Drug Benefit Council - Terms of Reference

The Drug Benefit Council (DBC) is an independent advisory body of professionals with expertise in drug therapy and drug evaluation and members of the public that makes recommendations to the Ministry of Health Services (the Ministry) Pharmaceutical Services Division (PSD) regarding the listing of drugs on the PharmaCare formulary. The approach is evidence-based and the advice reflects medical and scientific knowledge and current clinical practice. The recommendations of the DBC aim to improve and maintain the health and well-being of British Columbians.

1.0 Definitions

In these Terms of Reference, unless otherwise provided, the capitalized terms shall have the meanings set out in Appendix A attached hereto.

2.0 Mandate

The mandate of the DBC is to:

a) provide drug listing recommendations, including conditions and/or criteria for coverage where appropriate, to the Executive Director, of the Pharmaceutical Services Division - Drug Intelligence (PSD-DI), based on submissions; and

b) provide advice on specific therapeutic, clinical and pharmacoeconomic issues related to pharmaceuticals

c) function complementary to the national Common Drug Review framework that is supported by the Ministry.

3.0 Role and Reporting Structure

The role of the DBC is advisory in nature.

The DBC makes recommendations regarding the listing of drugs to the Executive Director of the PSD-DI through the Chair or Vice-Chair.

4.0 Responsibilities

The responsibilities of the DBC are:

a) to provide advice to the Ministry on the establishment of Drug Submission Requirements, including the periodic changes thereof;

b) to consider Submissions made by Submission sponsors, the Ministry or others, and all related Clinical Reviews, Pharmacoeconomic Reviews, and all other materials from the Drug Review Resource Committee (DRRC) prepared and submitted in accordance with the Ministry's standards;

c) to provide after consideration of a Submission, such Recommendations as the DBC considers appropriate;

d) to provide Reasons for Recommendation in respect of every Recommendation made by the DBC;

e) to consider Requests for Reconsideration (See Section 10)

f) to provide advice to the Executive Director of the PSD-DI, upon request;

g) to work with the Executive Director of the PSD-DI to respond to inquiries and requests for advice in regards to the Recommendations and Reasons for Recommendation of the DBC; and

h) to provide feedback to the Ministry regarding the quality of the reviews.

5.0 DBC Membership

5.1 Composition

The DBC shall be composed of three (3) public members and nine (9) professional members for a total of twelve (12) voting members, including a Chair and Vice-Chair.

5.2 Appointment

The Members, Chair and Vice-Chair of the DBC shall be appointed by the Minister.

Members are typically appointed for an initial term of one year and are eligible for two subsequent appointments of 2 and 3 years respectively for a maximum of 6 years. Length of term may be adjusted to ensure optimal succession planning.

5.3 Qualifications & Criteria

The DBC members should possess the following competencies:

- knowledge of issues related to the health care system at the community, regional and/or national level;
- experience in committee and/or community work;
- ability to comply with the *DBC Conflict of Interest Guidelines*;
- ability to act with integrity and independence of specific interests;
- ability to relate to and respect a diverse range of values and beliefs;
- ability to review and synthesize considerable amounts of information;
- availability to commit the time necessary to participate fully;
- experience or familiarity with government policy and decision making processes;
- experience working in a team based and/or collaborative decision making environment; and
- objectivity and strong reasoning skills, including the ability to understand complex systems.

Professional members should also possess the following competencies:

- accustomed to a rigorous, evidence-based drug review process;
- experience in critical appraisal of scientific literature; and
- expertise that may include the following:
    - critical appraisal skills (MD, Pharm D or equivalent experience)
    - general medicine or family medicine practice experience
    - internal medicine specialist practice;
    - medical ethics;
    - geriatric medicine practice;
    - clinical pharmacy or clinical pharmacology practice; or
    - health economics or economics.

Public members should also possess the following competencies:

- awareness of, and interest in, the perspectives of members of the general public on issues related to health care services and medicines;
- experience with public engagement;
- awareness of a health system focus which recognizes that drug therapies should be evaluated using a rigorous evidence-based approach; and
- at least one public member could potentially possess broad economic expertise.

