Ontario Steering Committee for Cancer Drug Programs, an ad hoc committee of the Committee to Evaluate Drugs

Terms of Reference

1. Authority

The Ontario Steering Committee for Cancer Drug Programs is established as an ad hoc committee of the Committee to Evaluate Drugs (CED), in accordance with section 6 of the CED Terms of Reference and Administrative Guidelines.

2. Objective

The objective of the Ontario Steering Committee for Cancer Drug Programs is to provide evidence based clinical, health research and health economic guidance to the Executive Officer (EO) of Ontario Public Drug Programs (OPDP) on: provincial cancer drug funding policies and decisions, program evaluation and drug-specific studies, and enhancements to cancer drug programs or initiatives in Ontario.

3. Membership

a. Composition

The Steering Committee shall be composed of the following individuals with a target membership of 12 members plus 1 Chair. All members must be selected by the Executive Officer, in consultation with Cancer Care Ontario (CCO).

- Oncologists and Hematologists
- Hospital oncology pharmacy representative
- Health Economist
- Patient representative
- Ex officio non-voting members:
    - Director, Provincial Drug Reimbursement Programs (PDRP), CCO
    - Director, OPDP, Ministry of Health and Long Term Care (MOHLTC)
    - CCO PDRP Program Managers
    - MOHLTC OPDP Program Managers
    - CCO PDRP Clinical Lead
    - OPDP Pharmacist
    - CCO Case-by-Case Review Program (CBCRP) Pharmacist (as required)
    - CCO Public Affairs (as required)
    - CCO Informatics (as required)

b. Chair

The Chair's responsibilities include:

- Presiding at all meetings of the Steering Committee, and being responsible for the general supervision of affairs and business of the Steering Committee
- Facilitating discussion at the Steering Committee
- Reporting as required to the Executive Officer and CCO's VP, Clinical Programs and Quality Initiatives. Regular operational reporting is to the Directors of OPDP and PDRP.
- Reporting as required to the MOHLTC's CED on drug funding recommendations.
- Working collaboratively with members of the Disease Site Groups and Disease Site Teams of CCO.
- Providing advice on other drug program matters related to the CED's mandate
- Reviewing and approving meeting minutes.
- Maintaining and recommending appropriate membership on the Steering Committee, to mitigate conflicts of interest and enhance the quality of discussions and recommendations.

The Chair is selected by the Executive Officer, in consultation with CCO's VP, Clinical Programs and Quality Initiatives.

The Chair may appoint an alternate Steering Committee member to chair a meeting or portion thereof in instances where he/she has to recuse him/herself from all or part of the meeting.

c. Minimum requirements

All Steering Committee members must meet the following requirements:

- The member is not employed by a pharmaceutical or related company
- The member complies with Conflict of Interest and Confidentiality requirements set out in these Terms of Reference

Members will work co-operatively with one another recognizing the unique contributions and skills that each brings to the Steering Committee.

Members representing a healthcare specialty must also meet the following requirements:

- Have a professional degree from a recognized institution in at least one of the following disciplines: medicine, pharmacy, pharmacology or health economics
- Be in active practice and/or engaged in research in either the community, hospital and/or academic setting
- Have a commitment to and experience with evidence-based medicine and interpretation of quantitative data

While not a requirement, it is desirable that professional members have additional formal training from a recognized institution in at least one of the following areas: health economics, pharmacoeconomics, pharmacology, epidemiology, critical appraisal skills, health informatics, health services research, health policy, ethics, system planning, and other relevant fields.

The patient representative must also meet the following requirements:

- Personal knowledge of, experience with, and understanding of issues related to cancer and its management (diagnosis, treatment and care);
- Demonstrated understanding and appreciation of patient needs and priorities;
- An overall understanding of other patient issues and health care concerns that may impact cancer patient communities on a broader scale.

While not a requirement, it is desirable that the patient representative has experience in system planning outside the health care sector (e.g. banking, other industry).

d. Withdrawal

Members who are absent from more than two meetings per year will automatically forfeit membership from the Steering Committee, unless prior approval was granted by the Steering Committee Chair.

