

# ADVISORY COMMITTEE ON PHARMACEUTICALS (ACP)

## Terms of Reference

The Advisory Committee on Pharmaceuticals (ACP) consists of representatives from the participating federal, provincial and territorial publicly funded drug plans and other related health organizations. This body provides advice to the CADTH Board of Directors and to the Common Drug Review (“CDR”) and Health Technology Assessment (“HTA”) Directorates to enable them to meet their goals and objectives.

**In these Terms of Reference, unless otherwise provided, the definitions set out in Appendix 1 attached hereto shall apply herein.**

### 1.0 Mandate

The mandate of the ACP is to provide advice:

- a) to the CADTH Board of Directors and the HTA Directorate on HTA pharmaceutical issues and assessments;
- b) to the CADTH Board of Directors and the CDR Directorate on the Common Drug Review (CDR) process; and
- c) to the CADTH Board of Directors and the two directorates on more effective sharing of pharmaceutical information nationally and internationally.

### 2.0 Responsibilities

The roles and responsibilities of the ACP are to:

- a) approve and prioritize topics for HTA pharmaceutical assessments;
- b) provide feedback on the HTA and CDR processes to the CADTH Board of Directors and the HTA and CDR Directorates;
- c) recommend, as needed, suitable candidates for nomination to Canadian Expert Drug Advisory Committee (CEDAC); as well as for the Scientific Advisory Committee (SAC);
- d) file Submissions or Requests for Advice to the CDR Directorate;
- e) serve as a liaison for HTA pharmaceutical assessment projects;

- f) undertake specific tasks related to HTA pharmaceutical assessments, or the CDR process as may be assigned by the CADTH Board of Directors;
- g) facilitate consultation and information exchange among the publicly funded drug plans, relevant organizations and CADTH;
- h) identify:
  - developments in pharmaceutical assessment
  - linkages with organizations relevant to CADTH's mandate
  - methods to promote CADTH
- i) work with CADTH's Scientific Advisory Committee in the development of methodologies and criteria for the prioritization of topics for HTA pharmaceutical assessments;
- j) identify important trends in the development and utilization of pharmaceuticals, and significant issues relevant to pharmaceutical assessment.

### 3.0 Accountability

The ACP is a jurisdictional advisory committee of CADTH that reports to the CADTH Board of Directors through ACP's Chair.

## 4.0 Membership

### 4.1 Composition

The ACP consists of Voting Members, Ex-officio Members and Observers.

a) ***Voting Members:***

There shall be one (1) Voting Member representing each Participating federal, provincial and territorial publicly funded drug plan (hereinafter referred to individually as "Drug Plan" and collectively as the "Drug Plans").

b) ***Ex-officio Members:***

The most senior staff member from each of the CADTH HTA and CDR Directorates shall be appointed as an Ex-officio Member of the ACP.

c) ***Observers:***

Each of the following organizations may appoint one Observer:

- i. Patented Medicine Prices Review Board

- ii. Canadian Institute for Health Information
- iii. Health Care Policy Directorate (Health Canada)
- iv. Marketed Health Products Directorate (Health Canada)
- v. Therapeutic Products Directorate (Health Canada)
- vi. Biologics and Genetic Therapies Directorate (Health Canada)
- vii. hospital pharmacist

The ACP Chair, in consultation with the CADTH secretariat, may invite other observer(s) to attend ACP meetings from time to time, as he/she deems appropriate.

#### **4.2 Appointment/Nomination Process**

Each Voting Member shall be appointed by the Drug Plan he/she represents.

In consultation with the ACP Chair, each Observer shall be appointed by the organization which has been given observer status as per the terms of reference.

#### **4.3 Term of Appointment**

Each Voting Member serves at the pleasure of the Drug Plan appointing him/her.

Each Observer serves at the pleasure of the organization appointing him/her.

#### **4.4 Committee Officers**

The officers of the ACP shall be the Chair and Vice-Chair.

The Voting Members shall choose, by majority vote, from their group the Chair and Vice-Chair.

The terms of the Chair and Vice-Chair shall be two years. The Chair will be chosen at the first meeting held in an even numbered year; and the Vice Chair will be chosen at the first meeting held in an odd numbered year.

