BPC Better Pharmacare Coalition

Response Paper to the BC Ministry of Health Services

- **DRAFT IMPLEMENTATION APPROACH TO PHARMACEUTICAL TASK FORCE RECOMMENDATIONS**
- **DRAFT TERMS OF REFERENCE FOR THE DRUG BENEFIT COUNCIL, AND**
- **DRAFT CONFLICT OF INTEREST GUIDELINES FOR THE DRUG BENEFIT COUNCIL**
- **POSITION ON "PROCUREMENT" OR "TENDERING" OF PHARMACEUTICAL OR MEDICAL DEVISE PRODUCTS**

Submitted by the Better Pharmacare Coalition

September 2, 2008

Better Pharmacare Coalition Response Paper

Introduction

The Better Pharmacare Coalition (BPC) wishes to thank BC Ministry of Health Services for the opportunity to attend the Multilateral Stakeholder Session held on July 17, 2008 when Pharmacare (PSD) shared its implementation plans for the Task Force Report and the details of the PSD's "White Paper."

The BPC's response to the PSD White Paper will be broken down into two sections:

- **Section 1** will include the Better Pharmacare Coalition response to the BC MOHS Draft Implementation Approach ("White Paper") to Pharmaceutical Task Force Recommendations with a focus on the Drug Review Process and the Draft Terms of Reference for the Drug Benefit Council. This section will also cover the BPC response to the Draft Conflict of Interest Guidelines for the Drug Benefit Council (DBC).
- **Section 2** will include the Better Pharmacare Coalition response to the BC MOHS' plans to introduce new "procurement" or "tendering" model(s) to purchase of pharmaceutical and other medical products.

A guiding principle for our Response Paper recognizes that the Government's implementation of the Task Force Report recommendations will have a significant impact on patient healthcare, access to medication, and healthcare costs in BC. The BPC's Response Paper reflects the concerns patients have towards the existing drug review process:

- Decision making process is not responsive, accountable or transparent and patients feel they are excluded
- Experts are not able to prescribe the right medicine to their patients
- Formulary policies force patients to try and fail on products their physicians know will not work for them
- Patients are being denied best care and treatment options because BC PharmaCare restricts coverage in many cases to the least expensive or 'best deal' medications and devices
- The process is highly redundant due to roles and functions performed by other groups such as Health Canada and the Common Drug Review
- There are no formal processes for patients to participate in the drug review process
- Patients are offered little or no explanation as to how a decision is made

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.

Background

The BPC is a joining together of provincial and national health organizations and health/disease consumer groups with a mandate to speak on behalf of its 2,000,000-plus members on issues related to the Government of British Columbia's PharmaCare (BC PharmaCare) program. The coalition was formed in 1997 in response to BC PharmaCare policy development not reflective of the medical literature, best clinical practice and the needs of patients in BC.

The BPC provides a common voice for patients and consumers on issues related to the Government of British Columbia's PharmaCare programs and strives to ensure appropriate and timely BC PharmaCare program coverage for evidence-based medications. Our members have shared concerns about policies that restrict choice and have a significant impact on patient quality of life and health-care budgets.

The Better Pharmacare Coalition Membership

Arthritis Consumer Experts (ACE)
BC Lung Association
BC Schizophrenia Society
Canadian Arthritis Patient Alliance (CAPA)
Canadian Association of Retired Persons (CARP)
Heart & Stroke Foundation of BC & Yukon
Kidney Foundation of Canada – BC Branch
Mood Disorders Association of BC
Osteoporosis Canada – BC Division
Parkinson Society of British Columbia
The Arthritis Society, BC &Yukon Division

Task Force Recommendations

The BC Government's Pharmaceutical Task Force recommendations, accepted by the Premier and Minister of Health, represent the most significant consideration from Government towards our province's drug policy in the past 15 years. Once implemented, the Task Force recommendations will position British Columbia as a leader in the area of pharmaceutical management reform in Canada, enabling the government to face one of the most challenging social and economic issues of our time.

Specifically, the Task Force recommendations for lowering generic drug pricing, replacing the Therapeutics Initiative, and improving dialogue with outside stakeholders through meaningful representation in BC PharmaCare decision-making processes represent positive first steps to improve the PharmaCare program for the benefit of all BC residents.

As part of its ongoing advocacy on behalf of the health of all British Columbians, BPC presented a submission to the Pharmaceutical Task Force in January 2008. In its presentation to the Task Force, Better Pharmacare Coalition raised concerns regarding British Columbia's existing approach to the listing of pharmaceuticals and other health-related products.
The BPC welcomed the decision by the Government to accept its 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."

Patient groups are a key player in the Task Force's recommended integrated approach to find ways to ensure British Columbians have timely access to the latest advances in health research including medicines and vaccines. The Task Force recommendations generally deliver what patients want, which must be good for the entire Province: provide greater choice for patients and access to the right drug, at the right time. Our members want improved coverage of medications on the BC drug formulary that will get them out of the hospital and back to work contributing to our provincial economy; not costing it money.

