

CANADIAN DRUG EXPERT COMMITTEE TERMS OF REFERENCE

The Canadian Drug Expert Committee (CDEC) is an advisory body to CADTH, the Canadian Agency for Drugs and Technologies in Health (CADTH), which makes drug-related recommendations and provides drug-related advice through the CADTH Common Drug Review and therapeutic review processes. CDEC recommendations and advice are provided to CADTH to inform key customers and a range of stakeholders.

1.0 Mandate

The CDEC mandate is advisory in nature and is to provide recommendations or advice to CADTH to inform:

- decisions regarding the funding of drugs (submitted through the CADTH Common Drug Review process)¹ within the publicly funded health care system in Canada (excluding Quebec)
- decisions and strategies regarding the optimal use of drugs (including therapeutic or class reviews) in Canada.

The approach is evidence-based and CDEC advice reflects medical and scientific knowledge, current clinical practice, economics, ethical considerations, patient perspectives, and social values.

2.0 Responsibilities

CDEC's responsibilities are:

- to provide funding and optimal use recommendations and advice to CADTH and participating federal, provincial, and territorial health ministries
- to identify areas requiring further research
- to validate practice and knowledge gaps, and key messages on related topics
- to support CADTH in the selection and development of intervention tools aimed at optimizing the prescribing and use of those drugs reviewed by the committee

¹ Submissions for oncology drugs used for the active treatment of cancer are filed with CADTH's pan-Canadian Oncology Drug Review (pCODR). All other drugs are reviewed through CADTH's Common Drug Review (CDR).

- to provide guidance to CADTH and participating federal, provincial, and territorial health ministries on other issues as requested.

3.0 Accountability

CDEC is an expert advisory committee of CADTH that reports to the CADTH President and CEO through the CDEC chair.

4.0 CDEC Membership

4.1 Composition

CDEC shall be composed of up to 14 core members — the “CDEC members” plus the chair.

Two of the 14 CDEC members shall be public members to bring a lay perspective. The remaining 12 CDEC members are technical experts who must hold qualifications as a physician, a pharmacist, an economist, or other professional health designation with expertise in one or more areas such as general practice, internal medicine, hospital or community pharmacy, clinical pharmacology, health economics, clinical epidemiology, health services research, drug utilization expertise, methodology and/or critical appraisal, ethics, or behaviour change.

While members are appointed because of their expertise, they do not represent a specific constituency. Members are expected to bring views based on their range of experience.

Non-member specialist experts (hereafter referred to as specialist experts) may be invited to participate in CDEC meetings to provide their expertise as required. Specialist experts are thought leaders and may be drawn from a variety of fields, such as the clinical setting, methodology, and health economics. These specialist experts will have experience relevant to the use of the particular drug or class of drugs or blood product or treatment of an identified condition. The number of specialist experts will be determined by the needs of each project.

Specialist experts must declare all real or potential conflicts of interest as defined by the *CADTH Conflict of Interest Guidelines*.

4.2 Appointment/Nomination Process

The nomination of CDEC members shall be as set out in the CDEC Nominating Committee Terms of Reference, attached as Appendix 1.

Candidates for CDEC public member positions will be selected with reference to the Profile of Public Members document.

The CDEC members, including the public members, shall be appointed by the CADTH President and CEO. The specialist experts shall be appointed by the CADTH President and CEO after:

- jurisdictions have been provided with an opportunity to propose names of experts for consideration
- consultation with the Chair of CDEC on a short list of candidates.

4.3 Term of Appointment

Initially, half of the CDEC members shall be appointed for a term of two years and half shall be appointed for a term of three years. Thereafter, unless otherwise dictated by business requirements, appointments will be for a term of two years. The term of any CDEC member, including public members, may be renewed at the discretion of the CADTH President and CEO for one additional term of two years in duration. CADTH intends to renew the membership in a balanced way and on an ongoing basis with the following objectives:

- to retain experienced CDEC members to maintain business continuity
- to recruit new members to CDEC to offer new strengths and perspectives.

