Canada's Drug Agency
L'Agence des médicaments du Canada

Fee Schedule for Pharmaceutical Reviews

March 2025

Record of Updates

Date	Summary of revisions
March 27, 2025	• Revised to include schedule B fee for applications reviewed through the pharmaceuticals with anticipated comparable efficacy and safety (PACES) process.
March 28, 2024	• Annual fee adjustment based on the Consumer Price Index.
June 5, 2023	• Fee adjustment effective for applications received on or after July 17, 2023.
April 13, 2022	• Annual fee adjustment based on the Consumer Price Index.
November 25, 2021	• Editorial revisions to reflect consolidation of the former CDR and pCODR processes under a single reimbursement review process. • New section added to provide details on scenarios where multiple application fees may be required. • Addition of complex review to the schedule E fee.
March 24, 2021	• Annual fee adjustment based on the Consumer Price Index
December 3, 2020	• Revisions to reflect renaming of CADTH reimbursement review process.
October 29, 2020	• Postponement of the schedule D fee for pCODR reconsiderations until the April 2021 expert committee meetings.
September 30, 2020	• Revisions to reflect the alignment of milestone 2 for invoicing oncology and non-oncology application fees.
June 25, 2020	• Discontinuation of the schedule B fee for applications received on or after June 30, 2020. • Notice that a schedule D fee will apply for requests for reconsiderations that are filed by industry sponsors for pCODR applications targeting the October 2020 expert committee meeting. • New schedule F fee for drugs that are reviewed through *the CADTH Process for Drugs with Expanded Health System* Implications.
April 29, 2020	• Annual fee adjustment based on the Consumer Price Index
January 9, 2020	• Revisions to reflect interim process for plasma protein products and process for cell and gene therapies.
March 28, 2019	• Annual fee adjustment based on the Consumer Price Index.
March 28, 2018	• Annual fee adjustment based on the Consumer Price Index.
February 13, 2018	• *Guidelines on Application Fees for CADTH Pharmaceutical Reviews* replace the separate application fee guidelines for the CDR and pCODR programs. • Reduced fee for the new biosimilar review process. • All submissions and resubmissions filed by manufacturers are subject to an application fee irrespective of the date of approval by Health Canada.
November 13, 2017	• All resubmissions that are filed by manufacturers on or after January 2, 2018 will be subject to an application fee.
March 5, 2015	• Original *Guidelines for Manufacturers on Application Fees for the pan-Canadian Oncology Drug Review.*
September 2, 2014	• Original *Guidelines for Manufacturers on Application Fees for the CADTH Common Drug Review.*

CDR = Common Drug Review; pCODR = pan-Canadian Oncology Drug Review programs.

1. Introduction

This document provides guidelines to industry sponsors on the application fees for the review of an application filed for review through of one the following programs:

- reimbursement reviews
- process for drugs with expanded health system implications

Canada's Drug Agency (CDA-AMC) may amend, from time to time, the *Fee Schedule for Pharmaceutical Reviews* and all matters related to the review processes. Amendments to, and clarifications of, the *Fee Schedule for Pharmaceutical Reviews* may be effected by means of directives (called *Pharmaceutical Reviews Update*) issued by CDA-AMC on an as-needed basis between formal revisions of the document. Any changes to the *Fee Schedule for Pharmaceutical Reviews* will be applied prospectively.

The application fees for pharmaceutical reviews were established to ensure that the appropriate amounts of fees are recovered from the sponsors in accordance with the mandate of the Conference of Deputy Ministers of Health. The fees will supplement existing federal, provincial, and territorial funding.

1.1. Scope

This document applies to all applications filed by industry sponsors that require a review as per the descriptions provided for the fee schedules presented in Table 1. The *Fee Schedule for Pharmaceutical Reviews* must be read in conjunction with the following documents found on the CDA-AMC website.

- *Procedures for Reimbursement Reviews*
- *Process for Drugs with Expanded Health System Implications*

1.2. Background

Application fees are required for all drug submissions and resubmissions filed by industry sponsors for review through the reimbursement review processes, which are pan-Canadian evidence-based processes for conducting consistent, clear, objective, and rigorous reviews of the clinical evidence, cost-effectiveness, and patient perspectives on these drugs. Application fees will not apply to any submission, resubmission, or request for advice filed by the public drug programs or tumour groups.

2. Fee Guidelines

This section provides information on the fee amounts, the types of fees charged, and guidelines on refunds.

2.1. General Contact Information

For questions regarding invoicing and the timing of the application fees payment or questions about your account, please contact Accounts Receivable by email at accountsreceivable@cda-amc.ca. Please quote your customer and invoice numbers in your email.