5.4 Responsibilities of the Chair and Vice-Chair

The Chair will chair the DBC meetings and shall be responsible for:

a) reporting on the DBC's activities to the Ministry;

b) acting as the key liaison between the DBC and the Ministry;

c) being the main spokespersons for the DBC;

d) setting the meeting agendas in collaboration with the Ministry;

e) articulating the consensus Recommendation and Reasons for Recommendations made at every meeting; and

f) ensuring the DBC Conflict-of-Interest Guidelines are properly applied to the DBC Review Process.

The Vice-Chair shall be responsible for:

a) assuming the DBC Chair's responsibilities at the request of the Chair or when the Chair is unable to fulfill his or her responsibilities;

b) act as the Chair of the Drug Review Resource Committee (DRRC) which oversees the Drug Review Resource Teams (DRRT)

c) ensuring that the DBC Conflict-of-Interest Guidelines are properly applied to the DRRC and DRRT.

5.5 Withdrawal from the DBC

Members are required to attend at least 75 per cent of the DBC meetings each year and members who do not comply will automatically forfeit membership in the DBC. However, the Chair has the discretion to approve, in advance, an extended absence of any Member (subject to the right of the Ministry to replace a Member at any time).

A Member may resign at any time upon written notification to the Chair and the Executive Director of the PSD-DI.

A Member may be removed from the DBC by Ministerial Order or rescindment of a Ministerial Order.

6.0 Conflict of Interest

All Members must abide by the terms of the DBC Review Process Conflict of Interest (COI) Guidelines.

Breach of these guidelines may result in removal of the member from the DBC.

7.0 Confidentiality

Participants are required to respect the confidentiality of any materials provided as part of the DBC Review Process and the discussions at the meetings. 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 DBC Review 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 DBC Review Process.

8.0 DBC Meetings

8.1 Nature of Meetings

The DBC shall hold meetings as required to carry out its responsibilities and to consider all Submissions made by the Submission sponsor, the Ministry or others, and all related Clinical Reviews, Pharmacoeconomic Reviews, and all other materials from the Drug Review Resource Teams prepared and submitted in accordance with the Ministry's standards.

Each meeting will have a time commitment of six to eight (6 to 8) hours as required for preparation prior to each meeting.

8.2 Frequency

The DBC will hold approximately ten (10) scheduled meetings each year. Each meeting shall be four hours in duration, depending on the agenda. Additional meetings may be held at the call of the Chair, or the Executive Director of the PSD-DI and may be held by teleconference or videoconference, if available.

8.3 Attendance

Members are required to attend at least 75 percent of the DBC meetings each year. A Member who is unable to attend the in-person meeting may request permission from the Chair to participate in the meeting by telephone or other communications facilities to permit such Member and all other persons participating in the meeting to hear each other. The Chair shall have sole discretion in deciding whether to grant permission to such Member's request.

8.4 Meeting Attendees

In addition to the DBC Members, only the following persons shall be permitted to attend meetings of the DBC:

a) experts and Reviewers by invitation only (see below); and

b) Ministry staff that are providing Secretariat functions;

c) Others as deemed appropriate by the Char

Experts and/or Reviewers may attend DBC meetings, by invitation only, in circumstances where the DBC has questions or requires clarifications regarding a Submission, a Request for Advice or a Reviewer's report. Such experts and Reviewers shall not, however, participate in, or be present during, any decision or vote on a Submission.

8.5 Quorum

The quorum at meetings of the DBC shall be eight (8) voting Members.

8.6 Recommendations

Recommendations are made on the basis of consensus.

Voting will be conducted if there is not a consensus on a recommendation. If a vote is required for a DBC Recommendation, the affirmative vote of at least 50 per cent plus 1 (50% +1) of the voting Members participating in the meeting, excluding abstentions, is required. Silent voting will be conducted, if it is deemed appropriate by the Chair.

