

December 14, 2007

Terms of Reference

Introduction

The Best Medicines Coalition (BMC) is a broad-based alliance of organizations and individuals promoting informed public policy, education, care, research and consumer-focused issues related to drug life cycle management, access to safe, effective and good quality drugs and health policy development. The members of the BMC represent millions of Canadians living with, or affected by, chronic disease or illness.

The BMC's primary focus is to be a meaningful participant in Canada's public policy and processes for prescription drugs to ensure appropriate review times; to ensure access to prescription medications in a broad based formulary; and to support the implementation of an effective surveillance system to monitor the ongoing safety of a drug once it is approved and in the market place, called life cycle drug management.

By definition, 'Best Medicines' as part of the name of the coalition, refers to the best evidence-based treatment and therapies for individuals living with disease or illness, including medications, medical devices to test and administer specified doses of medication, alternative therapies, and other therapeutics to which individuals require rapid and equitable access for preventing complications and for sustaining their health, well-being, and quality of life.

Mission

The Best Medicines Coalition (BMC) is committed to safe and timely access to the best evidenced-based medicines for all Canadians.

Goals

Through ethical partnerships between the Best Medicines Coalition, provincial and federal governments, non-profit and private sectors and other relevant stakeholders including disability and disease groups, our goals are to:

- Inform Canada's public policy related to drug life cycle management to ensure that Canadians have timely access to the best medicines relative to other developed countries;
- Ensure the implementation of a pan-Canadian system that provides efficient, equitable access to the best evidence-based medicines for all Canadians;
- Partner with governments and other relevant stakeholders to develop an effective model for the meaningful and equitable inclusion and participation of consumers/patients in Canada's drug life cycle management system and health policy development; and
- Further public awareness of relevant issues within the BMC Mission.

Participation

Participants in the BMC consist of:

1. Representatives of organizations, and individuals, who are living with or affected by a disease or health condition;
2. One Chair elected by the Steering Committee and who shall be a person living with or affected by a disease or health condition and willing to share with governments and the public their personal and community experience;
3. One Vice-Chair elected by the Steering Committee and who shall be a person living with or affected by a disease or health condition and willing to share with governments and the public their personal and community experience;
4. One Treasurer appointed by the Steering Committee and who shall be a person living with or affected by a disease or health condition;
5. An Operations Committee consisting of four persons elected from and by the Steering Committee;
6. A Steering Committee of members who are non-elected individuals living with or affected by a disease or health condition and demonstrating community leadership on BMC focused issues;
7. A paid Executive Director. The paid Executive Director shall be an “Ex-Officio” member;
8. A paid Coordinator. The paid Coordinator shall be an “Ex-Officio” member; and
9. A paid Accountant. The paid Coordinator shall be an “Ex-Officio” member.

The Chair shall be elected by a vote of the Steering Committee for a two-year term of office. For continuity, the out-going Chair shall serve for an additional year on the Operations Committee. The Operations Committee shall be elected from the Steering Committee membership for a one-year term with possibility for re-election. The Vice-Chair shall be a member of the Operations Committee who is elected by a vote of the Steering Committee for a one-year term of office. All members have an equal voice and a vote.

BMC is both an unincorporated and non-profit organization.

BMC Participant/Member Responsibilities

- a) Representatives of organizations should be appointed by their organizations to attend coalition meetings/teleconferences, and/or other health related meetings. It will be the responsibility of these representatives to update or report back to their organizations about issues and activities of the BMC. Individuals whose goals are aligned with those of the BMC and who are living with or affected by a disease or health condition may also join BMC and choose the issues in which they participate.
- b) Through the member organization, representatives to the BMC may or may not agree to lend their name to the Coalition for use in BMC materials (e.g. letters,

