

CADTH Canadian Drug Expert Committee Terms of Reference

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CADTH 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
- 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.

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).

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.

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.

5.7 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*.

5.8 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*.

Role of CADTH Canadian Drug Expert Committee Members

The role of the CDEC member is:

- to establish, maintain, and apply standards and methodologies to evaluate the therapeutic value and cost-effectiveness of pharmaceuticals
- to consider submissions made by manufacturers, and all related clinical reviews and economic reviews prepared and submitted in accordance with CADTH standards
- to evaluate submissions and requests for advice using a multicriteria approach that considers therapeutic advantages and disadvantages, cost-effectiveness, and patient and societal perspectives on the impact of the drug under review, compared with accepted or existing therapies
- to recommend, after consideration of a submission, to the provincial, territorial, and federal drug plans, those new drugs that should be considered for funding and under which conditions such products should be funded
- to provide reasons for every recommendation made to the provincial, territorial, and federal drug plans for public dissemination
- to provide advice and, if appropriate, a change to a previously issued recommendation, in response to every request for advice by the CADTH Drug Policy Advisory Committee (DPAC) Formulary Working Group (FWG) or the individual federal, provincial, and territorial drug plans
- to make recommendations and provide advice related to the identification, evaluation, and promotion of optimal therapy in drug prescribing and utilization in Canada
- to provide expertise and guidance with respect to intervention tools and strategies that will facilitate the adoption and implementation of a recommended optimal therapy.

Qualifications

All members, including the chair, shall demonstrate the following qualifications:

- currently not employed by any pharmaceutical or related companies
- ability and willingness to comply with *CADTH Conflict of Interest and Confidentiality* requirements
- availability/commitment of time to prepare for meetings and participate fully in CDEC
- knowledge and understanding of the mandate of CADTH and that of CDEC, including their role in the health care system
- willingness to work within the defined processes and parameters for reviewing pharmaceuticals, using a multicriteria approach that considers evidence-based medicine, cost-effectiveness, and societal values
- experience in committee and/or community work
- ability to communicate effectively
- ability to acquire the information and adopt the skills needed to successfully negotiate important issues
- strong listening skills
- 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 gain respect and credibility within a diverse range of stakeholders and the greater public

- ability to work constructively as a member of a team and appreciate the diverse viewpoints and opinions of CDEC members and outside specialist experts.

The following additional qualifications apply to all members of CDEC other than the public members:

- hold a professional degree from a recognized institution in at least one of the following disciplines: medicine, nursing, pharmacy, pharmacology, or health economics
- health care professionals must have experience in the Canadian health care system; being in active practice and/or having clinical research experience will be considered additional assets
- have an understanding of the use and delivery of prescription drugs within the Canadian context.

Public members are not expected to have a clinical or research background; however, they will be required to review and synthesize considerable amounts of information. The primary role of the public members is to represent the views and values of contemporary Canadian society. Public members do not represent any particular group or organization.

Remuneration

On appointment, CDEC members will receive the following:

- \$1,000 per day, pro-rated per half day based on a 7.5-hour full day
- any reasonable travel and lodging costs for CDEC or other CADTH meetings, in accordance with the *CADTH Travel Policy*.

Time Commitment

The anticipated time commitment of the CDEC members is up to two days per month (excluding travel time). Approximately half of this time is expected to be spent on preparation in advance of meetings. From time to time, members may be asked to deliver presentations, which will require additional preparation. Members will be required to attend in-person monthly, full-day CDEC meetings. Typically there will be 10 CDEC meetings held in Ottawa annually.

Term of Appointment

- The initial term of appointment will be for a period of two or three years.
- The appointment may be renewed at the end of the appointment term.
- The successful candidates will be required to adhere to the *CADTH Code of Conduct*.
- Candidates are required to declare any potential conflict of interest that might arise in the course of CDEC business.

Profile of CADTH Canadian Drug Expert Committee Public Members

Definition

For the purposes of the CADTH Advisory Committees, including CDEC, a public member is selected for the committee to represent the general public and not as a representative of any specific interest area, group, or organization.

General

All members are expected to comply with the *CDEC Terms of Reference*, including the provisions governing conflict of interest.

Time Commitment

CDEC members should expect to prepare for and attend scheduled meetings. Typically there will be 10 CDEC meetings held in Ottawa annually.

