

## **Conflict of Interest Guidelines for the Common Drug Review**

### **1.0 Purpose of the Guidelines**

- 1.1 These Conflict of Interest Guidelines (COI Guidelines) are intended to ensure the highest ethical standards and maintenance of the integrity of the Common Drug Review process. The principles of transparency and disclosure are essential to achieving these objectives. By disclosing relevant personal, occupational or financial connections; or interests with pharmaceutical companies and affected organizations, participants in Common Drug Review activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of the Common Drug Review process.

### **2.0 Definitions**

- 2.1 Unless otherwise stated, the definitions set out in Appendix 1 attached hereto shall apply.
- 2.2 In these COI Guidelines, the word “party” means a drug manufacturer who files a submission to have a drug listed on the drug plan formularies in a federal, provincial or territorial jurisdiction, (including such drug manufacturer's parent corporation, subsidiaries, affiliates and associated corporations) or organizations, including direct competitors, whose interests are affected by a drug submission filed by a drug manufacturer.

### **3.0 Applicability**

- 3.1 These COI Guidelines apply to all participants in the CDR process.

### **4.0 Scope of Conflict of Interest**

- 4.1 A conflict of interest refers to situations in which personal, occupational or financial considerations may affect, or appear to affect, the objectivity or

fairness of participants in the CDR process. A conflict of interest may be real, potential or perceived in nature.

- 4.2 A real conflict of interest arises where a participant in the CDR process has a private or personal interest, for example, a close family connection such as a spouse or child, or financial interest, with a party.
- 4.3 A potential conflict of interest may arise when a participant in the CDR process has a private or personal interest, such as an identified future commitment, with a party.
- 4.4 A perceived (or apparent) conflict of interest may exist when a reasonable well-informed person has a reasonable belief that a participant has a conflict of interest, even if there is no real conflict.

## 5.0 Disclosure

- 5.1 **All participants must disclose any conflict of interest, as defined above, in the form and manner prescribed by CADTH, at the earliest opportunity.** Before participants undertake any activities on behalf of CADTH or the CDR process, they are required to complete and submit a disclosure form.
- 5.2 All participants must complete the Conflict of Interest (COI) Disclosure Form annually. However, the obligation to disclose is ongoing and participants must continue to inform CADTH of any conflict of interest that arises, at the earliest opportunity.
- 5.3 A summary of the conflict of interest declaration for each CEDAC member will be publicly available on the CADTH website. COI declarations for all other participants will remain confidential to CEDAC members and the CADTH Vice-President, CDR. Additionally, potential relevant conflicts of CEDAC members and CDR reviewers are summarized and reviewed at each CEDAC meeting.
- 5.4 **Part I Disclosures**

Without limiting the generality of the foregoing, participants are required to disclose all interests or activities that occurred during the past two years to the CADTH Vice-President, CDR. Information shared may pertain to:

- i) receipt of funding for, or payment of, travel by a party
- ii) receipt of funding or honoraria from a party to be a speaker
- iii) receipt of funding or honoraria from a party for writing articles or editorials

- iv) receipt of funding or honoraria from a party for organizing conferences
- v) receipt of funding or honoraria from a party for giving educational lectures
- vi) receipt of any other financial support or honoraria from a party.

## **5.5 Part II Disclosures**

Without limiting the generality of the foregoing, participants are required to disclose all interests or activities that occurred during the past five years to the Vice-President, CDR.

Information shared may pertain to:

- i) employment with a party
- ii) receipt of payment as an advisor or consultant for a party
- iii) receipt of payment from a party for academic appointments (including endowed chairs)
- iv) receipt of funding or honoraria from a party for personal education
- v) receipt of funding or honoraria from a party for research grants.

## **5.6 Part III Disclosures**

In addition to disclosures made under Sections 5.4 and 5.5, participants are required to disclose any other activities or interests that affect or appear to affect the participant's objectivity or fairness.

- 5.7** Participants are required to disclose all of their stocks or stock options totalling more than \$10,000 (excluding mutual funds).
- 5.8** Participants are required to disclose all potential or pending future commitments with a party. The information to be disclosed relates to all interests and activities as described in Part I and Part II Disclosures outlined in sections 5.4 and 5.5.
- 5.9** All participants must sign and submit a COI Disclosure Form, as prescribed by CADTH.
- 5.10** All participants, other than CADTH staff, are required to disclose to the CADTH Vice-President, CDR, at the first opportunity, any contact with a party relating to a submission.
- 5.11** Before each CEDAC meeting, the Chair shall ask members if they have any conflicts of interest to disclose. Any CEDAC member with a conflict must disclose it and comply with the COI Guidelines and the Code of Conduct.