Notwithstanding anything set out in these Terms of Reference, the CADTH President and CEO shall have the right to remove and/or replace a CDEC member at or before the expiry of his/her term, upon the recommendation of the CDEC chair.

4.4 Committee Officers

The officers of CDEC shall be the committee's chair and vice-chair, appointed by the CADTH President and CEO from the CDEC members. Their respective appointments shall be for a term of three years, and may be renewed at the discretion of the CADTH President and CEO for one additional term.

The chair shall preside at all CDEC meetings to ensure all members fulfil their responsibilities. The chair is responsible for reporting on CDEC's activities to the CADTH President and CEO and shall act as the key liaison between CDEC and CADTH. The chair shall be the sole spokesperson for CDEC. In addition, the chair maintains the integrity of CDEC by ensuring that members adhere to the *CADTH Code of Conduct* and *Conflict of Interest Guidelines*. The chair also contributes to the selection process for new members.

The vice-chair shall, in the absence or disability of the chair, perform the duties and exercise the powers of the chair.

4.5 Withdrawal from CDEC

An individual may resign as a CDEC member at any time upon written notification to the CADTH secretariat.

CDEC members who are absent for more than three CDEC meetings per year will automatically forfeit membership in CDEC. However, the CDEC chair has the discretion to approve, in advance, an extended absence for any CDEC member.

5.0 CDEC Meetings

5.1 Frequency of Meetings

CDEC shall hold meetings as required to carry out its mandate and responsibilities. The CDEC schedule typically includes 10 meetings annually. However, CDEC meetings may be cancelled or rescheduled at the discretion of CADTH.

5.2 Notice of Meetings

Meetings of CDEC may be held at any time and place in Canada as determined by CADTH, provided that reasonable advance notice of such meeting is given to each CDEC member.

5.3 Quorum

The quorum at meetings of CDEC shall be 66% of members with active appointments.

5.4 Attendance

CDEC members shall attend all CDEC meetings. A CDEC member who is unable to attend an in-person meeting may request permission from the chair to participate in the meeting through such means as video conference, teleconference, or other communications methods. The chair shall have sole discretion in deciding whether to grant permission to such member's request, but shall only grant permission in exceptional circumstances.

5.5 Attendees

In addition to CDEC members and specialist experts, only the following persons shall be entitled to attend CDEC meetings:

- Health ministry officials appointed by participating jurisdictions may attend as observers, and may contribute information on practical considerations as described in the decision-making framework, but do not have the right to vote.
- Specialist experts may attend upon invitation but do not have the right to participate in the deliberations or to vote. Participation is in accordance with the decision-making framework.
- Relevant CADTH staff and external reviewers contracted by CADTH may actively participate in the presentation of information. The staff role includes provision of administrative and secretariat support. CADTH staff and external reviewers do not have the right to vote.
- Other individuals may be invited to attend as observers, at the discretion of the CDEC chair and CADTH.

5.6 Agenda

CDEC meeting agendas shall be developed by CADTH in consultation with the CDEC chair.

5.7 Conflict of Interest Disclosure

At the commencement of every meeting, the CDEC chair shall ask members if they have any conflicts of interest to disclose. Any CDEC member with a conflict must disclose it and comply with the *Conflict of Interest Guidelines* and *Code of Conduct*. Specialist experts will also be asked to declare conflicts of interest as per section 4.1 of the guidelines.

5.8 Decisions and Voting

No decision or recommendation can be made unless there is a quorum. Each CDEC member, excluding the chairperson of the meeting, shall be entitled to one vote on all matters coming before CDEC. In the event of an equality of votes on any decision, the chairperson of the meeting shall cast the deciding vote.

Every CDEC recommendation shall be decided by a majority of votes. Every voting member participating in the meeting, with the exception of the chair, must vote (i.e., for or against) on the motion for the adoption of a recommendation; a member cannot abstain from voting unless they have been recused as set out in the *CADTH Conflict of Interest Guidelines*.

