Health Canada Santé Canada

Guidance Document

Fees for the Review of Medical Device Licence Applications

Date adopted: 1997/05/01
Date posted: 2019/11/04
Effective date: 2020/04/01

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre:
Ligne directrice : Frais pour l'examen des demandes d'homologation des instruments médicaux

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, Ontario K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: November 2019

Cat.: H13-9/20-2019E-PDF
ISBN: 978-0-660-27439-3
Pub.: 180196

Document change log

Version	Guidance Document: Fees for the Review of Medical Device Licence Applications	**Replaces**	Guidance Document: Fees for the Review of Medical Device Licence Applications
Date	April 1, 2020 (posted November 4, 2019)	**Date**	November 20, 2015

Date	Change	Location (Section, paragraph)	Nature of and/or Reason for change
April 1, 2020 (posted November 4, 2019)	Content was updated	All	As of April 1, 2020, new fees along with a revised fee policy will come into force requiring significant changes to the guidance document
November 20, 2015	Administrative Change	S.2.2.2	As of November 9th, 2015, the Accounts Receivable address has changed

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

Please note that this guidance document is in effect as of April 1, 2020 and should be used for applications submitted on or after April 1, 2020. Previous versions of this guidance document are available upon request (hc.publications-publications.sc@canada.ca).

Table of Contents

1. Introduction

Before a medical device is authorized for sale in Canada, scientific evidence of its safety, efficacy and quality, as required by the Food and Drugs Act and Regulations, must be provided to Health Canada to determine whether the benefits associated with the product outweigh the risks. Health Canada has charged industry fees for these pre-market regulatory activities since 1998 in order to recover some of the associated costs.

1.1 Objective

This document provides guidance on how fees for the review of medical device applications will be administered in accordance with the Food and Drugs Act and as stipulated in the Fees in Respect of Drugs and Medical Devices Order and the Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act.

1.2 Policy statements

Manufacturers submitting Class II, III and IV medical device licence applications and licence amendment applications will be charged a fee. Fees are proportionate to the complexity of the regulatory activity. Note that unpaid fees are subject to collection procedures as per Government of Canada Directive on Public Money and Receivables (https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32505). Should fees not be paid, Health Canada has the authority to withhold services, approvals or rights and privileges.

As of April 1, 2020, new fees will be in effect. See Section 2.4 Applicable fees for further details. Further, as of April 1, 2020, Health Canada will:

- No longer consider deferring fees for manufacturers that have not completed their first full fiscal year of business nor will it reduce fees to manufacturers based on a product's gross revenue. However, existing terms and conditions previously granted on fee deferrals and remissions will be honored. See Appendix A for further details.
- Offer fee mitigation manufacturers who are small businesses, publicly funded health care institutions, or government organizations. See Section 2.2 Mitigation measures for further details.
- Credit manufacturers a portion of the fee in the event that a performance standard is missed. See Section 2.3 Missed performance standards for further details.

1.3 Scope and application

This guidance applies to manufacturers submitting a:

- Class II, III and IV medical device licence applications
- Licence amendment applications
- Private Label medical device licence applications
- Private Label licence amendment applications

Any other type of application not explicitly listed above is excluded along with medical devices that are:

- Class I
- Custom-made
- For special access
- For investigational testing involving human subjects

2. Guidance

This section provides detailed information on invoicing and fee payment, mitigation measures, missed performance standards, and applicable fees.

2.1 Invoicing and fee payment

Manufacturers must complete a Medical Devices Licence Application Fee Form (Fee Form)[1] and include it when filing every application. The form outlines the fees and includes sections on fee mitigation measures.

Upon receipt of the required documents, Health Canada will conduct a preliminary examination, verify and adjust the fee if required, and issue an invoice. For most applications this will mean an invoice is issued when the application is accepted into Review 1. However, for Class II and Private Label Licence and Amendment Applications, the invoice will be issued after the application has been deemed to be administratively complete. Regardless of when the invoice is issued, payment is due 30 days from date of issuance.

Should a Class III or IV medical device licence application be **rejected** during the preliminary examination period, Health Canada will issue a notice of rejection and an invoice for 10% of the applicable fee. Invoices will be issued at the time of rejection. Note that in the event a Class III or IV medical device application is **withdrawn** after a Screening Deficiency Letter has been issued, Health Canada will issue an acknowledgement of withdrawal along with an invoice of 10% of the applicable fee. However, if an application is withdrawn after Health Canada has issued a screening acceptance letter the invoice for 100% of the applicable fee will still be payable. In the case of Class II and Private Label licence and amendment applications, an invoice for 100% of the applicable fee will be issued once an application has been deemed to be administratively complete.

