Drug Benefit Council
Terms of Reference

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The Drug Benefit Council (DBC) is an independent advisory body composed of professionals with expertise in drug therapy and drug evaluation and members of the public that makes recommendations regarding the listing of drugs on the PharmaCare formulary to the Therapeutic Assessment and Access (TAA) branch, in the Pharmaceutical, Laboratory and Blood Services Division (PLSD) at the Ministry of Health (the Ministry). The recommendations of the DBC aim to improve the health and well-being of British Columbians. DBC advice is evidence-based and reflects medical and scientific knowledge, patient perspectives and current clinical practice.

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:

- provide drug listing recommendations and reasons for the recommendations, including conditions and/or clinical criteria for coverage where appropriate, to the Ministry, through the Executive Director, TAA, based on submissions;
- provide advice on specific therapeutic, clinical and pharmacoeconomic issues related to pharmaceuticals; and
- function complementary to the national Common Drug Review (CDR) 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 and reasons for the recommendations regarding the listing of drugs to the Ministry, through the Executive Director, TAA through the Chair or Vice-Chair of the DBC.

4.0 Responsibilities

The responsibilities of the DBC are:

- to provide advice to the Ministry on the establishment of drug submission requirements, including periodic changes thereof;
- to consider submissions made by drug submission sponsors (e.g., drug manufacturers, the Ministry or others), and specific documents including Clinical Reviews,

Pharmacoeconomic Reviews, public input patients, caregivers, and patient groups collected through the Ministry's "Your Voice" web page, Clinical Practice Review reports from experts, and other materials prepared and submitted to the CDR, the DBC and the Drug Review Resource Committee (DRRC) a sub-committee of the DBC;

- to provide recommendations and reasons for the recommendations for the drugs under review;
- to consider requests for reconsideration (See Section 10);
- to provide advice to the Executive Director, TAA;
- to work with the Executive Director, TAA to respond to inquiries and requests for advice regarding DBC recommendations and the reasons for the recommendations; and
- 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 public members and nine professional members for a total of 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 of Health.

Members are typically appointed for an initial term of one-year and are eligible for two subsequent appointments of two to three-years, respectively, for a maximum of six years. The length of term may be adjusted to ensure optimal succession planning.

5.3 Qualifications and Criteria

DBC members should possess broad knowledge and specific applicable experience(s). Collectively, members should comprise the following knowledge, competencies and experiences:

- knowledge of, or interest in, issues related to the health care system and various general public perspectives on issues related to health care services and pharmaceuticals at the community, regional and/or national level;
- knowledge of, or interest in, issues relevant to the Ministry, the mandate of PLBSD, and the mandate of the DBC;
- experience as a member of a committee and/or experience in community work;
- ability to comply with the terms of the BC Drug Review Process Conflict of Interest and Confidentiality Agreement guidelines;
- ability to act with integrity and independently of specific interests;

- ability to form constructive working relationships;
- ability and desire to understand and respond effectively to people from diverse backgrounds with diverse beliefs, perspectives and values;
- ability to consider alternative perspectives on issues;
- ability to work constructively as a member of a team;
- ability to communicate and to listen effectively;
- ability and willingness to raise potentially controversial issues in a manner that encourages dialogue;
- ability to gain respect and credibility within a diverse group of stakeholders and the wider public;
- ability to negotiate with others to achieve desired results;
- ability to review and synthesize large quantities of complex information;
- availability to commit the time necessary to participate fully;
- experience or familiarity with government policy and decision making processes;
- knowledge of rigorous and evidence-based drug review 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:

- familiarity with a rigorous, evidence-based drug review process;
- familiarity with, if not direct experience with conducting critical appraisal of scientific literature, in order to balance complex clinical and economic considerations when making population-based drug coverage recommendations;
- critical appraisal skills (based on MD, Pharm D or equivalent experience) for general medicine or family medicine practitioners, specialists and pharmacists; and

DBC membership should comprise professional members drawn from the following fields of expertise:

- general medicine or family medicine practice experience;
- internal medicine specialist practice;
- medical ethics;
- geriatric medicine practice;
- clinical pharmacy or clinical pharmacology practice; and
- 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
- one public member may 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:

- chairing DBC meetings;
- reporting on the DBC's activities to the PLBSD;
- acting as the key liaison between the DBC and the PLBSD;
- being the main spokespersons for the DBC;
- setting meeting agendas and assigning drug reviewer duties in collaboration with the Director, Formulary Management and Executive Director, TAA;
- assisting in the development and overseeing processes and protocols regarding drug coverage and listing recommendations;
- articulating the consensus recommendation and reasons for recommendations made at each meeting regarding the listing of drugs to the Executive Director, TAA, on behalf of the DBC membership;
- ensuring the Drug Review Process Conflict of Interest and Confidentiality Agreement guidelines are properly applied; and
- evaluating DBC members' performance annually according to the criteria, definitions and requirements of the Crown Agencies and Board Resourcing Office (CABRO) Performance Appraisal.

The Vice-Chair shall be responsible for:

- assuming the DBC Chair's responsibilities at the request of the Chair or when the Chair is unable to fulfill his or her responsibilities;
- act as the Chair of the DRRC which collaborates on Drug Review Resource Teams (DRRTs);
- ensuring that the Drug Review Process Conflict of Interest and Confidentiality Agreement guidelines are properly applied to the DRRC and DRRTs; and
- evaluating DRRC members' and the DBC Chair's performance annually according to the criteria, definitions and requirements of the CABRO's Performance Appraisal.

5.5 Withdrawal from the DBC

Members are required to attend at least 75 percent of DBC meetings each calendar 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 a 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, TAA.