The Chair shall preside at all meetings of the ACP. In addition, the Chair is responsible for reporting on ACP's activities to the CADTH Board of Directors and shall act as the key liaison between ACP and CADTH. The Chair shall be the sole spokesperson for ACP.

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

#### **4.5 Voting Rights**

Each Voting Member shall be entitled to one vote on all matters coming before the ACP.

Observers shall be entitled to attend all ACP meetings but shall not be entitled to vote.

Ex-officio Members shall be entitled to attend all ACP meetings and shall be entitled to participate in discussion but shall not be entitled to vote.

## **5.0 ACP Meetings**

### **5.1 Frequency of Meetings**

Teleconferences are held monthly or more frequently as required. Face-to-face meetings are held twice yearly.

### **5.2 Notice of Meetings**

Meetings of the ACP may be held at any time and place in Canada to be determined by the Voting Members, provided that reasonable notice of such meeting shall be given in advance to each Voting Member.

### **5.3 Quorum**

The quorum at meetings of the ACP shall be a majority of the appointed Voting Members.

### **5.4 Attendance**

All Voting Members shall attend ACP meetings. An ACP Member who is unable to attend a face to face meeting may request permission from the Chair to participate in the meeting via other means such as video conference, teleconference or other communications facilities. 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 Voting Members, Observers and Ex-officio Members, only the following persons shall be entitled to attend ACP meetings but have neither the right to participate, except as noted below, nor the right to vote:

- a) (the) CADTH President and CEO;
- b) CDR Directorate staff;
- c) HTA Directorate staff; and
- d) such other CADTH staff as the CADTH President and CEO may determine from time to time.

The CADTH staff attending the meeting shall serve as a resource to ACP. They will provide administrative and secretariat support and may actively participate in the presentation of information or discussions at the request of the ACP Chair. They shall also assist in obtaining additional information and/or expert advice at ACP's request.

## **5.6 Agenda**

The ACP meeting agendas are developed by the ACP Chair in consultation with the CDR and HTA Directorates.

## **5.7 Decisions**

No decisions 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 Voting Members participating in the meeting shall be required.

## **5.8 Records of Meetings**

Minutes shall be kept of all ACP meetings and shall be signed by the Chair of the ACP.

A copy of the minutes of every ACP meeting shall be sent to Voting Members, Observers, Ex-officio Members, relevant CADTH staff and the CADTH President and CEO.

## **6.0 Reimbursement of Expenses**

Voting Members shall be entitled to be paid by CADTH reasonable expenses incurred by them in the performance of their duties.

Teleconference expenses are paid by CADTH, as required.

The reimbursement of any additional expenses will require CADTH Board of Directors approval in advance.

## **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 at any time, and from time to time, by the CADTH Board of Directors.

## **7.3 Confidentiality**

It is the responsibility of Committee 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 Committee 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 and not generally available to the public. A Committee member shall not use information obtained as a result of his or her involvement on the Committee for his or her personal benefit. Each Committee member shall avoid activities which 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.

## **7.4 Sub-committees**

The ACP may form sub-committees and/or task groups to fulfill its mandate.

## APPENDIX 1

### CDR Definitions

In the Terms of Reference of the Advisory Committee on Pharmaceuticals, the following definitions apply, unless otherwise provided.

**ACP** – Advisory Committee on Pharmaceuticals.

**ACP Member** – a member of the ACP.

**ACP Terms of Reference** – the Terms of Reference established for the ACP by the CADTH Board of Directors.

**Applicant** – the person, corporation or entity filing a Submission.

**Budget Impact Analysis or BIA** – an analysis of the impact of a new drug product on drug plan expenditures.

**Business Day** – any day, other than a Saturday, Sunday, statutory holiday, or company holiday on which the Canadian Agency for Drugs and Technologies in Health office in Ottawa, Ontario is open for business during normal business hours.

**CADTH** – Canadian Agency for Drugs and Technologies in Health, a body corporate duly incorporated under the laws of Canada.

**CADTH Board of Directors** - The CADTH Board comprises 13 Directors appointed by the Deputy Ministers of Health of the federal government, nine provinces, and three territories. The Board is accountable to its Members, the participating federal, provincial and territorial health ministries, for the delivery of CADTH's programs.

