Health Canada Santé Canada

Guidance Document

Fees for the Right to Sell Drugs

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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 - Frais à payer pour le droit de vendre un médicament

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Document change log

Version	Guidance Document: Fees for the Right to Sell Drugs	**Replaces**	Guidance Document: Fees for the Right to Sell Drugs
Date	April 1, 2020 (posted November 4, 2019)	**Date**	June 13, 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 and policies will come into force requiring significant changes to the guidance document.
June 13, 2015	Amended Scope and Application	S1.3	Regulations Amending the Food and Drug Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drugs Act that are in Dosage Form) and Regulations Amending the Fees in Respect of Drugs and Medical Devices Regulations (DIN Requirements for Drugs Listed in Schedule C to the Food and Drug Act that are in Dosage Form)

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

Once a drug is authorized for sale in Canada, industry must pay an annual fee to retain the right to sell the drug in Canada. Health Canada has charged fees since 1995 in order to recover some of the associated costs with post-market regulatory activities such as assessing safety signals and trends and communicating about risks.

1.1 Objective

This document provides guidance on how fees for the right to sell drugs 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

A manufacturer will be charged a fee for the right to sell a drug each year that the drug is on the market in Canada. For the purposes of this document, a manufacturer is any entity or person who holds a Drug Identification Number assigned to a drug under section C.01.014.2 of the Food and Drug Regulations. Fees are charged for 12 month period which begins October 1 and ends September 30 of the following 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. See Section 2.5 Applicable fees for further details. Further, as of April 1, 2020, Health Canada:

- Will offer fee mitigation in specific circumstances. Fees may be waived or reduced for small businesses, publicly funded health care institutions and those owned by 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.
- Will charge four different fees depending on the drug type. See Section 2.5 Applicable fees for further details.
- Will no longer defer fees for manufacturers that have not completed their first full fiscal year of business nor will it reduce fees for manufacturers based on a product's gross revenue.

1.3 Scope and application

This guidance document applies to all drugs for which a Drug Identification Number is assigned (including Schedule C drugs) and the sale of the drug has commenced in Canada except where the drug is:

- an Extraordinary Use New Drug Submission filed under C.08.002.01 or an Abbreviated Extraordinary Use New Drug Submission filed under C.08.002.1 respectively of the Food and Drug Regulations
- a natural health product

2. Guidance

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

2.1 Regulatory requirements

Once a manufacturer has been issued a Drug Identification Number by Health Canada, the product is considered to be authorized for sale in Canada. However, manufacturers must complete and submit a Drug Notification Form within 30 days after commencing sale of the drug in Canada. For more information on the Drug Notification Form, please consult the Guidance document Regulatory requirements for Drug Identification Numbers (DINs) (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/regulatory-requirements-drug-identification-numbers.html).

2.1.1 Annual renewal

Before October 1st, of each year, manufacturers must confirm that all the information previously supplied with respect to that drug is correct. In June of every year, Health Canada sends each manufacturer an Annual Renewal Package with the following information:

- An Annual Drug Notification Form[1] listing drugs with Drug Identification Numbers that, according to Health Canada records as of the date of printing, have been notified as being offered for sale in Canada, are approved for sale, or are in dormant status
- Instructions on how to complete the Form
- Instructions on how to apply for small business fee mitigation
- Sale Discontinuation of Drug Form
- Any other information deemed necessary

Manufacturers should submit the completed Annual Drug Notification Form and any other applicable documents by mid-August to allow Health Canada sufficient time to update information in its regulatory and financial databases prior to issuing invoices on October 1st.

Note that payment is only due upon receipt of an invoice. See Section 2.2 Invoicing and fee payment for further details.

2.1.2 Dormant drug identification number

Products deemed dormant as of October 1st, will not be subject to right to sell fees. Note that Health Canada does not refund fees should a product become dormant after October 1st. For more information, please refer to guidance document Regulatory Requirements for Drug Identification Numbers (DINs).

1 Updated forms available as of March 2020.

2.1.3 Discontinued sale notification

Products deemed cancelled as of October 1st, resulting from a discontinuation of sale notification will not be subject to right to sell fees. If the sale of a product has been discontinued and Health Canada has not been notified before October 1st, the manufacturer is still liable for payment of the right to sell fee. For more information, please refer to Guidance document Regulatory Requirements for Drug Identification Numbers (DINs).

2.2 Invoicing and fee payment

Every October 1st, Health Canada sends invoices for the upcoming year based on the information manufacturers have provided in the Annual Drug Notification Form. The person on record as owning the Drug Identification Number when the invoice is issued is responsible for payment. The invoice and any subsequent monthly statements are prepared in the name of the Drug Identification Number holder and are sent to the regulatory affairs section of the company or address identified as the billing address for the Drug Identification Number holder on the returned Annual Drug Notification Form. Payment is due 30 days from date of issuance.

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

Drug right to sell fees can be requested to be waived or reduced for submissions or 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

To be considered for mitigation, manufacturers must apply by indicating the type of mitigation requested on the Annual Drug Notification Form[2]. 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

Manufacturers who meet the criteria of a small business will be invoiced at 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

[2] Updated forms available as of March 2020

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 of the applicable right to sell a drug fee.

Every year, manufacturers must indicate that they are requesting small business mitigation on the Annual Drug Notification 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 Drug Notification Form. Manufacturers who have not registered as a small business will be charged the full fee. Manufacturers must provide the following information when registering:

- 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
- 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's 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's 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

Right to sell fees will be waived for all publicly funded health care institutions. For example, hospitals producing radiopharmaceutical diagnostic isotopes will not have to pay a right to sell

fee. A publicly funding 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

Right to sell fees will be waived for branches or agencies 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 processing the Annual Drug Notification Form filed after April 1, 2020, will be tracked individually. In the event that Health Canada's Drug Product Database is not updated within 20 calendar days following receipt of a complete Annual Drug Notification Form, a 25% credit will be reflected on the invoice issued to the manufacturer.

2.5 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 1st. Health Canada's web site will be updated accordingly (https://canada-preview.adobecqms.net/en/health-canada/services/drugs-health-products/drug-products/fees.html).

The drug right to sell fee is an annual fee for the right to maintain a drug on the Canadian market. Fees are specific to the type of drug as follows:

- Veterinary drug
- Disinfectant (A drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in disinfecting environmental surfaces or medical devices C.01A.001 antimicrobial agent)
- Non-prescription drug (A drug that is not required to be sold only under prescription and that does not meet the definition of a disinfectant)
- All other drugs

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.

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