Health Canada Santé Canada

March 4, 2013

Notice

Guidance Document - Fees for the Right to Sell Drugs

Please find attached the new document *Guidance Document - Fees for the Right to Sell Drugs*. This guidance document replaces the document *Authority to Sell Drug Fees, Fee Reductions and Adjustment Requests*.

The *Guidance Document - Fees for the Right to Sell Drugs* provides manufacturers and regulatory correspondents guidance on the step by step process for annual notification in accordance with section C.01.014.5 of the *Food and Drug Regulations*.

In addition, the document provides guidance on the right to sell fees that are payable by manufacturers at the time of annual notification. These fees are in accordance with Part 2, Division 4, Fees for Right to Sell Drugs contained in *Fees in Respect of Drugs and Medical Devices Regulations*.

For more information please contact:

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Canada

Health Canada Santé Canada

GUIDANCE DOCUMENT

Fees for the Right to Sell Drugs

Published by authority of the
Minister of Health

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits of health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : *Ligne directrice - Frais à payer pour le droit de vendre une drogue*

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 related guidances.

Document Change Log			
Version	Guidance Document – Fees for the Right to Sell Drugs	**Replaces**	Authority to Sell Drug Fees, Fee Reductions and Adjustment Requests
Date	2013/03/04	**Date**	2011/06/01

Date	Change
2013/03/02	Changes were made for clarification
2011/06/01	The guidance document was rewritten to reflect the new cost recovery regulations entitled the *Fees in Respect of Drugs and Medical Devices Regulations*. Significant changes to this document include changes in the fee structure and in the remission and fee deferral processes.

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1 INTRODUCTION

This document provides guidance on the interpretation of the *Fees in Respect of Drugs and Medical Devices Regulations* (Fee Regulations) with a focus on how the Fees for the Right to Sell Drugs, contained in Part 2, Division 4 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 drugs reflects the current costs associated with the marketing of drugs, excluding natural health products and drugs for veterinary use only.

1.2 Policy Statements

A manufacturer that holds a drug identification number (DIN) assigned to a drug under section C.01.014.2 of the *Food and Drug Regulations* will be charged a fee for the right to sell that drug each year that the drug is on the market in Canada.

Fees are charged for the right to sell a drug in the upcoming year beginning October 1 and ending September 30 of the following year.

DIN holders that have not completed their first calendar year of selling a drug in Canada will have their fee deferred to the end of their first completed calendar year.

DIN holders are eligible for a remission of a portion of the right to sell fee when the fee exceeds 1.5% of the actual gross revenue (AGR) for that drug during the previous calendar year.

The fee is to be increased annually by 2%, rounded up to the nearest dollar, beginning on April 1, 2012.

1.3 Scope and Application

This guidance document applies to all drugs for which a DIN is assigned and the sale of the drug has commenced in Canada except where the drug is for veterinary use only. This guidance document does not apply to the right to sell drugs that are natural health products. If the drug is for veterinary use only then the *Authority to Sell Veterinary Drugs Fees Regulations* apply.

1.4 Background

In the early 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 drugs, including the costs associated with post-approval safety surveillance. However, the cost of service delivery has increased substantially since that time due to increasing volume of submissions, along with costs of inflation and other costs of doing business.

The fees for the right to sell drugs in the Fee Regulations aim to provide sufficient funding for Health Canada to meet service standards; to keep current with the assessment of signals and safety trends; and to produce risk communications concerning all regulated marketed health products. They also address costs associated with inflation.

1.5 Definitions

Actual Gross Revenue - The amount earned by the DIN holder from the sales in Canada of all drug products with the same DIN during the previous calendar year.

Annual Drug Notification Form - This form is a print-out of the information contained in the Drug Product Database listing the drug products the manufacturer, named in the form, is marketing in Canada as of the date printed on the form. This form is used to facilitate the annual renewal process.

Calendar Year - A period of twelve consecutive months commencing on January 1.