An individual may resign as a member at any time upon written notification to the Executive Officer.

e. Nomination of members

Members of the Steering Committee shall be selected by the Executive Officer, in consultation with CCO.

The application and selection process consists of the following steps:

- The existing membership of the Steering Committee is periodically reviewed to determine an appropriate mix of skills and expertise.
- Suggestions for potential new members of the Steering Committee could be obtained from the following sources: existing/departing/former members of the Steering Committee, Steering Committee Chair, MOHLTC OPDP management, CCO PDRP management, or EAP / CBCRP reviewers.
- Recruitment communications package is posted publicly and broadly distributed. Individual invitations are also sent to recommended individuals.
- Potential candidates are invited to indicate their interest in serving on the Steering Committee by submitting an application. If there is a need to recruit for the Chair, potential applicants will be asked to indicate their interest in serving as Chair.

- Qualifications of individuals are reviewed by the Steering Committee Chair, the MOHLTC and CCO on the basis of the professional and educational requirements for membership.
- The candidate is selected and written notification is sent to the candidate.
- The candidate's interest is confirmed.
- The Executive Officer will make the final selection after consulting with CCO.

f. Term

Each member of the Steering Committee shall be appointed for a term of up to three years.

4. Role statement / Responsibilities of the Steering Committee
    a. Cancer drug submissions
        i. Assist OPDP in reviewing, evaluating, and prioritizing drug proposal submissions (for the Evidence Building Program or as an in-Ontario funding submission)
        ii. Provide funding recommendations to the Executive Officer based on therapeutic value and cost-effectiveness, including any conditions for reimbursement and the rationale for each recommendation
        iii. Provide cancer system advice to the Executive Officer as required
        iv. Provide advice to the Executive Officer on the consideration of funding pathways for drugs, as required
        v. Monitor and re-evaluate on an ongoing basis, drugs funded under Ontario public drug programs with regard to their continued therapeutic value and cost effectiveness.
    b. Evidence Based Program (EBP) study design
        i. Provide input into the selection and scope of work of external analytic groups
        ii. Work collaboratively with the Disease Site Groups of CCO, external analytic groups, and CCO Informatics to provide input into the development of EBP study questions, analytic approach, study design and methodology
    c. Policy and Program guidance to OPDP
        i. Review and provide strategic and content input into the New Drug Funding Program (NDFP) and other program reporting framework and analytic reports
        ii. Provide advice on cancer drug program process and policy changes
        iii. Identify implications to cancer drug funding decisions and pathways
    d. Other responsibilities
        i. For the purposes of carrying out the responsibilities above, consult with professional groups as needed.

5. Reporting / Accountability

   The Steering Committee is an ad hoc committee of the Committee to Evaluate Drugs. The Steering Committee provides funding and non-funding advice to the Executive Officer of OPDP. Ultimately, all funding decisions are made by the Executive Officer.

   As an ad hoc advisory body, the Steering Committee is subject to applicable Treasury Board / Management Board of Cabinet directives.

6. Recommendation Process

   It is the intent of the Steering Committee to reach consensus on most of the issues discussed, as determined by the meeting agenda. If consensus cannot be reached, the method to arrive at the recommendation will be at the call of the Steering Committee Chair. When a vote is required (i.e., for funding recommendations), voting will be anonymous.

   Meetings will commence provided there is a quorum. A majority (50% + 1) of the total number of active members constitutes a quorum. In determining a quorum, the Chair is counted.

   If a quorum does not exist, then no business shall be transacted except to adjourn the meeting. If no one objects, debate may continue, but the only vote that may be taken is the one for adjournment. If later in a meeting the number falls below quorum requirements, business is not interrupted unless a member raises concerns about the decision at hand.

   No members may vote on any motion in respect of which he or she may have a conflict of interest as determined by the Chair.