Section 1: BPC response to the BC MOHS Draft Implementation Approach ("White Paper")

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. Currently, there are no formal processes for British Columbians to participate in the drug review process. The public has little or no explanation as to how a decision is made. The decision-making processes regarding listing should be open, transparent and inclusive with a meaningful role for public engagement and for the participation of those directly affected by the decision.

Time to listing is critical for someone living with a life threatening and/or chronic disease. That's why the overlap in national/provincial drug review and listing processes should be eliminated. The elimination of existing review process duplications would significantly improve reimbursement access to newer medications and, most importantly, would improve health outcomes for British Columbians.

I. Stakeholder - Patient Engagement

Task Force Report Recommendations

"Priority attention should be focused on development of an enhanced Formulary Management System together with improved stakeholder engagement….This work should be led by the PSD and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry."

- Report of the Pharmaceutical Task Force, April 2008

PSD White Paper

The PSD's immediate response to the Task Force recommendations to improve stakeholder engagement has been the establishment of a Stakeholder and Partner Relations branch responsible for stakeholder engagement through the implementation process.

BPC Response

A guiding principle in the development of stakeholder engagement policy setting is the meaningful involvement of all stakeholders in all stages of the policy setting process. As part of the establishment of the Stakeholder and Partner Relations (SPR) branch established by the MOHS in the spring of 2008, a transparent process should be developed for stakeholders who are involved in the various activities of the MOHS.

Research indicates that 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 on (Hiller et al, 1997; Gagliardi et al., 2008). Moreover, a key aspect to meaningful involvement is that participants are informed about the issues they are being asked to consider and make decisions about (Turnbull and Aucoin, 2006; Conover et al., 2002).

It has been argued that direct involvement of consumers (patients/users) can be problematic because they have a direct interest in the decisions being made (Litva et al., 2002; Entwistle et al., 1998; Boote et al., 2002). While it is true that many patient or consumer stakeholders do have an interest in health policy decisions, expert members of these committees also have interests and affiliations. In their research on Federal Advisory committees in the U.S. Ard and Natowicz (2001) showed that compared to consumer representatives who had no dual affiliations, academics who participated on advisory committees had 1 or more affiliations with industry. In addition, research has also shown that members of the public, who have little interest in the policy decisions are hard to engage and may provide less value for decisions that affect specific communities than those who have a direct experience (Gustafsson and Driver, 2005; Gagliardi et al., 2008).

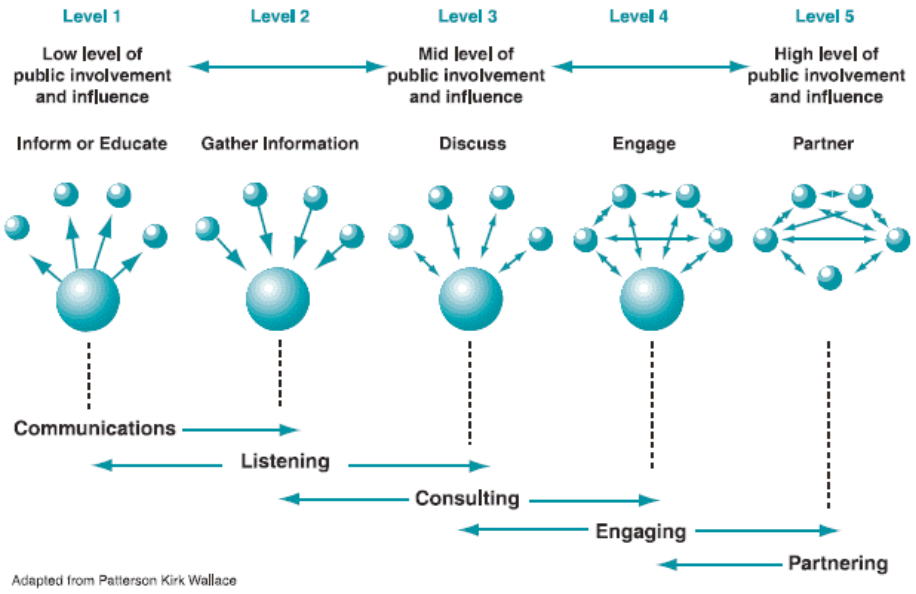
This is not to suggest that members of the 'general' public should not be involved. Rather, it is important that stakeholder engagement strategies ensure a broad range of stakeholders that are able to address a diversity of perspectives and experiences in policy decision.

Models of Public/Patient Engagement

Multiple models of stakeholder participation exist both nationally and internationally. Stakeholders may be involved in a number of different ways and a number of different levels. The decision of which model or framework to use depends on the goals and objectives of the program, while also paying attention to the principles of accountability, transparency, and democracy.

