



Executive Summary Response Paper to the BC Ministry of Health Services September 2008

The Better Pharmacare Coalition (BPC) has submitted to BC Ministry of Health Services a response paper to PharmaCare's (PSD) implementation plans for the Task Force Report contained in the PSD's "White Paper" distributed at the July 17th Multilateral stakeholder meeting.

After reviewing the draft materials of the PSD's White Paper, the BPC has concluded that certain sections are not aligned with the spirit of the Task Force report and that many of the recommendations of the Task Force report, accepted by the government, are not fully represented in the White Paper's draft process.

The BPC welcomed the decision by the Government to accept the Task Force's patient-focused recommendations aimed at improving the BC PharmaCare program. The BPC supports the government's decision to implement the Task Force recommendations in accordance with six guiding principles, the first of which states "the best interests of the patient are paramount."

Drug Review Process Overview

A new drug review process must be designed to include the needs of patients and ensure British Columbians have timely and effective access to the latest advances in health research. However, the Pharmaceutical Task Force found that BC PharmaCare currently has one of the slowest and most costly drug review processes in the country. Moreover, patient groups find the decision-making process to be non-responsive, non-accountable, and non-transparent. There are no formal processes for patients to participate in the drug review process and patients are offered little or no explanation as to how a decision is made.

The Task Force recommendations envision a drug submission review and approval process that provides an opportunity for greater patient involvement in their health care by involving the public in every step of the drug approval process.

I. Stakeholder - Patient Engagement

Consumer, or patient, representatives provide a unique perspective on living with disease that the 'general public' does not provide. In particular, they are able to speak to issues of side effects, living with illness, barriers to community participation and other direct experiences those members of the public, who do not, or have not, lived with illness would not be able to comment.

II. Therapeutic options for patients

The BPC firmly believes Government must help strengthen patient-physician-pharmacist relationships and provide patients improved access to prescription medications best suited to their medical conditions.

The use of “the right drug, at the right time, for the right patient” could, if managed properly, have a very significant impact on reduced levels of hospitalization, the reduction of adverse drug reactions, improved health outcomes, including quality-of-life outcomes that are vitally important in the setting of chronic disease management.

III. Drug Benefit Council (DBC)

BPC supports the recommendation to reconstitute the DBC and expand membership to increase the level of public engagement, accountability and transparency. BPC believes this key decision making body should be composed of a broad base of knowledgeable disease specialists (researchers and clinicians) and patients with a mandated focus to provide sound, evidence-based advice. The BPC believes that the Draft Terms of Reference broaden membership in numbers but do not substantially change criteria for membership from those that exist today (i.e. TI members).

BPC would urge Government to follow the recommendations of its Task Force and appoint public members through a selection process external to the PSD. BPC recommends that the PSD consider adopting the guidelines used by Health Canada, which has already established COI guidelines for public involvement in pharmaceutical related expert advisory committees and working groups.

Conceptually, the BPC feels the new DBC proposed by the Task Force will not duplicate the efforts of the CDR. However, in the PSD’s proposed Submission Review Process, the BPC is concerned that there may be some unnecessary functional overlap with CDR and Health Canada processes.

IV. Drug Review Resource Committee (DRRC)

The DRRC (as outlined in the Task Force Report and PSD white paper) is a subcommittee of the DBC. The Task Force Report states that the DRRC is designed and structured to develop and maintain a registry of subject matter experts from which to select members for Drug Coverage Review Teams (DCRTs). The DRRC is not designed in the Task Force Report to “act as an independent group to gather the necessary evidence and clinical considerations for the DBC” or to “replace the role presently performed by the Therapeutics Initiative” as the PSD recommends in its White Paper.

V. Drug Coverage Review Teams (DCRTs)

The BPC endorses the key elements of the Task Force Report regarding the creation and function of the DCRTs operating as therapeutically-aligned review bodies.

The BPC opposes the PSD recommendation to limit the drug review process to the DRRC and two other subcommittees. The BPC believes this structure would not enhance stakeholder engagement in the pre- and post-submission processes. Instead, it would establish a linear process, which will result in continued backlogs and delays in drug reviews. Because DCRT members make representation to the DBC, BPC believes there should be a role for disease- or condition-specific patient stakeholders in DCRT.

VI. New Target Timelines

The BPC supports the PSD's stated goal to position BC as a leader in Canada for improved and transparent review timelines and decision-making. BPC believes that creating multiple drug review teams composed of experts in the specific therapeutic areas being reviewed will result in improved target times as compared to those proposed in the PSD's White Paper.

The BPC feels that "Target Time-to-Decision" times are not aggressive enough – nine months for a standard submission is not acceptable, nor are the other targets, particularly when one considers that most of the work has already been done by Health Canada and CDR. BPC believes a realistic target to place a drug on the BC PharmaCare reimbursement formulary should be between 30-90 days after receiving a 'recommendation to list' from the Common Drug Review. For medicines that receive a "no" from the CDR, BPC believes a realistic time frame for the PSD to make a determination to list, or not to list, should be between 90 – 120 calendar days.

VII. Accountability and Transparency

The accountability and transparency elements outlined in the White Paper are positive steps forward in the drug submission review process. BPC supports PSD's efforts as they relate to improve the sharing of information on the Ministry's website and implementing new performance measures.

The BPC recommends that the PSD implementation team meet with stakeholders on a quarterly basis to monitor and guide the implementation of the Task Force report. BPC further recommends that this group present progress reports and performance measures to the Minister as part of an annual program review. Separately, BPC would also gladly participate in an annual opportunity for an accountability session with the Deputy Minister of Health and any other initiatives to improve the level of constructive engagement between the consumers we represent and the Government.

VIII. Draft Conflict of Interest (COI) guidelines for the new Drug Benefit Council

The BPC supports BC PharmaCare's decision to adopt COI Guidelines for the new Drug Benefit Council. Conceptually, they would eliminate the opportunity for members to serve simultaneously on multiple committees and for individuals to be in a position to vote on their own recommendations. However, the COI guidelines, as stated, combined with the Draft Terms of Reference, are too narrow and restrictive and would limit DBC membership to TI-type academics and researchers currently involved in the review process.

The notion that potential members should or could be eliminated from consideration for a post due to experience (personal or family) with disease would virtually eliminate the entire population of BC – including government – from participating.

IX. BC MOHS new “procurement” or “tendering” model(s)

The BPC has serious concerns about how cost containment initiatives such as tendering may adversely affect patient access or choice to a wide array of effective medicines and health products. Patient care is enhanced by increasing choice; limiting choice to innovative medicines flies in the face of patient individuality.

Cost containment initiatives, including Reference Based Pricing and Therapeutic Substitution, and the potential of sole tendering, harm BC patients and frustrate physicians who feel they are not in control of the care plan that is best for their patient's condition. Moreover, the negative affect these initiatives have on the doctor/patient relationship represent a dangerous threat to quality health care.

The Ministry of Health Service's implementation plans regarding procurement must be consistent with the Task Force recommendations. Without a clear consensus, the Ministry needs to conduct further direct and meaningful consultation among all stakeholders to address the divergent stakeholder interests and develop a fair and cohesive policy on procurement.