

CADTH CANADIAN DRUG EXPERT COMMITTEE TERMS OF REFERENCE

1.0 MANDATE

The Canadian Drug Expert Committee (CDEC) is a CADTH committee that makes recommendations regarding the reimbursement and the optimal use of certain pharmaceutical products to publicly funded drug programs in the federal, provincial, and territorial ministries of health in Canada that participate in the program.

2.0 ROLES AND RESPONSIBILITIES

The responsibilities of CDEC (herein referred to as “the committee”) include:

- use CADTH reviews and input from stakeholders (patient representatives, clinical experts, and pharmaceutical manufacturers) to develop recommendations as to whether certain pharmaceutical products should be reimbursed, and the conditions for reimbursement
- use CADTH reviews and input from stakeholders (patient representatives, clinical experts, and pharmaceutical manufacturers) to develop recommendations as to what reimbursement or other policies would promote the optimal use of certain pharmaceutical products in Canada
- provide guidance to CADTH and participating federal, provincial, and territorial ministries of health, as requested, on other issues related to reimbursement and the optimal use of pharmaceuticals.

CDEC may be directed to form subcommittees and/or task groups to fulfill its mandate.

3.0 AUTHORITY

The committee shall report to the President and CEO through its Chair.

4.0 MEMBERSHIP

The committee is composed of 16 members, as follows:

- one Chair
- three patient representatives
- one ethicist
- eleven expert members who hold qualifications as physicians, pharmacists, health economists, or other professional health designations, and have expertise and experience in one or more of the following areas: health economics, health policy or administration, pharmacy, clinical pharmacology, general medical practice, internal medicine, and any other recognized medical specialty. Members are expected to have experience and knowledge related to health technology assessment, reimbursement policy, and/or epidemiology.

4.1 Appointment Process

The members shall be identified through a public call for nominations. Members shall be appointed by the CADTH President and CEO.

4.2 Removal

Notwithstanding anything set out in these terms of reference, the President and CEO of CADTH shall have the right to remove and/or replace a CDEC member at or before the expiry date of his or her term.

4.3 Resignation

A member may resign from office by providing the Chair and CADTH President and CEO with a written resignation; such resignation becomes effective when received by CADTH or at the time specified in the resignation, whichever is later.

5.0 TERM OF OFFICE

Members of CDEC shall normally be appointed for a three-year term, but the term may be renewed once at the discretion of the President and CEO.

Any member who has served two consecutive terms of office shall not normally be eligible for reappointment to the committee until a period of at least one year has elapsed since the end of that member's second consecutive term in office.

For the purposes of succeeding to the role of Chair, a member may be appointed for additional terms(s) in accordance with section 6.2.

The President and CEO may appoint a member who has served two consecutive terms of office for an additional term for the purpose of that member serving as an officer or if a third term is in the best interests of CADTH.

6.0 OFFICERS

The officer of the committee is the Chair.

6.1 Appointment Process

One member shall be appointed by the President and CEO to serve as Chair of the committee.

6.2 Term

Officers shall ordinarily hold office for a term of three years from the date of their appointment as Chair, irrespective of years served as a member. The term may be renewed once at the discretion of the President and CEO.

Any officer who has served two consecutive terms of office shall not be eligible for appointment to the committee as a member until a period of at least one year has elapsed since the end of that officer's second consecutive term in office.

6.3 Powers and Duties

The Chair shall, when present, preside at all meetings of the committee. The Chair shall act as the committee spokesperson when directed to do so by the President and CEO. Per sections 7.3 and 14.0, the Chair shall participate in the development of meeting agendas and report on committee activities to the CADTH Board of Directors.

7.0 MEETINGS

CDEC will meet in person on a monthly basis, on a pre-specified day of each month. Under exceptional circumstances, additional meetings may be called.

7.1 Attendance

Members shall make best efforts to attend all meetings of the committee. A member who is unable to attend an in-person meeting may request permission from the Chair to participate in the meeting via teleconference or other means. Permissions will be granted provided all members are in agreement. Alternates are not permitted to attend in place of a member.

7.2 Quorum

A majority (50% plus one) of voting members of the committee shall constitute quorum.

7.3 Agenda

Meeting agendas are prepared by CADTH in consultation with the committee Chair.

7.4 Decision-Making

Decisions of CDEC shall ordinarily be made by a majority vote of the members in attendance. The Chair of the meeting shall not vote except in the event of a tie, in which case the Chair of the meeting may exercise a vote. All committee members must support the decisions of the committee.

7.4.1 Abstaining

Although full participation of members is in the best interests of the work undertaken by the committee and CADTH, in some cases members may abstain from voting. If a member is not present for the majority of the discussion on the motion being passed, or if the member feels unable to vote for moral reasons, the member may abstain from voting.

When a member abstains, their vote is not counted and the decision is made by a majority of remaining voting members.

7.5 Minutes

CADTH staff keep a written record of meetings of the committee. A copy of the minutes will be provided to each member of the committee.

7.6 Attendees

In addition to CDEC members and observers invited in accordance with section 7.7, only the following persons shall be entitled to attend CDEC meetings:

- members of CADTH Pharmaceutical Advisory Committee and Formulary Working Group (FWG)
- members of participating drug plans
- specialist experts (as subsequently noted)
- members of the pan-Canadian Pharmaceutical Alliance (pCPA)
- CADTH staff (as subsequently noted).