Canada

Health Canada has established a Public Involvement Continuum that ranges from Level 1, which is characterized by a low level in involvement, to Level 5, which represents a partnership and shared responsibility.



Federal examples

Office of Consumer and Public Involvement (OCAPI) In 1999, Health Canada, acting through the Health Products and Food Branch (HPFB) established the Office of Consumer and Public Involvement (OCAPI). OCAPI "provides information and opportunities for Canadians - and especially consumers of the products we regulate - to become meaningfully involved in the decision-making processes of the Health Products and Food Branch (HPFB) regarding priorities, policies and programs" (Health Canada website, accessed September 13, 2007). Since its inception, OCAPI has implemented a broad range of stakeholder participation measures, including public consultations, public advisory committees, expert advisory committees, and face to face meetings.

Organizational/Institutional examples

Stakeholder participation strategies have also been implemented within various Canadian institutions and organizations.

Canadian Blood System

Following the Krever Inquiry on the Tainted Blood Scandal, consumer stakeholders have been directly involved in the risk management processes of the blood system. In explaining the rationale for involvement, both Justice Krever and the management of the Canadian Blood Services have publicly stated that a key way to build support for policy decisions, as well as identify risks is to include those who are directly impacted by these decisions (Krever, 1997; Ezekial, 2008; CBS website).

Barriers to public/patient engagement - Steps for Success

Many barriers to stakeholder involvement have been identified in the academic literature, as well as in government policy documents that frame public participation. It is important to briefly address these in order to ensure appropriate and meaningful participation.

Knowledge and Training: In order to ensure success, all participants have a solid understanding of the process of decision-making and their role in that process. This means that training, if needed, is available to participants and that materials provided to the group are accessible to everyone involved.

Appropriate Resources (lack of resources): There must be appropriate resources available for stakeholders to participate. This means they must be able to access the materials and have enough time to prepare for meetings. This also includes financial resources to participate. Stakeholders must be reimbursed for any costs associated with their participation so as to ensure that there are no financial barriers to participation.

Attitudes of 'Expert' or 'Government' members: All members on the committee must be educated about the role and value of patient and public stakeholders.

Meaningful and Early Involvement: It is critical to ensure that public and patient stakeholders are included from the beginning of any system redesign and play a meaningful role in the decision-making process. Their inclusion cannot simply be a token mechanism to depict transparency and gain acceptance for policies.

II. Drug Review Process

Task Force Recommendations

"The Task Force [has] concluded that the current process for the evidence-based review of pharmaceutical products considered for listing in British Columbia can, and must, be improved."

"The Task Force is of the view that government's intention to expand, or alter, DBC membership to increase the level of public engagement is appropriate but the addition of a single public member will not be sufficient to meet that goal. The appointment of not less than three public members, selected through a process external to the PSD , would be both more appropriate and consistent with what the Ministry of Health has already done with respect to the governance of the Medical Services Commission. This step would be more compatible with modern governance practices, would provide for increased public and patient engagement and would substantially assist in addressing accountability and transparency expectations."

- Report of the Pharmaceutical Task Force, April 2008

PSD White Paper

The PSD's model for a new Drug Review process is a significant improvement of the existing system and contains many principles that the BPC considers key, specifically the establishment of an advisory board/council which is

- independent, transparent and accountable;
- designed to provide sound, evidence-based advice; and
- made up of a broad base of community-nominated, knowledgeable disease specialists (professionals and patients).

BPC Response

The BPC acknowledges the Ministry's efforts to improve the Government's PharmaCare program so that it provides British Columbians with the broadest and deepest scope of reimbursement coverage possible for medically necessary medications.

As we stated at the July 17th multi-lateral stakeholder session, the BPC supports the Recommendations of the Pharmaceutical Task Force Report and the sections relating to the optimization of the decision-making process for the listing of pharmaceuticals (pp. 6-14 Task Force Report), including Chart One of the Submission Review Process illustrating the structure, which is also contained in the PSD White Paper. However, the Pharmaceutical Task Force also concluded that BC PharmaCare currently has one of the slowest and most costly drug review processes in the country. The drug review process in Canada is a long, winding road and, at times, a frustrating and life threatening one for BC residents.

Before a medication arrives at the Therapeutics Initiative (TI), it has already been deemed safe and effective by Health Canada after exhaustive scientific, clinical and manufacturing standards review. In other words, medications reviewed by the TI are already approved for sale in Canada. Their efficacy has already been establish through phase I, II and III double-blinded, randomized control trials, the highest level of evidence required to license a drug in any jurisdiction. Individuals with private insurance or sufficient financial resources can purchase them. Unfortunately, people who depend on BC PharmaCare are the ones who are left to wait. That has a harmful and discriminatory effect on those who most need help: seniors and low income citizens. In fact, denying reimbursement for reasons of cost is a violation of the human rights code.