Knowledge, Experience, and Abilities:

- knowledge of, or interest in, issues related to the health care system
- knowledge of, or interest in, issues relevant to CADTH's mandate and that of CDEC
- experience in committee and/or community work
- demonstrated awareness of, and interest in, the perspectives of members of the general public on issues related to health care services and medicines
- 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 gain respect and credibility within a diverse range of stakeholders and the greater public
- ability to work constructively as a member of a team
- ability to form constructive working relationships
- ability to communicate effectively
- ability to review and synthesize considerable amounts of information.

CADTH Conflict of Interest Guidelines for CADTH Expert Committee and Panel Members

1.0 Purpose of the Guidelines

1.1 These Conflict of Interest (COI) Guidelines are intended to ensure the highest ethical standards and maintenance of the integrity of the work undertaken by CADTH. The principles of transparency and disclosure are essential to achieving these objectives. By disclosing relevant personal, occupational, professional or financial relationships with, or interests in, a Party (all as defined in section 2.2), participants in CADTH activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of CADTH's programs and processes.

2.0 Definitions

2.1 In these COI Guidelines, the word "Member" means, unless otherwise stated, a committee or panel member who is appointed in accordance with the specific Terms of Reference of a CADTH committee or panel. CADTH is not precluded from appointing experts, as Members of the Committee, who may have interactions and/or relationships with one or more Parties (as defined below).

2.2 In these COI Guidelines, the word "**Party**" means an individual, corporation, entity, association or organization, which has an interest in CADTH's recommendations. "**Parties**" has a corresponding meaning.

2.3 A Member has a "**personal interest**" where:

a) the Member or a related person

i) has an affiliation or association with, or membership in, any group, organization or special interest group of relevance to the Committee's or Panel's mandate;

ii) has a non-arm's length relationship with any group, organization or special interest group of relevance to the Committee's or Panel's mandate;

b) a related person has a financial, occupational or professional relationship with, or interest in a Party.

2.4 "**Arm's length**" means the relationship which exists between parties who are strangers to each other, and who bear no special duty, obligation or relation to each other.

2.5 A "**related person**" is a spouse, a partner or an immediate family member of the Member.

2.6 A person has an "**occupational relationship**" with a Party where the person is an employee of, or engaged by, such Party.

2.7 A person has a "**professional relationship**" with a Party including, without limitation, in situations where the person is providing advice to the Party, with or without remuneration.

2.8 A person has a "**bias**" when he/she has an inclination or prejudice for or against someone or something.

2.9 A person has a "**professional opinion**" when he/she has a view, judgment, or assessment about a particular matter formed on the basis of prior academic knowledge or an objective conclusion based on a research project.

3.0 Applicability

3.1 These COI Guidelines apply to all Members.

4.0 Scope of Conflict of Interest

4.1 A conflict of interest refers to situations in which personal, occupational, professional or financial considerations, either direct or indirect, may affect or compromise, or appear to affect or compromise, an individual's objectivity, fairness or professional judgment in carrying out his/her duties as a Member of a CADTH committee or panel.

4.2 A conflict of interest may be real, potential or perceived in nature.

- a) A real conflict of interest arises where a Member has a bias, or a personal, occupational, professional or financial relationship with, or interest in, a Party, which may affect or compromise, or appear to affect or compromise, his/her work with CADTH.
- b) A potential conflict of interest incorporates the concept of foreseeability: when a Member can foresee that a private or personal interest may someday be sufficient to influence his/her work with CADTH, but has not yet (for example, an identified future commitment with a Party).
- c) A perceived or apparent conflict of interest may exist when there is a reasonable apprehension, which a reasonably well-informed person could properly have, that a conflict of interest exists, even if, in fact, there is neither a real nor a potential conflict.

4.3 It is acknowledged that individuals have varied backgrounds, ideas, biases and personal experiences and influences that may colour how they view or react to someone or something. In certain instances, it may be advisable, or even essential that individuals contribute their experience, expertise and/or knowledge to the resolution of the issues at hand. Expertise in an area, or familiarity with the relevant issues, is not of itself a disqualification on account of conflict of interest nor is the holding of tentative views on a matter of relevance to the Committee's mandate. However, a bias capable of unfairly affecting the outcome of the case will lead to a conflict of interest.

