



**Canadian Agency for Drugs and Technologies in Health**  
**Consultation on Patient Input into Common Drug Review Assessments**

**January 27, 2010**

**Introduction to the Best Medicines Coalition:**

As a national alliance of patient organizations, the Best Medicines Coalition welcomes the opportunity to participate in the Canadian Agency for Drugs and Technologies in Health (CADTH) consultation regarding patient input into Common Drug Review (CDR) assessments. Meaningful patient engagement and mechanisms for incorporating patient input are concepts which the Best Medicines Coalition believes are vital to bringing relevance to the health technology review process. Comprehensive reviews of pharmaceutical treatments must encompass a range of data and expert input, including that of patients.

The Best Medicines Coalition is comprised of Canadian patient organizations and individual patient advocates who share a commitment to ensuring safe, timely and equitable access to evidence-based medicines for all Canadians. Representing millions of patients living with or affected by chronic disease or other illnesses, the organization is engaged in a range of related policy discussions, including pharmaceutical review, reimbursement, treatment, life cycle management and safety issues. As a patient-driven organization, the Best Medicines Coalition develops positions independently from private sector or government organizations.

**Best Medicine Coalition Process:**

The Best Medicines Coalition operates within a formalized structure, as outlined in its *Terms of Reference* ([www.bestmedicines.ca](http://www.bestmedicines.ca)). Each member organization or individual member is represented on a large Steering Committee from which an Operating Committee is elected annually, including a Chair who is elected for a two-year term. The Operations Committee oversees all BMC activities, including developing policy positions and representing the organization at consultations and other meetings. Members from both the Steering Committee and the Operations Committee form smaller Working Groups, which work on specific issues.

In the case of the CADTH patient input proposal, this concept was first discussed by the Steering Committee at the Best Medicines Coalition's Annual General Meeting in September, 2009. When the proposed template and guidance document were released, these documents were considered by the Common Drug Review Working Group and the Operations Committee. From these discussions, feedback points were developed which were then shared with the broad membership, for review and input. Therefore, the points outlined in this document represent input from a range of organizations. It should be noted that some member organizations may have differing views on some of the issues addressed below or in some cases may have provided input on broader range of issues than what the Best Medicines Coalition itself has chosen to address in this forum.

### **Developing Meaningful Patient Input:**

In general the Best Medicines Coalition is supportive of the principles, concepts and approach outlined in the proposal for CDR patient input presented by CADTH. There is broad agreement that this initial incarnation of a patient input model represents a significant step forward towards an increasingly cooperative relationship between patients and CADTH, one which allows for comprehensive patient engagement and brings value to the system. Within this context, it is hoped that CADTH and Canadian patients can work together over the coming months and years to further refine this process.

In reviewing the documents, the Best Medicines Coalition has focussed its input on the following four issues: conflict of interest declarations; timelines for patient input; use of patient input material; and evaluation processes.

Recommendations are summarized as follows:

#### **1. Conflict of Interest Declarations:**

Some degree of disclosure of conflicts is appropriate and important to achieving the goal of increased transparency. However, conflict of interest declarations should not be used as the basis for excluding patients from decision-making reviews about access to drugs.

Certain aspects of what is now outlined in this section of the patient input template must be clarified. CADTH needs to provide further explanation on what level of detail is required, providing specific examples and direction. Importantly, there needs to be further understanding on how this conflict of interest information will be incorporated into the review process. For example, there must be full understanding about whether input provided by groups funded by pharmaceutical companies will be discounted somehow or if this information is being provided purely in the interests of openness and transparency. Patient groups like the Best Medicines Coalition must be consulted as these concepts are developed.

There would be merit to separating patient group conflict of interest declarations from the core patient contribution regarding a specific drug. It is recommended that a two-step process for patient group submissions be considered, whereby groups could pre-register with CADTH, providing organizational information, including conflict and membership information, and receive pre-approval. This would be followed up with submission on a specific drug at the time of a review. The need to filter out patient groups prompted by pharmaceutical interests solely for the purposes of providing input on a drug to CDR is understood, but this must not compromise the value of legitimate patient input. In addition, also in the interests of openness and transparency, CADTH should post information about the submitting patient organizations on its website, including conflict information.

#### **2. Timelines for Patient Input:**

It is understood that CADTH is committed to conducting reviews expeditiously and that delay of the entire process to allow for patient input must be avoided. However, a short, fifteen day period from when patient groups are informed about a new submission until input is required is problematic for most patient organizations. Indeed, this would severely limit the breadth and quality of input received and considered by the CDR. Working with limited resources and often relying on volunteers, this short timeline for input would make it challenging for groups to connect with individual patients, share insights and create a meaningful and thoughtful

submission. In addition, individual patients who are not eligible to submit on their own would have to seek out and liaise with a patient group for their input to be considered, demanding even more time. An appropriate balance between not extending the process and facilitating meaningful input must be found. It is recommended that at least a 30-day (month) period be allowed from when a submission is filed. In addition to not derailing other organizational activities, a 30-day reply period would give time for patient groups to gather information from individuals not closely connected to a group.