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. This is also true for the inclusion of specialist physicians that the patient groups work with, who have real world experience with many of these drugs. The Task Force is extremely clear on the need for clinical trials and to better understand the needs of the patient population.

The BPC believes individual patient needs should be the guiding principle in any drug approval process. 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. Specifically, the Task Force recommendations call for the participation of knowledgeable patients living with disease to sit on decision-making committees and drug reviews to provide real world experience.

The BPC strongly agrees with the Task Force recommendations to add “real world” experience and perspective into the drug review process – a key component that is lacking in the current process, including the:

- Ability to look at and consider other forms of evidence other than RCTs e.g. qualitative retrospective and prospective studies, patient experience;
- The participation of appropriate disease specialists (professionals and patients) will assist in determining best-practice guidelines for the listing of safe and effective medications, devices and supplies in BC;
- The input and participation by epidemiologic and clinical experts as well as the addition of economic analysis support, to examine the full economic impact across the whole health system as well as those areas of government significantly impacted by indirect health care costs (e.g. Ministries of Housing and Social Development and Small Business and Revenue).

As noted above, issues of representation are central to stakeholder engagement strategies. While the MOHS is looking for “individuals that can best represent the public at large”, there are important issues to consider in terms of knowledge. It is important that a broad range of experience is included in the DBC, which means not simply members of the ‘general public’, but those that are able to speak to the experience of requiring medication, side effects, and access issues. Research has shown that a key benefit of including stakeholders in health policy

decisions is the experiential expertise they bring to the process (Grant-Pearce, 1998). BPC recommends that at least two of the members of the DBC be individuals who have direct experience with the health system, preferably living with ongoing health challenges.

Stakeholders who want to participate should have to demonstrate knowledge of the Canadian and provincial health system, as well as a sustained interest in health matters. To achieve this, all participants should have to submit a curriculum vitae or resume that clearly outlines their interest, background and links to the community.

Therapeutic options for patients

Task Force Recommendations

"The need for a new, more responsive, system will become even more apparent as we move towards a greatly enhanced level of "personalized medicine" where professionals will be more able to select the most appropriate drug for particular genotypes of patients. This trend towards use of "the right drug, at the right time for the right patient" could, if managed properly, have a very significant impact on levels of hospitalization, the reduction of adverse drug reactions and improved quality of life for patients suffering from chronic illnesses. These outcomes will not only produce tangible improvements in patient outcomes, but by reducing demands on the health care system caused by ineffective or inappropriate drugs, will also have an impact on the overall costs of the health care system."

- Report of the Pharmaceutical Task Force, April 2008

The first guiding principle of the Task Force recommendations states "the best interests of the patient are paramount."

The doctor/patient relationship is critical. In our current system, experts are not able to access the full spectrum of treatment options and prescribe the right medicine to their patients. Although accountability for the right drug choice resides with physicians, formulary policies force patients to try and fail on products their physicians know will not work for them. A key consideration when factoring in the "best interests of patients" is that one size does not fit all. 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. However, if through careful monitoring it is found that the medication does not benefit the patient, BPC does not expect Government to pay for it.

Drug Benefit Council (DBC)

Task Force Recommendations

The Task Force Report recommended that the Drug Benefit Committee be reconstituted as the Drug Benefit Council and responsible for the overall review process. It calls for broadening the membership beyond "the existing Drug Benefit Committee [that] confines its reviews to a relatively small community of experts and, as a result, the array of potential expertise that could be deployed to consider the merits of listing submission is not as broad, nor as deep, as it ought to be."

- Report of the Pharmaceutical Task Force, April 2008

PSD White Paper

The PSD recommends a reconstitution of the Drug Benefit Committee as the Drug Benefit Council – an independent, evidence-based, and arms length advisory body to make drug listing recommendations to the Ministry with at least two, and up to three, members of the public to sit on the 11-member DBC.

BPC Response

BPC supports the recommendation to reconstitute the Drug Benefit Committee and expand membership in the new Drug Benefit Council (DBC) 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.

As stated in our submission to the Pharmaceutical Task Force, the BPC believes that appropriate disease specialists (professionals and patients) can play a vitally important role assisting BC PharmaCare in determining suitable guidelines for use of Health Canada-approved, Common Drug Review "recommended to list" drugs in BC, "line extensions,"or, a new indication for an already approved drug.