4.4 The following are meant to illustrate examples of conflicts of interest and are not meant to be exhaustive:

- a) A Member has a pecuniary or financial interest in a decision when he/she stands to gain or lose by that decision, either in the form of money, gift, favour or other special consideration
- b) A Member has a private or personal interest sufficient to impair, influence or appear to influence the objective exercise of his/her official duties as a Member;
- c) A Member is a party to a claim, application or proceeding for or against CADTH;
- d) A member uses CADTH confidential information for his/her own purpose or benefit or the benefit of a friend or family member or knowingly divulges CADTH confidential information to any person other than another Member, unless the disclosure is required by law.

5.0 Disclosures

- 5.1 Before a Member participates in any CADTH activity, the Member must disclose any conflict of interest, as described in section 4.0, by completing and submitting a Conflict of Interest Disclosure Form in the form and manner prescribed by CADTH. All Members must complete the COI Disclosure Form at least annually. **However, the obligation to disclose conflicts of interest is ongoing and Members must inform CADTH of any conflict of interest that arises during the period of their Committee or Panel commitment as soon as it is known to them. The Member is required to forward an updated COI Disclosure form to CADTH immediately following such notification.**
- 5.2 In addition to the foregoing, Members will be required, at the commencement of every Committee or Panel meeting to disclose any conflict of interest, as described in section 4.0.

5.3 Schedule 1 Disclosures

- 5.3.1 Without limiting the generality of the foregoing, Members are required to disclose to CADTH, by completing the attached Schedule 1, all interests or activities that occurred during the past three (3) years in which they or a related person benefited. Information to be disclosed includes, but is not limited to:
- a) receipt of gifts, favours or hospitality from a Party;
 - b) receipt from a Party of funding for, or payment of, travel;
 - c) receipt of funding or honoraria from a Party for speaking engagements;
 - d) receipt of funding or honoraria from a Party for giving educational lectures;
 - e) receipt of funding or honoraria from a Party for organizing conferences;
 - f) receipt of funding or honoraria from a Party for writing articles or editorials;
 - g) receipt of any other financial support, honoraria or gift from a Party.

5.4 Schedule 2 Disclosures

- 5.4.1 In addition to other disclosures made under these Guidelines, and without limiting the generality of the foregoing, Members are also required to disclose to CADTH, by completing the attached Schedule 2, all interests or activities that occurred during the past three (3) years in which they or a related person benefited. Information to be disclosed includes, but is not limited to:
- a) employment or engagement with a Party;
 - b) receipt of payment as an advisor or consultant for a Party;
 - c) receipt of funding or honoraria from a Party for research;
 - d) receipt of payment from a Party for academic appointments (including endowed chairs);
 - e) receipt of funding or honoraria from a Party for personal education.
 - f) receipt of funding from a Party for an unrestricted grant.
 - g) other financial interests which include securities (including stocks, shares, stock options and warrants, but excluding mutual funds managed by a person or persons with whom the Member deals at arm's length) or ownership interest held in a Party.

5.5 Schedule 3 Disclosures

- 5.5.1 In addition to disclosures made under these Guidelines, and without limiting the generality of the foregoing, Members are required to disclose to CADTH, by completing the attached Schedule 3, any other activities, affiliations or interests in the past three (3) years that affect or compromise, or may appear to affect or compromise, the Member's objectivity, fairness or professional judgment in carrying out their duties as a Member of a CADTH Committee or Panel.
- 5.5.2 The interests to be listed in Schedule 3 include, but are not limited to:
- a) advice to, or close association with, a Party;
 - b) professional relationship with a Party,
 - c) the Member's participation as investigator in clinical trials of relevance to the Committee's or Panel's mandate;
 - d) professional opinions (as defined in section 2.9) expressed publicly by the Member of relevance to the Committee's or Panel's mandate;
 - e) the Member's involvement in the promotion of a product of relevance to the Committee's or Panel's mandate;
 - f) papers written by the Member of relevance to the Committee's or Panel's mandate;
 - g) the Member providing expert testimony in Court in regard to a matter of relevance to the Committee's or Panel's mandate;
 - h) the Member's affiliation with, association with, or membership in, any group, organization or special interest group of relevance to the Committee's or Panel's mandate;
 - i) lobbying activities on the part of the Member of relevance to the Committee's mandate;
- 5.5.3 In addition, Members are required to disclose in Schedule 3 all potential or pending future commitments with a Party.

