholders indicated support for both service standards and fees.

Canada has been at the forefront of the domestic regulation of production of cannabis for medical purposes. The quality of production of cannabis for medical purposes by Canadian producers has been internationally recognized. Cannabis for medical purposes produced by Canadian LPs is being exported to support the needs of other countries. Canada differs from other international jurisdictions in its lack of fees for licence applicants and caps on the number of LPs.

6.0 Recommendations

Recommendation 1

Examine opportunities for modernizing the licensing process through a consolidated data system (such as a case management system), including an online interface, in support of increased efficiency and effectiveness of the licensing program.

Considering the sheer volume of information associated with each application (in both paper and electronic format), the current application management tools employed by OMC are of limited efficiency, and cannot easily generate reliable and sophisticated licensing activity data or reports. Furthermore, the use of the generic email account as the principal information management tool for the program creates risks related to information management. A consolidated data system could better support OMC's ability to help current and future applicants make informed business decisions while also supporting monitoring and reporting on the application process.

Recommendation 2

Develop internal and external communication processes, tools and materials with the intent of increasing access by Licensed Producers and applicants to the information necessary to support informed business decisions.

LPs and applicants have unmet information needs related to interpretation of some regulatory requirements and application processing (including status) which can limit their ability to make informed business decisions. Updated SOPs reflecting the requirements of the ACMPR would support OMC and Regulatory Operations and Regions Branch (RORB) staff in consistently discharging their responsibilities and help them better engage with applicants and existing LPs.

Recommendation 3

Engage in risk-based reviews of compliance and enforcement activities as a means of increasing the efficiency and effectiveness of the licensing program.

As part of improvements to the licensing of producers of cannabis for medical purposes in late May 2017, Health Canada has taken risk-based steps to improve efficiency and effectiveness in some areas; however, there remain potential opportunities for further efficiencies. As such, the risk-based approach to determining the frequency and the areas of focus of inspections could be regularly reviewed to ensure alignment to the relative risks to the system and harms of non-compliance.

Recommendation 4

Study options to allow for collection of fees and the introduction of service standards for the issuance of new and renewed licences, as well as import and export permits, in support of the timely provision of outputs and increased economy.

Service standards and fees are common elements of licensing programs in Canada and internationally for regulated private goods. OMC stakeholders have expressed support for both as mechanisms for improving the timeliness of the application experience. Cost recovery may present an opportunity for addressing long-term funding concerns and provide stability, as well as improve the experience of applicants and producers.

Appendix 1 – Logic Model

Reach	Canadians who require access to cannabis for medical purposes; Licensed Producers and licensed producer applicants; Authorized health care practitioners; Law enforcement agencies; Provincial/Territorial and Municipal governments; International governments and authorities		
Activities	Review applications	Conduct inspections Monitor compliance	Provide information to licensed producers and other stakeholders
Outputs	Licences Registrations Import/export permits Security clearances	Inspection reports Warning letters	Guidance Information bulletins Reports and market data
Immediate Outcomes	Licensed producers, registered persons and other stakeholders have access to the information they need to make informed decisions.		
Intermediate Outcomes	Licensed producers and registered persons are compliant with the regulations.	Canadians register with licensed producers to access cannabis for medical purposes.	
Ultimate Outcome	Quality-controlled legal supply of Cannabis for Medical Purposes available in the Canadian Market in accordance with regulations.		

Appendix 2 – Evaluation Description

Evaluation Scope

The scope of the evaluation covered the licensing of producers of cannabis for medical purposes, for the period from September 1, 2014 to June 30, 2017.

Health Canada's new activities as of August 2016 associated with the registration of individuals authorized to produce a limited amount of cannabis for their own medical purposes or to designate someone to produce it for them is out of scope for this evaluation.