   Where, in the discretion of the Chair, the special knowledge of a given Committee member or members is required, the Chair may defer the discussion of a matter placed before the Committee pending the attendance of the member or members.

7. Administrative and Financial support

   Financial support will be provided by the MOHLTC. Administrative support will be provided by OPDP and PDRP staff. This includes, among other things, scheduling meetings, and developing and circulating agendas, meeting materials and minutes.

8. Remuneration and Reimbursement

   Each Steering Committee member is required to enter into an agreement with the MOHLTC.

   Steering Committee members will be paid a per diem, in an amount to be determined.

   Note: Steering Committee members are reimbursed for reasonable expenses related to travel, meals, accommodation and other out-of-pocket expenses in accordance with applicable Treasury

Board/Management Board of Cabinet directives such as the *Travel, Meal and Hospitality Expenses Directive.*

9. Meetings

There will be four to six meetings per year. Additional meetings may be scheduled on an as needed basis. Meetings will be held in the Greater Toronto Area and, in an effort to facilitate attendance, will be scheduled with maximum notice whenever possible. It is expected that members will attend each meeting in person due to the time-sensitive nature of the work and decisions. Steering Committee members may participate in a meeting by teleconference only with prior approval of the Chair.

A meeting may be cancelled at the call of the Chair if there are no issues on the agenda as of a week in advance of the meeting.

10. Minutes

The minutes of Steering Committee meetings are prepared by MOHLTC and/or CCO staff after each meeting with the assistance of the Chair as required. Names of the members present shall be entered in the minutes, which shall be approved at a later meeting of the Steering Committee or by other means, where the minutes may be corrected if necessary. The final minutes shall be approved by the Chair and the respective directors of the MOHLTC and CCO drug programs. Records of meetings shall be accurate minutes of the actual motions, resolutions, and results of deliberations. It is the intent of the Steering Committee to be transparent and publicly disclose their advice to Executive Officer, excluding any confidential data. Some of the Committee's recommendations may be summarized in other documents (e.g., transparency bulletins).

11. Re p o r t s

Where appropriate, reports on drug submissions/review or program advice shall be in writing, dated and signed. The authors of reports are required to follow the CED consultants / reviewers' guidelines regarding report content and format. After reviewing and considering the report, the Committee makes a recommendation to the Executive Officer. The Committee may make a recommendation to the Executive Officer in respect of any drug listing or any other matter related to the mandate of the CED, as it considers appropriate.

12. Co n s u l t a n t s

The Committee may request that the Executive Officer seek an opinion from an external consultant or a committee of external consultants. Services from these consultants are obtained through contractual arrangements and complement the expertise available on the Steering Committee. Any opinion from an external consultant to the Steering Committee shall be communicated to the Committee either orally or in writing. At the request of the Chair, the external consultant may participate in the Steering Committee meeting. The Committee may review these external opinions and provide any additional comments and recommendations to the Executive Officer, as appropriate.

13. Indemnification

The Ministry indemnifies Committee members against any claims, expenses or liabilities ("Claims") that may be incurred by a member by reason of being or having been a Steering Committee member. The indemnity applies only to Claims that are referable to the period during which the member was actually serving as a member of the Committee.

The indemnity does *not* apply with respect to Claims:

a) arising from any circumstances for which coverage is provided under an insurance policy or claims fund to the extent that the member is indemnified or covered under such policy or fund;
b) in which the member did not act honestly and in good faith with a view to the best interest of the Crown;
c) brought about or contributed to by the member's dishonesty, gross negligence or wilful misconduct if a judgement or other final adjudication adverse to the member establishes that there was dishonesty, gross negligence or wilful misconduct on the member's part which was material to the cause of action as adjudicated; or
d) brought against the member by the Crown.