6.0 Principles for Dealing with COI

- 6.1 If the Member is not certain whether he/she is in a conflict of interest position, the matter may be brought to the attention of Committee Chair or the CADTH Executive Team member responsible for the Committee or Panel for advice and guidance.
- 6.2 If there is any question or doubt about the existence of a conflict of interest, the Committee Chair in conjunction with a CADTH Executive Team member shall determine whether a conflict exists. Such determination shall be final.
- 6.3 A number of committee or panel governance models may be used to facilitate the work of a Committee or Panel. In the event that a Committee or Panel uses a Chair and Vice Chair model, section 6.3.a) shall apply. Should the Committee or Panel use a co-Chair model, 6.3.b) shall apply.
- a) **Chair and Vice Chair Model:** The Chair of committee or panel meetings should have no conflict of interest in connection with any matter relevant to the Committee's or Panel's mandate. Except as otherwise provided herein, the Committee or Panel Chair chairs all meetings of the Committee or Panel. In the absence of the Chair, the Vice Chair shall act in his/her stead. The determination of whether the Chair or Vice Chair, as applicable, has a conflict of interest shall be determined by the CADTH President and CEO. If it is determined that the Chair or Vice Chair, as applicable, has a conflict of interest on a

matter relevant to the Committee's or Panel's mandate, he/she shall not participate in any deliberation or vote in respect of such matter. In the event that both the Chair and Vice Chair have a conflict of interest, the CADTH President and CEO shall appoint the chair of the meeting.

- b) **Co-Chair Model:** The Co-chair(s) of meetings should have no conflict of interest in connection with any matter relevant to the Committee's mandate. Except as otherwise provided herein, the Co-Chairs chair all meetings of the Committee. In the absence of one Co-Chair, the other Co-Chair shall be the sole chair of the meeting. The determination of whether a Co-Chair has a conflict of interest shall be determined by the CADTH President and CEO. If it is determined that a Co-Chair has a conflict of interest on a matter relevant to the Committee's or Panel's mandate, he/she shall not participate in any deliberation or vote in respect of such matter. In the event that both Co-Chairs have a conflict of interest, the CADTH President and CEO shall appoint the chair of the meeting.

- 6.4 In determining whether a Member or the Committee Chair has a conflict of interest, the Member, Committee Chair and CADTH shall be guided by these COI Guidelines and the COI Flowchart set out in Schedule 4 (the "**COI Flowchart**"). The following terms used in the COI Flowchart have the meaning set out below.

Discussion: With proper disclosure of interest, a Member with a conflict of interest can participate in discussions with other Members of the Committee or Panel. A discussion will occur when the purpose of the meeting is to consider a matter in an open and informal setting, and where ideas are shared liberally (e.g. brainstorming, identifying options...), but where there is no deliberation or decision.

Deliberation: A deliberation will occur when the purpose of the meeting is to consider the reasons for and against certain options (e.g. evaluating the options and potential recommendations...). Refer to the COI Flowchart to determine when a Member may participate in deliberations.

Decision: A decision will occur when the purpose of the meeting is to arrive at a determination usually by way of a consensus or a vote (e.g. voting on which option will be recommended). Refer to the COI Flowchart to determine when a Member may participate in decision making or voting.

Direct Impact: When considering if a particular matter or issue could have a direct impact on the Member's financial or personal interest, one must consider what benefit may result and if it is a benefit contemplated by Section 4. If it is, then one must answer "yes" and move on to the next question in the COI Flowchart. If the interest is not one that falls within the scope of Section 4, then it is not a benefit, thus not a direct impact on the Member's financial or personal interests.

Essential: A member will become essential to the Committee or Panel when expertise is limited and, as a result, the Member is required in order for CADTH to fulfill its mandate.

- 6.5 Except as otherwise provided herein or in the COI Flowchart, the Member who has a conflict of interest must abstain from participation in any discussion on the matter, shall not attempt to personally influence the outcome, shall refrain from voting on the matter and, unless otherwise decided by the Committee Chair, must leave the meeting room for the duration of any such discussion or vote.

- 6.6 When a conflict of interest exists, the Committee Chair has the authority to exclude a Member from the Committee or Panel meeting. In circumstances where the expertise pool is limited, and a Member's participation is essential to the work of the Committee and reasonable efforts have been made without success to find a suitable replacement with no conflicts, the Chair may grant a waiver in order to allow the Member to participate, and/or to limit his/her participation in the meeting, whether this participation be his/her right to vote or his/her right to participate in discussions or deliberations.
- 6.7 The disclosure and decision as to whether a conflict exists, and the Chair's or the President and CEO's, as applicable ruling on any matter relating to a conflict of interest, shall be duly recorded in the minutes of the meeting. The time the Member left and returned to the meeting shall also be recorded.
- 6.8 It is the responsibility of every Member who is aware of a conflict of interest on the part of another Member to raise the issue for clarification, first with the Member in question and, if still unresolved, with the Committee Chair.

