

Conflict of Interest Guidelines For the Drug Benefit Review Process

1.0 Purpose of the Guidelines

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

2.0 Definitions

“Chair” means the chairperson of the Drug Benefit Council;

“Drug Benefit Review Process” means all or any portion of the drug review process performed by the Drug Benefit Council, Drug Review Resource Committee and Drug Review Resource Teams;

“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 Benefit Review Process;

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

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

“PSD-DI Executive Director” means the Executive Director of Drug Intelligence, Pharmaceutical Services Division, British Columbia Ministry of Health Services (the Ministry);

“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.

“Vice-Chair” means the Vice-Chair of the Drug Benefit Council.

3.0 Applicability

These Conflict of Interest Guidelines apply to all Participants.

4.0 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 Benefit Review Process.

5.0 Process for Determining Existence of Conflict of Interest

- 1) Each Participant must provide the disclosure of information as required in Section 6.0 of these Conflict of Interest Guidelines. The Chair, in consultation with the Drug Benefit Council, will determine if the interest or relationship of a Participant in the Drug Benefit Council amounts to a conflict of interest in relation to a specific Submission. The Vice Chair, in consultation with 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 amounts to a conflict of interest in relation to a specific Submission.
- 2) If it is determined that the circumstances or interests of the Participant amount to a conflict of interest in relation to a specific Submission, the Participant shall not participate in the Drug Benefit Review Process in relation to that Submission.

6.0 Disclosures of Conflicts of Interest

- 1) Upon the appointment of a Participant to the Drug Benefit Council, Drug Review Resource Committee or a Drug Review Resource Team, the Participant is required to complete and submit a Drug Benefit Review Process Conflict of Interest Disclosure Form (Appendix A) to the Secretariat.
- 2) In addition, all Participants must complete and submit an updated Drug Benefit Review Process Conflict of Interest Disclosure Form annually 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 arises at the earliest opportunity.
- 4) Without limiting the generality of the foregoing, as part of the Drug Benefit 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 Benefit 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 Chair, at the first opportunity, any contact with an Entity relating to a Submission.
- 6) When Participants receive Drug Benefit Review Process meeting agendas and/or drug submission review assignments, 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 Benefit Review Process Conflict of Interest Disclosure Form) must be declared in writing, as soon as possible.

7.0 Confidentiality

The content of each completed Drug Benefit Review Process Conflict of Interest Disclosure Form, and any declaration of conflicts of interest disclosed before a meeting, shall remain confidential. Only the Chair, members of the Drug Benefit Council and the Secretariat shall have access to this confidential information.

8.0 Amendment to the Conflict of Interest Guidelines

After appropriate consultation, the Conflict of Interest Guidelines may be amended by the Ministry in consultation with the Drug Benefit Council and other interested parties.

Revised March 11, 2009

Appendix A

**Drug Benefit Review Process
Conflict of Interest Disclosure Form**

To: Secretariat, Drug Benefit Council

1. I have read and understood the Drug Benefit 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 shared with the Chair and members of the Drug Benefit Council. I also understand that the information disclosed will not be made public, unless otherwise agreed to, 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 Benefit 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 of any change in circumstances 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 with the Drug Benefit Review Process.

Date

Print Name

Signature

Appendix B

**Conflict of Interest Confidential Disclosure Form
(Specific to Drug Benefit Review Process)
(Page 1 of 1)**

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

Participants should provide this information in writing to the Secretariat using this form (add pages as necessary) or, alternatively, on a separate form citing the agenda item or drug submission and providing details of the potential conflict of interest.

Drug Name	Indication	Entity	Potential Conflict
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Date

Print Name

Signature