In order to be entitled to indemnification under the member's agreement with the Ministry, in respect of any notice of a claim received by the member, the member must:

i. immediately and without delay deliver to the Ministry (through the Director of Legal Services of the Ministry of Health and Long-Term Care) a notice setting forth in reasonable detail the particulars of the Claim;
ii. upon the written request of the Ministry, furnish to the Ministry copies of any document, or provide to the Ministry any information that relates to the Claim that is in the possession or under the control of the member; and
iii. take all reasonable steps necessary to secure and preserve the member's rights in respect of the Claim.

The Ministry has the right to participate in or assume control of the negotiation, settlement or defence of any Claims. In no event is a member permitted to negotiate, settle, compromise or pay any Claims without the prior written consent of the Ministry. If the Ministry elects to participate in or assume control of the negotiation, settlement or defence of the Claim, the involved member is required to cooperate fully with the Ministry and to be represented by legal counsel chosen by the Ministry unless, in the opinion of such counsel, there would arise a conflict of interest. In the event of a conflict of interest, the member is entitled, after consulting with the Ministry, to retain legal counsel of his/her choice.

14. Conflict of interest

In addition to complying with the conflict of interest policy set out in this paragraph 14, Steering Committee members are required to conduct themselves in accordance with the conflict of interest rules set out in Ontario Regulation 381/07 made under the *Public Service of Ontario Act, 2006* ("PSOA Regulation"). It is the responsibility of each Steering Committee member to review the conflict of interest rules in the PSOA Regulation. If there is a conflict between the content of these terms of reference and the PSOA Regulation, the PSOA Regulation shall govern.

14.1 Definition

Members of the Steering Committee are prohibited from engaging in any activity or having any involvements or providing any services where such activity, involvement, or the provision of such services may have the effect of placing, potentially placing, or creating the appearance of placing the member's personal, pecuniary or professional interests in conflict with the interests of the Ministry or the member's duties to provide impartial advice to the Ministry.

A conflict of interest can be defined as a situation in which a public official or government appointee has a private or personal interest sufficient to influence or to appear to influence the objective exercise of his or her official duties. Similarly, a conflict of interest is said to exist "when the private interests of an individual are at variance with his or her official duties and responsibilities to the government." [Government of Canada, Ethical Conduct in the Public Sector: Report of the Task Force on Conflict of Interest (Ottawa: Supply and Services, 1984) p. 29].

14.2 Disclosure of Conflict of Interest

A Steering Committee member who has a personal or pecuniary interest, either individually or through his/her family, in a matter related to his or her duties to the Steering Committee, must, at the first opportunity, disclose the nature of the conflict of interest to the Chair of the CED and the Ministry ("family" is interpreted to include spouse, parents or children of the appointed member).

Members are required to:

a) complete and submit to the Chair of the CED and the Ministry a conflict of interest declaration form at the time of their appointment to the Steering Committee;
b) complete and submit to the Chair of the CED and the Ministry an updated conflict of interest declaration form every year; and
c) on an ongoing basis throughout the term of the member's appointment, disclose any conflicts of interest to the Chair of the CED and the Ministry as soon as such conflict comes to the attention of the member.

The Chair of the CED may make inquiries as he or she considers appropriate in response to a member's disclosure of a conflict or potential conflict or where the Chair has concerns that a conflict of interest rule

has been or is about to be contravened. Such inquiries may include discussing the matter with the member and notifying the Ministry about the conflict or potential conflict.

Where the Chair of the CED determines that there is a conflict of interest or there is a potential or perceived conflict of interest, the Chair of the CED shall give the member of the Steering Committee directions that he or she considers appropriate to address the actual, potential or perceived conflict. Subject to a direction from the Chair of the CED, if any, a Steering Committee member who has a conflict of interest in respect of a given matter must refrain from participating in anyway in such matter and must refrain from voting or attempting to influence any vote in respect of that matter. The Chair of the CED must record any declared conflict of interest and notify the Ministry of the nature of the conflict. The Chair of the CED is responsible for ensuring that all Committee members are mindful of this policy on conflict of interest and the PSOA Regulation.