The Task Force recommendation as it relates to the number and selection of public members to the DBC is clear, "the appointment of not less than three public members selected through a process external to the PSD." (p. 10)

BPC would urge Government to follow the recommendations of its Task Force and appoint public members through a selection process external to the PSD. However, BPC believes that the Board Resourcing Office may not be the most appropriate agency to carry out the role of making the short list of candidates for the Minister's consideration. 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. BPC believes that the Health Canada guidelines are clearer cut than those provided by the BRDO and were created to specifically address "public" members.
Below is a selection rationale provided by Health Canada for its Advisory Committees and external appointees:

- They can provide independent sources of information;
- Often public members comprise the only expertise that can bring leading-edge knowledge to bear on issues. (e.g., for new technologies, clinical applications, or disease states);
- External advisors foster partnerships between the Branch and its clientele;
- External advisors facilitate understanding and appreciation of Health Canada policies;
- External advisors provide a mechanism to communicate policies externally;
- External advisors increase the transparency of the decision-making process.

Ministry's Draft Terms of Reference for the Drug Benefit Council

After a review of the PSD's draft terms of reference for the Drug Benefit Council Appendix A of the Draft white paper, the BPC has concluded that the scope of the DBC as defined is unclear. The BPC believes there is a lack of transparency within the Terms of Reference for the DBC to review drug classes and therapeutic issues related to drug benefits. The BPC believes that additional detail on the process and rationale for reviewing therapeutic issues should be outlined. For example, reasons for recommendation should be detailed and sufficient to explain to submitters or applicants the reasons why a give submission was not successful.

The BPC also feels that the process for meeting with applicants/submitters to receive and discuss recommendations is not clearly stated in the Draft Terms of Reference. The DBC's role should include providing the opportunity for consultation with stakeholders to seek clarification and additional information from submission sponsors (as recommended on Page 12 of the Task Force Report). As part of this process, BPC believes there should be an appeal or re-submission process.

In its Report, the Task Force states: "any unnecessary overlap between the CDR and BC formulary management system is reduced to the fullest extent possible" (p. 25 Report of the Pharmaceutical Task Force). Conceptually, the BPC feels the proposed DBC 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.

The BPC believes that the Terms of Reference broaden membership in numbers but do not substantially change criteria for membership from those that exist today (i.e. TI members). Membership of the DBC needs to be expanded to include epidemiologic and medical researchers and clinicians with expertise in clinical trial methods and qualitative health outcomes studies as well as individuals with experience in Public Health Administration. These areas of expertise are vitally important given that a significant percentage of the PharmaCare budget is spent on prescription medications to treat chronic conditions where the burden of indirect health care costs to the government are far greater than direct health care costs (e.g. drug expenditures). Appointment term limits need to be specific and should be staggered so as not to lose continuity of knowledge.

Membership on the DBC membership should also be expanded to allow for individuals who may be able to make valuable contributions to the process but do not necessarily have previous experience on a drug plan expert advisory committee.

As BPC stated in its submission to the Task Force, there should be a reasonable and transparent remuneration schedule for DBC members and DCRT members (per diems/stipend similar to other government consulting groups). However, the schedule of six one-day DBC meetings per year is not sufficient to significantly improve the times-to-listing as required by the Task Force Recommendations. BPC believes to achieve improved timeline targets, the DBC meetings should be held 12 times annually.

Drug Review Resource Committee

Task Force Recommendations

The Task Force envisioned a new Drug Review Resource Committee (DRRC) that would function as a subcommittee of the DBC but not serve as a review body. Its mission, instead, would be to build and maintain a registry of qualified, knowledgeable and experienced experts to serve on Drug Coverage Review Teams (DCRTs). The Task Force recommended that the DRRC would not make recommendations to the DBC.

PSD White Paper

The PSD proposes the DRRC to serve as an independent group to gather the necessary evidence and clinical considerations for the DBC and replace the role presently performed by the TI. PSD also suggests that the DRRC would make recommendations to the DBC.

BPC Response

The BPC is very concerned about the PSD's interpretation of the role and function of the DRRC and how dramatically misaligned it is with the Task Force Recommendations. The DRRC (as outlined in the Task Force Report and PSD white paper) is a subcommittee of the DBC. 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.

The Task Force Report states that the DRRC is a subcommittee of the DBC designed and structured to develop and maintain a registry of subject matter experts from which to select members for Drug Coverage Review Teams (DCRTs) not serve as a review body. The selection of a subject matter expert to work in conjunction with the Drug Intelligence Director on a drug review file is the last function. The BPC recommends further discussion with PSD to clarify the structure and function of the DRRC and ensure its alignment with what is designed in the Task Force Report's Submission Review Process chart.

As stated in the Task Force Report, but not contained in the PSD White Paper, the concept of the DRRC is to perform the function of maintaining a registry of qualified, experienced and knowledgeable reviewers to serve on the DCRTs. This function of the DRRC would represent a new and unique approach to the drug submission review process in Canada.

Drug Coverage Review Teams (DCRT)

Task Force Recommendations

"The proposed approach would establish a DRRC that would be responsible for the maintenance of a much larger open registry of experts to participate in Drug Coverage Review Teams (see Chart). These DCRTs, with expertise appropriate to the therapeutic area under consideration, would critically review the applicable literature, clinical studies, submissions and, where applicable, reports of the Common Drug Review in order to provide the DBC and, ultimately the PSD with the best possible advice – both therapeutic and economic – as to whether a product should be listed for coverage.

