Health Canada Santé Canada

Guidance Document

Fees for the Review of Veterinary Drug Submissions and Applications

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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 pour l'examen des présentations et demandes des médicaments vétérinaires.

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Document change log

Version	Guidance Document: Fees for the Review of Veterinary Drug Submissions and Applications	**Replaces**	Guidance Document on Cost Recovery Veterinary Drug Submission Evaluation Fees
Date	April 1, 2020 (posted November 4, 2019)	**Date**	February 2002

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.

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 submissions and 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

Before a veterinary drug 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 1995 in order to recover some of the associated costs.

1.1 Objective

This document provides guidance on how fees for the review of veterinary drug submissions and 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

Sponsors submitting veterinary drug submissions or applications will be charged a fee. Fees are proportionate to the type and complexity of the regulatory activity. Note that unpaid fees are subject to collection procedures as per the 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. Furthermore, 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 federal, provincial or territorial governments. See Section 2.2 Mitigation measures for further details.
- Will charge a reduced fee or credit 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 sponsors submitting a:

- New Drug Submission
- Supplement to a New Drug Submission
- Abbreviated New Drug Submission
- Supplement to an Abbreviated New Drug Submission
- Notifiable Change
- Experimental Studies Certificate Application
- Investigational New Drug Submission
- Protocol Review
- Drug Identification Number Application
- Emergency Drug Release Application
- Veterinary Health Product Notification

Any other type of submission or application not explicitly listed above is excluded.

2. Guidance

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

2.1 Invoicing and fee payment

The Veterinary Drug Submission Application and Fee Form[1] outlines the fees in effect for the particular year in question and also includes sections on fee mitigation measures. Sponsors must complete this form and include it with every submission or application, with the exception of:

- Experimental Studies Certificate Applications, which require a Veterinary Drug Experimental Studies Certificate Application Form
- Emergency Drug Release Applications, which require an Emergency Drug Release Application and Fee Form. Please contact hc.edr-dmu.sc@canada.ca for further information
- Veterinary Health Product Notifications. Please contact hc.vhp-psa.sc@canada.ca for applicable forms and further information

Payment should not be included when filing the submission.

For information on timing of fee payments for submissions that are subject to joint review or parallel review with a foreign regulatory authority, please contact hc.vdd.skmd.so-dgps.dmv.cp.sc@canada.ca.

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 submissions this will mean an invoice is issued at the time the submission is accepted into Review 1. However, for Investigational New Drug Submissions, Protocol Reviews, Emergency Drug Release Applications, and Veterinary Health Product Notifications, the invoice will be issued at the time of review decision. Regardless of when the invoice is issued, payment is due 30 days from the date of issuance**.**

Should a submission or application be **rejected** during the preliminary examination period (i.e., found to be deficient at screening), Health Canada will issue a notice of rejection along with an invoice for 10% of the applicable fee. Invoices will be issued at the time of rejection. Note that in the event a submission or application is **withdrawn** after a Screening Deficiency Notice has been issued, Health Canada will issue an acknowledgement of cancellation along with an invoice of 10% of the applicable fee. However, if a submission or application is withdrawn after Health Canada has issued a screening acceptance letter or reached a decision on submissions or applications that are not subject to a preliminary examination, the invoice for 100% of the applicable fee will still be payable.

[1] Updated fee forms available as of March 2020

Timing of Withdrawal	% of Fee Applicable
Before acceptance into review and no Screening Deficiency Notice has been issued	0%
Before acceptance into review, but after a Screening Deficiency Notice has been issued	10%
After a screening acceptance letter is issued, or a final review decision for investigational New Drug Submissions, Protocol Reviews, Emergency Drug Release Applications and Veterinary Health Product Notifications	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".

Sponsors 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 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, sponsors must apply at the time of filing by indicating the type of mitigation requested on the Veterinary Drug Submission Application and Fee Form (or applicable form as indicated in Section 2.1). In the case of small businesses, sponsors 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

Sponsors who meet the criteria of a small business will be invoiced at the reduced fees described below. However, if at any point Health Canada determines that the sponsor 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;

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

Sponsors must indicate that they are requesting small business mitigation on the Veterinary Drug Submission Application and Fee Form (or applicable fee form as indicated in Section 2.1), as well as indicate if this is their first submission ever filed. Sponsors must formally register (https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees.html) as a small business prior to submitting a submission or application. Sponsors who have not registered as a small business will be charged the full fee. Sponsors 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
- Financial 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 sponsor's company whereby the sponsor's company holds 50% or more of the affiliate's votes or shares
- Control the sponsor's company whereby the affiliate holds 50% or more of the sponsor's company's votes or shares
- Share a parent company with the sponsor whereby they are controlled by the same company that controls the sponsor'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 sponsor's financial 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 sponsor 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 financial 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 drug submissions or applications filed by publicly funded health care institutions. For example, hospitals filing submissions for 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/territorial government, and is:

- licensed, approved or designated by a province/territory in accordance with the laws of the province/territory to provide care or treatment to persons or animals suffering from any form of disease or illness; or
- 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 submissions filed by a branch or agency of the Government of Canada or of a province or territory. For example, a provincial/territorial Department of Natural Resources or Agriculture and Agri-Food Canada will not have to pay fees.

2.3 Missed performance standards

Performance for all submissions or applications filed after April 1, 2020, will be tracked individually[2]. 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, which is defined as "the period from date of acceptance to date of first decision" not including any review clock pauses.[3]

In the event that a submission or application is not reviewed within the established performance standard, sponsors will be credited 25% of the fee originally paid. Health Canada will credit the sponsor's account within 30 days. Note that submissions or applications that are part of a joint review or reviewed in parallel with a foreign regulatory authority are not subject to a credit in the event of a missed performance standard.

In the case of Investigational New Drug Submissions, Protocol Reviews, and Emergency Drug Release Applications, the credit will be issued concurrently with the invoice at the time of the review decision.

[2] Note that performance for all submissions or applications filed prior to April 1, 2020, will continue to be rigorously monitored and will be processed in the order in which they are received.

[3] 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 Guidance for Industry - Management of Regulatory Submissions for more information regarding pausing the clock during the review period.

2.4 Applicable fees

The applicable fees are laid out in Schedule 2 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://canada-preview.adobecqms.net/en/health-canada/services/drugs-health-products/funding-fees/veterinary-drugs.html).

Note that the fee payable is based on the filing date of the submission or application. That is, the date Health Canada deems the submission or application to be administratively complete with all elements completed to Health Canada's standards. The filing date and the date Health Canada receives the submission or application will be the same if the submission or application is accepted for preliminary examination as is with no adjustments required. However, the filing date will lag behind the date of receipt in the event that Health Canada finds the submission or application to be administratively incomplete and must ask the sponsor for additional information. For example, if a submission 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.

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

2.5 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.

Submission/Application Inquiries
Submission and Knowledge Management Division
By email: hc.vdd.skmd.so-dgps.dmv.cp.sc@canada.ca

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Address Locator: 1918B
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By email: hc.ar-cr.sc@canada.ca
By phone: 613-957-1052 or 1-800-815-0506
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