For questions regarding the type of fee charged for your application, please contact CDA-AMC.

2.2. Application Fees

2.2.1. Application Fee Schedule

Application fees will be charged based on the schedule in Table 1, plus applicable taxes. Applicable taxes include GST/HST and/or QST. The application fee schedule provides broad guidance on the fee schedules. CDA-AMC reserves the right to make case-by-case determinations as to the applicable fee schedule.

Table 1: Application Fee Schedule

Schedule	Application type	Fee
A	Application reviewed through the standard review process	$99,660
B	Application reviewed through the pharmaceuticals with anticipated comparable efficacy and safety (PACES) process	$89,690
C	Application reviewed through the tailored review process	$49,810
D	Request for reconsideration of a draft recommendation	$9,690
E	Application reviewed through the complex process	$147,580
F	Application reviewed through the process for drugs with expanded health system implications	$174,180

Note: A case-by-case assessment may be made to the fee schedule, where there are multiple indications included in one application.

2.2.2. Multiple Application Fees for Submissions

A case-by-case assessment is made regarding the application fee when there are multiple indications included in one application. Multiple fees are assessed to ensure that the application fee accurately reflects the level of effort and resources required to review the application. CDA-AMC bases this decision on the following four factors:

- The indications are sufficiently different to require consultation with different clinical specialists.
- The indications are best addressed through separate review reports and/or expert committee recommendations.

- The indications have been studied in separate clinical development programs (e.g., separate clinical trials for each population).
- The sponsor has filed different economic models and budget impact analyses for each of the indications.

The final decision is made by CDA-AMC based on the considerations noted above. It is important to note that not all the factors need to be met for an application to warrant multiple application fees.

Any sponsor's that are uncertain about the application fees are encouraged to contact CDA-AMC early in the presubmission phase to seek guidance. Sponsors with questions must submit an eligibility inquiry form.

2.2.3. Annual Increase in Application Fees

CDA-AMC may increase application fees annually beginning on April 1st based upon fluctuations in the Consumer Price Index (CPI) determined by the Bank of Canada "Total CPI." The increase shall be based on the average monthly increase in the CPI for the preceding April to January. Revised fee schedules will take effect on April 1st or no sooner than one month after they are made available for the current year.

2.3. Fee Payment Procedures

All payments must be made in Canadian funds. Payments made by electronic fund transfer are preferred. Please contact accountsreceivable@cda-amc.ca to discuss other payment options.

2.3.1. Milestones for Payment of Application Fees

Fees will be charged at two process milestones for all fee schedules with the exception of schedule D fees, which will be charged at one milestone. Table 2 sets out the milestones.

Table 2: Milestones for Payment of Application Fees

Schedule	Milestone 1			Milestone 2			Total fee
	Description	Per cent due	Amount due	Description	Per cent due	Amount due	
A	Initiation of review	70%	$69,762	Draft reports sent to sponsor	30%	$29,898	$99,660
B			$62,783			$26,907	$89,690
C			$34,867			$14,943	$49,810
E			$103,306			$44,274	$147,580
F			$121,926			$52,254	$174,180
D	Request accepted	100%	$9,690	Not applicable	0%	$0	$9,690

2.3.2. Submission of Payment

An initial invoice for the application fee owing will be sent based on the schedule and milestone description noted in Table 2.

Payments by electronic fund transfer are preferred. New sponsors should contact accountsreceivable@cda-amc.ca for financial information.

All application fees are due within 30 calendar days of receipt of an invoice. If fee payment is not received within 30 days, the following will occur:

- A reminder will be provided indicating that payment is past due. It is the sole responsibility of the sponsor to pay any fees by the due date and although it is our intention to send subsequent reminders of unpaid fees, it shall not be obligated to do so.
- If payment remains outstanding after 45 calendar days, all work on the review will be temporarily suspended. Once a review is suspended, there is no assurance that the review will be completed in time for the originally targeted expert review committee meeting. If the review of an application has been temporarily suspended due to the non-payment of fees, CDA-AMC makes no commitments or guarantees as to the date on which such work will be resumed, or the expert committee meeting at which the application will be considered.
- Once payment in full is received, CDA-AMC will resume its work on the suspended application as soon as it can be reasonably accommodated based on available resources and application volumes.
- In the case of a request for reconsideration, the expert committee recommendation will not be issued until full payment is received by CDA-AMC.

Please contact accountsreceivable@cda-amc.ca to discuss payments that are not electronic fund transfers or credit cards.