- 5.12 Participants shall not be involved in a submission in which they have a conflict of interest.
- 5.13 The CEDAC Chair, in consultation with the CADTH Vice-President CDR, has the authority to determine if the circumstances or interests of a participant amount to a conflict of interest in respect to a submission that is before CEDAC.

## **6.0 Confidentiality**

- 6.1 Participants are expected to respect the confidentiality of any materials provided as part of the CDR process. No participant shall knowingly divulge any such information to any person other than another participant, unless the participant is legally required to do so. A participant shall not use information obtained as a result of his or her involvement in the CDR process for his or her personal benefit. Each participant shall avoid activities which might create appearances that he or she has benefited from confidential information received during the course of his or her activities with the CDR process.

## **7.0 Amendment to the COI Guidelines**

After appropriate consultation, the COI Guidelines may be amended at any time by CADTH.

## Conflict of Interest Disclosure Form

**To: The CADTH Vice-President CDR**

I have read and understood the Conflict of Interest Guidelines (COI Guidelines) and I agree to be bound by the obligations contained therein. I understand that it is my responsibility to report to the Vice-President, CDR any real, potential or perceived conflict of interests as defined in the CADTH COI Guidelines, and to disclose the information requested in the COI Guidelines.

**If you are a CADTH Contractor:** I understand this information may be shared with the Members of CEDAC. Furthermore, I understand that the information disclosed will not be made public, unless otherwise agreed to and will be held on file by the CADTH Vice-President, CDR.

**CADTH Contractor to initial:** \_\_\_\_\_

**OR**

**If you are a CEDAC member:** As a member of CEDAC, I also understand that a summary of my conflict of interest declaration will be publicly available on the CADTH website.

**CEDAC Member to initial:** \_\_\_\_\_

I have reviewed my activities and interests as they relate to the matters itemized in the disclosure section of the COI Guidelines. Attached in Schedules 1, 2 and 3 is a list of those activities and interests.

I hereby certify that I have disclosed all relevant information with respect to any matter involving pharmaceutical companies or organizations that may place me in a real, potential or perceived conflict of interest situation. Except as otherwise disclosed in Schedules 1, 2 and 3 attached, I declare that I have no conflict of interest to report, as defined in the COI Guidelines.

I promise to inform CADTH of any change in circumstances that may create a conflict of interest, as soon as it is known to me.

I agree not to disclose or misuse, in any way, information I may receive in the course of my duties and activities with the CDR process.

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_____	_____	_____
Date	Print Name	Signature

## Schedule 1

### Conflict of Interest (COI) Disclosure Form

#### Part I – Disclosures

##### Part I

Disclosures are required under Section 5.4 of the COI Guidelines for those activities or interests during the past two years that involve any pharmaceutical company or organization, particularly as they relate to the following areas as required under Section 5.4 (add pages as necessary). Refer to Instructions for Completion attached.

Pharmaceutical Company or Organization	Drug or Topic involved/Year of funding	Travel Funding or Payment	Funding or Honoraria for Educational Lectures	Funding or Honoraria for Organizing Conferences	Funding or Honoraria for Writing Articles or Editorials	Any Other Financial Support, Honoraria or Gifts

\_\_\_\_\_

Date

\_\_\_\_\_

Print Name

\_\_\_\_\_

Signature

## Schedule 2

### Conflict of Interest (COI) Disclosure Form

#### Part II and III - Disclosures

**Part II and III**

Disclosures are required under Section 5.6, and 5.8 of the COI Guidelines for those activities or interests during the past five years that involve any pharmaceutical company or organization (add pages as necessary). Refer to Instructions for Completion attached.

