Health Canada Santé Canada

GUIDANCE DOCUMENT

Fees for the Review of Medical Device Licence Applications

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Health Products and Food Branch

Canada

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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.

As a corollary to the above, it is equally important to note that 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.

Document Change Log			
Date	**Change**	**Location (section, paragraph)**	**Nature of and/or Reason for Change**
2015/11/20	Administrative Change	S.2.2.2	As of November 9th, 2015, the Accounts Receivable address has changed.
2013/09/09	List of current fees for the review of Class II, III and IV medical device licence applications and remission processing were removed. A hyperlink was added to the site containing the updated fee documents. Minor changes were made to improve the focus of the document.	Appendices 1 and 2 (removed) S.2.3 S.2.4 S.2.5	All fees have been removed from guidance documents to gain efficiencies in updating fees. Fee documents and forms will continue to be updated.
2013-06-10	Revision of the definition of Fee Verification Period	S.1.5 Definitions	Regulatory amendment to the *Fees in Respect of Drugs and Medical Devices* (Fee Regulations) to distinguish between Fee Verification Period for an application for a new licence and an application for an amendment to a licence.
2013-04-01	Annual 2 % increase in fees	Appendices 1 and 2	In accordance with s. 4 of the Fee Regulations
2012-04-01	Annual 2 % increase in fees	Appendices 1 and 2	In accordance with s. 4 of the Fee Regulations
2011-04-01	Significant changes to this document include changes to the fee structure and the addition of information on remissions and deferrals		The guidance document was rewritten to reflect the new Fee Regulations.

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1. INTRODUCTION

This document provides guidance on the interpretation of the *Fees in Respect of Drugs and Medical Devices Regulations* with a focus on how the fees for the review of medical device licence applications contained in Part 3 of these regulations will be administered.

1.1 Policy Objectives

To ensure that the cost recovery system to defray the cost to government of applying the principles of risk assessment and risk management in the regulation of medical devices reflects the current costs associated with the review of applications for a medical device licence.

1.2 Policy Statements

Manufacturers submitting Class II, III and IV medical device licence applications and licence amendment applications will be charged a review fee. Fees are proportionate to the complexity of the application, and for eligible manufacturers, the actual gross revenue in respect of the sale of the medical device for which the application is made.

Manufacturers that have not completed their first fiscal year upon submission of the application are eligible for a fee payment deferral period of one year starting on the date of submission of the licence application.

Manufacturers are eligible for a remission of a portion of the review fee when the applicable fee exceeds 2.5% of the actual gross revenues during the fee verification period for the medical device for which a licence application or licence amendment application has been made.

1.3 Scope and Application

This guidance document applies to manufacturers submitting Class II, III or IV medical device licence applications and licence amendment applications to Health Canada. All the requirements for a Class II, III or IV medical device licence application also apply to a request for the reinstatement of such a licence under subsection 41(2) of the *Medical Devices Regulations*.

Fees for the review of medical device licence applications apply only to Class II, III and IV medical devices. The following types of medical devices are exempt from fees:

- Class I medical devices;
- Custom-made medical devices;
- Medical devices for special access;
- Medical devices for investigational testing involving human subjects;

- Private Label medical devices.

1.4 Background

Manufacturers of medical devices must hold a medical device licence to import or distribute a Class II, III or IV medical device in Canada. In the late 1990s, Health Canada was given the authority under the *Financial Administration Act* to charge industry user fees in order to recover some of the costs related to service delivery for medical devices. However, the cost of service delivery has increased substantially since that time due to increasing volume and complexity of applications, along with costs of inflation and other costs of doing business.

The *Fees in Respect of Drugs and Medical Devices Regulations* aim to provide sufficient funding for Health Canada to meet service standards and support access to medical devices to Canadians in a timely manner. They also address costs associated with inflation. This guidance document has been updated to reflect the new requirements in these regulations.

1.5 Definitions

Actual Gross Revenue - The amount earned by a manufacturer during the fee verification period from sales in Canada of a medical device that is the subject of a Class II, III or IV medical device licence application or licence amendment application.