Drug Notification Form - This form is provided to the manufacturer upon the issuance of a DIN by Health Canada. It is to be used by the manufacturer to fulfil their obligation to notify Health Canada within 30 days of the commencement of the sale of the drug product on the Canadian market.

First Completed Calendar Year - The completion of a period of twelve consecutive months commencing on January 1 following the date on which the drug product was first marketed in Canada.

Manufacturer - For the purpose of this document, manufacturer is a DIN holder.

1.6 Acronyms

AGR	Actual Gross Revenue
ADNF	Annual Drug Notification Form
DIN	drug identification number

DNF Drug Notification Form
SIPD Submission and Information Policy Division

2 GUIDANCE FOR IMPLEMENTATION

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 Fees for the Right to Sell Drugs, contact the Submission and Information Policy Division (SIPD) by phone at 613-946-1151, by fax at 613-954-3067 or by email at sipdannual_annuelledppr@hc-sc.gc.ca.

2.2 Regulatory Requirements Related to the Fees for the Right to Sell Drugs

2.2.1 Issuance of a Drug Identification Number (DIN)

Before a drug is authorized for sale in Canada, it must be issued a DIN in accordance with section C.01.014.2 or C.08.002 of the *Food and Drug Regulations*.

2.2.2 Drug Notification Form (DNF)

Upon issuance of a DIN, the manufacturer is provided with a DNF which must be completed and returned in accordance with section C.01.014.3 of the *Food and Drug Regulations* within 30 days after commencing sale of the drug in Canada.

2.2.3 Annual Notification

In accordance with section C.01.014.5 of the *Food and Drug Regulations*, a manufacturer of a drug must annually, before October 1, notify Health Canada that the drug is still on the market and that all the information previously provided pertaining to the drug is correct.

2.2.4 Discontinued Sale Notification

In accordance with C.01.014.7 of the *Food and Drug Regulations*, if the sale of a drug in Canada is discontinued, the manufacturer must notify Health Canada within 30 days of the day that the sale was discontinued.

Failure to Notify Health Canada of Discontinued Sale

If sale of a product has been discontinued but **no written** notice has been received by Health Canada before October 1, the manufacturer is **still** liable for payment of the right to sell fee.

If the ownership of a product has been transferred to another company and the new owner has marketed the product with a new DIN, the previous DIN holder must notify Health Canada if the sale of their product is discontinued. Otherwise an annual right to sell fee will be applied to both the old DIN and the new DIN since both are on Health Canada records as being on the market.

2.3 Fee Payment

Instructions on the payment of fees are contained in the document How to Pay Fees.

2.3.1 Who is Responsible for Payment?

The person on record as owning the DIN when the invoice is issued is responsible for payment. The invoice and any subsequent monthly statements are prepared in the name of the DIN owner and are sent to the regulatory affairs section of the company or address identified as the billing address for the DIN owner on the returned ADNF.

2.3.2 Where to Submit Payment of Invoice

Health Canada
Accounts Receivable, Room B350
Address locator 3203B,
Ottawa, Ontario
KIA OK9
Canada

2.3.3 Annual Fee

In 2011, the annual fee for the right to sell a drug for which a DIN has been assigned is $1,020. Note that there is an annual increase in the fee (see Adjustment of Fees below for further information). The fee is paid in advance of the year that it covers. For example, fees paid on October 1, 2011 cover the right to sell from October 1, 2011 to September 30, 2012. The only exception occurs when there is a fee deferral for a drug that has not completed its first calendar year on the market (see section 2.4 for further information on deferrals).

Adjustment of Fees

The right to sell fee is to be increased annually by 2%, rounded up 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. Additionally, Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of those reviews, if necessary.

Therefore, the right to sell fee for the years 2011 to 2013 are as follows:

Year	Right to Sell Fee (CDN$)
2011	1,020
2012	1,041
2013	1,062

2.3.4 When to Pay Fees

Fees are charged for the right to sell a product in the upcoming year beginning October 1 and ending September 30 of the following year. Invoices for the annual fee for the right to sell are sent on October 1 each year and must be paid within 30 days.

Do not send payment with the completed ADNF in August.