Pharmaceutical Company or Organization	Drug or Topic involved/year of funding	Employment or Payment as Advisor or Consultant	Research Funding or Grants	Payment for Academic Appointments (endowed chairs)	Personal Education Funding	Stocks or Stock Options of More Than \$10,000 (excluding mutual funds)

\_\_\_\_\_

Date

\_\_\_\_\_

Print Name

\_\_\_\_\_

Signature

## Schedule 3

### Conflict of Interest (COI) Disclosure Form

#### General Disclosure

List those activities or interests involving pharmaceutical companies or organizations (not already listed in Schedules 1 and 2) that affect or appear to affect the participant's objectivity or fairness (e.g., employment of spouse or child; financial interest or investment in business enterprise or corporation; lobbying or promotional activities; or any other interest or activity that may create a reasonable apprehension of a conflict of interest, etc.).

Name of Pharmaceutical Company or Organization	Nature or Description of Activities or Interests

List those activities or interests involving pharmaceutical companies or organizations with whom a potential or pending future commitment (as outlined in Section 5.9). Details of the nature of the commitment are to be provided.

Name of Pharmaceutical Company or Organization	Nature, timing and value of the Future Commitment

\_\_\_\_\_
\_\_\_\_\_
\_\_\_\_\_

Date
Print Name
Signature

## **Conflict of Interest (COI) Disclosure Form**

### **Instructions for Completion**

1. For each activity, in addition to the Pharmaceutical Company or Organization, list the drug/topic involved and the year of funding in the 2<sup>nd</sup> column.
2. Include all moneys received within the last 2 years as honoraria, gifts, trips, or personal education grants.
3. Include all payments received within the last 5 years as salary, research grants, academic appointments (endowed chairs) and educational, and consultation fees.
4. Include stock and stock options totalling more than \$10,000 (excluding mutual funds)

## APPENDIX 1: CDR Definitions

In the document in which this Appendix is contained, the following definitions shall apply, unless otherwise provided.

**ACP** – Advisory Committee on Pharmaceuticals.

**ACP Member** – a member of the Advisory Committee on Pharmaceuticals.

**ACP Terms of Reference** – the Terms of Reference established for the ACP by CADTH's Board of Directors.

**Additional Information** – any information (excluding New Information) that is requested by the Review Team, CEDAC or CDR Directorate and required to complete the review of the Submission or Resubmission, or to explain or clarify information related to the Submission or Resubmission. Providing this information does not affect the review queue; however, if there is a delay in providing it or if the quantity and complexity of the requested information is significant, there may be a consequent delay in completion of the review.

**Applicant** – the person, corporation or entity filing a Submission or Resubmission.

**Appropriate comparator(s)** – currently accepted therapy.

**Budget Impact Analysis or BIA** – an analysis of the impact of a new Drug product on Drug Plan expenditures.

**Business Day** – any day – other than a Saturday, Sunday, statutory holiday, or company holiday – on which the Canadian Agency for Drugs and Technologies in Health (CADTH) office in Ottawa, Ontario is open for business during normal business hours.

**CADTH** – Canadian Agency for Drugs and Technologies in Health, a body corporate duly incorporated under the laws of Canada.

**CDR** – Common Drug Review.

**CDR Director** – the CADTH staff person appointed as director of the CDR Directorate.

**CDR Directorate** – the directorate established within CADTH to support the CDR process.

**CDR Nominating Committee** – the nominating committee established, according to the CEDAC Terms of Reference, for recommending candidates for appointment to CEDAC.

**CEDAC** – Canadian Expert Drug Advisory Committee.

**CEDAC Brief** – a brief prepared by CDR Directorate staff for the members of CEDAC, consisting of but not limited to:

- the Manufacturer's Executive Summary of the Submission or Resubmission

- a list of unpublished studies known to the Manufacturer
- the Reviewers' Reports relating to the Submission or Resubmission
- the Manufacturer's written comments about the Reviewers' Reports, if any
- the Reviewers' Replies, if any.

**CEDAC Member** – a member of the Canadian Expert Drug Advisory Committee.

**CEDAC Terms of Reference** – the Terms of Reference established for CEDAC by CADTH's Board of Directors.

**Clarification** – a written response, approved by the CEDAC Chair, to a Drug Plan's Request for Clarification of a CEDAC Recommendation.

**Clinical Review** – the review of published and unpublished information about the comparative safety, efficacy, effectiveness (when available) and use of a Drug in the management of a disease or condition.