A member may be removed from the DBC by the Chair or the Executive Director, TAA at any time.

6.0 Conflicts of Interest

All members must abide by the terms of the Drug Review Process Conflict of Interest and Confidentiality Agreement guidelines.

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

7.0 Confidentiality

DBC members are required to respect the confidentiality of any materials provided as part of the Drug Review Process and the discussions at the meetings. No participant shall knowingly divulge any such information to any person other than another member, unless the member is legally required to do so. A member shall not use information obtained as a result of his or her involvement in the Drug Review Process for his or her personal benefit. Each member 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 Drug Review Process.

8.0 DBC Meetings

8.1 Nature of the Meetings

The DBC shall hold meetings as required to carry out its responsibilities and to consider all drug submissions made by drug submission sponsors - whether manufacturers, the Ministry or others. At DBC meetings, Clinical Reviews, Pharmacoeconomic Reviews, Clinical Practice Review reports, and all other materials from the DRRTs prepared and submitted in accordance with the Ministry's standards will be reviewed.

Each meeting will have a time commitment of up to eight hours for preparation prior to each meeting.

8.2 Frequency

The DBC will hold approximately ten scheduled meetings each year. Each meeting shall be approximately four hours long, depending on the agenda. Additional meetings may be held at the call of the Chair, or the Executive Director, TAA and may be held by teleconference or videoconference, if available or necessary.

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 teleconference. The Chair shall have sole discretion to decide whether to grant permission to such a request from a Member.

8.4 Meeting Attendees

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

- experts and DRRT reviewers, by invitation only (see below);
- Ministry staff that are providing Secretariat services; and
- Others as deemed appropriate by the Chair or Executive Director, TAA.

Experts and/or Reviewers may attend DBC meetings, by invitation only, in circumstances where the DBC has questions or requires clarifications regarding a drug submission, a Request for Advice or a DRRT report. These experts and reviewers shall not, however, participate in, or be present during, any deliberation about a consensus on a recommendation or a vote on a recommendation.

8.5 Quorum

The quorum at meetings of the DBC shall be 50 percent plus one members.

8.6 Recommendations

Recommendations and reasons for the recommendations are made on the basis of a consensus of opinion among DBC members.

Voting will be conducted if there is not a consensus on a recommendation. If a vote is required for a recommendation and reasons for the recommendation, the affirmative vote of at least 50 percent plus one 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 attending a DBC meeting must leave during any vote.

8.7 Reasons for the 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 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 staff in PLBSD.

8.9 Records of Meetings

The Ministry shall keep permanent records in accordance with the government Administrative Records Classification System (ARCS). ARCS is an information schedule used to classify, file, retrieve and dispose of administrative records.

The following documents will be saved in accordance with the ARCS scheduling:

- all recommendations made by the DBC; and
- all reasons for recommendation given by the DBC.

8.10 Seeking Information Clarification

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

- additional written information from submission sponsors to carry out their mandate; and/or
- 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 will be provided by the PLBSD.

10.0 Request for Reconsideration of Recommendations

Following a DBC recommendation, the drug submission sponsor will be provided an embargoed copy of the recommendation and reasons for recommendation.

The submission sponsor may file a Request for Reconsideration on two grounds:

- that the recommendation is not supported by the evidence reviewed by the DBC, or
- that the DBC review and process for reviewing the drug submission, including the process completed by the DRRC and/or DRRTs, 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 could be considered as a resubmission. For resubmissions where the original drug submission was reviewed by the CDR, submission sponsors are required to resubmit their first to the CDR, and to follow the CDR requirements and procedures.

APPENDIX A: Definitions

In the DBC Terms of Reference, the following definitions shall apply, unless otherwise provided.

ARCS – the Administrative Records Classification System is an information schedule used to classify, file, retrieve and dispose of administrative records. ARCS covers BC Government and broader public sector organizations organization and management of records.

CABRO – the Crown Agency Board Resourcing Office, with approval by the Minister of Health, selects the most qualified individuals with the highest personal and professional integrity to serve as members of the DBC.

Conflict of Interest Guidelines – the conflict of interest guidelines that apply to members of the DBC and other stakeholders participating in the BC Drug Review Process.

DBC – Drug Benefit Council

Drug Review Process – the BC Drug Review Process includes internal Ministry reviews, DBC reviews, the Drug Review Resource Committee and Drug Review Resource Teams.

DRRC – Drug Review Resource Committee, a sub-committee of the DBC

DRRT – Drug Review Resource Team

Drug Submission Sponsor – Individual or organization (e.g., drug manufacturer, clinician, market access group) that submits a drug for review to the Ministry.

Executive Director, TAA – the Executive Director of the Therapeutic Assessment and Access branch in the Pharmaceutical, Laboratory and Blood Services Division**,** Ministry of Health

Member – Member of the DBC

PLBSD –Pharmaceutical, Laboratory and Blood Services Division, Ministry of Health

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 the recommendation

Recommendation – an evidence-based recommendation from the DBC, made after consideration of review criteria, in response to a drug submission or resubmission made by a drug submission sponsor.

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

Reviewer – an expert and/or member of a Drug Review Resource Team selected to conduct a Clinical or Pharmacoeconomic Review, or to prepare a Clinical Practice Review report.

Drug Submission – a drug 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 – a drug submission from a drug submission sponsor for a drug and indication previously reviewed by the DBC that includes new information to address the reasons for the past recommendation made by the DBC. For resubmissions in which the original drug submission was reviewed by the CDR, sponsors are required to resubmit the drug for review to the CDR and to follow the CDR requirements and procedures before the Ministry will consider reviewing the resubmission.