[1] Updated fee forms available as of March 2020

Timing of Withdrawal	% of Fee Applicable
Class II and Private Label Licence and Amendment Applications	
After application has been deemed to be administratively complete	100%
Class III or IV Licence and Amendment Applications	
Before acceptance into review, assuming a Screening Deficiency Letter has not been issued	0%
Before acceptance into review, but after a Screening Deficiency Letter has been issued	10%
After a Screening Acceptance Letter has been issued	100%

Instructions on the payment of fees are further outlined in the document How to Pay Fees (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cost-recovery/pay-fees.html). All payments must be in Canadian funds. Cheques must be made payable to the "Receiver General for Canada".

Manufacturers wishing to dispute a particular fee should contact Health Canada's Food and Drugs Act Liaison Office (FDALO) (https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/food-drugs-act-liaison-office.html).

2.2 Mitigation measures

Fees can be requested to be waived or reduced for applications filed by:

- A small business
- A publicly funded health care institution
- Any branch or agency of the Government of Canada or of a province or territory
- By organizations sponsoring Medical Devices to be sold for the purposes of Implementing Canada's Access to Medicines Regime under section 43.2 of the Medical Device Regulations

To be considered for mitigation, manufacturers must apply at the time of filing by indicating on the Fee Form the type of mitigation requested. In the case of small businesses, manufacturers will be required to register as a small business and to ensure that their registration information is kept up to date.

2.2.1 Small business

Manufacturers who meet the criteria of a small business will be invoiced for the reduced fees described below. However, should Health Canada subsequently determine that the

manufacturer does not qualify as a small business the full fee is then due. Therefore, an additional invoice will be issued for the difference between the full fee payable and the original invoice. In the case where the submission or application was reviewed for free, an invoice will be issued for the full amount due.

A small business is defined as any business, including its affiliates, that:

- has fewer than 100 employees OR
- has between $30,000 and $5 million (CAD) in annual gross revenues

Manufacturers that meet the above definition are eligible for a 50% reduction on all medical device licence applications, as well as a "one-time only" waiving of fees for their very first application filed with Health Canada. However, should that first application be subsequently withdrawn prior to final decision or not receive a positive decision, it is still considered the first filed application. As such, no future application will be reviewed for free.

Manufacturers must indicate that they are requesting small business mitigation on the Fee Form, as well as indicate whether it is their first application ever filed with Health Canada. Manufacturers must formally register (https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees.html) as a small business prior to submitting an application. Manufacturers who have not registered as a small business will be charged the full fee. Manufacturers must provide the following information when registering:

- Name of company
- Annual gross revenue for their last completed fiscal year
- Number of full-time or equivalent employees for their last completed fiscal year
- Fiscal year end date
- Affiliate status
- Breakdown of the above information for each affiliated company
- Contact information for all companies listed

Affiliated companies are defined as those that:

- Are controlled by the manufacturer's company whereby the manufacturer's company holds 50% or more of the affiliate's votes or shares
- Control the manufacturer's company whereby the affiliate holds 50% or more of the manufacturer's company's votes or shares
- Share a parent company with the manufacturer whereby they are controlled by the same company that controls the manufacturer's company

In the event that a company has not yet completed a full fiscal year, it is permissible to use estimates/projections with respect to annual gross revenue and number of employees. In this situation Health Canada will follow-up once the manufacturer's fiscal year end date has passed to verify their small business status.

Note that at any point in time, Health Canada may request additional information from the manufacturer to verify their small business status. This may include (but is not limited to):

- Records that identify the number of persons employed for the previous fiscal year
- Financial statements
- Tax returns
- Corporate and/or management organization charts
- Other official documents issued or certified by a business registration authority

2.2.2 Publicly funded health care institutions

Fees will be waived for all medical device licence applications filed by publicly funded health care institutions. For example, hospitals filing an application for heart valves will not have to pay a fee. A publicly funded institution is defined as an institution that is funded by the Government of Canada or a provincial government, and is:

a) Licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness; or
b) Owned or operated by the Government of Canada or a province and/or territory and provides health services.

2.2.3 Government organizations

Fees will be waived for applications filed by a branch or agency of the Government of Canada or of a province or territory. For example, the Department of National Defense or the Public Health Agency of Canada will not have to pay fees.