- news releases, fact sheets) on an issue-by-issue basis. BMC participants will be asked to opt in or out on any specific issue. To this end, written notice with the given issue or document will be circulated with a set time to opt in or opt out. Silence will be understood as consent, therefore, anyone who fails to reply by the deadline will be understood to have opted in.
- c) Participants in BMC will assist in work plan activities (attend meetings, add sit on committees, prepare reports, advise on BMC documents).
 - d) Participants will make recommendations on coalition issues related to the BMC work plan and activities.
 - e) The Steering Committee shall hold at least two meetings per year (face-to-face or teleconference). A quorum for meeting will be 50 per cent plus one of voting members. Notes will be taken for meetings and distributed with action items and responsibilities.
 - f) All participants will be asked to attend an Annual Review Meeting and Strategy Session.
 - g) Participants can select issue areas of interest and all those expressing interest in a topic will become a team who will facilitate all work on that issue including meeting attendance, policy papers.

Chair Responsibilities

- a) The Chair shall act as spokesperson for the BMC or may delegate other participants to speak on behalf of BMC.
- b) The Chair will have other Steering Committee members as co- signers of official documents on the part of BMC if they have contributed to the document.
- c) The Chair will act as primary contact for sponsors, government and member organizations. However, the BMC paid Executive Director shall also have contact with sponsors.
- d) The Vice-Chair will be appointed as an alternative to the Chair if he or she is unable to attend a meeting or conference on behalf of the BMC. If the Vice-Chair is not available, any other qualified member may be appointed as an alternative.
- e) In conjunction with the Operations Committee, the Chair will oversee the BMC budget and report on financials.
- f) The Chair or delegate will lead each meeting or teleconference and request declaration of conflict of interest (as per conflict of interest guidelines).
- g) The Chair will provide verbal or written updates to members via bi-annual reports and to sponsors as requested. The Chair will ensure the Operations Committee meeting notes are distribute to Steering Committee members as a regular update.
- h) The Chair will empower all members to participate in a meaningful, equitable way in all BMC discussions and decision-making processes.
- i) The Chair will support and work to capacity build core competencies within the membership to enable their equitable and meaningful participation in internal and external discussions, meetings, conferences, etc.
- j) The Chair will take his/her direction from the Operations Committee and the BMC Steering Committee Membership.

Vice-Chair Responsibilities

- a) The Vice-Chair, in the absence of the Chair, will be Acting Chair.

Treasurer's Responsibilities:

- a) In conjunction with the Operations Committee, Chair and Accountant, the Treasurer will oversee the BMC budget and report on financials.
- b) In conjunction with the Accountant, the Treasurer will have co-signing authority on BMC cheques, whereby two signatures are required for all cheques over \$1000.

Operations Committee Responsibilities:

- a) The Operations Committee will serve as advisors and actively assist in the leadership of BMC;
- b) in conjunction with the Chair, the Operations Committee oversee the BMC budget and report on financials;
- c) assist the Chair with meetings or teleconferences and request declaration of conflict of interest (as per conflict of interest guidelines);
- d) be available and accessible for quick response and operational decisions;
- e) act as spokespeople for the BMC on related issues.
- f) attend meetings and/or represent the BMC when needed;
- g) assist in capacity building within the Steering Committee and BMC participants; and
- h) act as project/team leaders on BMC issues and work with other team members to draft position papers and attend meetings.

Executive Director Responsibilities

- a) The paid Executive Director will report directly to the Chair.
- b) The paid Executive Director will work closely with the Chair, topic leaders and members to develop, approve and implement a strategic work plan and budget, which will reflect activities and expected expenditures for 6 months to 1 year.
- c) The paid Executive Director will ensure that an agreement has been signed with BMC and its Chair.
- d) In conjunction with Chair and Operations Committee, prepare an annual report and bi-annual report.
- e) Other responsibilities as assigned upon agreement that these coincide with or replace others as higher priorities in the work plan.

Coordinator Responsibilities

- a) The paid Coordinator will report directly to the Executive Director.

- b) The paid Coordinator will ensure that an agreement has been signed with BMC and its Chair, with all responsibilities outlined within that agreement.
- c) The paid Coordinator will take, distribute and archive minutes of all meetings.