Experts and/or Reviewers must leave during any vote.

8.7 Reasons for Recommendation

When making a Recommendation, the DBC shall also provide Reasons for Recommendation and these Reasons for Recommendation will be distributed in accordance with the procedure established.

A Recommendation and Reasons for Recommendations on Requests for Advice will be recorded on the Recommendation and Reason for Recommendation for Request for Advice template.

8.8 Agenda

The meeting agendas of the DBC shall be developed by the Chair that is chairing the DBC meeting in collaboration with the Ministry.

8.9 Records of Meetings

The Ministry shall keep permanent records in accordance with ARCS. ARCS is a combined records classification and scheduling system that facilitates the efficient and systematic organization, retrieval, storage, and destruction or permanent retention of the government's administrative records:

a) all Recommendations made by the DBC; and

b) all Reasons for Recommendation given by the DBC.

8.10 Seeking Information Clarification

At the discretion of the DBC Chair, the DBC may seek:

a) additional written information from submission sponsors to carry out their mandate; and/or

b) additional information from experts or other stakeholders to carry out their mandate.

9.0 Secretariat, Administrative and Logistical Support

Secretariat, administrative, and logistical support for the DBC is provided by the Ministry.

10.0 Request for Reconsiderations of Recommendations

Following a DBC Recommendation, the submission sponsor will be provided an embargoed copy of the DBC Recommendation and Reasons for Recommendation.

The Submission Sponsor may file a Request for Reconsideration on two grounds:

a) That the DBC recommendation is not supported by the evidence reviewed by the DBC, or

b) That the DBC Review Process of the submission reviewed, including the process completed by the Drug Review Resource Committee (DRRC) and/or Drug Review Resource Teams (DRRT) was not properly followed.

If the sponsor has new information on a submission that addresses the reasons for a recommendation made by the DBC, this would not qualify for a Request for Reconsideration but would be considered a resubmission. For resubmissions where the original drug submission was reviewed by the Common Drug Review (CDR), sponsors would be required to resubmit to the CDR and follow CDR requirements and procedures.

APPENDIX A: Definitions

In the Drug Benefit Council Terms of Reference, the following definitions shall apply, unless otherwise provided.

Conflict of Interest Guidelines or COI Guidelines – the conflict of interest guidelines of the Drug Benefit Council Process, adhered to by the members of the DBC and other external experts.

DBC – Drug Benefit Council

DBC Review Process – Drug review process completed by the Drug Benefit Council, Drug Review Resource Committee (DRRC) and Drug Review Resource Teams (DRRT)

DRRC – Drug Review Resource Committee

DRRT – Drug Review Resource Teams

PSD-DI Executive Director – the Executive Director of the Drug Intelligence, Pharmaceutical Services Division of the BC Ministry of Health Services

Member – Member of the Drug Benefit Council

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).

Reasons for Recommendation – the detailed, written reasons given by the DBC regarding Recommendations made by the DBC.

Recommendation – an evidence-based recommendation, made after consideration of Review Criteria, by the DBC in response to a Submission or Resubmission made by a manufacturer.

Request for Advice – a written request made by Ministry to the DBC for advice on specific therapeutic**,** clinical or pharmacoeconomic issues.

Reviewer – an expert selected to conduct a clinical or Pharmacoeconomic Review.

Submission – A submission consists of:

- a written application made by a manufacturer, together with supporting documentation, to have a drug listed on the Ministry formulary; or
- a written request for advice made by the Ministry, together with supporting documentation; or
- any other therapeutic review request made by Ministry as required.
- resubmission defined as a when a sponsor has new information on a submission that addresses the reasons for recommendation made by the DBC. For

resubmissions where the original drug submission was reviewed by the Common Drug Review (CDR), sponsors would be required to resubmit to the CDR and follow CDR requirements and procedures.

Revised March 5, 2010

X:\DrugIntelligence\Briefing Notes\2010\822479_DBC_Terms_of_Reference_Mar_5_2010.docx