Anticipated Gross Revenue - The amount a manufacturer expects to earn during the fee verification period from sales in Canada of a medical device that is the subject of a Class II, III or IV medical device licence application or licence amendment application.

Examination - The review of the original information submitted by a manufacturer in support of a medical device licence application or licence amendment application, as well as solicited and unsolicited information, with the purpose of determining whether the medical device meets the safety and effectiveness requirements of the *Medical Devices Regulations*. If the information is found to be acceptable, a medical device licence is issued. Examination is commonly known as review, and is referred to as such in this guidance document.

Fee Verification Period - The Fee Verification Period that is applicable to medical devices that are the subject of a Class II, III or IV medical device licence application is the period beginning on the day a medical device is first sold under the licence in Canada and ending two years after that day.

The Fee Verification period that is applicable to medical devices that are the subject of a Class III or IV **licence amendment** application is the period beginning on the day on which the licence is amended and ending two years after that day.

Filing date – Refers to the final central registry file date allocated to an application once it is deemed administratively complete by Health Canada [that is (i.e.), once all elements and forms required for processing are completed and submitted to Health Canada]. This date may differ from the date of original filing should the application be considered administratively incomplete at the time of receipt.

Preliminary Examination - The examination of the original information submitted by a manufacturer in support of a medical device licence application or licence amendment application, as well as solicited and unsolicited information, to ensure they are complete for the purpose intended. If the information is found to be acceptable on preliminary examination, it is accepted for review. Preliminary examination is commonly known as the screening process, and is referred to as such in this guidance document.

2. GUIDANCE FOR IMPLEMENTATION

This section provides detailed information on how and where to submit fees, the fee payment schedule, fee structure and fee remissions.

2.1 General Contact Information

For questions regarding your invoice payment or your account balance, contact Accounts Receivable by phone at 613-957-1052 or 1-800-815-0506; by fax at 613-957-3495; or by email at AR-CR@hc-sc.gc.ca. Please have your customer account or invoice number available.

For questions related to the interpretation of the fee structure as it applies to your application, including invoice disputes, contact the Medical Devices Bureau, Device Licensing Services Division by phone at 613-957-7285 or by email at mdb_enquiries@hc-sc.gc.ca.

2.2 Fee Payment Procedures

2.2.1 Forms

The licence application and licence amendment application forms for Class II, III and IV medical devices contain a fee section that was developed to help manufacturers identify the appropriate medical device licence category and associated fee as outlined in the *Fees in Respect of Drugs and Medical Devices Regulations*. The fee section also includes information on remission and deferral requests. A completed form should accompany each medical device licence application or licence amendment application.

The forms can be located on the Health Canada website (http://www.hc-sc.gc.ca/dhp-

mps/md-im/applic-demande/form/index-eng.php).

2.2.2 Where to Submit Payment

Where to submit payment of the medical device licence application fee is dependent on the amount of the fee to be paid. Payments should be submitted as follows:

Payments for $5,000 or less per application:

Payments for $5,000 or less should be included with the medical device licence application and sent to:

Device Licensing Services Division
Medical Devices Bureau
Therapeutic Products Directorate
Health Canada
2934 Baseline Road
Address Locator: 3403A
OTTAWA, Ontario
K1A 0K9

Payments for more than $5,000 per application:

Payments for more than $5,000 should be made in response to an invoice and sent to:

Health Canada
Accounts Receivable, P/L: 1918B
18th Floor, Room 1804B, Jeanne-Mance Building
161 Goldenrod Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9

All cheques should be in Canadian funds and made payable to the "Receiver General for Canada."

2.2.3 Payment Schedule

The timing of payment of the medical device licence application fee is dependent on the amount of the fee to be paid. Payments are due as follows:

Fees of $5,000 or less:

- 100% of the fee is due at the time the application is submitted.

Note: When licence applications are not accepted for further review, the manufacturer will receive a remission of 90% of the fees paid.

