



## **Conflict of Interest Guidelines for the Common Drug Review (CADTH Contractor)**

### **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 (CDR) 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 CDR activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of the CDR process.

### **2.0 Definitions**

- 2.1 In these COI Guidelines, the word “participant” means, unless otherwise stated, CADTH staff, reviewers, CEDAC members, and any experts and consultants retained to assist in the CDR process.
- 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 Canadian Expert Drug Advisory Committee (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 Participants are required to disclose all of their stocks or stock options totalling more than \$10,000 (excluding mutual funds).

## 5.7 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.

5.8 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 (CADTH Contractor)**

**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.

I understand that CADTH takes reasonable care to prevent the unauthorized use or disclosure of this information beyond the contract administrator and program personnel. 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.

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

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Print Name

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Signature



## Schedule 2

### Conflict of Interest (COI) Disclosure Form

#### Part II Disclosures

Disclosures are required under Section 5.5 and 5.6 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).

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. Declare dollar amounts of all payments received within the last 5 years as salary, research grants, academic appointments (endowed chairs) and educational, and consultation fees.
3. Declare dollar amounts of stock and stock options totalling more than \$10,000 (excluding mutual funds)

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) (\$)

I do not have any declarations for Schedule 2.

\_\_\_\_\_

Date
Print Name
Signature

## Schedule 3

### Conflict of Interest (COI) Disclosure Form

#### Part III 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 5.8). 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

**I do not have any declarations for Schedule 3.**

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Date
Print Name
Signature