In order to remind manufacturers of the annual renewal process, Health Canada sends an Annual Renewal Package in June to each manufacturer with notified products. The package contains the following:

- The ADNF which contains a list of drugs with DINs that, according to Health Canada records as of the date of printing, have been notified as being offered for sale in Canada, and for which discontinued notifications have not been received by Health Canada;
- Instructions for the completion of the ADNF;
- A Right to Sell Drugs Fee Remission Request and Attestation Form;
- A notice to alert the manufacturer that the right to sell fee for products that have not completed their first calendar year on the market will be deferred until the end of the first calendar year;
- Any other information deemed necessary.

The completed ADNF and, when applicable, a Right to Sell Drugs Fee Remission Request and Attestation Form, **must** be submitted to Health Canada no later than mid-August (see section 2.5 for further information on fee remissions). This allows time for fee remission requests to be validated and reflected on the invoice.

2.4 Deferral of Fees and Timing of Deferred Payment

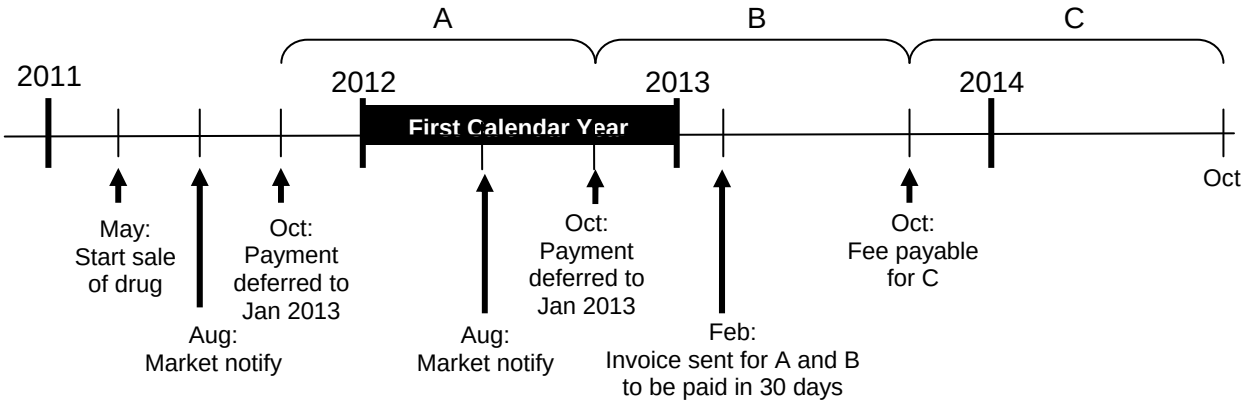
Section 35. (4) of the Fee Regulations states that if the manufacturer has not completed its first calendar year of selling a drug, the payment of the fee is deferred to the end of the first complete calendar year that the drug is on the market (that is, is payable on January 1 following completion of that year). This deferral provides an opportunity for manufacturers to accumulate actual revenue data from the sale of the new product in its first calendar year to determine if the manufacturer is eligible for a fee remission (see section 2.5.3 below for further information on remission of deferred fees).

The total fee payable on January 1 includes the fee for each period of October 1 to September 30 that has commenced. Note that although the fee is payable January 1, Health Canada does not issue the invoice until February. The fee is due 30 days following issuance of the invoice.

Figure 1 shows an example of when payments would be due for a product commencing sale in May 2011. The fee payment for period A is deferred to the end of the first calendar year and is payable January 1, 2013. The fee payment for period B is also deferred to January 1, 2013. In February, 2013, the manufacturer will be invoiced as follows:

$1,020 (period A) + $1,020 (period B) + 2% x $1,020 (annual increase) = $2,061

Figure 1



2.5 Fee Remission

2.5.1 Eligibility for Fee Remission

In order to be eligible for fee remission under section 35. (2) of the Fee Regulations, the right to sell fee must be greater than 1.5% of the manufacturer's AGR from the sale of the drug, in Canada, in the previous calendar year.