Evaluation Issues

Issues	Evaluation Questions
Design and Delivery	• Is the licensing program delivering on its intended outputs? • Have the licensing program's activities and the delivery methods been compliant with, and efficient in consideration of, regulatory requirements? Are there aspects that could have been done differently while achieving the same results? • Is the licensing program undertaking its activities in an economical manner? Have the regulatory requirements been administered in an economical manner? • What risks is the licensing program encountering as it delivers on its intended outputs? To what extent have risk mitigation strategies applied to date been effective in reducing the likelihood and impact of any emerging issues?
Achievement of Immediate Outcomes	• Do licensed cannabis producers, and licensed producer applicants, have access to the information they need to make informed decisions regarding their licensing and/or amendment applications?* • What risks is the licensing program encountering as it works towards its intended outcomes? To what extent have risk mitigation strategies applied to date been effective in reducing the likelihood and impact of any emerging issues? *This question addresses the licensing related aspect of the immediate outcomes identified in the logic model (Appendix 1)
Alternative design and delivery	• How does the licensing program for producers of cannabis for medical purposes compare to that of other controlled substances and/or regulated products in Canada? • How does the licensing program for producers of cannabis for medical purposes in Canada compare with other licensing requirements internationally? • How do the physical and personnel security requirements for cannabis for medical purposes compare to other controlled substance or regulated products in Canada? • How do the physical and personnel security regulations for cannabis producers compare with other licensing requirements internationally? • Are there alternative mechanisms or processes that could be considered for licensing cannabis producers in Canada?

Data Collection and Analysis Methods

Evaluators collected and analyzed data from multiple sources. Data collection started in March 2017 and ended in September 2017. In early 2018, additional information on important developments occurring after the end of the scoping period were provided by the program and has been included in the report to provide further context on findings, conclusions and recommendations.

Document review – approximately 200 documents pertinent to cannabis for medical purposes and to licensing programs were reviewed for information regarding design and delivery of activities.

Key informant interviews – 36 individual interviews and 3 group interviews were conducted with a total of 43 stakeholders: 20 internal stakeholders (OMC=9, RORB=7, CLRB=3, Office of Controlled Substances=1), 13 external stakeholders (health care authorities, cannabis industry associations and industry consultants, security experts, and representatives from other federal departments), 4 international stakeholders, and 6 applicants. Interviews were, with a few exceptions, conducted by 2 evaluation team members, one with a primary responsibility for taking notes. Notes and transcripts were analysed with NVivo.

Survey of licensed producers – A survey of LPs was administered between May 18, 2017 and June 2, 2017. The survey was sent to the 40 producers that were licensed at the time. Twenty-six of them participated.

Financial data review – Program's financial data from 2013-14 to 2017-18 were reviewed, including budget appropriations and actual expenditures for OMC (due to the timing of the evaluation, actual expenditures for 2017-18 were not available).

International comparative analysis – information on cannabis for medical purposes programs in eight other jurisdictions (Colorado, New York, Oregon, Washington, Australia, Germany, Israel, and Uruguay) were reviewed to gather information on alternative delivery options.

Licensing programs comparative analysis – information on five comparable licensing programs operating under the Health portfolio (Prescription Drugs, Medical Devices, Industrial Hemp, Natural Health Products, and Human Pathogens and other Toxins) were reviewed to identify alternative designs and lessons learned that could be applied to the cannabis for medical purposes licensing program.

Performance data review – Performance data for licensing activities conducted between September 1, 2014 and June 30, 2017 were reviewed.

Licensing application file review – 10 licensing application files were reviewed. Applications were chosen randomly with a stratified selection to ensure representation of applicants over the different years of the program's implementation.

Endnotes

[1] *Controlled Drugs and Substances Act* – Accessible at http://laws-lois.justice.gc.ca/eng/acts/C-38.8/

[2] *Access to Cannabis for Medical Purposes Regulations* – Accessible at http://laws.justice.gc.ca/eng/regulations/SOR-2016-230/

[3] Regulatory Impact Analysis Statement - *Marihuana Medical Access Regulations*

[4] The government-wide strategic and operating review conducted was aiming at achieving at least $4 billion in ongoing government-wide savings by 2014-15.

[5] Regulatory Impact Analysis Statement – *Access to Cannabis for Medical Purposes Regulations*

[6] Heath Canada: Application Process: Becoming a Licensed Producer of Cannabis for Medical Purposes

[7] Heath Canada: Improving the Licensing of Production of Cannabis for Medical Purposes - Backgrounder

[8] Cannabis for Medical Purposes - Licensing and Inspection 2.0: Inspector training presentation – July 2017

[9] Evaluation of the Canadian Agricultural Loans Act Program, by the Office of Audit and Evaluation of Agriculture and Agri-Food Canada – Report available at http://www.agr.gc.ca/eng/about-us/offices-and-locations/office-of-audit-and-evaluation/evaluation-reports/evaluation-of-the-canadian-agricultural-loans-act-program/?id=1401475853238