5.9 Records of Meetings

CADTH shall keep a record of minutes from all CDEC meetings, including recommendations and advice and related discussions and reasons.

Once approved by the chair, minutes shall be distributed to all CDEC members, observers, and appropriate CADTH staff.

6.0 Remuneration/Honorarium

A reasonable remuneration or honorarium for all CDEC members and experts shall be fixed by CADTH.

CDEC members and specialist experts shall be entitled to be paid reasonable expenses incurred by them in the performance of their duties.

7.0 General Provisions

7.1 Secretariat and Administrative Support

Secretariat and administrative support is provided by CADTH.

7.2 Amendment to Terms of Reference

These Terms of Reference may be amended from time to time by the CADTH President and CEO.

7.3 Indemnity

Every CDEC member shall be indemnified and saved harmless by CADTH from and against:

- all costs, charges, and expenses which such CDEC member sustains or incurs in or about any action, suit or proceedings, which is brought, commenced or prosecuted against him or her, or in respect of any act, deed, matter or thing whatsoever, made, done or permitted by him or her, in or about the execution of the duties of such member or in respect of any such liability
- all such other costs, charges, and expenses which he or she sustains or incurs in or about or in relation to the affairs thereof, except such costs, charges or expenses as are occasioned by his or her own wilful neglect or default.

7.4 Code of Conduct

Every person attending CDEC meetings must abide by the *CADTH Code of Conduct*.

7.5 Confidentiality

It is the responsibility of CDEC members to know what information is confidential and to obtain clarification when in doubt. Except as he or she may be compelled by applicable legal process, a CDEC member must, both while having and after ceasing to have that status, treat as confidential all information regarding the policies, internal operations, systems, business, or affairs of CDEC and of CADTH obtained by reason of his or her status as a CDEC member and that which is not generally available to the public. A CDEC member shall not use information obtained as a result of his or her involvement on the committee for his or her personal benefit. Each CDEC member shall avoid activities that may create appearances that he or she has benefited from confidential information received during the course of his or her duties as a CDEC member.

7.6 Subcommittees

CDEC may form subcommittees and/or task groups to fulfil its mandate. The reimbursement of any expenses associated with subcommittees will require CADTH approval in advance.

APPENDIX A

CDEC Nominating Committee Terms of Reference

1.0 CDEC Nominating Committee

1.1 Composition

The CDEC Nominating Committee shall be composed of the following members, who shall each have the right to vote at meetings of the CDEC Nominating Committee:

- The Drug Policy Advisory Committee (DPAC) chair and three representatives from DPAC as designated by the DPAC chair
- CDEC chair, once appointed
- Two to three senior CADTH staff members appointed by the CADTH President and CEO.

1.2 Role and Responsibilities Relating to Nomination of Members

The role and responsibilities of the CDEC Nominating Committee shall be:

- to receive nominations for the appointment of members to CDEC
- to identify potential candidates for appointment as members to CDEC
- to maintain a record of all nominations received
- to recommend to the CADTH President and CEO, on request, a slate of candidates to fill vacancies of members.

1.3 Meeting Attendees

In addition to the members of the CDEC Nominating Committee, only the following persons shall be entitled to attend meetings of the CDEC Nominating Committee, but will not have the right to vote:

- the CADTH President and CEO
- CADTH staff member acting as recording secretary.

The CADTH staff member attending the meeting as recording secretary shall serve as resource to the CDEC Nominating Committee. They provide administrative and secretariat support. He or she shall also assist in obtaining additional information at the CDEC Nominating Committee's request.