Manufacturers outside Canada

Manufacturers who own drug products and are outside Canada must determine their eligibility for remission by using their AGR received for total sales of all the drug products with the same DIN in Canada. Therefore, if the manufacturer sells the drug products with the same DIN through more than one importer in Canada, the remission is based on the AGR that the manufacturer receives from the sales of all the importers of the drug with the same DIN.

2.5.2 Documentation (Right to Sell Drugs Fee Remission Request and Attestation Form)

In order to be granted a fee remission, the manufacturer, in accordance with section 35. (2) of the Fee Regulations, **must** provide with the completed ADNF a statement certified by the individual responsible for the manufacturer's financial affairs that sets out the AGR from the sale of the drug in the previous calendar year i.e. The Right to Sell Drugs Fee Remission Request and Attestation Form.

Financial person responsible for several manufacturers

Persons who are responsible for the financial affairs of several manufacturers must submit a separate fee remission attestation form for each manufacturer that has been assigned a unique company code. The company code is comprised of a four or five digit number assigned by the Drug Products Database. It is used as the account number and is found on the ADNF above the DIN owner's name.

AGR questioned by Health Canada before invoice is sent

If it is determined, on the basis of any information available to Health Canada, that the statement submitted by the manufacturer or their financial affairs person is inaccurate or inadequate to determine the manufacturer's AGR in the previous calendar year, Health Canada may require the manufacturer to provide sales records that have been audited by a qualified independent auditor. These audited sales records will be used to determine the fees payable and an invoice reflecting the confirmed or corrected fee payable will be sent. If the manufacturer fails to provide the audited sales records as requested by Health Canada within 60 days of the date of the request, an invoice for the full applicable fee will be sent.

AGR questioned by Health Canada after invoice is sent

If it is determined, on the basis of any information available to Health Canada, that the statement submitted by the manufacturer or their financial affairs person is inaccurate or inadequate to determine the manufacturer's AGR in the previous calendar year, Health Canada may require the manufacturer to provide sales records that have been audited by a qualified independent auditor. If the sales records submitted by the manufacturer establish that the fee remission calculated and submitted by the manufacturer is correct, no further action will be taken. If the sales records establish that the fee calculated and submitted by the manufacturer is less than the amount owing under section 34 of the Fee Regulations, the difference is immediately payable. If the sales records submitted establish that the fee owing is less than the amount submitted by the manufacturer, the amount in excess will be remitted to the manufacturer.

2.5.3 Calculation of Fee with Remission

If the manufacturer meets the fee remission eligibility, the fee is calculated as follows: (Assuming the right to sell fee is more than 1.5% of the AGR)

AGR x 1.5% = the fee payable

For example: Based on an AGR of $58,000 and a right to sell fee of $1,020, the fee with remission payable would be $58,000 x 1.5% = $870. The manufacturer would be sent an invoice for $870.

2.5.4 Calculating and Requesting Remission of Fees Where Payment was Deferred

Eligibility for fee remission and calculation of fee

In order to be eligible for fee remission under section 35. (2) of the Fee Regulations, the right to sell fee must be greater than 1.5% of the manufacturer's AGR from the sale of the drug, in Canada, in its **first calendar year**.

For the example in Figure 1 (assuming the manufacturer was eligible for a remission), the fee payable January 1, 2013 would be calculated as follows:

1.5% x AGR (first calendar year) x 2 (for periods A and B) = fee payable

Request for Remission of Deferred Fees

If the manufacturer is eligible for a remission of deferred fees, a Right to Sell Drugs Fee Remission Request and Attestation Form must be completed and submitted to Health Canada before January 20 following completion of the first complete calendar year that the product was on the market. If January 20 falls on a weekend then the deadline is moved to the first Monday following January 20. This form includes a statement certified by the individual responsible for the manufacturer's financial affairs that sets out the AGR from the sale of the drug in its first calendar year. Health Canada will review the documentation and will issue an invoice in February with the appropriate fee for payment in 30 days.

The manufacturer must be prepared to submit, upon request, additional information concerning the determination of the AGR as outlined in Section 2.5.2.