Fees over $5,000:

- 10% of the fee is due upon receipt of a notice that the application has been found to be incomplete following screening;

- 75% of the fee is due upon receipt of a notice that the application has been found to be complete following screening and accepted for further review;

- 25% of the fee is due once the review of the application has been completed.

2.2.4 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. The fee will then be payable in accordance with the payment schedule outlined in section 2.2.3 of this guidance document.

2.3 Fee Structure

Fees are increased annually by 2%, rounded upwards to the nearest dollar, beginning April 1, 2012. An annual adjustment factor is necessary to ensure that service standards continue to be met. Each year, a Notice of Intent will be published in *Canada Gazette, Part I* setting out the

revised fees. The Notice of Intent and the fee documents with the revised fees are found on the Health Canada website (http://hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php).

The fee to be paid for a medical device licence application or licence amendment application is the one in effect at the time of submission.

2.3.1 Class II Medical Devices

The fee to be paid for the review of a Class II medical device licence application is outlined in the Medical Device Licence Application Review Document (http://web.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php). There is no fee for a Class II medical device licence amendment application.

2.3.2 Class III and IV Medical Devices

The fees for the review of the various categories of Class III and IV medical device licence applications and licence amendment applications are outlined in the Medical Device Licence Application Review Document (http://web.hc-sc.gc.ca/dhp-mps/finance/fees-frais/index-eng.php). Refer to the *Guidance Document for the Interpretation of Significant Change* for further information on what constitutes a significant change.

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.

2.4 Fee Remission

2.4.1 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 section 2.4.3), 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.

The application for remission of fees will be reviewed within 15 days. The manufacturer will be notified in writing whether the application for remission of fees has been accepted or rejected.

2.4.2 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 (http://web.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index-eng.php). 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.

2.4.3 Eligibility for Remission and Required Documentation

A manufacturer is eligible for a remission of fees when the fee for the medical device licence 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:
   - the anticipated gross revenue is $100,000 or less; and
   - 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 as a minimum:
   - a marketing plan/product plan for the medical device;
   - sales history prior to product upgrades or sales history of similar products;

- estimated market share (i.e., product's market potential compared to the total market for similar products in Canada);
- average sale price and demand;
- 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:
   - that the manufacturer is applying for a remission; and
   - the fee they propose to be charged (i.e., 10% of their anticipated gross revenue for that medical device).

2.4.4 Payment Schedule

If the application for fee remission is accepted, the manufacturer will pay the applicable fee according to the payment schedule outlined in section 2.2.3 of this guidance document. Therefore, if the proposed applicable fee is $5,000 or less, it should be included with the application.

If the application for fee remission is rejected by Health Canada, the difference between the amount paid and the actual amount of the fee is payable according to the payment schedule outlined in section 2.2.3 of this guidance document.

2.4.5 Confirmation of the Actual Gross Revenue Following the Fee Verification Period

Within 60 days after 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 individual responsible for the manufacturer’s financial affairs. The record should include:

- a sales report from an automated accounting system showing the financial period covered, the actual gross revenue in Canadian funds, and photocopies of sales slips itemized by product or licence number; or
- a report from an auditor if no automated system exists.

If it is determined at the end of the fee verification period that the amount paid was **less** than 2.5% of the actual gross revenue for that product, the manufacturer must pay the lesser of:

- the difference between 2.5% of the actual gross revenue and the amount originally

paid; and
- the difference between 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 was **more** than 2.5% of the actual gross revenue and that the actual gross revenue was $100,000 or less, the difference between the actual amount and the amount paid will be remitted to the manufacturer.

If it is determined, based on any information available to Health Canada, that the sales records provided by the manufacturer are 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 fee verification period; or
- the audited sales records within 60 days of request.

2.5 Fees for the Sale of Medical Devices for the Purposes of Implementing the General Council Decision

Manufacturers applying to sell a medical device for the purpose of implementing the General Council Decision must pay the applicable licence application fee. Once the manufacturer provides Health Canada with a copy of the authorization under section 21.04 of the *Patent Act*, the manufacturer will be granted remission of the whole amount of the fee paid.