CADTH Pharmaceutical Advisory Committee members appointed by federal, provincial, and territorial ministries of health and provincial cancer agencies shall be entitled to attend. At each meeting, the FWG Chair (or his or her delegate from among the FWG members) will be given the opportunity to provide the perspective of FWG on submission(s) for consideration by CDEC. These attendees shall not have the right to participate in CDEC deliberations or to vote (i.e., beyond the steps of information gathering and clarification).

Specialist experts may be invited to attend CDEC meetings to provide their expertise, as required. Specialist experts are thought leaders and may be drawn from a variety of fields, such as clinical settings, methodology, health economics, for example. These specialists 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 based on the project.

CADTH staff attending the meeting shall serve as a resource to CDEC. The staff provides administrative and secretariat support, and may actively participate in the presentation of information, Requests for Advice, submissions, resubmissions, and Reconsiderations of an Initial Recommendation at the request of the CDEC Chair. The staff shall also assist in obtaining additional information and/or expert advice at CDEC's request.

7.7 Observers

CADTH, in consultation with the Chair, may invite observer(s) to attend committee meetings from time to time.

The committee shall have the right to exclude observers from any meeting held in camera, either in whole or in part.

8.0 CANADIAN PLASMA PROTEIN PRODUCT EXPERT SUB-COMMITTEE

The Canadian Plasma Protein Product Expert Sub-Committee (CPEC) is a sub-committee of CDEC. CPEC makes recommendations regarding the reimbursement and the optimal use of plasma protein products to CDEC.

8.1 Authority

The sub-committee shall report to CDEC through its Chair.

8.2 Membership

The sub-committee is composed of 18 members, as follows:

- those members of CDEC as noted in section 4.0
- two plasma protein product experts.

8.2.1 Appointment Process

The members shall be identified through a public call for nominations. Members shall be appointed by the CADTH President and CEO.

8.2.2 Removal

Notwithstanding anything set out in these terms of reference, the President and CEO of CADTH shall have the right to remove and/or replace a CPEC member at or before the expiry date of his/her term.

8.2.3 Resignation

A member may resign from office by giving a written resignation to the Chair and CADTH President and CEO; such resignation becomes effective when received by CADTH or at the time specified in the resignation, whichever is later.

8.3 Term of Office

Members of CPEC shall normally be appointed for a one-year term, but the term may be renewed once at the discretion of the President and CEO.

8.4 Meetings

CPEC will meet as needed in conjunction with CDEC meetings held on a pre-specified day of each month. Under exceptional circumstances, additional meetings may be called.

8.4.1 Attendance

Members shall make best efforts to attend all meetings of the committee. Alternates are not permitted to attend in place of a member.

8.4.2 Quorum

A majority (50% plus one) of voting members of the committee shall constitute quorum.

8.4.3 Decision-Making

Decisions of CPEC shall ordinarily be decided by a majority vote of the sub-committee members in attendance. The Chair of the meeting shall not vote except in the event of a tie, in which case the Chair of the meeting may exercise vote. All sub-committee members must support the decisions of CPEC.

8.4.4 Recommendations

Recommendations will be written by CPEC and presented to CDEC at the CDEC meeting by one or both of the plasma protein product experts.

8.4.5 Attendees

In addition to CPEC members and observers invited in accordance with section 8.4.5, the following persons shall be entitled to attend CPEC meetings:

- members of CADTH Pharmaceutical Advisory Committee
- members of participating drug plans
- members of the pCPA
- Canadian Blood Services staff
- CADTH staff.

For more information see section 7.6

8.4.6 Observers

CADTH, in consultation with the Chair, may invite observer(s) to attend committee meetings from time to time.

8.4.7 Additional information

In addition to the terms of section 8, CPEC shall comply with sections 9 to 16.

9.0 CODE OF CONDUCT

All members of the committee shall comply with the CADTH code of conduct.

10.0 CONFLICT OF INTEREST

All members of the committee shall comply with the CADTH conflict of interest policy. Conflicts of interest shall be declared at the start of each meeting.

11.0 INDEMNIFICATION

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

- all costs, charges, and expenses that such CDEC member sustains or incurs in or about any action and suit of proceedings that 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 committee members or in respect of any such liability
- all such costs, charges, and expenses that he or she sustains or incurs in or about in relation to the affairs thereof, except such costs, charges, or expenses as are occasioned by his or her own wilful neglect or default.

12.0 CONFIDENTIALITY

It is the responsibility of CDEC members to know what information is confidential and to obtain clarification from CADTH when in doubt. Except as compelled by the 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 the committee and of CADTH obtained by reason of his or her status as a committee member and 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 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 committee member.

More details on confidentiality are set out in the CADTH code of conduct (available on the CADTH website).

13.0 REMUNERATION

Members may be eligible to receive remuneration in accordance with the CADTH policy on remuneration. Expenses incurred in the course of performing duties as a committee member are eligible for reimbursement in accordance with the CADTH travel policy.

14.0 REPORTING

CDEC shall make a report to the CADTH Board of Directors at least annually through its Chair by verbal and/or written means.

15.0 SECRETARIAT SUPPORT

Secretariat support for CDEC shall be provided by CADTH staff.

16.0 AMENDMENTS TO THE TERMS OF REFERENCE

These terms of reference may be amended at any time at the discretion of the CADTH President and CEO.