Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

CANADA'S DRUG AGENCY PROGRAM

Standard Scientific Advice Process

Standard Timeline: Please contact scientific.advice@cda-amc.ca for more information or if you require customized timelines.

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	January 20, 2016	
All	v2.0	September 30, 2020	Updates to all sections
All	v3.0	October 2024	Update to section 2.3, 3.0. Update to the agency's name and email

Table of Contents

1. Application

1.1 Submit online application.

Review the application procedure and submit the online application.

The online form:

- provides Canada's Druga Agency (CDA-AMC) with details about the drug for which advice is sought
- allows applicants to propose a date for the Scientific Advice meeting; a Scientific Advice staff member will contact the applicant to discuss potential meeting dates
- requires applicants to declare that they have read and agree to the information on the website about the Scientific Advice Program policies, guidelines, and processes.

After receiving an application, CDA-AMC contacts the applicant within ten (10) business days to clarify information, to discuss proposed dates for the Scientific Advice meeting, discuss next steps, and answer questions.

1.2 The application is assessed for eligibility.

CDA-AMC assesses the application for Scientific Advice.

Approval of the application for Scientific Advice is subject to satisfactory verification of the following:

- the drug product type meets eligibility requirements for Scientific Advice
- there is availability in the Scientific Advice schedule for the time desired by the applicant

Once the application has been approved and a specific date for the Scientific Advice meeting has been set, CDA-AMC provides the applicant with a schedule of key milestone dates, instructions for the secure exchange of documents, and website links to templates for use in the process.

1.3 The applicant receives the first invoice.

Once CDA-AMC confirms the approval, the first invoice will be issued to the applicant. The payment of this Scientific Advice fee confirms the applicant's intent to proceed with the Scientific Advice meeting for the predetermined date (refer to Scientific Advice Fee Schedule).

Please refer to the Fee for Scientific Advice Web page for more information and details on fee payments.

2. Briefing Book

2.1 Submit *Briefing Book*.

Submit the *Briefing Book* 14 weeks before the Scientific Advice meeting.
The *Briefing Book* provides background information and specifies the questions or issues for which advice is sought.

Questions or issues for which Scientific Advice is sought should be specific, and wording should be clear and concise. Each question or issue should be accompanied by an explanation of the applicant's position and a detailed rationale. The *Briefing Book* should not exceed 50 pages (excluding annexes).

The *Briefing Book* template and the *Guidance on the Briefing Book for Scientific Advice* should be used in preparing the *Briefing Book*. Please contact scientific.advice@cda-amc.ca if you wish to submit a briefing book prepared for another organization.

2.2 The applicant receives the *Briefing Book* clarification questions.

A. CDA-AMC sends written clarification questions on the *Briefing Book* to the applicant about 4 weeks after the *Briefing Book* is submitted.

B. An optional clarification teleconference can be scheduled and held.

If CDA-AMC requests clarification, an optional clarification teleconference may be held between CDA-AMC and the applicant, if desired by either party. One or two representatives from each organization may attend the teleconference. The teleconference occurs after the written questions are received and before responses are provided by the applicant. No official minutes are recorded, as the teleconference is intended to allow for informal clarification and discussion.

C. The applicant provides written responses to CDA-AMC.

In addition to responses to the clarification questions, the applicant may prepare an *Addendum to the Briefing Book*, if desired. The original *Briefing Book* content should not be altered.

The *Clarification on the Briefing Book for Scientific Advice* template is used by CDA-AMC to indicate clarification questions and by the applicant to document responses. The *Addendum to the Briefing Book for Scientific Advice* template should be used by the applicant if an addendum is required. When completing these documents, the applicant should include only information directly relevant to the questions posed by CDA-AMC.

2.3 The applicant receives the second invoice within 2 weeks after the Briefing Book is received.

3. Scientific Advice Meeting

The Scientific Advice meeting is a 3-hour, meeting where CDA-AMC discusses the advice with the applicant based on the questions or issues submitted in the *Briefing Book*.

The Scientific Advice meeting is held virtually, unless otherwise requested. CDA-AMC and the applicant exchange names and titles of attendees prior to the meeting. Roles of the representatives should be clearly indicated.

CDA-AMC representatives at the meeting may include the director of Science & Methods, the manager of Scientific Advice, one to three additional Scientific Advice staff members, one to three external experts, and additional CDA-AMC staff members, as required. Applicants are permitted up to ten (10) active representatives at the meeting. For virtual meetings, additional representatives are permitted as observers.

The meeting is chaired by CDA-AMC . At the beginning of the meeting, the applicant has an opportunity to provide a brief presentation on the drug for which Scientific Advice is sought. The presentation should include an overview of the drug, proposed indication(s), the clinical development program and planned economic analyses, if applicable. The remainder of the meeting time is used for CDA-AMC to discuss the advice with the applicant.

The Scientific Advice meeting occurs 14 weeks after submission of the *Briefing Book*.

4. Record of Scientific Advice (ROSA)

4.1 The applicant receives the written *ROSA*.

The applicant receives the written *ROSA,* which summarizes the advice discussed at the meeting, approximately 4 weeks after the Scientific Advice meeting.

4.2 The applicant submits *ROSA* clarification questions (optional).

A. The applicant has the option of submitting *ROSA* clarification questions to CDA-AMC after receiving the *ROSA*.

If no request is received, the applicant is deemed to have waived the right to request clarification.

If clarification is requested, one (1) set of written clarification questions must be submitted within 10 business days using the *Clarification on the Record of Scientific Advice* template. This document should be no more than six (6) pages when submitted by the applicant (not including the cover page). The clarification questions must be directly related to the Scientific Advice provided. No new questions can be addressed at this point.

B. A clarification teleconference is held, if needed.

If written clarification questions are submitted, an optional clarification teleconference is held between CDA-AMC and the applicant, if desired by either party. One or two representatives from each organization may attend the teleconference. The teleconference occurs after the written questions are submitted by the applicant and before responses are provided by CDA-AMC. No official minutes are recorded, as the teleconference is intended to allow for informal clarifications and discussion.

C. CDA-AMC provides written responses to the *ROSA* clarification questions.

4.3 The applicant receives the final invoice.

The final invoice for the Scientific Advice fee is issued after the *Record of Scientific Advice* is received. After the completion of the optional *ROSA* clarification process and payment of the final invoice, the application is closed.

CDA-AMC sends an online survey, and the applicant offers feedback on the process and the Scientific Advice provided. Applicants are requested to provide their feedback within 4 weeks so that it can be considered by CDA-AMC for future applications as soon as possible.