Conflict of Interest Guidelines
for the B.C. Drug Review Process
(Last revised February 15, 2016)

Purpose of the Guidelines

These B.C. Drug Review Process Conflict of Interest Guidelines are intended to ensure the highest ethical standards and maintenance of the integrity of the Drug Review Process. The principles of transparency and disclosure are essential to achieving these objectives. Participants in all aspects of the Drug Review Process will ensure that conflicts of interest, and potential conflicts of interest, are identified and resolved, thereby preserving the objectivity and credibility of the Drug Review Process.

Definitions

"Drug Review Process" means all or any portion of a Drug Submission review or Project Evaluation performed by the B.C. Ministry of Health, Drug Benefit Council, Drug Review Resource Committee and Drug Review Resource Teams;

"Drug Review Process Conflict of Interest Disclosure Form" means the forms attached as Appendix A and Appendix B;

"Drug Submission" means:

a) a written application made by an Entity, together with supporting documentation, to have a drug listed on the Ministry's formulary; or
b) a written request for advice made by the Ministry, together with supporting documentation.

"Entity" means any company, organization (including government or university) or individual that may have a direct or indirect interest in the matters under consideration in the Drug Review Process;

"Immediate Family Member" means the spouse or dependent child of the Participant;

"Participant" means any individual that participates (whether through approval, disapproval, decision, providing advice, voting, recommendation or otherwise) in the Drug Review Process, including members of the Drug Benefit Council, Drug Review Resource Committee, and Drug Review Resource Teams;

"Project Evaluation" means a Clinical Evidence Review or Pharmacoeconomic Review project;

"Project Material" means accounting records, findings, software, data, code, designs, plans, specifications, drawings, working papers, reports, documents and other documentation that are submitted as part of a Drug Submission review or Project Evaluation; and

"Secretariat" means the part of the Ministry of Health that acts as secretariat for the Drug Review Process, including Drug Benefit Council, Drug Review Resource Committee, and Drug Review Resource Teams.

Scope of Conflict of Interest

A conflict of interest may exist whenever a Participant or an Immediate Family Member of a Participant has a direct or indirect interest or relationship, financial or otherwise, with an Entity that may affect or reasonably appear to affect the objectivity or fairness of the Participant in the Drug Review Process.

Process for Determining Existence of Conflict of Interest

1) Each Participant must disclose information as required in Section 6.0 of these Conflict of Interest Guidelines. The Secretariat, in consultation with the Chair of the Drug Benefit Council, will determine if the interest or relationship of a Participant in the Drug Benefit Council amount to a conflict of interest in relation to a specific Drug Submission. The Secretariat, in consultation with the Chair of the Drug Review Resource Committee, will determine if the interest or relationship of a Participant in the Drug Review Resource Committee or Drug Review Resource Teams amount to a conflict of interest in relation to a specific Drug Submission. The Secretariat will determine if the interest or relationship of a Participant in a Project Evaluation, not linked to a specific Drug Submission, amount to a conflict of interest.

2) A conflict of interest does not preclude a Participant from engaging in the Drug Review Process, however, if the Secretariat determines that the circumstances or interests of a Participant amount to a conflict of interest in relation to a specific Drug Submission or Project Evaluation, the Secretariat reserves the right to:
   a) note the type and context of the conflict in relation to that Drug Submission or to that Project Evaluation on project materials; or
   b) decline engaging a Participant in the Drug Review Process in relation to that Drug Submission or to that Project Evaluation; or
   c) Select an alternative Participant without a conflict

Disclosures of Conflicts of Interest

1) Upon a Participant's engagement in the Drug Review Process, including participation on the Drug Benefit Council, Drug Review Resource Committee or on a Drug Review Resource Team, each Participant is required to complete and submit a Drug Review Process Conflict of Interest Disclosure Form (Appendix A and Appendix B) to the Secretariat.

2) In addition, all Participants must complete and submit an updated Drug Review Process Conflict of Interest Disclosure Form annually or upon request to the Secretariat.

3) Notwithstanding paragraphs 1) and 2) above, the obligation to disclose potential conflicts of interest is ongoing, and all Participants must inform the Secretariat of any potential conflict of interest that arise at the earliest opportunity.