**Clinical Reviewer** – a Reviewer who conducts a Clinical Review.

**Code of Conduct** – the code of conduct for CADTH committees approved by CADTH's Board of Directors.

**Confidential Information** – has the meaning given to it in the *CDR Confidentiality Guidelines*.

**Confidentiality Guidelines** – the guidelines respecting confidentiality adopted by the CADTH Board regarding CDR.

**Confidential Price** – a price per unit (generally lower than the listed current market price) that is submitted as part of the CDR submission requirements and that is not publicly disclosed by CDR without permission from the Manufacturer. If the Confidential Price becomes effective, it must be available to all CDR-participating drug plans.

**Conflict of Interest Guidelines or COI Guidelines** – the conflict of interest guidelines adopted by CADTH's Board of Directors for CEDAC, Reviewers and External Experts.

**Directive** – written information from CADTH amending, interpreting, updating or clarifying any process, procedure, guideline, terms of reference, code of conduct or document relating to the CDR.

**Drug** – an active substance considered to be a drug under the Canadian Food and Drugs Act and Regulations, which is sold for human use.

**Drug Plans** – the participating publicly funded federal/provincial/territorial drug plans.

**Embargo Period** – refers to a period of time [ten (10) Business Days following the issuance of the Recommendation and Reasons for Recommendation] during which the Recommendation and Reasons for Recommendation are neither acted on by Drug Plans,

nor are publicly available. During this period, the Manufacturer may submit a Request for Reconsideration or ACP, or Drug Plans may submit a Request for Clarification.

**External Expert** – an individual with appropriate qualifications and expertise required for some aspect of the review of the Submission or Resubmission, and whose services are obtained on a contract basis, as required.

**Final Reasons for Recommendation** – the Reasons for Recommendation attached to the Notice of Final Recommendation.

**Final Recommendation** – the applicable Recommendation, or Recommendation on Reconsideration, attached to the Notice of Final Recommendation.

**Formulary** – a list of Drugs covered as benefits, as determined by each Drug Plan.

**F/P/T** – federal, provincial and territorial.

**Information Specialist** – a CADTH staff member who specializes in information retrieval and management in a health sciences research environment.

**Manufacturer** – a Drug manufacturer.

**New Active Substance** – a therapeutic substance that has never before been approved for marketing in any form. It may be:

- a chemical or biological substance not previously approved for sale in Canada as a drug
- an isomer, derivative or salt of a chemical substance previously approved for sale as a drug in Canada but differing in properties regarding safety and efficacy
- a biological substance previously approved for sale in Canada as a drug, but differing in molecular structure, nature of the source material or manufacturing process.

**New Combination Product**– consists of two or more Drugs that have not been previously marketed in Canada in that combination. It may consist of either two or more New Drugs, or two or more previously marketed Drugs, or a combination of New Drug(s) and previously marketed Drug(s).

**New Drug** – a New Active Substance that has not previously been marketed in Canada.

**New Indication** – a condition or disease that has not previously been approved for the use of the Drug.

**New Information** – new clinical information (not previously submitted or published) or new cost information that significantly impacts on the cost-effectiveness of the Drug and which does not form part of the original Submission or Resubmission. If the New Information is in support of improved efficacy, it must be in the form of a randomized

controlled trial. If the New Information is in support of improved safety, case-control or cohort studies will be accepted if randomized controlled trials are unavailable.

**NOC or NOC/c** – Notice of Compliance or Notice of Compliance with Conditions issued by Health Canada, giving authorization to market a drug in Canada.

**Notice of Final Recommendation** – the notice issued according to Section 7 of the *Procedure for Common Drug Review*.

**Old Drug** – any Drug that is not a New Drug.

**Participants** – unless otherwise stated, CADTH staff, Reviewers, CEDAC Members and any experts retained to assist in the CDR process.

**Pharmacoeconomic Review** – the critical appraisal of the published and unpublished information about costs and consequences of Drugs and their impact on individuals, health care systems and society (i.e., value for money of Drugs).

**Pharmacoeconomic Reviewer** – a Reviewer who conducts a Pharmacoeconomic Review.

**PMPRB** – Patented Medicine Prices Review Board.

**Priority Review** – a preferred status in the review queue and on the CEDAC agenda for drugs meeting the Priority Review criteria. All steps in the CDR procedure are completed and timelines are not truncated.

**Reasons for Recommendation** – the detailed, written reasons given by CEDAC regarding Recommendations, or Recommendations on Reconsideration, made by CEDAC. The Reasons for Recommendation are released to the Manufacturer and Drug Plans only and are not publicly available during the Embargo Period.