If insufficient fees are received, all work on the application will cease until the issue has been resolved. Should the sponsor be unable or unwilling to provide the required fees, the application may be withdrawn by the sponsor or CDA-AMC will cancel the review. The sponsor may refile the application at a future date with the appropriate fees, without prejudice. Fees paid by a cheque that is not cleared due to insufficient funds (NSF) will be considered outstanding. Any fees associated with the NSF cheque incurred by CDA-AMC will be charged to the sponsor. Any other fees associated with stop-payment requests, closed account fees, or any other such charges will also be charged back to the sponsor. Post-dated payments will not be accepted. Any overpayments will be refunded to the sponsor.

Wire payments of invoiced fees will be accepted only when wired in Canadian funds, as specified on the invoice.

Please include your company name, product name, project code, and invoice number with any wire payments.

Please ensure all service charges — including fees charged by your bank or any intermediary banks — are covered by your payment. CDA-AMC is not responsible for any fees charged during the transfer process. Failure to pay the full amount outstanding will result in a balance owing on your account. Any payments sent in non-Canadian funds will be rejected. If problems occur with the transaction, please contact your financial institution.

2.3.3. Deferred Fees and Fee Exemptions

No application fees are eligible for any fee deferral or exemptions.

2.4. Performance Metrics and Partial Refunds

2.4.1. Performance Metric

Subject to the exceptions set forth in Table 4, which follows, non-compliance with the metric noted in Table 3 will result in a refund.

Table 3: Performance Metrics

Process	Milestones	Performance metric	Compliance target	Refund for non-compliance
Reimbursement review	Date the file is accepted for review by CDA-AMC to the date the draft recommendation is issued to the sponsor and drug programs.	180 calendar days	95%	25% of the application fee payable back to the sponsor
Expanded Health System Implications	Date the file is accepted for review by CDA-AMC to the date the draft recommendation is issued.	270 calendar days		

There may be instances in which CDA-AMC is prevented from achieving the performance metric because of circumstances beyond the reasonable control of CDA-AMC, including, and without limitation, those circumstances set forth in the following Table 4. CDA-AMC shall not be in breach of the performance metrics and shall not incur any liability to the sponsor or be responsible for any refund of application fees if and to the extent it is delayed and prevented from achieving the performance metrics due to circumstances beyond its control. During the period that such circumstances continue, the timelines shall be suspended. CDA-AMC shall resume its work as soon as is reasonably possible and the performance metric timelines shall resume from the date on which CDA-AMC is reasonably able to resume its work. As the embargoed recommendation will not be issued until the Notice of Compliance (NOC) or NOC with conditions (NOC/c) has been received by CDA-AMC, there may be situations where CDA-AMC is unable to issue the expert committee's recommendation within 180 calendar days as result of the application requirements not being complete. In such circumstances, the sponsor will not be entitled to a refund.

Table 4: Factors That May Influence Review Timelines

Scenario
Voluntary withdrawal by the sponsor
Time required for the sponsor to provide additional information
Temporary suspension of a review due to incomplete information
Temporary suspension of a review due to non-payment of the application fee
Substantial deviation between the proposed indication provided at the time of filing a submission on a pre-NOC basis and the final indication approved by Health Canada
Deferral of the recommendation by the expert committee pending clarification of specific issues
Withdrawal of marketing authorization for a drug by Health Canada
Non-issuance of marketing authorization by Health Canada
Delay in issuing marketing authorization by Health Canada (e.g., pause the clock request)
Submission requirements (e.g., final product monograph) not finalized in time for CDA-AMC to achieve the performance target
New information filed by the sponsor during the review

NOC = Notice of Compliance.

Please refer to the Procedures for Reimbursement Reviews and the Process for Drugs with Expanded Health System Implications for details regarding each of the scenarios noted in Table 4.

There may be other factors not included in the preceding Table 4 that are beyond our control and may impact the timing of a review. The determination as to whether a circumstance leading to a delay is beyond the reasonable control of CDA-AMC shall be made by CDA-AMC, acting reasonably, and shall be final and binding on the sponsor and all other parties. CDA-AMC shall advise the sponsor in writing, as soon as practicable after such circumstances arise, of the delay and the circumstances beyond the control of CDA-AMC that have resulted in the delay.

2.4.2. Refunds of Application Fees

Except as expressly provided for in this guidance document, application fees are non-refundable regardless of the final recommendation. Sponsors who withdraw from the process after the review has been initiated and before reaching milestone 2 shall receive a refund of 50% of the total amount invoiced. Those who withdraw on or after milestone 2 shall not receive a refund. Schedule D fees are always non-refundable.

Table 5: Details Regarding Refunds for Application Fees

Refund Amount	Time of Withdrawal From Review Processes
50% refund	Before milestone 2
No refund	On or after milestone 2