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

Confidentiality Guidelines for Scientific Advice

Version: 3.0
Publication Date: October 2024
Report Length: 5 Pages

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	
2, 3.3, 3.5	v2.0	September 30, 2020	Information added to sections 2, 3.3a., 3.3f, and 3.5.
All, 3.4	v3.0	October 2024	Update to organization's name and section 3.4

These guidelines are intended to ensure that Confidential Information obtained and produced pursuant to the Scientific Advice Program is protected and handled in a consistent manner by Canada's Drug Agency (CDA-AMC). By applying to the Scientific Advice Program, the applicant consents to these guidelines and agrees to be bound by the terms and conditions herein.

1. Confidential Information

All information and documentation submitted by or on behalf of an applicant as part of the Scientific Advice Program, including drug name and company name, and all information and documentation produced by CDA-AMC as part of the Scientific Advice Program, are considered to be "Confidential Information." All written and verbal communication related to the Scientific Advice application is also considered to be Confidential Information. Applicants and CDA-AMC must clearly and conspicuously mark documents as Confidential.

2. Access to Information and Freedom of Information Legislation

Canada's Drug Agency is a private, not-for-profit organization and is therefore not subject to either federal access to information or provincial or territorial freedom of information statutes. However, it is important to note that, for the parallel Scientific Advice process, authorized recipients from participating organizations have their own confidentiality guidelines and procedures and may be subject to freedom of information and access to information legislation over which CDA-AMC has no control. Any freedom of information or access to information requests should be made through the appropriate organization and not to CDA-AMC.

3. Handling Confidential Information

3.1 Responsibilities of Recipients of Confidential Information

a) Recipients of Confidential Information (i.e., CDA-AMC, applicants, authorized recipients, and/or patient representatives, as applicable) will use reasonable care to prevent the unauthorized use, disclosure, publication, or dissemination of all Confidential Information.

b) Recipients of Confidential Information (i.e., CDA-AMC, applicants, authorized recipients, and/or patient representatives, as applicable) will not disclose any Confidential Information submitted by or on behalf of the applicant or produced by CDA-AMC as part of the Scientific Advice Program to any third party except as permitted by these guidelines; as agreed by expressed, advance, written permission from both CDA-AMC and the applicant; or as required by law or by order of a legally qualified court or tribunal.

3.2 Responsibilities of Canada's Drug Agency

a) CDA-AMC will use the applicant's Confidential Information solely for the purpose of carrying out its responsibilities pursuant to the Scientific Advice Program.

b) CDA-AMC shall utilize secure filing and storage, websites, and tracking processes for handling applicants' Confidential Information and Scientific Advice information. Scientific Advice files will be kept separate from other CDA-AMC files.

3.3 Disclosure of Information

a) All applicant documents and Confidential Information submitted as part of the Scientific Advice Program and all documents produced by CDA-AMC as part of the Scientific Advice Program may be released to the following "authorized recipients":

- CDA-AMC staff, as required (requirement to be determined at the sole discretion of Canada's Drug Agency)

- external experts involved in the Scientific Advice Program
- staff from organizations participating in the parallel Scientific Advice process (e.g., Health Canada, Institut national d'excellence en santé et en services sociaux [INESSS], or the National Institute for Health and Care Excellence [NICE]).

b) Applicant documents and Confidential Information submitted as part of the Scientific Advice Program and documents produced by CDA-AMC as part of the Scientific Advice Program may be released to patient representatives involved in the Scientific Advice Program only with express written permission from the applicant, as indicated in the declaration section of the Scientific Advice application form.

c) CDA-AMC staff involved in the Scientific Advice Program and any other CDA-AMC staff with whom Scientific Advice information is shared are required to comply with these guidelines. All CDA-AMC staff must also comply with the confidentiality clauses in their employment contracts and with the *Conflict of Interest Policy* and guidelines for employees.

d) External experts involved in the Scientific Advice Program are required to comply with these guidelines in the same manner and to the same extent as CDA-AMC and will be subject to a *Non-Disclosure Agreement*. All external experts contracted by CDA-AMC must also comply with the *Conflict of Interest Policy* and guidelines for contractors.

e) Patient representatives involved in the Scientific Advice Program are required to comply with these guidelines in the same manner and to the same extent as CDA-AMC, and will be subject to a *Non-Disclosure Agreement*. All patient representatives must also comply with the *Conflict of Interest Policy*.

f) Staff from participating organizations (for the parallel Scientific Advice process) are required to comply with the applicable legislation, policies, and confidentiality guidelines to which their organization is subject.

3.4 Recording of Meeting Minutes

a) Applicants, CDA-AMC staff, external experts, and patient representatives may record minutes, in writing, from teleconferences andmeetings, as required. Written meeting minutes are considered to be Confidential Information.

b) Audio recording of the Scientific Advice meeting is not permitted by any party.

3.5 Documents That May Be Shared With Authorized Recipients

a) All or sections of the following documents may be shared with authorized recipients, and when permitted under section 3 b) hereof, with patient representatives, and may be posted on a confidential website accessible only by persons authorized according to these guidelines:

- completed application form
- *Briefing Book for Scientific Advice*
- *Clarification on the Briefing Book for Scientific Advice*
- *Addendum to the Briefing Book for Scientific Advice*
- *Record of Scientific Advice* (drafts and final)
- *Clarification on the Record of Scientific Advice*
- meeting minutes.

All previously listed documents also include those documents involved in parallel Scientific Advice.

b) No documents will be posted on the CDA-AMC public website.

3.6 Archiving and Disposal of Documents Containing Confidential Information

a) One complete set of all electronic documents associated with a Scientific Advice application is kept on file in secure storage for as long as there may be a need to refer to the documents.

b) CDA-AMC will determine, at its sole and absolute discretion, if there is a need to refer to this information.

c) CDA-AMC staff undertakes regular reviews of archived material. Any material that CDA-AMC determines to be no longer required is disposed of as subsequently described in sections 6 d) and 6 e).

d) At the completion of a Scientific Advice application, CDA-AMC disposes of all hard copies of documents supplied by the applicant and produced by CDA-AMC as part of the Scientific Advice Program by confidential shredding.

e) At the completion of a Scientific Advice application, external experts and patient representatives must delete or dispose of all documentation (electronic and hard copy) that was provided and produced as part of the Scientific Advice Program, including information which may have been stored on a hard drive of a computer or in emails.