

CDR Confidentiality Guidelines

The Canadian Agency for Drugs and Technologies in Health (CADTH) has developed the following Confidentiality Guidelines to ensure the Confidential Information obtained for the purpose of the Common Drug Review (CDR) process is protected. These guidelines ensure appropriate steps and procedures are in place and that Confidential Information is handled in a consistent manner. CADTH complies with these Confidentiality Guidelines when handling information, as part of the CDR process. A Manufacturer is deemed to have consented to the Confidentiality Guidelines by filing a Submission or by supplying other information to CADTH for the CDR process. These Confidentiality Guidelines constitute an agreement between CADTH and the Manufacturer. A Manufacturer and all authorized recipients, named in this document, will maintain the confidentiality of documents that CADTH shares with them that are labelled as “Confidential.”

Definition

“Confidential Information” (including Confidential Price) is information supplied by a Manufacturer. It includes any non-public scientific, technical, or commercial information about a Manufacturer’s business or a Manufacturer’s product received as a result of the exchange of information as part of the CDR process, but which does not include information that:

- a) was already in the possession of CADTH, External Reviewer(s) assigned to review the Submission or Resubmission, CDEC Members, External Experts (when contracted to provide specific information in relation to the Submission or Resubmission), Formulary Working Group (FWG) Members, federal/provincial/territorial (F/P/T) governments, F/P/T health authorities, Drug Plans, Health Canada, or the Patented Medicine Prices Review Board (PMPRB), without restriction as to its use or disclosure;
- b) is or becomes available to the general public other than as a result of a breach of the procedures contained herein (information available to the general public includes but is not limited to published articles, Drug prices, and product monographs); or
- c) a third party (who is not under any obligation as to confidentiality or non-disclosure) rightfully discloses to CADTH, External Reviewer(s) assigned to review the Submission or Resubmission, CDEC Members, External Experts (when contracted to provide specific information in relation to the Submission or Resubmission), FWG Members, federal/provincial/territorial (F/P/T) governments, F/P/T health authorities, Drug Plans, Health Canada, or PMPRB, without restriction as to its use or disclosure.

Confidential Information shall be marked as “Proprietary” or “Confidential,” with an appropriate legend, marking stamp, or other obvious written identification by the Manufacturer. Only

information that has not previously been made public and is confidential should be labelled or identified as such.

Confidential Information also includes Confidential Information about a Manufacturer's product that is provided to CADTH by Health Canada, with authorization from the Manufacturer.

Access to Information and Freedom of Information Legislation

CADTH is a private, not-for-profit organization and is therefore not subject to either federal access to information or provincial/territorial freedom of information statutes. However, Manufacturers are asked to consent to their information being exchanged with F/P/T governments, F/P/T health authorities, Drug Plans, Health Canada, and the PMPRB by signing a letter in the form available in the Manufacturers' Submission Guidelines. These bodies have their own confidentiality procedures and are subject to provincial or federal freedom of information and access to information legislation. CADTH has no jurisdiction or control over those procedures and statutory requirements. Manufacturers should be aware of those procedures and requirements when including Confidential Information in a Submission or Resubmission.

Handling Confidential Information

1. Responsibilities of CADTH

- a) CADTH will use reasonable care to prevent the unauthorized use, disclosure, publication, or dissemination of Confidential Information that is included in and related to Manufacturers' Submissions and Resubmissions, and labelled "Proprietary" or "Confidential;"
- b) CADTH will not disclose Confidential Information in and related to the Manufacturers' Submissions or Resubmissions to any third party except as permitted by these Confidentiality Guidelines, or as required by law or by order of a legally qualified court or tribunal;
- c) CADTH will use the Manufacturer's Submission or Resubmission and Confidential Information solely for the purpose of carrying out its responsibilities with respect to the Common Drug Review;
- d) CADTH has in place secure filing and storage, websites, and processes for tracking Manufacturers' Submissions or Resubmissions and Confidential Information;
- e) CADTH has in place internal processes for dealing with Manufacturers' Submissions or Resubmissions and Confidential Information in hard copy and electronic format, as described in the following sections.

2. Release of Manufacturer's Information

- a) A Manufacturer's Submission or Resubmission, including the Manufacturer's Confidential Information, may be released to the following (the "Authorized Recipients"):
 - CADTH Staff
 - Review Team
 - CDEC Members

- FWG Members
 - F/P/T governments and Drug Plans
 - F/P/T health authorities
 - Health Canada
 - PMPRB.
- b) CADTH Staff are required, as a condition of employment, to comply with CADTH's confidentiality requirements, Code of Conduct, and Conflict of Interest guidelines.
- c) All Reviewers, CDEC members, and Expert Advisors must abide by the confidentiality clauses contained in their Code of Conduct and/or Conflict of Interest Guidelines and/or contracts.
- d) FWG members are required to sign a non-disclosure agreement requiring them to comply with these Guidelines. (Note: Drug Plans, F/P/T governments, F/P/T health authorities, Health Canada, and the PMPRB are not required to sign non-disclosure agreements, as they have their own processes and statutory requirements to address confidentiality issues, as previously described.)
- e) The Manufacturer's Submission or Resubmission, or parts of it, including Confidential Information, may be discussed amongst any or all of the bodies named in the letter signed by the Manufacturer authorizing unrestricted communication about the Drug.
- f) In the case of a Pre-NOC Priority Review Submission, information regarding the Manufacturer's product, including Clarifaxes and other relevant information, may be shared between Health Canada and CADTH, as authorized in a signed letter from the Manufacturer.