**CDR** – Common Drug Review

**CDR Director** – the CADTH staff person appointed as director of the CDR Directorate.

**CDR Directorate** – the directorate established within CADTH to support the CDR process.

**CDR Nominating Committee** – the nominating committee established according to the CEDAC Terms of Reference for recommending candidates for appointment to CEDAC.

**CEDAC** – Canadian Expert Drug Advisory Committee

**CEDAC Brief** – a brief prepared by CDR Directorate staff for the members of CEDAC consisting of:

- i) An itemization of the Manufacturer's Submission to CDR
- ii) The Reviewers' Reports relating to the Submission
- iii) The Manufacturer's written comments about the Reviewers' Reports, if any, and
- iv) The Reviewers' Replies, if any.

**CEDAC Member** – a member of the Canadian Expert Drug Advisory Committee

**CEDAC Terms of Reference** – the Terms of Reference established for CEDAC by the CADTH Board of Directors.

**Clarification** – a written response, approved by the CEDAC Chair, to a Drug Plan's Request for Clarification of a CEDAC Recommendation.

**Clinical Review** – the critical appraisal of the published and unpublished information about the safety, efficacy, effectiveness (when available) and use of a Drug in the management of a disease or condition.

**Clinical Reviewer** – a Reviewer who conducts a Clinical Review.

**Conflict of Interest Guidelines or COI Guidelines** – the conflict of interest guidelines established by CADTH for experts committee members, reviewers and external experts.

**Confidential Information** has the meaning given to it in the Confidentiality Guidelines.

**Confidentiality Guidelines** – the guidelines respecting confidentiality adopted by the CADTH in respect of CDR.

**Directive** – a written directive from CADTH amending, interpreting or clarifying any process, procedure, guidelines, terms of reference, code of conduct or document relating to the CDR.

**Drug** – a substance, considered to be a drug under the Canadian Food and Drugs Act, which is sold for human use.

**Drug Plans** – the participating, publicly-funded federal, provincial and territorial drug plans.

**Ex-Officio Member** - This individual holds a position on a committee by virtue of her/his office/position at CADTH. The ex-officio member is entitled to participate in the meetings but is not entitled to vote.

**Final Reasons for Recommendation** – the Reasons for Recommendation attached to the Notice of Final Recommendation.

**Final Recommendation** – the applicable Recommendation, or Recommendation on Reconsideration, attached to the Notice of Final Recommendation.

**Formulary** – a list of Drugs that are covered as benefits as determined by each Drug Plan.

**F/P/T** – federal, provincial and territorial

**Information Specialist** – a CADTH staff member who specializes in information retrieval and management in a health sciences research environment.

**Manufacturer** – a Drug manufacturer

**New Chemical Entity** – an active moiety that has not been previously approved for sale in Canada by Health Canada and marketed in Canada.

**New Combination** – consists of two or more active moieties that have not previously been approved for sale in Canada and marketed in Canada in that combination. It may consist of either two or more new active moieties or two or more old active moieties or a combination of new and old active moieties.

**New Information** – the new clinical trial(s) or information that will significantly affect cost-effectiveness and which do not form part of the original Submission.

**NOC or NOC/c** – Notice of Compliance or Notice of Compliance with Conditions issued by Health Canada, giving authorization to market a drug.

**Notice of Final Recommendation** – the notice issued according to *Section 3.1* of the *Procedure for Common Drug Review*.

**Observers** - Observers to the ACP can be appointed, in consultation with the ACP Chair, by organizations which have been given observer status as per the terms of reference. Each Observer serves a term as defined by the organization he/she has been appointed by. Observers are entitled to attend all ACP meetings but are not entitled to vote.

**Participants** – unless otherwise stated, CADTH staff, Reviewers, CEDAC Members and any experts retained to assist in the CDR process.

**Participating Drug Plans:** a publicly funded drug plan administered by a member of CADTH.

**Participating F/P/T Health Ministry:** a Member of CADTH that is either a federal, provincial or territorial government as represented by its Deputy Minister of Health.