Accountant Responsibilities

- a) The paid Accountant will report directly to the Chair, Treasurer and Executive Director.
- b) The paid Accountant will maintain all financial records and provide monthly updates to the Chair, Treasurer and Executive Director on finances.
- c) The paid Accountant will issue cheques for all expenses, and, along with the Treasurer, be the co-signer on all cheques over \$1000.
- d) The paid Accountant will provide an annual financial report for inclusion in the annual report.

Reporting relationships

The BMC paid Executive Director will provide support as agreed upon in the work contract.

The BMC will produce bi-annual and annual progress reports for sponsors and others, as well as for participant organizations and individuals. For-profit organizations that have financially supported BMC, and other donors or supporters from government and elsewhere, will be acknowledged in these reports. Other specific reports will be generated on an as needs basis.

All BMC representatives/organizations must abide by the terms of the Conflict of Interest Guidelines (see Attachment 1).

At the start of every meeting, the Chair will ask participants if they have any conflicts of interest to disclose. Any participant with a conflict must disclose such conflict and comply with the Conflict of Interest Guidelines.

Meetings

The BMC will hold meetings as required to carry out its strategic work plan activities. In addition to BMC members, participants/ observers will be permitted to attend with prior written notification to all BMC organizations/representatives.

Amendment to Terms of Reference

These terms of reference may be amended at any time, and from time-to-time, by the BMC after appropriate consultation and discussion regarding risk management issues or areas which BMC should or must consider, and for which BMC must establish criteria or guidelines. As such it is a living document.

Guiding Principles and Values of BMC

The BMC believes that excellence in health care is a fundamental right in Canada. We believe we have an obligation and moral responsibility to work towards all parties engaged in providing health services, be they governments, for profit and non profit organizations, or citizens are transparent in their motivations, methods and activities. By so doing we encourage the development of practices that are fair, equitable, necessary, and will be of benefit to all concerned. In turn, the BMC pledges to be transparent, respectful, and accountable to participant organizations and individuals, the public, and partners with whom BMC engages in various activities.

The BMC strives to achieve its mission and goals for Canadians and at the same time to build balanced external partnerships/relationships which will benefit all parties. To achieve this, the BMC has set out Principles and Codes for Ethical Conduct and Partnerships (Attachment 2).

ATTACHMENT 1

BMC CONFLICT OF INTEREST GUIDELINES

Volunteers

All participants are volunteers who come together for a common purpose. Participants bring their personal values and the interests of their participating organizations with them, on the understanding that the goals of the Best Medicines Coalition (BMC) will take precedence.

Defining Conflict of Interest

Conflict of interest exists when a person has a private or job-related interest potentially sufficient to influence how she or he might conduct BMC business. Conflict exists whether he or she is actually influenced.

Conflict of interest may arise for any number of reasons but those most commonly encountered by coalitions would fall into one of the following broad categories.

- Interest in personal revenues dependent on BMC decisions – refers to employees, consultants and contractors receiving income from BMC. These individuals relinquish membership and voting privileges to do so.
- Commitment or obligation to incompatible goals of another organization – refers to the assumption that the mission and goals of BMC are accepted by voting members and that BMC goals are pre-eminent in matters subject to a vote;
- Unauthorized use of confidential or other BMC information and documents – refers to the essential environment of trust and confidentiality in Steering Committee discussions, which must be protected.

Declaring Conflict of Interest

Where a conflict of interest, actual or perceived is deemed to be present:

- The conflict must be declared to the Chair, or in his/her absence the Vice Chair acting as Chair, and participants prior to the business of the meeting.
- The nature of the conflict is to be recorded in the minutes of the meeting.
- The participant declaring a conflict may take part in the discussions or leave the meeting room for the said discussion, at the discretion of the Chair, and will have no vote.

Affect on Quorum

Absence from part of a meeting for a declared conflict of interest would not adversely affect the quorum of the meeting.