7.0 Publication of Conflict of Interest Declarations

- 7.1 A summary of the Member's expertise, experience, affiliations and conflict of interest declaration will be posted and publicly available on the CADTH website.
- 7.1.1 If the Member has contributed expertise or acted in an authorship role to a CADTH publication, a summary of the Member's expertise, experience, affiliations and conflict of interest declaration will be included in that publication.

8.0 Amendment to the COI Guidelines

After appropriate consultation, the COI Guidelines may be amended at any time by CADTH, subject to approval of the President and CEO.

Appendix A: Conflict of Interest Disclosure Form

CADTH Expert Committee and Panel Members

I have read and understood the Conflict of Interest (COI) Guidelines and I agree to be bound by the obligations contained therein. I understand that it is my responsibility to report to CADTH any real, potential or perceived conflicts of interest as defined in the COI Guidelines, and to disclose the information requested in the COI Guidelines.

As a member of a CADTH Committee or Panel, I also understand that a summary of my expertise, experience, affiliations and conflict of interest declaration will be publicly available on the CADTH website and in all CADTH publications to which I have contributed in an advisory (i.e. have made recommendations) or authorship role.

I understand that the information disclosed will be retained on file by CADTH.

I have reviewed my investments, affairs, affiliations, activities and interests and have accurately completed the attached Schedules 1, 2 and 3.

I hereby certify that I have disclosed all relevant information with respect to any matter involving a Party that may place me in a real, potential or perceived conflict of interest situation. Except as otherwise disclosed in the attached Schedules 1, 2 and 3, I declare that I have no conflict of interest to report, as defined in the COI Guidelines.

I undertake and promise to inform CADTH of any change in circumstances that may create a conflict of interest as soon as it is known to me.

Date

Print Name

Signature

Name of Committee/Panel

Conflict of Interest Disclosure Form – Schedule 1

(Reference: COI Guidelines Section 5.3)

Disclosures are required under Section 5.3 of the Conflict of Interest Guidelines for those activities or interests involving any Party during the past three years which benefited the Member or related person, particularly as the activities relate to the following areas (add pages as necessary):

Name of Party (see section 2.2 for definition)	Drug, technology or topic involved and year of funding	Check (✓) type of benefit as appropriate							Check (✓) type of benefit as appropriate			
		Gifts, etc.	Travel funding or payment	Funding or honoraria for:					Value of funding or benefit			
				Speaking engagements	Educational lectures	Organizing conferences	Writing articles or editorials	Other* (see below)	\$0 – \$5,000	\$5,001 – \$10,000	\$10,001 – \$50,000	Over \$50,000

*Other gifts/funding/honoraria: please provide details:

I do not have declarations for Schedule 1.

_____ Date

_____ Print Name

_____ Signature

Conflict of Interest Disclosure Form – Schedule 2

(Reference: COI Guidelines Section 5.4)

Disclosures are required under Section 5.3 of the Conflict of Interest Guidelines for those activities or interests involving any Party during the past three years which benefited the Member or related person, particularly as the activities relate to the following areas (add pages as necessary):

Name of Party (see section 2.2 for definition)	Drug, technology or topic involved and year of funding	Check (✓) type of benefit as appropriate							Check (✓) type of benefit as appropriate			
		Employment or engagement	Payment as advisor or consultant** (see below)	Funding or honoraria for:					Value of funding or benefit			
				Research funding or grants	Payment for academic appointment (endowed chairs)	Personal education funding	Unrestricted grants	Securities	\$0 – \$5,000	\$5,001 – \$10,000	\$10,001 – \$50,000	Over \$50,000

**Payments as advisor/consultant: please provide details:

I do not have declarations for Schedule 2.

_____ Date

_____ Print Name

_____ Signature

Conflict of Interest Disclosure Form – Schedule 3

(Reference: COI Guidelines Section 5.5)

List those activities, affiliations or interests involving a Party in the past three years (not already listed in Schedules 1 and 2) that may affect or compromise, or appear to affect or compromise the Member's objectivity, fairness or professional judgment (as outlined in Section 5.5.1). See list of examples in Section 5.5.2.