4) Without limiting the generality of the foregoing, as part of the Drug Review Process Conflict of Interest Disclosure Form, and as part of the ongoing duty of disclosure, Participants are required to disclose the following information in relation to themselves and their Immediate Family Members:
   a) amount and source of payments received from any Entity over the previous three years which total $2,000 or greater per year including salary, honoraria, royalties, and payments for services rendered;
   b) funds received from any Entity for research during the previous three years;
   c) number of shares and current value of stock (excluding mutual funds) held in any Entity for which the current value is $2,000 or greater;
   d) any current ownership interest in an Entity that is not publicly traded;

e) any current financial arrangement with an Entity in which the value of compensation could be influenced by the outcome of the Drug Review Process;

f) employment by or appointment to the board of directors of an Entity during the previous three years; and

g) any additional interest, affiliation or relationship with an Entity which may create or reasonably be perceived as creating a conflict of interest.

5) In addition to disclosure pertaining to potential conflicts of interest, for greater transparency all Participants are required to disclose to the Secretariat, and as the case may be the Chair of the Drug Benefit Council and/or Chair of the Drug Review Resource Committee, at the first opportunity, any contact with an Entity relating to a Drug Submission.

6) When Participants receive Drug Review Process information and documents (e.g., meeting agendas, drug submission review assignments, etc.), they shall review the details provided in the materials to ensure that neither they nor their Immediate Family Members have potential conflicts of interest with any Entity involved. Any potential conflicts of interest (including any that have been previously disclosed in the initial or annual Drug Review Process Conflict of Interest Disclosure Form) must be declared in writing, as soon as possible.

Confidentiality

The content of each completed Drug Review Process Conflict of Interest Disclosure Form, and any declaration of conflicts of interest disclosed before a meeting, shall remain confidential. Only appropriate Ministry representatives, the Secretariat, and as the case may be the Chair of the Drug Benefit Council, and appropriate members of the Drug Benefit Council, shall have access to this confidential information.[1]

[1] The Ministry may also be instructed under the law to release conflict of interest disclosures.

B.C. Drug Review Process
Conflict of Interest Disclosure Form

To: Secretariat, B.C. Ministry of Health Drug Review Process

1) I have read and understood the Drug Review Process Conflict of Interest Guidelines ("Conflict of Interest Guidelines") and I agree to be bound by the obligations contained therein. I understand that it is my responsibility to report to the Secretariat any potential conflict of interest as defined in the Conflict of Interest Guidelines, and to disclose the information requested in the Conflict of Interest Guidelines. I understand that if a potential conflict arises this information may be disclosed to appropriate Ministry representatives, the Secretariat, Chair of the Drug Benefit Council, and appropriate members of the Drug Benefit Council. I also understand that the information disclosed will not be made public, unless otherwise agreed to or required by law, and will be held on file by the Secretariat.

2) I understand that for the purposes of the Conflict of Interest Guidelines, and for the purpose of this Conflict of Interest Disclosure Form, "Entity" means any company, organization or individual that may have a direct or indirect interest in the matters under consideration in the Drug Review Process.

3) I have reviewed my activities and interests, and those activities and interests of my immediate family members (spouse or dependent child) as they relate to the matters itemized in the disclosure section of the Conflict of Interest Guidelines. Attached is the full listing of those activities and interests, which I certify discloses all relevant information with respect to my and my immediate family members' activities and interests in relation to any Entity.

4) I promise to inform the Secretariat about any change in circumstances, with respect to my and my immediate family members' activities and interests in relation to any Entity, that may create a conflict of interest, as soon as it is known to me.

5) I agree not to disclose or misuse, in any way, information that I may receive in the course of my duties and activities in connection with the Drug Review Process.

Date	Print Name	Signature

Conflict of Interest Confidential Disclosure Form
for the B.C. Drug Review Process

Disclosures are required under Section 6 of the Drug Review Process Conflict of Interest Guidelines -- All Participants must declare potential conflicts of interest (including any that have been previously included in the Drug Review Process Conflict of Interest Disclosure Form) as soon as possible (preferably within forty-eight hours) after receiving Drug Review Process information and documentation (e.g., meeting agendas, drug submission review assignments, etc.).

Participants are required to provide this information in writing to the Secretariat using this form (add pages as necessary) or, alternatively, on a separate form citing the information and/or documentation received, or drug submission under review, and providing details of the conflict of interest and/or potential conflict of interest.

Drug Name	Indication	Entity	Potential Conflict

Date	Print Name	Signature