### **3. Use of Patient Input Material:**

It is understood that in any new process there are many unknowns but further clarification is necessary regarding what will happen to patient input material once it is submitted. It is recommended that CADTH provide a full and detailed explanation on how input received from patient groups will be used and incorporated into the current review process. Specifically, it should be clarified whether or how patient experiences would be ranked in comparison to other scientific evidence provided.

In addition, it is recommended that patient groups receive a written response on how patient input information has been used or an explanation of why it wasn't given consideration or incorporated in the decision-making process. Patient groups deserve to have direct feedback considering the effort put forward to prepare a submission, but such feedback also provides a learning experience so the process can be improved. A procedure must also be in place for patient input to be sought and considered where a pharmaceutical product has been re-submitted.

### **4. Evaluation Phase:**

It is important that the CDR review process, including the patient input process, be evaluated on a regular basis and reformed as necessary. Therefore, it is recommended that an annual review of the effectiveness of the patient input process be mandated. Patients and other stakeholders must be fully involved in both evaluations and revisions.

### **Moving Towards Implementation:**

The Best Medicines Coalition is steadfast in its goal that public bodies, including the CDR, deliver a service that addresses the needs of Canadian patients in an efficient, consistent and effective manner. Patients, who are ultimately the most impacted by decisions, must be significantly involved and consulted. In addition, transparency and fairness must be integrated, allowing patients and other stakeholders a greater understanding of processes and rationale for actions. An appeal process involving patients must allow recourse on all decisions.

The CADTH proposal for patient input into CDR reviews addresses some of the principles outlined above and is a significant step forward towards a transparent and fair system, which has the potential to contribute and provide value to the Canadian health care system. The Best Medicines Coalition looks forward further refinement of the CDR patient input proposal, in consultation with patients, and to working with the CDR to ensure that its review decisions reflect the experiences and needs of Canadian patients.

**Best Medicines Coalition Membership:**

**Operations Committee 2009-2010**

Linda Wilhelm, Individual Member (Chair)  
Louise Binder, Canadian Treatment Action Council  
Dr. Katharina Kovacs-Burns, Individual Member  
Denis Morrice, Epilepsy Ontario (Treasurer)  
Holly Vengroff, CARP, A New Vision of Aging for Canada

**Steering Committee (Current Member Organizations & Individual Members):**

Arthritis Consumer Experts - [www.arthritisconsumerexperts.org](http://www.arthritisconsumerexperts.org)  
Asthma Society of Canada - [www.asthma.ca](http://www.asthma.ca)  
Canadian Arthritis Patient Alliance - [www.arthritis.ca/capa](http://www.arthritis.ca/capa)  
Canadian Breast Cancer Network - [www.cbcn.ca](http://www.cbcn.ca)  
Canadian Cancer Action Network - [www.ccanceraction.ca](http://www.ccanceraction.ca)  
Canadian Hemophilia Society - [www.hemophilia.ca](http://www.hemophilia.ca)  
Canadian Pain Society - [www.canadianpainsociety.ca](http://www.canadianpainsociety.ca)  
Canadian Skin Patient Alliance - [www.skinpatientalliance.ca](http://www.skinpatientalliance.ca)  
Canadian Treatment Action Council - [www.ctac.ca](http://www.ctac.ca)  
Cancer Advocacy Coalition of Canada - [www.canceradvocacy.ca](http://www.canceradvocacy.ca)  
CARP, A New Vision of Aging for Canada - [www.carp.ca](http://www.carp.ca)  
Centre for ADD/ADHD Advocacy Canada - [www.caddac.ca](http://www.caddac.ca)  
Epilepsy Ontario - [www.epilepsyontario.org](http://www.epilepsyontario.org)  
Gastrointestinal Society - [www.badgut.com](http://www.badgut.com)  
Hepatitis C Council of British Columbia - [www.bchepcouncil.ca](http://www.bchepcouncil.ca)  
Kidney Cancer Canada - [www.kidneycancercanada.org](http://www.kidneycancercanada.org)  
Lymphoma Foundation Canada - [www.lymphoma.ca](http://www.lymphoma.ca)  
Osteoporosis Canada - [www.osteoporosis.ca](http://www.osteoporosis.ca)  
Ovarian Cancer Canada - [www.ovariancanada.org](http://www.ovariancanada.org)  
Tourette Syndrome Foundation of Canada - [www.tourette.ca](http://www.tourette.ca)  
Dr. Katharina Kovacs Burns, Individual Member  
Maureen Gatz-Faubert, Individual Member  
Marjorie Harris, Individual Member  
Lisa Mortell, Individual Member  
Linda Wilhelm, Individual Member

***For further information:***

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