Name of Party (see section 2.2 for definition)	Nature or description of activities or interests (see Section 5.5.2)	Check (✓) type of benefit as appropriate				
		Financial value of benefit or internal (if any)				
		\$0 – \$5,000	\$5,001 – \$10,000	\$10,001 – \$50,000	Over \$50,000	

List those activities, affiliations or interests involving a Party with whom the Member has a potential or pending future commitment (as outlined in Section 5.5.3). Provide details on the nature of the commitment.

Name of Party (see section 2.2 for definition)	Nature and timing of the future commitment	Check (✓) type of benefit as appropriate				
		Financial value of benefit or internal (if any)				
		\$0 – \$5,000	\$5,001 – \$10,000	\$10,001 – \$50,000	Over \$50,000	

I do not have declarations for Schedule 3.

Date

Print Name

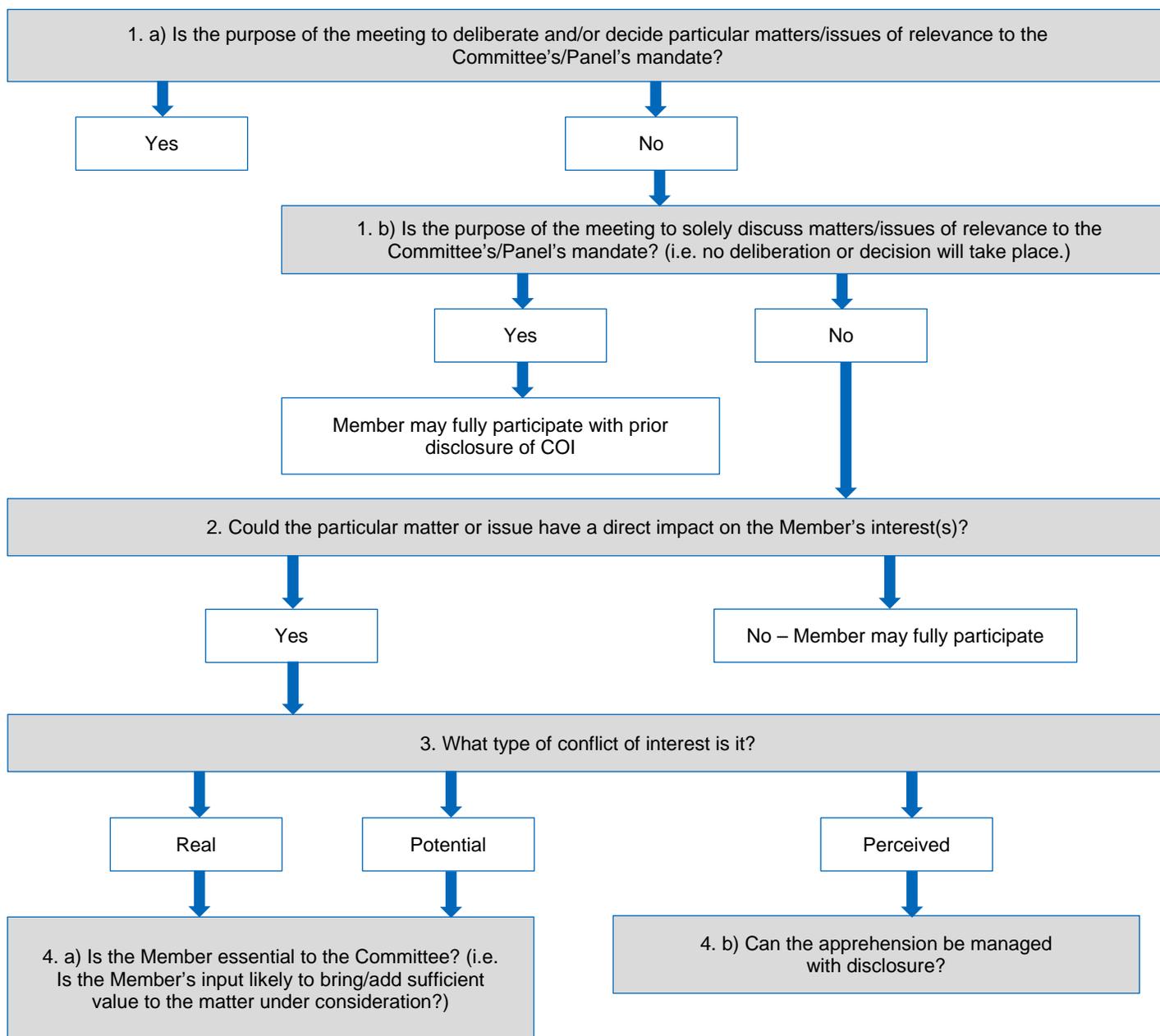
Signature

Schedule 4

(Reference: COI Guidelines Section 6.0)