2.0 Nomination of Candidates for Appointment as Members

2.1 The nomination process of candidates for appointment to CDEC as members shall be as follows:

- CADTH advises the CDEC Nominating Committee of all vacancies and anticipated vacancies.
- CADTH shall publish a notice of CDEC vacancies and anticipated vacancies on the CADTH website and shall, through electronic means or otherwise, share the notice through its subscription service.
- Federal, provincial, and territorial jurisdictions; relevant health professional bodies; individual health and other professionals; and the general public may propose to the CDEC Nominating Committee, upon being notified of vacancies and anticipated vacancies, nominees that meet the member qualifications set out in the *CDEC Terms of Reference*. The CDEC Nominating Committee may also propose nominees, and interested candidates may nominate themselves.
- The name and short *curriculum vitae* of each nominee, together with a short rationale supporting the nomination, must be submitted to the CDEC Nominating Committee with each nomination.
- The Nominating Committee shall keep a record of all nominations received.
- From time to time, at CADTH's request, the CDEC Nominating Committee will recommend to the CADTH President and CEO a slate to fill vacancies, with consideration to the following:
 - in the case of a public member, the candidate's qualifications and suitability with reference to the Profile of Public Members of the CADTH Expert Advisory Committees and
 - in the case of other members, the candidate's:
 - qualifications
 - expertise/credentials in disciplines related to the prescribing or dispensing and use of drugs within the Canadian context and/or the evaluation or critical appraisal and/or experience in developing guidelines
 - experience on a drug advisory or other expert committee (this will be considered an asset but is not a requirement)
 - ability to comply with the *CADTH Conflict of Interest Guidelines*
 - availability/commitment of time to participate fully in CDEC.
- The Nominating Committee's recommended slate of candidates shall:
 - in the case of CDEC's chair, propose one candidate only
 - in the case of CDEC's vice-chair, propose one candidate only
 - in the case of public members, propose a number of candidates equal to the number of vacancies to be filled, plus two
 - in the case of CDEC's other members, propose a number of candidates equal to the number of vacancies to be filled, plus three.

2.2 The recommended slate shall be accompanied by the *curriculum vitae* and written rationale in support of each proposed candidate.

2.3 After due consideration, the CADTH President and CEO may appoint as members those candidates selected from the slate recommended by the CDEC Nominating Committee.

3.0 General Provisions

3.1 Agenda

Nominating Committee meeting agendas shall be developed by the committee chair in conjunction with CADTH staff.

3.2 Conflict of Interest Disclosure

At the commencement of each meeting, the chair shall ask members if they have any conflicts of interest to disclose. Any member with a conflict must disclose such conflict and comply with the *Conflict of Interest Guidelines* and *Code of Conduct*.

3.3 Quorum

A majority of the members appointed to the Nominating Committee shall constitute a quorum at meetings of the committee.

3.4 Decisions

No decision can be made unless there is a quorum. Decisions will typically be made by consensus. If a vote is necessary, a simple majority of the quorum is required.

3.5 Records of Meetings

Minutes shall be kept of all Nominating Committee meetings and shall be signed by the chair.

A copy of the minutes of every committee meeting shall be sent to members of the committee, relevant CADTH staff, and the CADTH President and CEO.

3.6 Indemnity

Every Nominating Committee member shall be indemnified and saved harmless by CADTH from and against:

- all costs, charges, and expenses that such member sustains or incurs in or about any action, suit or proceedings, which is brought, commenced or prosecuted against him or her, or in respect of any act, deed, matter or thing whatsoever, made, done or permitted by him or her, in or about the execution of the duties of such member or in respect of any such liability
- all such other costs, charges, and expenses that he or she sustains or incurs in or about or in relation to the affairs thereof, except such costs, charges or expenses as are occasioned by his or her own wilful neglect or default.

3.7 Secretariat and Administrative Support

Secretariat and administrative support for the Nominating Committee is provided by CADTH.

3.8 Amendment to the Terms of Reference

The *CADTH Terms of Reference* may be amended at any time, and from time to time, by the CADTH President and CEO.

3.9 Code of Conduct

Every person attending the Nominating Committee meetings must abide by the *CADTH Code of Conduct*.