The Task Force also suggests that a revitalized process should also make provision for a greater degree of pre-submission and post-submission engagement between PSD staff and industry applicants to ensure that submissions are as complete as possible and to substantially improve budget impact information that the DBC and PSD will require in order to make the most appropriate recommendations and decisions as possible." (p.12) - Report of the Pharmaceutical Task Force, April 2008

The new Drug Coverage Review Teams (DCRTs), as envisioned by the Task Force, were to replace the role currently preformed by TI and represented a major innovation on the present drug review process. Under this new body, drug reviews would be performed by therapeutic area experts with listing recommendations provided to the DBC. The Task Force recommends that multiple DCRTs would operate simultaneously reviewing different drug submissions, significantly speeding up the overall review process.

PSD White Paper

The DCRTs were not developed in the PSD White Paper with any mention of their structure or functions; instead, PSD proposed establishing one clinical and one pharmacoeconomic review team each reporting to the DRRC with membership subject to the highly restrictive Conflict of Interest Guidelines.

BPC Response

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. As stated earlier in this document, BPC considers it vitally important that when reviewing medications for specific diseases that clinical experts are involved as well as patients living with disease. Experiential knowledge about illness and medications is a key to ensuring appropriate and effective policy decisions. For example, as cost is an important issue to BC PharmaCare, issues of adherence and experience with medications would help to shed light on areas that quantitative research may not address.

Establishment of New Target Timelines

Task Force Recommendations

The Pharmaceutical Task Force concludes that BC PharmaCare currently has one of the slowest and most costly drug review processes in the country.

The Task Force recommends establishing new target review/listing decision guidelines with the goal to substantially improve time-to-listings and to benchmark performance against other jurisdictions.

PSD White Paper

The PSD states the Ministry of Health Services' goal is to establish and meet timeframes which would position BC as a leader in Canada for timely, transparent decision making. It pledges to address target timelines through the categorization of drug submissions based on complexity of the submission. PSD also proposes an additional submission pathway for clinicians.

BPC Response

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. However, the Task Force did not make recommendations for drugs to be categorized into three groups as proposed by PSD. BPC believes this process is more likely to increase the complexity of the process and thereby increase review timelines. The categorization of drug submissions is not necessary if the DCRTs are fully implemented and properly resourced. 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. In fact, there does not appear to be a difference, on paper, between the "Time to Decision" performance now and the projected improvement targets in the White Paper.

The BPC believes PSD should benchmark against national and international best practices and attempt to not just meet these, but exceed them. As stated in our submission to the Task Force, 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.

The BPC agrees with the White Paper's assertion that "BC's drug review process would be continuously reviewed taking into consideration stakeholder feedback." BPC believes PSD should have an external work-flow or quality improvement expert initially review the new process and then conduct external reviews of the process on a regular basis to look for further improvements and ensure the process was meeting the needs outlined in the Task Force recommendations.

Finally, the proposal for a "clinician submission pathway" was not part of the Task Force recommendations. While allowing clinicians a formal pathway to make drug submissions could open up local community trials and improve outcomes research, the concept is not fully developed in the White Paper and needs to be further discussed with stakeholders.

Accountability and Transparency

Task Force Recommendations

"At present stakeholder relations are managed almost exclusively by representatives of the PSD. While the Task Force sees this as useful, and believes it will be important for an even greater degree of engagement in the future, it would also be beneficial if patient groups and the other key stakeholders had an annual opportunity for an accountability session with the Deputy Minister of Health to discuss progress on improved patient outcomes and the level of constructive engagement between the parties."

- Report of the Pharmaceutical Task Force, April 2008

PSD White Paper

The White Paper recommends actual times-to-decision for individual submissions to be publicly reported on the Ministry website. It also endorses performance measures for the Ministry's drug review process to be developed, and applied on a go-forward basis, and reported in the MoHS' PSD Annual Report.

BPC Response

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.

To ensure that the principles of accountability and transparency are embedded into the overall drug review and approval process, BPC recommends the Ministry of Health follow several guidelines:

- Use of lay language for public materials;
- Make the process more accessible to the public;
- Public record of meetings (paying attention to issues of confidentiality).

The BPC believes the Ministry needs to take a more "results-based" approach to its drug review and approval process as recommended by the Auditor General in March of 2006 (see attached report). Areas cited for improvement include:

- Developing stated strategic objectives;
- Linking objectives to actions that will lead to accomplishing these objectives (e.g. resources, plans, actions);
- Developing solid performance measure and monitoring progress; and
- Measurement of achievements (and shortcomings) and taking action to further improve (TQI approach).

