

Fee Schedule for Scientific Advice

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Revision History

Periodically, this document will require updates and revisions as part of the ongoing process of improvement activities. The following version control table, as well the version number and date on the cover page, is to be updated when any updates and revisions are made and copies updated.

Section	Revision number	Date	Description and changes made
All	v1.0	November 22, 2016	Original
2. 1, 2.2.1, Table 1, 2.2.2, 2.2.3, 2.2.4	v2.0	June 1, 2023	Update to contact information Increase in the fee range Addition of a change fee Changes to the timing of invoices Removal of credit card payments Additional details regarding refunds
All	v3.0	October 2024	Update to organization's name



1. Introduction

This document provides guidance on the charging of the fee for the provision of Scientific Advice at Canada's Drug Agency (CDA-AMC). Scientific Advice is offered to pharmaceutical companies on a cost-recovery basis, and therefore fees may change as required. CDA-AMC may amend, from time to time, the *fee schedule for Scientific Advice* and all matters related to Scientific Advice. Amendments to, and clarifications of, the fees may be affected through an update to the *fee schedule*, with notification posted on the Scientific Advice website. Any changes to the *fee schedule* will be applied prospectively, with the company obliged to pay the fee that was in effect at the time of the original application for Scientific Advice.

1.1 Scope

This document applies to all applications submitted to CDA-AMC for the provision of Scientific Advice. This document must be read in conjunction with the information and documents on the Scientific Advice website.

1.2 Background

The Scientific Advice Program at CDA-AMC is a voluntary, fee-for-service consultation offered to pharmaceutical companies. Through this program, CDA-AMC offers advice on early drug development plans from a Canadian health technology assessment perspective.

Scientific Advice is offered at an early point in the drug development process. This provides pharmaceutical companies with an opportunity to adjust their development plans based on advice from CDA-AMC.

2. Implementation Guidance

This section provides information on the fee, how the fee is charged, and guidance on payment and refunds.

2.1 General Contact Information

For questions regarding the fee payment, the timing of the payment, or your account, please contact Accounts Receivable by email at accountsreceivable@cda-amc.ca. Please have your customer number and invoice number readily available.

For questions regarding requests for Scientific Advice or for process-related questions, please contact Scientific Advice at scientific.advice@cda-amc.ca.

2.2 Fee Payment Procedures

All payments must be made in Canadian funds. Payments must be payable to the "Canadian Agency for Drugs and Technologies in Health."

2.2.1 Fee Schedule

The fee for Scientific Advice ranges from \$80,000 to \$125,000 based on the scale of the project. All fees are in Canadian dollars and are subject to applicable taxes (GST/HST or QST).

The total fee will be determined following submission of the *Briefing Book*. A Final Fee Letter and updated fee schedule will be provided within 2 weeks following the *Briefing Book* submission.

An online application and a confirmation letter are required to reserve the mutually agreed-upon time frame for the Scientific Advice meeting. CDA-AMC reserves the right to charge an additional fee of up to \$10,000 should the reserved meeting time be changed by more than 1 week from the agreed-upon time frame.



Table 1: Fee Schedule

Milestone	Invoice timing	Fee ^a
Invoice #1	Confirmation letter received	\$25,000
Invoice #2	Final fee letter received ^b	\$ TBD (This is the balance remaining less 15% of the total fee)
Invoice #3	Record of Scientific Advice received	\$ TBD (15% of the total fee)
	Total (before taxes)	\$ TBD

TBD = to be determined.

2.2.2 Submission of Payment

Invoices will be sent for the fee owing once each of the milestones noted in the *fee schedule* has been reached. Payments made by cheque are to be sent to:

Canada's Drug Agency Attn: Accounts Receivable 600 – 865 Carling Ave. Ottawa, ON K1S 5S8 Canada

CDA-AMC also accepts payment by electronic funds transfer (EFT) to the bank account stipulated on the invoice.

2.2.3 Payment of Fees

All fees are due within 30 calendar days of receipt of invoice or the due date noted on the invoice. If payment is not received when due, the following steps will occur:

- A reminder will be provided that indicates that payment is past due. It is the sole responsibility of the applicant to
 pay any fees by the due date and, although CDA-AMC may in its discretion send reminders of unpaid fees, it
 shall not be obligated to do so.
- If payment remains outstanding 15 calendar days after the due date, all work will be temporarily suspended.
 Once work is suspended, there is no assurance that the Scientific Advice will be prepared on schedule to meet the original deadline. If Scientific Advice work has been temporarily suspended due to the nonpayment of fees, CDA-AMC makes no commitments or guarantees as to:
 - o the date on which such work will be resumed
 - o the date of the Scientific Advice meeting as originally planned.
- Once payment in full is received, CDA-AMC will resume its work on the suspended Scientific Advice application as soon as it can be reasonably accommodated based on available resources and application volumes.

Acceptable forms of payment include EFT, wire transfers, cheques, money orders, and international bank drafts. **Only Canadian funds are accepted**.

The preferred method of receiving payment is **by EFT or wire payments**. These payments will be accepted only when provided in **Canadian funds** per the instructions provided on the invoice.

^a. All invoices due within 30 calendar days of the invoice and are nonrefundable.

^b. Final fee letter issued within 2 weeks following Briefing Book submission.



Please include your company name, product name, and invoice number with any EFT or wire payments.

Cheques, money orders, and international bank drafts should be payable to "Canadian Agency for Drugs and Technologies in Health". Cheques drawn from non-Canadian banks *must* be issued in coordination with a referenced Canadian bank (that is, referenced on the cheque), otherwise, they will *not be accepted*. As previously noted, the work will be temporarily suspended if insufficient fees are received. Payment by a cheque not cleared through the CDA-AMC bank account due to insufficient funds (i.e., NSF) will be considered outstanding. Any fees associated with the NSF cheque incurred by CDA-AMC will be charged to the applicant. Any other fees associated with stop-payment requests, closed-account fees, or any other such charges will also be charged back to the applicant. Postdated payments will not be accepted. Any overpayments will be refunded to the applicant.

Please ensure that 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 outstanding amount will result in a balance owing on your account. Any payments sent in non-Canadian funds will be rejected.

2.2.4 Refunds of Fees

Except as expressly provided for in these guidelines, the fees are nonrefundable regardless of the final advice provided.

As payments are invoiced on a milestone basis, no refunds are provided. Any invoice issued will be considered owing to CDA-AMC, should the applicant withdraw before rendering payment.

2.3 Deferred Fees and Fee Exemptions

Fees for Scientific Advice are not eligible for any deferral or exemptions.