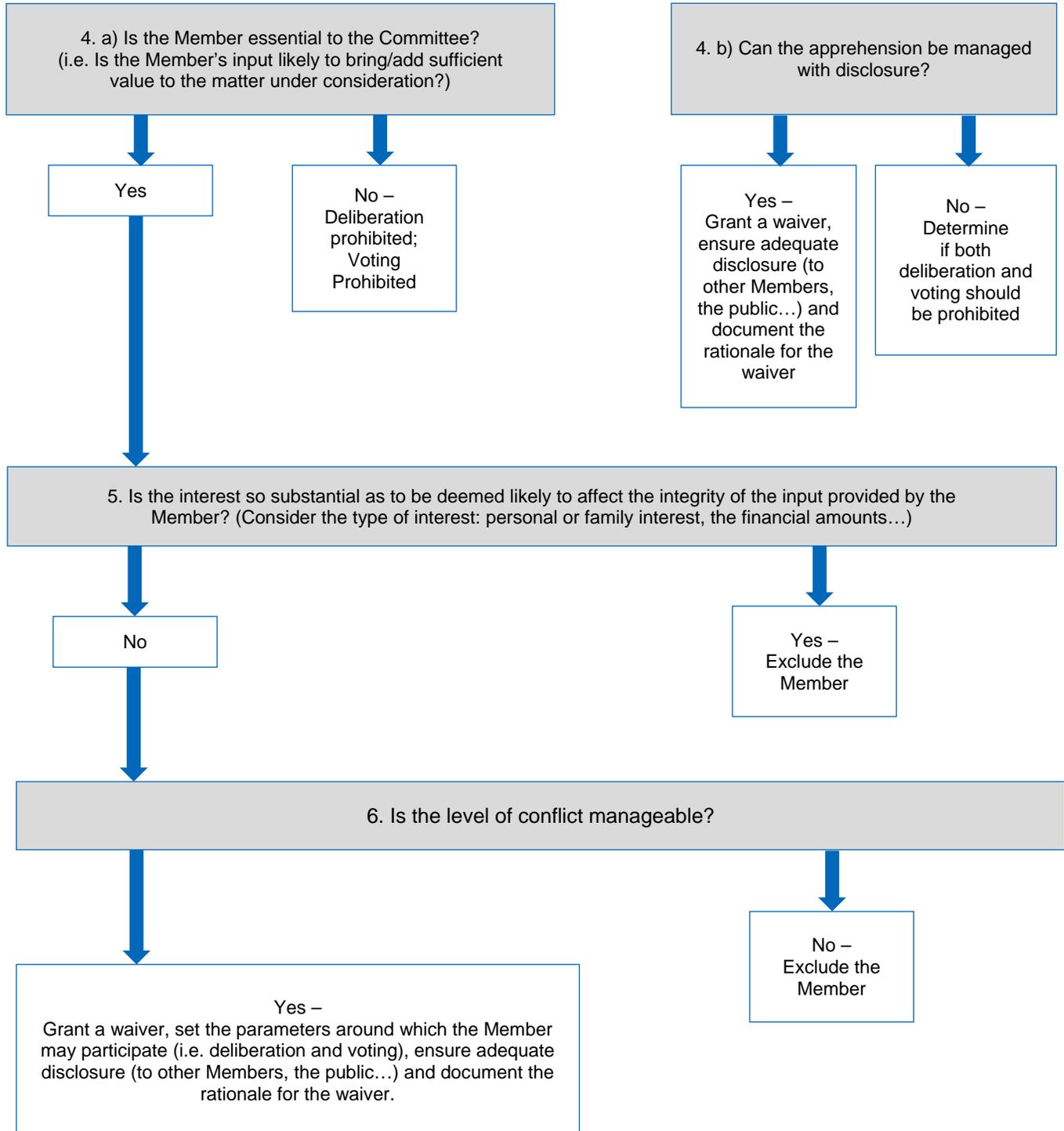
COI Flowchart

All Members are required to disclose COI's in accordance with the COI Guidelines.



