

## CDR CONFIDENTIALITY GUIDELINES

The Canadian Agency for Drugs and Technologies in Health (CADTH) and the Common Drug Review (CDR) Directorate have developed the following Confidentiality Guidelines to ensure the protection of Confidential Information obtained under the CDR program. These guidelines ensure appropriate steps and procedures are in place and that Confidential Information is handled in a consistent manner. CADTH and the CDR Directorate comply 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 the CDR Directorate. The Confidentiality Guidelines constitute an agreement between CADTH and the Manufacturer.

### Definition

Confidential Information (including Confidential Price) is information supplied by a Manufacturer in a document that is clearly marked with the word “confidential” or other similar language, and any other 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 described in the next section (*Access to Information and Freedom of Information Legislation*), but which does not include information that:

- a) was already in the possession of CDR Directorate Staff, External Reviewer(s) assigned to review the Submission or Resubmission, CEDAC Members, External Experts (when contracted to provide specific information in relation to the Submission or Resubmission), ACP Members, 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 CDR Directorate Staff, External Reviewer(s) assigned to review the Submission or Resubmission, CEDAC Members, External Experts (when contracted to provide specific information in relation to the Submission or Resubmission), ACP Members, F/P/T governments, F/P/T health authorities, Drug Plans, Health Canada, or PMPRB without restriction as to its use or disclosure.

Manufacturers who supply Confidential Information are responsible for clearly identifying it as such. 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 the CDR Directorate by Health Canada with authorization from the Manufacturer during the CDR Directorate's review of a Pre-NOC Priority Review Submission.

## **Access to Information and Freedom of Information Legislation**

CADTH is a private, non-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 and the CDR Directorate have 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. When information is received by the CDR Directorate through access to information or freedom of information legislation, it is treated in the same way as a Manufacturer's Submission or Resubmission is treated, according to these Guidelines. Any Confidential Information received by the CDR Directorate through access to information or freedom of information legislation is treated as Confidential Information pursuant to these Guidelines.

## **Handling Confidential Information**

### **1. Responsibilities of the CDR Directorate**

- a) The CDR Directorate will use reasonable care to prevent the unauthorized use, disclosure, publication or dissemination of Manufacturers' Submissions and Resubmissions, and Confidential Information.
- b) The CDR Directorate will not disclose Manufacturers' Submissions or Resubmissions, or Confidential Information, 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) The CDR Directorate 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) The CDR Directorate has in place secure filing and storage, websites, and processes for tracking Manufacturers' Submissions or Resubmissions and confidential documents;
- e) The CDR Directorate has in place internal processes for dealing with Manufacturers' Submissions or Resubmissions and Confidential Information, 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"):
  - CDR Directorate Staff
  - Review Team
  - CEDAC Members
  - ACP Members
  - F/P/T governments and Drug Plans
  - F/P/T health authorities
  - Health Canada
  - PMPRB.
- b) All persons described in the preceding paragraph, including ACP members, but excluding Drug Plans, F/P/T governments, F/P/T health authorities, Health Canada, and the PMPRB, are required to sign a non-disclosure agreement requiring them to comply with these Guidelines. (Note: F/P/T governments, F/P/T health authorities, Drug Plans, Health Canada, and PMPRB have their own processes and statutory requirements to address confidentiality issues, as previously described.)
- c) 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.
- d) 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 the CDR Directorate, as authorized in a signed letter from the Manufacturer.

CDR Directorate Staff and all Reviewers, CEDAC members, ACP members, and Expert Advisors must abide by the confidentiality clauses contained in their Code of Conduct and/or Conflict of Interest Guidelines.

## 3. Documents that May Be Shared

- 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
  - CEDAC Recommendation
  - CEDAC Brief
  - CEDAC Reconsideration Brief
  - CEDAC Recommendation on Reconsideration.

- b) The following documents are shared with a Manufacturer with respect to Submissions or Resubmissions, or in respect to an ACP or Drug Plan Submission or Resubmission that affects the Manufacturer's Drug:
- Reviewers' Reports
  - CEDAC Recommendation
  - CEDAC Recommendation on Reconsideration
  - Plain Language CEDAC Final Recommendation
  - 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.
  - CEDAC Final Recommendation with Confidential Information removed (both the Technical version and the Plain Language version)
  - Overview of CDR Clinical and Pharmacoeconomic Review Reports
- d) 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 the CDR Directorate, as authorized in a signed letter from the Manufacturer.

#### **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, the CDR Directorate may use unpublished studies or the Confidential Price supplied by the Manufacturer, in addition to the evidence that the CDR Directorate identifies and compiles regarding the Drug. These reports, which form the basis for the CEDAC 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 Reasons for Recommendation and Plain Language Reasons for Recommendation**

The Technical version of the Reasons for Recommendation and the Plain Language Reasons for Recommendation may contain Confidential Information. Each document will be sent to the Manufacturer. The Manufacturer 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 CEDAC Final Recommendation, the CDR will redact the Confidential Information by "blacking" it out and may indicate:
  - that Confidential Information was used by CEDAC to make its listing Recommendation; and
  - that the Manufacturer requested that the Confidential Information be deleted, pursuant to the CDR Confidentiality Guidelines
- If the Confidential Information is mentioned in any public document, the CDR Directorate 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. The Manufacturer 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, CDR will redact the Confidential Information by “blacking” it out and may 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.
- If the Confidential Information is mentioned in any public document, the CDR Directorate may make reference to such relevant information.

**5. CEDAC Minutes**

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

**6. Archiving of Confidential Documents**

- a) One complete set of all paper and electronic documents, including confidential ones 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. The CDR Directorate staff undertakes regular reviews of archived material. Any material that the CDR Directorate determines to be no longer required is disposed of as described below in section 7.
- b) Extra copies of paper and electronic documents associated with the review of a Drug are disposed of as described below in section 7.

**7. Disposal of Confidential Documents**

- a) The CDR Directorate disposes of extra copies of the Submission or Resubmission, including confidential documents 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) The CDR Directorate advises the Manufacturer, in writing, that it has disposed of extra copies of documents.
- c) When the Manufacturer instructs the CDR Directorate 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.

## **8. Drug Plan Information**

The CDR Directorate shall protect the confidential nature of any information provided by a Drug Plan that is clearly marked “confidential”, and shall not share such information with Manufacturers or others except as permissible by the applicable Drug Plan(s).