Confidentiality

The Chair with support of BMC participants, choose the timing and format for release of its information and documents. Participants shall respect matters of a confidential nature, meaning those not available to the general public, which are shared as part of BMC business. Participants shall not publicly disclose BMC information or use it for purposes outside BMC without the prior consent of the Coalition participants.

Responsibilities of the Chair

The Chair has the responsibility to inform participants of the policy and to call for declaration of conflicts at the beginning of each meeting, once the agenda has been agreed. The Chair will determine whether a participant with a conflict, or an ex-officio participant, should partake in discussions preceding a vote or should be absent.

Failure to Comply

For non-declaration of a conflict and taking part in the BMC, a participant could be asked to resign and the affected decisions could be reconsidered.

Breach of confidentiality of any confidential BMC information or documents could result in a participant being asked to resign.

Ex-officio

Employees, consultants, contractors, observers and supporters of the BMC are invited to attend meetings to report on their work and to offer insight into the implementation of projects. They may, or may not, be asked to participate in discussions unrelated to their assignments, at the discretion of the Chair. They are not volunteers and as such do not have voting privileges for any BMC topics, whether or not such topics are related to their assignments. Their agreements must contain a confidentiality clause.

ATTACHMENT 2

PRINCIPLES AND CODES FOR ETHICAL CONDUCT AND PARTNERSHIPS

BMC Principles and Codes for Ethical Conduct

To ensure that the mission and goals of BMC are not influenced or jeopardized, the following principles and codes of conduct will be applied:

- With the understanding that there are few resources available for BMC to access, and that BMC will be competing with other groups and organizations for funding, BMC must become proactively engaged in partnerships with government, industry, and others, to achieve its means through its mission and goals.
- Increased public examination of what organizations do for them and how their dollars are spent has increased the need to be accountable, transparent, and respectful of public, donor and stakeholder supporters.
- Putting best medicines, pharmacare program (the equitable access to medications Canada-wide), drug review on the national priority agenda is a priority of BMC.
- BMC believes it is unique in its structure, providing a broad based voice of Canadians living with or dealing with chronic diseases. BMC speaks expertly in areas of healthcare and drug review reform, from the patient and consumer point of view or experience.
- Values are patient centered and focused.
- BMC discloses all funding sources for all its activities.
- The sources of all materials or documents presented are identified.
- BMC develops positions on health policy, products or services in collaboration with consumers, the academic community and health care providers and government free from concern or constraint of other organizations.

Principles and Code of Ethics for Partnerships

- Relationships with donors take place within the context of the Best Medicines Mission and Guiding Principles.
- BMC will actively solicit sponsorships from organizations, foundations, membership and other groups or individuals for both operating and project purposes. This funding constitutes 100% of BMC's funds.
- The BMC does not endorse any specific products or services. This should not be seen as a barrier to partnership or collaboration. BMC is seen to have a voice on the opinions and decisions of patients and consumers, whose organizations are members of BMC.
- BMC accepts only unrestricted grants and consulting fees for educational and other activities. BMC will formally and officially define the parameters of its relationships and partnerships with sponsors and others so as to ensure no undue influence or conditions override BMC's mission, goals, priorities, or operations.
- BMC employees or volunteers do not own shares in any company providing support, except as part of group pension or investment plans.

- No BMC employee or volunteer has equity interest or receives personal “in-kind” support of any kind from any health-related organization other than their salaried position.
- The BMC will openly disclose all corporate support received on an annual basis, and openly respond to any inquiries about support. The exact amount of support from different groups and organizations is considered confidential and may be disclosed only upon permission of these groups or organizations.
- The acknowledgement or recognition of sponsors and supporters will be equitable and objective across all BMC activities.
- BMC encourages multi-sponsored events and activities, and all exclusive relationships must be cleared by BMC members and parties concerned.
- Agreements between BMC and partners will be encouraged to ensure open transparency in the relationships.