**Recommendation** – an evidence-based recommendation made by CEDAC, after consideration of Review Criteria, in response to a Submission or Resubmission made by a Manufacturer, ACP or by one or more Drug Plans, or in response to a Request for Advice regarding a CEDAC recommendation or Reasons for Recommendation made by ACP or by one or more Drug Plans. The Recommendation is released to the Manufacturer and Drug Plans only and is not publicly available during the Embargo Period.

**Recommendation on Reconsideration** – the conclusion reached by CEDAC on reconsideration of the Submission or Resubmission, as described in Section 6.4.4(a) of the *Procedure for Common Drug Review*.

**Reconsideration Brief** – the CEDAC Brief, CEDAC Recommendation, CEDAC Reasons for Recommendation, and Request for Reconsideration.

**Record of Advice** – the detailed advice given by CEDAC in reply to a Request for Advice.

**Reply** – a response by a Reviewer to a Manufacturer’s comments about a Clinical or Pharmacoeconomic Review conducted by that Reviewer.

**Report** – a report produced by a Reviewer in accordance with Reviewer Guidelines.

**Request for Advice** – a written request made to by ACP or by one or more Drug Plans to CEDAC for advice on specific therapeutic, clinical or pharmacoeconomic issues, or regarding a CEDAC Recommendation or Reasons for Recommendation.

**Request for Clarification** – a written request from a Drug Plan for clarification of a CEDAC Recommendation.

**Request for Reconsideration** – a written request from Manufacturers to have a CEDAC Recommendation reconsidered.

**Request for Withdrawal** – a written request by an Applicant to withdraw a Submission or Resubmission from the review process.

**Resubmission** – the request by a Manufacturer, Drug Plan or the ACP to have an original Submission, that is under review or has received a Notice of Final Recommendation, reviewed again through the CDR process on the basis of New Information that was not previously provided in the original Submission or considered by CEDAC. The Resubmission goes to the end of the review queue.

**Review Criteria** – the following criteria are considered by CEDAC in making a listing recommendation:

- clinical studies, which assess safety and/or efficacy of the Drug in appropriate populations (when available, effectiveness data will be compared with accepted therapy)
- therapeutic advantages and disadvantages relative to accepted therapy
- cost-effectiveness relative to current accepted therapy.

**Review Team** – a team of individuals – including CDR Staff Reviewers, Contracted Reviewers and External Experts (clinical experts, methodologists, or other experts) with appropriate qualifications and expertise – assembled by the CDR Directorate to undertake the review of a Submission or Resubmission, or to prepare a Report in response to a Request for Advice.

**Review Template** – a template developed by the CDR Directorate for use by Reviewers to prepare Review Reports that are consistent in type of content and format.

**Reviewer** – an expert selected to conduct a Clinical or Pharmacoeconomic Review in accordance with Reviewer Guidelines established by the CDR Directorate.

**Reviewer Guidelines** – the CADTH guidelines adopted by the CDR Directorate that set out how a Reviewer must conduct, and report on, a Clinical Review or a Pharmacoeconomic Review.

**Rules of Procedure** – the rules of procedure established by CADTH’s Board of Directors for CADTH’s committees.

**Submission** – a submission to the CDR consisting of:

- a written application made by a Manufacturer, together with supporting documentation, to have a Drug listed on the Drug Plans’ Formularies; or
- a written request, together with supporting documentation, if any, made by ACP or by one or more Drug Plans, to consider the listing status of Drugs already on Formularies, to conduct Drug class reviews, or to undertake any other Drug-related review(s), as required.

**Submission Guidelines** – the guidelines adopted by CADTH that outline how Submissions from Manufacturers must be prepared and submitted.

**Submission Requirements** – information that is required by the CDR Directorate to undertake the Clinical and Pharmacoeconomic Reviews of Drugs and other information that is required by the Drug Plans in making listing decisions. The Submission Requirements consolidate the requirements for the CDR and the Drug Plans. The Requirements apply to Submissions and Resubmissions.

**Systematic Review** – involves a review of a clearly formulated question using systematic and explicit methods to identify, critically appraise and summarize relevant studies (published and unpublished) according to predetermined criteria. Reported outcomes can be synthesized either quantitatively or narratively to summarize the results of included studies.