The BPC supports the PSD White Paper recommendation for a process for continuous improvement that factors in stakeholder feedback. BPC feels there is an important role for public/patient participation in setting performance standards that are not considered in the PSD White Paper.

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. Regular and meaningful meetings would provide valuable feedback and assist Government in planning and preparing for future pharmaceutical-related health care needs of British Columbians.

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.

Draft Conflict of Interest Guidelines for the Drug Benefit Council

Task Force Recommendations

"We recommend a new approach that would substantially increase the level of expertise available to support effective and timely drug reviews, increase transparency and improve the quality of information required to properly support the role of the DBC."

"The existing PSD approach to conflict of interest guidelines is also so restrictive in that they exclude participation by disease-specific specialists who likely have the most to offer on the potential value of new therapies. An expanded approach would facilitate the engagement of expertise of other entities including, but not limited to, the Centre for Applied Health Research, the Centre for Infectious Inflammatory and Immunologic Disease, the Centre for Molecular Medicine and Therapeutics and other highly regarded academic groups."

- Report of the Pharmaceutical Task Force, April 2008

In its discussion of DBC Membership and Conflict of Interest Guidelines, the Task Force was clear that no members of the TI or DCRTs should participate as members in the DBC. It suggests that the Board Resourcing Office may be the most appropriate agency to carry out appointments. The Task Force also states that the existing PSD approach to conflict of interest guidelines is so restrictive that they exclude participation by disease-specific specialists who likely have the most to offer on the potential value of new therapies. The Report called for the expanded approach to membership models, including the Centre for Applied Health Research, Centre for Infectious Inflammatory and Immunologic Disease, Centre for Molecular Medicine and Therapeutics.

PSD White Paper

The PSD's proposed Conflict of Interest (COI) guidelines for the new Dug Benefit Council set out definitions for COI, as well as the requirements and processes for the disclosure of any conflicts by DBC members.

The PSD's COI guidelines essentially are the same as those under the CDR. The PSD does not refer to the role of the Board Resourcing Office. It also does not refer to the structures of other highly regarded government and academic groups to model membership appointment for the DBC.

BPC Response

While PSD can benefit greatly from the use of external advisors, BPC recognizes that external advisors may have affiliations with regulated industries, the healthcare community or special interest groups, thus raising conflict of interest concerns. PSD therefore must attempt to achieve a balance between these two sometimes divergent considerations and will make a reasonable effort to enable the Drug Benefit Council to take advantage of external expertise while avoiding conflict of interest situations.

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.

Instead, 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. As a result, the COI guidelines run against the spirit of the Task Forces guiding principle to "place the interests of British Columbia patients first", not to mention they are out of step with COI guidelines presently in use in Canada.

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.

The COI Guidelines effectively treat "domain knowledge" as an attribute to be avoided, as opposed to valued. Domain knowledge is critically important in evaluating evidence and making recommendations. The COI guidelines eliminate individuals such as patients, clinicians and researchers with valuable, specific domain knowledge from participating in the drug review process and consequently fail to support the PTF recommendations related to "maintaining the requirement for the input of therapeutic and clinical experience in the review process…" while protecting the process from inappropriate influence created by conflicts of interest.

Health Canada has developed an excellent series of conflict of interest guidelines that PSD should consult as best practices in Canada. All external advisors to Health Canada are required to make a formal disclosure of real, potential or perceived situations of conflict of interest, prior to providing service, and during their term of service. Committees are encouraged to take advantage of external expertise while avoiding conflict of interest situations. External members of Health Canada are required to comply with conflict of interest requirements, recognizing that confirmation of a situation of conflict of interest can result in limiting the member's role in a particular discussion, or terminating a member from the committee.

SECTION 2
BPC response to the BC MOHS "procurement" or "tendering" model(s)

This section will include the BPC response to the BC MOHS' plans to introduce new "procurement" or "tendering" model(s) to purchase pharmaceutical and other medical products. Although no "white paper" was provided on this topic during the July 17th Multilateral Stakeholder Session, extensive discussion took place on the topic during the afternoon session.

Generic drugs

Task Force Recommendations

"The Task Force believes that British Columbia should vigorously pursue an overall reduction in the cost of generic drug products and, further, the development of more rational transparent and accountable reimbursement arrangement with pharmacies."

- Report of the Pharmaceutical Task Force, April 2008

BPC Response

The BPC strongly agrees that efficient and effective procurement and service delivery options can help counter sustainability pressures facing health care. We recognize generic drug manufacturers play an important role in Canada's healthcare system; however, BC pays one of the highest prices for generic drugs of any jurisdiction in Canada.

The BPC agrees with the Task Force recommendations to negotiate pricing with generic drug manufacturers commensurate with pricing in other jurisdictions and to reinvest the savings into innovative and breakthrough drugs that merit listing on the BC Pharmacare drug reimbursement formulary.

