

# **Atlantic Common Drug Review**

---

## **Atlantic Expert Advisory Committee**

### **Terms of Reference**

September 2010

# Atlantic Expert Advisory Committee

## TERMS OF REFERENCE

The Atlantic Expert Advisory Committee (AEAC) is an independent advisory group composed of physicians, pharmacists and other persons with expertise in drug therapy and drug use evaluation. The committee makes recommendations to the Atlantic Ministers of Health (or delegate) regarding the listing of drugs on the Atlantic provincial drug plan formularies. The approach is evidence-based and the advice reflects the best available medical and scientific knowledge and current clinical practice.

### 1.0 Mandate

The mandate of the AEAC is advisory in nature and is to:

- a) review the clinical and pharmacoeconomic evidence of drugs under review
- b) make recommendations regarding the coverage of drug therapies, including conditions and/or criteria for coverage where appropriate.

### 2.0 Responsibilities

The AEAC's responsibilities are:

- a) to consider submissions made by drug manufacturers or the Atlantic Pharmacare Review Committee (APRC) (i.e. Atlantic Drug Plan Managers)
- b) to evaluate submissions in terms of therapeutic advantages and disadvantages and cost-effectiveness of the drug or drug class under review
- c) to provide after consideration of a submission, recommendations to the Atlantic Ministers of Health
- d) to provide advice and, if appropriate, a change to a previously issued recommendation
- e) To provide feedback to the ACDR secretariat regarding the quality of the reviews.

### 3.0 Accountability

The AEAC is an expert advisory committee of the Atlantic Common Drug Review that reports to the Atlantic Ministers of Health (or delegate) via the APRC.

### 4.0 AEAC Membership

#### 4.1 Composition

The AEAC shall be composed of ten members, including a chair and vice-chair.

The members must hold qualifications as a physician, a pharmacist, an economist or other professional designation with expertise in one or more areas such as, but not limited to:

- a) general practice
- b) internal medicine
- c) geriatric medicine
- d) hospital or community pharmacy
- e) clinical pharmacology
- f) pharmacoeconomics
- g) clinical epidemiology

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

The nomination of AEAC members shall be undertaken by the APRC. Each provincial drug plan will appoint members from their province. Membership will be reviewed every two years by the APRC to ensure there is appropriate expert and provincial representation.

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

All AEAC members' terms shall be for a term of two years, with an option to renew this term. The appointment of members who miss more than two consecutive meetings will be reviewed by the APRC.

#### **4.4 Committee Officers**

The officers of AEAC shall be the Chair and Vice-Chair who shall be appointed by the APRC from the AEAC members. Their respective appointment shall be for a term of two years and may be renewed at the discretion of the APRC.

The Chair shall preside at all meetings of AEAC. 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 Committee**

An individual may resign as an AEAC member at any time upon written notification to the ACDR Secretariat.

#### **4.6 Voting Rights**

Each AEAC member, excluding the chairperson of the meeting, shall be entitled to one vote on all matters coming before committee. However, in the event of a tie, the chairperson of the meeting shall have a casting or deciding vote.

## **5.0 AEAC Meetings**

### **5.1 Conduct of Meetings**

Meetings will be conducted by generally accepted rules of order.

### **5.2 Frequency of Meetings**

The AEAC shall hold meetings as required to carry out its mandate and responsibilities. The AEAC will generally meet at least four times annually.

### **5.3 Location of Meetings**

Meetings will be held in Halifax. Attendance by conference call can be arranged when required.

### **5.4 Quorum**

The quorum at meetings of the AEAC shall be a majority of the voting members with active appointments, including the chair. Each vote requires a quorum.

### **5.5 Member participation**

Members will be responsible for reviewing the meeting package materials in preparation for each meeting and for leading the discussion on specifically assigned topics.

### **5.6 Attendees**

In addition to AEAC members, the following persons shall be entitled to attend AEAC meetings:

- a) Members of the Atlantic Pharmacare Review Committee (APRC)
- b) ACDR coordinator
- c) Others, such as representatives of Atlantic Provincial Drug Plans, experts, reviewers, etc., as approved by the APRC may be invited to attend as observers.

### **5.7 Agenda**

The AEAC meeting agendas shall be developed by the APRC in consultation with the ACDR coordinator.

### **5.8 Conflict of Interest Disclosure**

At the commencement of every meeting, the Chair shall ask AEAC 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 for the Atlantic Expert Advisory Committee (see Appendix 1).

## **5.9 Decisions**

No decision can be made unless there is a quorum.

### **5.9.1 Recommendations**

Every AEAC recommendation shall be decided by a majority of votes. Every AEAC member participating in the meeting (with the exception of the chairperson of the meeting) must vote (i.e., for or against) on the motion for the adoption of a recommendation; a member cannot abstain from voting. However, in the event of an equality of votes, the chairperson of the meeting shall cast the deciding vote.

After considering a submission, the AEAC shall make a recommendation to the Atlantic Ministers of Health regarding the benefit status of the drug on Atlantic Provincial Drug Plan Formularies, including reasons for the recommendation. This may include, but is not limited to, recommendations to list, not list or delist a drug, restrict coverage of a drug to a specific indication, or limit duration of therapy.

## **5.10 Records of Meetings**

Minutes of meetings shall be prepared by the ACDR coordinator and, after their approval by the AEAC at the following meeting, shall be sent to all Atlantic Provincial Drug Plans.