2.2.4 Canada's access to medicines regime

Fees will be automatically deferred for manufacturers that concurrently file an application with an application to sell a medical device under section 43.2 of the Medical Device Regulations until such time as a medical device licence is issued. Further, manufacturer's fees will be waived entirely if they subsequently receive an authorization under section 21.04 of the Patent Act.

2.3 Missed performance standards

Performance for all applications filed after April 1, 2020, will be tracked individually. The Performance Standards for Fees in Respect of Drugs and Medical Devices Order (https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/performance-fees-drugs-medical-devices.html) defines the applicable standard associated with each activity and fee. Most standards reflect the time to complete Review 1,

Iteration 1, which is defined as "the period from date of acceptance to date of first decision" not including any review clock pauses.[2]

In the event that a medical device licence application is not reviewed within the established performance standard, manufacturers will be credited 25% of the fee originally paid. Health Canada will credit the manufacturer's account within 30 days. Note that applications that are part of a joint review or reviewed in parallel with a foreign regulatory authority or applications for medical device combination products are not subject to a refund in the event of a missed performance standard.

In the case of Class II and Private Label Licence and Amendment Applications the credit will be issued concurrently with the invoice (i.e., an invoice will be issued for 75% of the applicable fee).

2.4 Applicable fees

The applicable fees are laid out in Schedule 1 of the Fees in Respect of Drugs and Medical Devices Order. Beginning on April 1, 2021, fees will increase annually to keep up with inflation by an amount equivalent to the Consumer Price Index from the previous year. Health Canada will publish a Notice of Intent in Canada Gazette (http://www.gazette.gc.ca/accueil-home-eng.html) every fall specifying the fee amounts that will take effect the following April 1. Health Canada's web site will be updated accordingly (https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/fees-respect-human-drugs-medical-devices.html).

Note that the fee payable is based on the filing date of the application. That is, the date Health Canada deems the application to be administratively complete with all elements completed to Health Canada's standards. The filing date and the date Health Canada receives the application will be the same if the application is accepted for preliminary examination with no adjustments required. However, the filing date will lag behind the date of receipt in the event that Health Canada finds the application to be administratively incomplete and must ask the manufacturer for additional information. For example, if an application is received on March 15, 2021 but adjustments are required, and is only deemed administratively complete on April 5, 2021, then the fee in place on April 5 is the applicable fee.

Note that an application that is received after 5:00pm Eastern Standard Time, on a weekend, or on a statutory holiday is considered received on the next Health Canada business day.

The fees for the review of the various categories of Class II, III, IV, and private label medical device licence applications and licence amendment applications are outlined in the Medical

[2] In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance. Please see the Management of Medical Device Licence Applications Guidance for more information regarding pausing the clock during the review period (effective date: April 1, 2020)

Device Licence Application Review Fees Document (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/fees.html).

Should a change in fee category occur during the review of an application, an invoice will be reissued for the appropriate amount, or a credit will be applied to the sponsor's account.

There is no fee for a Class III or IV medical device licence amendment application that does not require a scientific review. For example, the following changes would not require review and therefore no fee would be charged:

- A change in the name of the manufacturer;
- A change in the name of the device;
- A change in the medical device identifier.

Refer to the Guidance Document for the Interpretation of Significant Change for further information on what constitutes a significant change.

2.5 General contact information

Hours of service are Monday to Friday from 8 a.m. to 4 p.m. (EST) and closed statutory holidays. Phone calls and emails will be responded to within 10 business days.

Application and Invoice Inquiries
Medical Devices Directorate, Bureau of Device Licensing Services
By email: hc.mdb.enquiries-enquetes.bmm.sc@canada.ca
By phone: 613-957-7285

Payment Inquiries
Accounts Receivable
Chief Financial Officer Branch
Address Locator: 1918B
18th Floor, Room 1804B, Jeanne Mance Building
161 Goldenrod Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9
By email: hc.ar-cr.sc@canada.ca
By phone: 613-957-1052 or 1-800-815-0506
By fax: 613-957-3495

Appendix A: Fee deferrals and remissions

Note that as of April 1, 2020, Health Canada will no longer offer deferrals to manufacturers that have not completed their first calendar year of selling a medical device, or remission fees based on individual product sales. Thus, the following information is specific to manufacturers who have applied for or been granted a fee deferral or remission prior to April 1, 2020, as per Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act.

1.1 Deferred Payments

If a manufacturer has not completed its first fiscal year on the day that the medical device licence application is submitted, the manufacturer will be granted a one-year deferral of payment from the day the application is submitted. The deferral will also be applicable to fees associated with a licence amendment for the medical device that become payable within that one-year period. At the end of the one-year period, the manufacturer must pay all of the applicable fees.