3. Documents that May Be Shared with Authorized Recipients

- a) The following documents and the information contained in them, including Confidential Information, may be shared with the Authorized Recipients and may be posted on a confidential website accessible only by persons authorized according to these Confidentiality Guidelines:
- Manufacturer's Submission or Resubmission
 - Reviewers' Reports
 - Manufacturer's Comments About Reviewers' Reports
 - Reviewers' Replies to Manufacturer's Comments
 - CDEC Recommendation
 - CDEC Brief
 - CDEC Reconsideration Brief.
- b) The following documents are shared with a Manufacturer with respect to Submissions or Resubmissions, or in respect to a Drug Plan Submission or Resubmission that affects the Manufacturer's Drug or a Request for Advice about a Recommendation that may result in a new Recommendation. The Manufacturer maintains the confidentiality of these documents.
- Reviewers' Reports
 - CDEC Recommendation
 - CDEC Recommendation on Reconsideration
 - Plain Language CDEC Final Recommendation (until posted on CADTH website)
 - Response to Request for Clarification

- Request for Advice
 - Overview of CDR Clinical and Pharmacoeconomic Review Reports.
- c) The following documents are posted on the CADTH website:
- Tracking document indicating the status of a Drug, including a Pre-NOC Priority Review Submission, in the review queue.
 - CDEC Final Recommendation with Confidential Information removed (both the Technical version and the Plain Language version)
 - Overview of CDR Clinical and Pharmacoeconomic Review Reports.
- d) Information regarding the Manufacturer's product, including Clarifaxes and other relevant information, may be shared between Health Canada and CADTH, as authorized in a signed letter from the Manufacturer (e.g., Pre-NOC Priority Review Submission).

4. Referring to Manufacturer's Confidential Information in the CDR Publicly Available Documents (i.e., the Documents Posted on the CADTH Website)

In the preparation of the CDR Clinical Review Report and the CDR Pharmacoeconomic Review Report, CADTH may use unpublished studies or the Confidential Price supplied by the Manufacturer, in addition to the evidence that CADTH identifies and compiles regarding the Drug. These reports, which form the basis for the CDEC Reasons for Recommendation and other CDR publicly available documents, may contain Confidential Information (including Confidential Price), as identified by the Manufacturer. In such cases, the following provisions shall apply:

a) Technical and Plain Language Recommendation Documents

The Technical version and the Plain Language Recommendation documents may contain Confidential Information. Each document will be sent to the Manufacturer, who will be asked to identify any Confidential Information to be redacted in both the Technical and Plain Language versions of the Final Recommendation.

If the Manufacturer instructs that the Confidential Information be deleted from the CDEC Final Recommendation:

- CADTH will redact the Confidential Information by removing it and will indicate:
 - that Confidential Information was used by CDEC to make its listing Recommendation; and
 - that the Manufacturer requested that the Confidential Information be deleted, pursuant to the CDR Confidentiality Guidelines.
- CADTH will describe the quantity of information that was redacted and will provide a general description of the type of information (e.g., Confidential Price, unpublished study results, etc.) that was redacted.
- If the Confidential Information is mentioned in any public document, CADTH may make reference to the name of the study or such relevant information.

b) Overview of the CDR Clinical and Pharmacoeconomic Review Reports

The Overview, which may contain Confidential Information, will be sent to the Manufacturer, who will be given the opportunity to identify the Confidential Information to be redacted from the publicly available version of the document.

If the Manufacturer instructs that any of the Confidential Information be deleted from the Overview:

- CADTH will redact the Confidential Information by removing it and will indicate:
 - that Confidential Information was included in the Overview; and
 - that the Manufacturer requested that the Confidential Information be deleted, pursuant to the CDR Confidentiality Guidelines.
- CADTH will describe the quantity of information that was redacted and will provide a general description of the type of information (e.g., Confidential Price, unpublished study results, etc.) that was redacted.
- If the Confidential Information is mentioned in any public document, CADTH may make reference to such relevant information.

5. CDEC Minutes

Minutes of the CDEC meetings are released only to CDEC members, and to the President and Chief Executive Officer of CADTH.

6. Archiving of Documents Containing Confidential Information

- a) One complete set of all paper and electronic documents, including documents containing Confidential Information associated with the review of a Drug, is kept on file in secure storage for as long as there may be a need to consult them. CADTH staff undertake regular reviews of archived material. Any material that CADTH determines to be no longer required is disposed of, as subsequently described in section 7.
- b) Extra copies of paper and electronic documents associated with the review of a Drug are disposed of, as subsequently described in section 7.

7. Disposal of Documents Containing Confidential Information

- a) CADTH disposes of extra copies of the Submission or Resubmission, including documents containing Confidential Information supplied by a Manufacturer, by confidential shredding unless the Manufacturer requests that they be returned. (Note: One complete set of all documents [paper and electronic] associated with the review of a Drug is kept on file, as described above in section 6.)
- b) CADTH advises the Manufacturer, in writing, that it has disposed of extra copies of documents.
- c) When the Manufacturer instructs CADTH that extra documents are to be returned to the Manufacturer, the following apply:
 - The Manufacturer must request the return of the documents in the Cover Letter at the time of filing a Submission or Resubmission.
 - The extra copies of documents are returned to the Manufacturer as directed by the Manufacturer, at the Manufacturer's expense.
- d) Reviewers are requested to delete and confirm the deletion of all Confidential Information in their electronic files.