Further, unless previously discussed and/or directed by the Ministry, members should not make public presentations at such events as conferences and workshops and/or accept sponsorship by manufacturers or pharmaceutical associations to speak or advise on general matters related to the Steering Committee or the Ministry so as to avoid creating the appearance of partiality or unfairness. This is applicable whether or not the Steering Committee member is financially rewarded for his/her services or participation in such events. (It is recognized, however, that from time to time Steering Committee members will be retained by manufacturers or pharmaceutical associations with respect to discrete projects that are not related to the Ontario Public Drug Programs. In such cases, Steering Committee members are still bound by the conflict of interest provisions set out above and in the PSOA Regulation.) It is essential that the Steering Committee be regarded as an independent advisory body, providing neutral and objective advice to the Executive Officer on scientific and technical matters relating to drug products. Accordingly, a Steering Committee member who has been contacted directly by a drug manufacturer (or a consultant/agent acting on behalf of a drug manufacturer) in respect of a drug submission or other issue being considered by the Committee or the Ministry must immediately disclose the nature of the contact to the Chair of the CED. Members are encouraged to request representatives of drug manufacturers to direct their inquiries to the Ministry or CCO for appropriate action and response.

15. Confidentiality

Steering Committee members will have access to confidential information presented to them in the performance of their duties on the Steering Committee. “Confidential Information” means information that is not available to the public and that, if disclosed, could result in harm to the Ministry or could give the person to whom it is disclosed an advantage and includes all data and information in oral, written, graphic, recorded or any other form which is disclosed to the member either directly or indirectly by the Ministry or its stakeholders (including drug manufacturers) in connection with the performance by the member of his/her Steering Committee duties or which the member may have acquired in the course of, or incidentally to, the performance of his/her duties.

All Confidential Information which comes into the possession of Steering Committee members is received by them on behalf of the Ministry and for the sole purpose of enabling the Steering Committee to provide advice to the Executive Officer. Both during and after the term of a member's appointment to the Steering Committee, the member is required to:

1. hold in confidence and treat as confidential all Confidential Information;
2. not use Confidential Information in a business or undertaking outside his or her appointment to the Committee;
3. not request or seek to obtain any Confidential Information, except to the extent that the member requires such Confidential Information to perform his or her duties;
4. not disclose, directly or indirectly, to any person, entity, or organization (including, if applicable, the member's organization and persons who work within the member's organization who have not entered into a confidentiality agreement with the Ministry) any Confidential Information without receiving prior written authorization from the Ministry. In the event that the member is required to disclose Confidential Information under law, the member shall, prior to such disclosure and tithe extent possible, consult the Ministry as to the proposed form and nature of the disclosure;
5. not accept a gift, directly or indirectly, in exchange for disclosing Confidential Information;
6. take all reasonable precautions to protect the Confidential Information from theft, loss and any other unauthorized access, use or disclosure (e.g. ensuring that all Confidential Information is stored securely; ensuring that all files or file cabinets containing Confidential Information are locked when not under the member's personal supervision and maintaining personal custody of all keys or combinations; safeguarding any computer passwords; etc.)
7. notify the Ministry in writing at the first reasonable opportunity if Confidential Information is stolen, lost or accessed by unauthorized persons; and
8. upon the termination of the member's appointment to the Steering Committee, destroy or return to the Chair of the CED or the Executive Officer all materials containing Confidential Information in whatever media or form and not make or retain any copies of the Confidential Information; and
9. act at all times in accordance with the requirements of the *Freedom of Information and Protection of Privacy Act*, the *Personal Health Information Protection Act, 2004*, and Ministry policies.

The member may allow an assistant (i.e. a person who provides clerical support to the member to assist the member in performing his or her duties) to have access to Confidential Information provided that such access by the assistant is reasonably necessary to enable the member to carry out his or her duties and the member takes reasonable measures to ensure that the assistant is apprised of and observes the confidentiality requirements described above.

16. Review and amendment of Terms of Reference

The foregoing Terms of Reference will come into effect on _____ and may be amended by the MOHLTC from time to time.