Health Canada Santé Canada

Guidance Document

Medical Device Licence Renewal and Fee for the Right to Sell Licensed Medical Devices

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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 - Renouvellement de l'homologation d'un instrument médical et frais à payer pour le droit de vendre un instrument médical homologué.

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Document change log

Version	Guidance Document: Medical Device Licence Renewal and Fee for the Right to Sell Licensed Medical Devices	**Replaces**	Guidance Document: Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices
Date	April 1, 2020 (posted November 4, 2019)	**Date**	November 4, 2013

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.
September 9, 2013	Fees for the Right to Sell Licenced Medical Devices were removed. A hyperlink to the site containing the updated fee documents was added to this Guidance Document. Minor changes were made to improve the focus of the document.	S.1.2 S.3.1 Appendix 1 Appendix 2	All fees have been removed from guidance documents to gain efficiencies in updating fees. Fee documents and forms will continue to be updated.

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).

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1. Introduction

This guidance document provides medical device manufacturers and their regulatory correspondents with the steps involved in renewing a medical device licence. The renewal process has two purposes: the first is to confirm whether the medical device will continue to be sold in Canada and the medical device licence will remain active; the second is to collect information that must be assessed prior to invoicing for the right to sell fee.

1.1 Objective

This document provides guidance on how the fee for the right to sell medical devices 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 of medical devices that are licensed for sale in Canada are required to inform Health Canada each year before November 1 that the information submitted with their licence application and any subsequent amendments have not changed. This is referred to as the licence renewal process.

Manufacturers of licensed Class II, III, and IV medical devices are charged an annual fee, payable at the time of licence renewal, for the right to sell their devices in Canada. The fee is charged annually for the twelve month period beginning on November 1 of each year. 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. These fees will increase annually to keep up with inflation. See Section 2.5 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 credit 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.
- Will offer fee mitigation in specific circumstances. Fees may be waived or reduced for small businesses, publicly funded health care institutions and federal, provincial or territorial governments. See Section 2.3 Mitigation measures for further details.
- Will charge a reduced fee in the event that a performance standard is missed. See Section 2.4 Missed Performance Standards for further details.

1.3 Scope and application

This guidance document applies to Class II, III, and IV medical devices for which medical device licences have been issued by Health Canada.

2. Guidance

This section provides detailed information on the annual licence renewal procedure, invoicing and fee payment, mitigation measures, missed performance standards, and applicable fees.

2.1 Annual licence renewal procedure

Early in August of each year, Health Canada sends each manufacturer who is marketing licensed Class II, III or IV medical devices in Canada an annual licence renewal package to help the manufacturer fulfil their regulatory obligation under Section 43 of the Medical Devices Regulations (MDR). If the manufacturer has provided Health Canada with the name and address of their regulatory correspondent, the renewal package will be sent to that person instead of to the manufacturer. If a manufacturer has not received a renewal package by September 1, they or their regulatory correspondent should request the package by emailing hc.license.renewal.sc@canada.ca.

Note: Manufacturers must notify Health Canada if there is a change regarding the regulatory correspondent or contact information previously submitted. Failure to do so may result in the cancellation of a licence.

2.1.1 Annual renewal package

The renewal package contains the Annual Medical Device Licence Renewal Form[1] with instructions for its completion and return as well as including information on applying for Small Business Fee Mitigation. The Renewal Form is generated for each manufacturer and contains the following information:

- Regulatory correspondence address of the manufacturer
- Name of the regulatory correspondent and their contact information
- Attestation page
- Section 43 of the MDR
- Name of the manufacturer
- A listing of all the manufacturer's licensed devices, their licence number and class that are currently on the market

Note: Licences issued after July 27 are not included on this form. All new licences issued between July 27 and November 1 will be automatically renewed. This action will reduce the administrative burden to manufacturers and to the Medical Devices Directorate. Manufacturers are still required to pay a renewal fee and will be invoiced for licences issued between July 27 and November 1 in December when all other Medical Device Licences are invoiced.

[1] Updated forms available as of March 2020.