Tendering

Task Force Recommendations

In exploring options for change in Procurement and service delivery options, the Task Force recommends that the PSD adopt a cautious approach to broadened use of tendering processes:

"If Government ultimately elects to proceed with the increased use of tendering, care should be taken to develop tendering criteria that will be attentive to the value of patient choice, that will avoid the deployment of older inferior products and, where possible, tendering requirements should be designed to maintain participation of multiple suppliers perhaps through having variable shares of the market opportunity determined by the quality of their respective bids. It is also very important that the tendering process, together with any associated evaluation criteria/processes, be transparent, clearly communicated to all potentially interested parties and fair. Task Force members further noted that the tendering process, a cost controlling procurement methodology, should not be utilized as an indirect method to effect clinical outcomes, (for example, tendering to indirectly implement therapeutic substitution)."

- Report of the Pharmaceutical Task Force, April 2008

BPC Response

The topic of tendering was not addressed by the Ministry of Health is its White Paper. The stakeholder feedback from the July 17, 2008 stakeholder session revealed a divergence of opinions and interpretations of tendering and procurement models without a clear consensus for the PSD implementation team to act upon.

The BPC acknowledges that efficient and effective procurement and service delivery options can help counter sustainability pressures facing health care. However, the BPC also recognizes that sustainability is dependent on government breaking down the internal silos to ensure that cost savings in one department are accounted for by expenditures in other departments (i.e. hospital budgets versus BC PharmaCare).

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. These cost containment initiatives are short-term solutions that simply push costs to other parts of the healthcare system and generate negative health outcomes for patients. Moreover, the negative affect these initiatives have on the doctor/patient relationship represent a dangerous threat to quality health care. Government must discontinue the practice of trying to pick "winners and losers" in determining which drugs in which category should be covered and by how much. Those are

choices to be made together by doctors and patients, the people who know the medical and experiential circumstances, the experts who have the education, training and experience to make such judgments.

"Vertical tendering" where there is demonstrated bioequivalence (identical chemical compounds) can result in significantly lowering prices without compromising care and is fully acceptable to the BPC. However, tendering horizontally across a class and assuming that the drugs are roughly equivalent is damaging to BC residents and unacceptable to the BPC.

Sole product tendering severely limits patient and physician choice but also pits manufacturers against manufacturers in pursuit of market share. This ends up creating even more frustration and switching for patients as tenders expire and are renewed. It also focuses all attention on 'the bottom line' which clearly puts patients' needs in last place. Sole tendering also discourages research, investment and economic growth as it promotes a 'winner takes all' environment. This in turn creates stagnation in scientific discovery, advancement and intellectual property rights.

Consider the New Zealand experience with the tendering of statins, which has been an unmitigated disaster and caused significant harm to patients, sometimes resulting in death (New Zealand Medical Journal , "PHARMAC and the statin debacle," 23 June 2006). What the world has learned from the New Zealand model is that cost-cutting efforts via limiting availability of new medicines results in additional pressures in other parts of the healthcare system and unintended and costly health outcomes, such as increased hospitalizations, re-admissions and increased disease incidence (e.g. coronary heart disease).

While the New Zealand model delivered monetary savings, it came with "real world" costs to patients and consumers. New Zealand's "finances-first" approach to drug therapy means that many patients are denied the drug(s) best suited to a particular patient's health history and disease status and lead to slower recovery times, an increase in adverse events, and other important unintended health outcomes (Stewart et al, 2008).

Not surprisingly, New Zealand has higher disease burdens and worse health care outcomes compared to other OECD countries where access to innovative medicines is not restricted. For example, in a time when coronary heart disease is declining in industrialized countries, New Zealand has the highest frequency of coronary by-pass surgery compared to France, UK, Italy, Canada and Australia (OECD Health Data, 2007).

The New Zealand tendering experience with the prescription medication, Ritalin, also saw one unexpected legal consequence for the government in that it found itself bound to a supplier for a given period of time and was not able to open the tender when it wanted to add more choice after the fact. ("Pharmac changes mind on drug swaps," New Zealand Herald, September 17, 2007).

The BPC recommends that BC PharmaCare should work closely with the Purchasing Commission, a BC health economist expert in the area of unintended consequences of tendering and other experienced procurement bodies to examine the ramifications of tendering and consider the examples in other countries such as New Zealand before making decisions on procurement and tendering. All tenders should be evaluated across the board by the various stakeholders affected, particularly the impact on patients and the ability for physicians to provide quality care.

The Task Force report recommends that if tendering is going to be used in the province of BC that it should be both transparent and fair. In a recent policy brief by Aidan Hollis, he argues that the process currently established with a product olanzapine is neither transparent nor fair.[1] He feels that the sole source tendering process allows for the government to get lower prices but provides no option for patients to receive the product at the same price. He argues due to the non-transparent sole supplier winner take all approach that it will have an effect on the competitive model with the generic sellers.

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.