Continued on next page

Schedule 4



CADTH Code of Conduct Agreement Form for Members of CADTH Committees and Expert Review Panels

I have read and understand the provisions contained in this Code of Conduct, and agree to abide by those provisions.

Print Name

Signature

Date (valid up to 5 years from date)

Preamble:

This Code of Conduct has been prepared to clearly and openly express the expectations for Members of CADTH Committees and Expert Review Panels (hereinafter “Committees/Panels”) in carrying out their duties. In order to serve as a member of a Committee/Panel, members must agree to and comply with this Code of Conduct.

The Code is designed to clearly set out principles, values and standards of behaviour that guide the decisions or deliberations that are encompassed within the responsibilities of CADTH Committees/Panels and support the effective operations of the CADTH Committees/Panels.

1. Applicability

All Members of CADTH Committees/Panels must abide by this Code of Conduct.

- 1.1. This Agreement form, once signed, will be retained on file at CADTH and will apply to any and all Committees/Panels in which the Member participates.
- 1.2. This Agreement form is valid for a maximum of 5 (five) years from date signed.

2. Conduct

2.1. Equality

Members, while representing diverse backgrounds, skills and experiences, will have an equal voice and equal representation on the Committee/Panel.

2.2. Participation

Members will actively participate in discussions.

Members will partake in active listening and provide opportunity for all members to participate in discussions.

Members shall maintain a level of professional competence and knowledge required to discharge their obligations and duties.

2.3. Respect

Members will not always agree with one another on all issues, but debates will be conducted in an atmosphere of mutual respect and courtesy.

Members have an obligation to act fairly in the conduct of their duties.

Members will support all properly authorized actions and once a decision has been made, the Committee/Panel will speak with one voice.

2.4. Focus

Members will not partake in sidebar discussions.

Members will not partake in double tasking (e.g. no blackberries).

2.5. Transparency

Members will bring forth all issues.

Members will engage in direct exchange of information, opinions, and ideas.

2.6. Confidentiality

Members will respect the confidentiality of all information (including verbal information), and materials received when carrying out their duties.

Members shall not intentionally divulge any such information to any person other than another Committee/Panel Member unless legally required to do so.

Members shall not use information obtained as a result of their involvement in Committee/Panel matters for personal benefit.

2.7. Meeting Preparedness

Members will regularly attend meetings.

Members will read meeting materials in advance of the meeting and will be prepared to fully participate in the discussion.

3. Compliance

If a Member does not comply with this Code of Conduct, CADTH reserves the right to terminate the Member's participation on the Committee/Panel.

4. Communications

All third party (media, industry, professional associations, patient groups, etc.) requests for information regarding the Committee/Panel are to be directed to CADTH Corporate Communications for response. Members are not to respond to third party requests unless directed or assigned by CADTH to do so.

Statement of Interest and Qualifications

Canadian Drug Expert Committee (CDEC) Member Role

Nominees are asked to describe why they are interested in the role (up to 250 words).

Nominees are asked to describe their relevant qualifications and experience.

Nominee holds a professional degree from a recognized institution in at least one of the following disciplines: medicine, nursing, pharmacy, pharmacology, or health economics (up to 150 words).

Nominee is a health care professional with experience in the Canadian health care system (being in active practice or having clinical research experience will be considered additional assets) (up to 150 words).

Nominee has an understanding of the use and delivery of prescription drugs within the Canadian context (up to 150 words).

Nominee has knowledge and an understanding of the mandate of CADTH and that of CDEC, including their roles in the health care system (up to 150 words).

Nominee has experience in committee and/or community work (up to 150 words).

Nominee has the ability to work constructively as a member of a team and to appreciate the diverse viewpoints and opinions of CDEC members and outside specialist experts (up to 150 words).

Statement of Interest and Qualifications

Canadian Drug Expert Committee (CDEC) Public Member Role

Nominees are asked to describe why they are interested in the role (up to 250 words).

Nominees are asked to describe their relevant qualifications and experience.

Nominee has demonstrated awareness of, and interest in, the perspectives of members of the general public on issues related to health care services and medicines (up to 150 words).

Nominee has knowledge of, or interest in, issues related to the health care system (up to 150 words).

Nominee has knowledge of, or interest in, issues relevant to CADTH's mandate and that of CDEC (up to 150 words).

Nominee has experience in committee and/or community work (up to 150 words).

Nominee has the ability to relate to and respect a diverse range of values and beliefs (up to 150 words).