Instructions for Completing the Renewal Form:

- Correct any changes to the name of the contact person or their contact information in the space provided to the right of the contact information
- A senior official of the Manufacturer or their designated regulatory correspondent must sign the attestation
- Indicate medical device licences that should be discontinued by placing an [X] beside the medical device licence number in the discontinue column. This means that the manufacturer has stopped marketing the device or family of devices in Canada
- If all the products for which medical device licences that are listed are to remain on the Canadian market, place an [X] in the appropriate column

As noted above, if the relationship between a regulatory correspondent and a manufacturer is no longer in effect, the manufacturer must notify Health Canada of the change as well as who is attending to their regulatory matters, either the manufacturer or a new regulatory correspondent. Failure to do so may result in cancellation of the licence.

Changes not accepted on the Renewal Form

Changes to information other than changes to the contact information and notification of discontinuance must be made by submitting the appropriate amendment forms listed below and available on the Health Canada website:

- Medical Devices Licence Amendment Fax-Back Form – Guidance for Non-Significant Additions/Deletions (non-significant changes to catalogue numbers)
- Medical Devices Licence Amendment Fax-Back Form – Guidance for Changes to Manufacturer's Name and/or Address of Existing Device Licences
- Licence Amendment Fax-Back Form – Guidance for Changes to the Name of a Device for Existing Device Licences
- Class II Medical Device Licence Amendment Application Form
- Class III Medical Device Licence Amendment Application Form
- Class IV Medical Device Licence Amendment Application Form

2.1.2 Return of the renewal form

The completed renewal form must be emailed to the Bureau of Device Licensing Services of the Medical Devices Directorate before November 1 of the year it is received hc.license.renewal.sc@canada.ca.

Note: No fee payment should accompany the return of the forms (see section 2.1.3 Processing the Renewal Form and Invoicing below).

2.1.3 Processing the renewal form and invoicing

Renewal applications are processed on receipt. Invoices are mailed in December for payment within 30 days. The invoice documentation confirms renewal of the medical device licence(s), describes the licence(s) and the associated fee(s). No new medical device licences are issued as a result of the renewal process.

2.1.4 Failure to renew

Failure to comply with section 43 of the MDR may result in cancellation of existing medical device licences. The invoicing process will bill only valid renewed medical device licences.

Medical device licences not renewed have either been discontinued by the manufacturer, or have been cancelled by the Medical Devices Directorate for failure to renew by the November 1 deadline.

If a medical device licence has been cancelled, the product is no longer permitted to be offered for sale in Canada. In order to bring the medical device back into compliance, the manufacturer or regulatory correspondent is required to submit a new medical device licence application, as well as pay all applicable fees.

2.2 Invoicing and fee payment

Manufacturers must wait for their invoice, which will be sent in December, before submitting their payment. 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).

2.3 Mitigation measures

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

- A small business
- Publicly funded health care institutions
- Any branch or agency of the Government of Canada or of a province or territory

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

2.3.1 Small business

Eligible manufacturers 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.

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 25% reduction on all renewal fees.

Manufacturers must indicate that they are requesting small business mitigation on the Annual Medical Device Licence Renewal Form. 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 Annual Medical Device Licence Renewal Form. 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 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

2.3.2 Publicly funded health care institutions

Fees will be waived for all renewed licences filed by publicly funded health care institutions. For example, hospitals producing radiopharmaceutical diagnostic isotopes 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.

2.3.3 Government organizations

Fees will be waived for all renewed licences 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 a right to sell fee.

2.4 Missed performance standards

Performance for all medical device licence applications filed after April 1, 2020, will be tracked individually. In the event that Health Canada's Medical Devices Licence Listing database is not updated within 20 days following receipt of a complete Annual Notification Package, a 25% credit will be reflected on the invoice issued to the manufacturer.

2.5 Applicable fees

Health Canada carries out post-market monitoring and assessment of medical devices. The fee for the right to sell a licensed medical device is used to pay for a portion of these activities. The fee is charged annually for the twelve month period beginning on November 1 of each year.

The applicable fee is 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/medical-devices/fees.html).

2.6 General contact information

Service hours are Monday to Friday from 8 a.m. to 4 p.m. (EST) and closed statutory holidays. Emails and fax will be responded to within 10 business days.

Licence Renewal Inquiries
Medical Devices Directorate
By email: hc.licence.renewal.sc@canada.ca

Interpretation of the Fees for the Right to Sell Licensed Class II, III or IV Medical Devices Inquiries
Medical Devices Directorate, Bureau of Device Licensing Services
By email: hc.mdb.enquiries-enquetes.bmm.sc@canada.ca

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