## **6.0 Remuneration/Honoraria**

Honoraria and travel expenses will be paid in accordance with the provincial Government policy in the province where the member resides.

## **7.0 General Provisions**

### **7.1 Secretariat and Administrative Support**

Secretariat and administrative support for AEAC is provided by Nova Scotia Pharmaceutical Services and jointly funded by the Atlantic Provincial Drug Plans.

### **7.2 Amendment to Terms of Reference**

These Terms of Reference may be amended at any time, and from time to time, by the APRC.

## **Appendix 1**

### **Conflict of Interest Guidelines for the Atlantic Common Drug Review Atlantic Expert Advisory Committee (AEAC) Members**

#### **1.0 Purpose of the Guidelines**

1.1 These Conflict of Interest Guidelines (COI Guidelines) are intended to ensure the highest ethical standards and maintenance of the integrity of the Atlantic Common Drug Review (ACDR) process. The principles of transparency and disclosure are essential to achieving these objectives. By disclosing relevant personal, occupational or financial connections; or interests with pharmaceutical companies and affected organizations, participants in ACDR activities will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of the ACDR process.

#### **2.0 Definitions**

2.1 In these COI Guidelines, the word “participant” means, unless otherwise stated, ACDR secretariat, reviewers, AEAC members, and any experts and consultants retained to assist in the ACDR process.

2.2 In these COI Guidelines, the word “party” means a drug manufacturer who files a submission to have a drug listed on the drug plan formularies in an Atlantic jurisdiction, (including such drug manufacturer’s parent corporation, subsidiaries, affiliates and associated corporations) or organizations, including direct competitors, whose interests are affected by a drug submission filed by a drug manufacturer.

#### **3.0 Applicability**

3.1 These COI Guidelines apply to all participants in the ACDR process.

#### **4.0 Scope of Conflict of Interest**

4.1 A conflict of interest refers to situations in which personal, occupational or financial considerations may affect, or appear to affect, the objectivity or fairness of participants in the ACDR process. A conflict of interest may be real, potential or perceived in nature.

4.2 A real conflict of interest arises where a participant in the ACDR process has a private or personal interest, for example, a close family connection such as a spouse or child, or financial interest, with a party.

4.3 A potential conflict of interest may arise when a participant in the ACDR process has a private or personal interest, such as an identified future commitment, with a party.

4.4 A perceived (or apparent) conflict of interest may exist when a reasonable well-informed person has a reasonable belief that a participant has a conflict of interest, even if there is no real conflict.

## **5.0 Disclosure**

5.1 All participants must disclose any conflict of interest, as defined above, to the ACDR coordinator at the earliest opportunity and before participants undertake any activities on behalf of the ACDR process.

5.2 The obligation to disclose is ongoing and participants must continue to inform the ACDR coordinator of any conflict of interest that arises, at the earliest opportunity.

5.3 Potential relevant conflicts of AEAC members and ACDR reviewers are reviewed at each AEAC meeting.

### **5.4 Part I Disclosures**

Without limiting the generality of the foregoing, participants are required to disclose all interests or activities that occurred during the past two years to the ACDR coordinator.

Information shared may pertain to:

- i) receipt of funding for, or payment of, travel by a party
- ii) receipt of funding or honoraria from a party to be a speaker
- iii) receipt of funding or honoraria from a party for writing articles or editorials
- iv) receipt of funding or honoraria from a party for organizing conferences
- v) receipt of funding or honoraria from a party for giving educational lectures
- vi) receipt of any other financial support or honoraria from a party.

### **5.5 Part II Disclosures**

Without limiting the generality of the foregoing, participants are required to disclose all interests or activities that occurred during the past five years to the ACDR coordinator.

Information shared may pertain to:

- i) employment with a party
- ii) receipt of payment as an advisor or consultant for a party
- iii) receipt of payment from a party for academic appointments (including endowed chairs)
- iv) receipt of funding or honoraria from a party for personal education
- v) receipt of funding or honoraria from a party for research grants.

5.6 Participants are required to disclose all of their stocks or stock options totaling more than \$10,000 (excluding mutual funds).

## 5.7 Part III Disclosures

In addition to disclosures made under Sections 5.4 and 5.5, participants are required to disclose any other activities or interests that affect or appear to affect the participant's objectivity or fairness.

5.8 Participants are required to disclose all potential or pending future commitments with a party. The information to be disclosed relates to all interests and activities as described in Part 1 and Part II Disclosures outlined in sections 5.4 and 5.5.

5.9 All participants, other than the ACDR secretariat, are required to disclose to the ACDR coordinator, at the first opportunity, any contact with a party relating to a submission.

5.10 Before each AEAC meeting, the Chair shall ask members if they have any conflicts of interest to disclose. Any AEAC member with a conflict must disclose it and comply with the COI Guidelines and the Code of Conduct.

5.11 Participants shall not be involved in a submission in which they have a conflict of interest.

5.12 The AEAC Chair, in consultation with the ACDR coordinator, has the authority to determine if the circumstances or interests of a participant amount to a conflict of interest in respect to a submission that is before AEAC.

## 6.0 Confidentiality

6.1 Participants are expected to respect the confidentiality of any materials provided as part of the ACDR process. No participant shall knowingly divulge any such information to any person other than another participant, unless the participant is legally required to do so. A participant shall not use information obtained as a result of his or her involvement in the ACDR process for his or her personal benefit. Each participant shall avoid activities which might create appearances that he or she has benefited from confidential information received during the course of his or her activities with the ACDR process.