**Pharmacoeconomic Review** – the critical appraisal of the published and unpublished information about costs and consequences of Drugs and their impact on individuals, health care systems and society (i.e. value for money of Drugs).

**Pharmacoeconomic Reviewer** means a Reviewer who conducts a Pharmacoeconomic Review.

**Priority Review** – a preferred status in the review queue and on the CEDAC agenda for drugs meeting the Priority Review criteria. All steps in the CDR procedure are completed and timelines are not truncated.

**Reasons for Recommendation** – the detailed, written reasons given by CEDAC regarding Recommendations, or Recommendations on Reconsideration, made by CEDAC.

**Recommendation** – an evidence-based recommendation, made after consideration of Review Criteria, by CEDAC in response to a Submission made by a Manufacturer, ACP or by one or more Drug Plans.

**Recommendation on Reconsideration** – the conclusion reached by CEDAC on reconsideration of the Submission as described in *Section 2.4.4(a)* of the *Procedure for Common Drug Review*.

**Reconsideration Brief** – the CEDAC Brief, CEDAC Recommendation, CEDAC Reasons for Recommendation. Manufacturer's Request for Reconsideration.

**Record of Advice** – the detailed advice given by CEDAC in reply to a Request for Advice.

**Reply** – a response by a Reviewer to a Manufacturer's comments about a Clinical or Pharmacoeconomic Review conducted by that Reviewer.

**Report** – a report produced by a Reviewer in accordance with Reviewer Guidelines.

**Request for Advice** – a written request made by ACP or by one or more Drug Plans to CEDAC for advice on specific therapeutic, clinical or pharmacoeconomic issues.

**Request for Clarification** – a written request from a Drug Plan for clarification of a CEDAC Recommendation.

**Request for Reconsideration** – a written request from Manufacturers to have a CEDAC Recommendation reconsidered.

**Resubmission** – the request by a Manufacturer, Drug Plan or the ACP to have an original Submission reviewed again via the CDR process on the basis of New Information that was not previously provided in the original Submission.

**Review Criteria** – the following criteria are considered by CEDAC in making a listing recommendation:

- i) Clinical studies, demonstrating the safety, efficacy and effectiveness compared to alternatives
- ii) Therapeutic advantages and disadvantages relative to accepted therapy
- iii) Cost-effectiveness relative to accepted therapy.

**Reviewer** – an expert selected to conduct a clinical or pharmacoeconomic review in accordance with Reviewer Guidelines established by the CDR Directorate.

**Reviewer Guidelines** – the CADTH guidelines adopted by the CDR Directorate that set out how a Reviewer must conduct, and report on, a Clinical Review or a Pharmacoeconomic Review.

**Scientific Advisory Committee (SAC)** - CADTH expert advisory committee that provides advice regarding scientific methods and research-related issues to the CADTH Board of Directors, and the HTA, CDR and COMPUS Directorates.

**Submission** – A submission to the CDR consisting of:

- i) A written application made by a Manufacturer, together with supporting documentation, to have a Drug listed on the Drug Plans' formularies; or
- ii) A written request made by ACP or by one or more Drug Plans, together with supporting documentation, if any, to consider the listing status of Drugs already on formularies, to

conduct Drug class reviews or to undertake any other Drug-related review(s) as required. Submission includes a **Resubmission**.

**Submission Coordinator** – a CDR Directorate staff person assigned to coordinate the activities associated with the review of a Submission or Request for Advice.

**Submission Guidelines** – the guidelines adopted by CADTH that outline how Submissions from Manufacturers must be prepared and submitted.

**Submission Requirements** – information the CDR Directorate needs to perform the clinical and pharmacoeconomic reviews of drugs and additional information the Drug Plans use in making listing decisions. The Submission Requirements consolidate the requirements for the CDR and the Drug Plans.

**Voting Members:** means a Member appointed by each Participating federal, provincial and territorial publicly funded drug plan (hereinafter referred to individually as “Drug Plan” and collectively as the “Drug Plans”) to a jurisdictional advisory committee. The appointed Voting member shall have the right to designate, from time to time, a nominee to represent, and to vote on behalf of and in place of such Voting Member, at meetings of the jurisdictional advisory committee.