In order to qualify for the deferral period, a statement signed by the individual responsible for the manufacturer's financial affairs specifying the commencement date of the fiscal year must be submitted with the application.

If it is determined, on the basis of any information available to Health Canada, that the statement submitted by the manufacturer is inaccurate, the payment deferral will not be granted.

1.2 Fee Remission

1.2.1 General Information

A manufacturer who files a Class II, III or IV medical device licence application or licence amendment application may apply for a remission in fees. The applicable documentation (see Appendix 1.2.3), the remission processing fee and a completed fee section in the licence application form indicating that the manufacturer is applying for a remission in fees must be included with the licence application or licence amendment application.

1.2.2 Remission Processing Fee

A remission processing fee is required for Class III and IV medical device licence applications and licence amendment applications. The remission processing fee is contained in the medical device licence application forms (https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/forms.html). The remission processing fee must be included with the licence application or licence amendment application. Class II medical devices are exempt from the remission processing fee.

The remission processing fee is for the assessment of the information submitted with the application for remission of fees and the audited sales records, and is not considered part of the review fee for the medical device licence application or licence amendment application.

This fee will not be deducted from the fees payable for the application review.

1.2.3 Eligibility for remission and required documentation

A manufacturer is eligible for a remission of fees when the fee for the medical device application or licence amendment application is greater than 2.5% of the actual gross revenue from the sale of that medical device in Canada during the fee verification period if its revenue is $100,000 or less.

The manufacturer must provide the following to support the application for fee remission:

1. A statement signed by the individual responsible for the manufacturer's financial affairs indicating that:
    a. The anticipated gross revenue is $100,000 or less; and
    b. Certifying that the fee payable for the applicable medical device licence application or amendment application is greater than 2.5% of the anticipated gross revenue.

2. Information establishing that the applicable fee is greater than 2.5% of the anticipated gross revenue. This information should provide an accurate measure of the current market situation for the proposed product and should include at a minimum:
    a. A marketing plan/product plan for the medical device
    b. Sales history prior to product upgrades or sales history of similar products
    c. Estimated market share (i.e., product's market potential compared to the total market for similar products in Canada)
    d. Average sale price and demand
    e. A comparison to similar products on the Canadian market or other similar markets (for example, e.g., United States, European Union)

3. A medical device licence application form indicating:
    a. That the manufacturer is applying for a remission; and
    b. The fee they propose to be charged (i.e., 10% of their anticipated gross revenue for that medical device).

1.2.4 Payment procedure

The manufacturer will be notified in writing if the application for remission of fees has been accepted or rejected. If the application for remission is accepted by Health Canada, the fee for the review of a medical device application will be an amount equal to 10% of the anticipated gross revenue. In contrast to the remission processing fee, which must be included upon filing of the medical device application, the review fee should not be included at the time of filing. Rather, the fee will become payable upon receipt of an invoice from Health Canada.

If the application for a fee remission is rejected, the manufacturer will receive an invoice for the full amount of the review fee.

1.2.5 Confirmation of the actual gross revenue following the fee verification period

Within 60 days of the end of the fee verification period, the manufacturer must provide sales records in regard to the sales of the medical device in Canada during the fee verification period. The sales records must be prepared in accordance with generally accepted accounting principles and certified by the person responsible for the manufacturer's financial affairs. The records should include:

- Sales report from an automated accounting system showing the financial period covered and the actual gross revenue in Canadian funds; or
- Report from an auditor if no automated accounting system exists.

If it is determined at the end of the fee verification period that the amount paid by the manufacturer was **less** than 10% of the actual gross revenue for that product, the manufacturer must pay the lesser of the difference between:

- 10% of the actual gross revenue and the amount originally paid; or
- The fee payable and the amount originally paid.

Payment is due within 60 days after the day on which the fee verification period ended.

In contrast, if it is determined at the end of the fee verification period that the amount paid by the manufacturer was **more** than 10% of the actual gross revenue for that product, the difference between the amount paid and 10% of the actual gross revenue will be credited to the manufacturer.

If it is determined, based on any information available to Health Canada, that the sales records provided by the manufacturer were not adequate to determine the manufacturer's actual gross revenues, Health Canada may require the manufacturer to provide sales records that have been audited by a qualified independent auditor (i.e., a chartered accountant).

The difference between the amount of the fee paid and the full applicable fee will be immediately payable if the manufacturer does not provide Health Canada with the:

- Sales records within 60 days after the end of the verification period; or
- Audited sales records within 60 days of request.