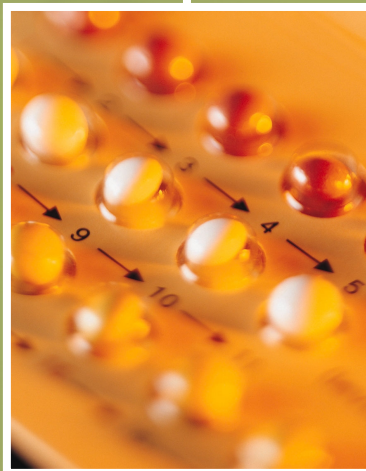


# REPORT OF THE PHARMACEUTICAL TASK FORCE

TO THE  
HONOURABLE GEORGE ABBOTT  
MINISTER OF HEALTH  
PROVINCE OF BRITISH COLUMBIA

APRIL, 2008



April 10, 2008

Honourable George Abbott  
Minister of Health  
Government of British Columbia  
PO Box 9050, Stn Prov Govt  
Victoria, BC V8W 9E2

Dear Minister Abbott:

We have the honour to transmit herewith the Report of the  
Pharmaceutical Task Force.

It has been our privilege to undertake this challenging task. We hope  
our conclusions will assist you and the Government of British Columbia  
in finding a constructive way forward with the evolution of  
pharmaceutical policy in our Province.

We would be pleased to make ourselves available to discuss our findings  
with you in greater detail.

Yours truly,

A handwritten signature in black ink, appearing to be 'Don Avison', with a stylized, flowing script.

Don Avison  
Chair

ON BEHALF OF THE PHARMACEUTICAL TASK FORCE

George L. Morfitt (Alternate Chair), Susan Paish, QC, Gordon Cross,  
Dr. Robert Sindelar, Paul Gudaitis, Russell Williams, David Hall,  
Dr. Mark Schonfeld.

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## Task Force Mandate and Membership

In November, 2007 the Minister of Health established a Pharmaceutical Task Force and invited recommendations regarding how the Ministry of Health could achieve progress in the following areas:

1. optimization of the decision making process for the listing of pharmaceuticals and devices to produce timely, transparent decisions based upon sound science while appropriately protecting the public interest;
2. procurement and service delivery options for pharmaceuticals and medical devices that will achieve and maximize value to patients and value for money objectives;
3. identification and strengthening of common objectives related to patient care and choice and the building of positive relations between government decision makers and industry to achieve those objectives;
4. the effectiveness of the Common Drug Review process and proposals for improvements;
5. the effectiveness, transparency and future role of the Therapeutics Initiative in supporting the listing process of drugs, or a more viable and cost-effective alternative.

The membership of the Task Force included senior industry representatives from the patent

medicine, medical device and retail pharmacy communities, the Dean of the Faculty of Pharmaceutical Sciences at the University of British Columbia, the Chief Executive Officer of the BC Medical Association, two senior representatives of the Ministry of Health, the former Auditor General of British Columbia (Alternate Chair) and the President of the University Presidents' Council (Task Force Chair). The Project Charter established to guide the work of the Task Force is reproduced at Schedule 'A' to this Report.

The Task Force met on nine occasions from December of 2007 through to late February of 2008. Submissions were received from, and in most cases the Task Force met with, the BC Pharmacists Association, the Canadian Generic Pharmaceutical Association, the Canadian Association of Chain Drug Stores, Rx&D<sup>1</sup>, MEDEC (Canada's Medical Device Technology Companies), the Better PharmaCare Coalition, the Canadian Diabetes Association and the senior leadership of the research components of the Vancouver Coastal Health Research Institute, the Child and Family Research Institute (Provincial Health Services Authority), the Providence Health Care Research Institute and the Senior Associate Dean, Research of the Faculty of Medicine at the University of British Columbia.<sup>2</sup>

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<sup>1</sup> The entity which represents Canada's research-based pharmaceutical companies.

<sup>2</sup> The Dean of Medicine, subsequently made himself available to the Task Force to offer further commentary and clarification, particularly with respect to the operations and accountabilities associated with the Therapeutics Initiative housed within the Faculty of Medicine.

In addition to the submissions from the groups mentioned above, the Task Force met with representatives of the National Common Drug Review (video conference) and UBC's Therapeutics Initiative, with the Assistant Deputy Minister in the Ministry of Health responsible for administration of the Pharmaceutical Services Division (PSD) and the

Executive Director of the Drug Intelligence unit of the PSD.

The Task Force also heard from Dr. Chris Corbett of CSCW Systems Corporation (CSCW) who was made available by the Ministry of Health to discuss the content of a Ministry-sponsored review CSCW conducted in respect of the Province's PharmaCare program in 2003/4.<sup>3</sup>

## Managing Pharmacare: The BC Context

### I. The Role and Objectives of the Pharmaceutical Services Division

The Task Force met first with the Assistant Deputy Minister and the Executive Director of the Drug Intelligence Unit of the PSD to receive a comprehensive overview of the PSD's approach to the administration of pharmaceutical policy, the processes applicable to the evidence-based review of submissions for the listing of new drug therapies in BC, cost pressures faced by the PharmaCare program and on other complex factors which influence the environment that program administrators and policy makers work within. The discussion with senior representatives of the PSD addressed:

- the PSD's Mission, Goals and Objectives;
- baseline information about the pharmaceutical distribution environment in BC;

- the nature of BC's drug review processes including the respective roles of the PSD, the Drug Benefit Committee, the Therapeutics Initiative and how BC interacts with related external processes such as the national Common Drug Review (CDR) and the Patented Medicine Prices Review Board (PMPRB);
- the demands on the PSD to effectively manage the rising costs associated with the PharmaCare program;
- the impact cost pressures have on decisions regarding the province's formulary management system; and
- strategies which have been – or likely will be – deployed to further contain the cost of pharmaceutical products eligible for reimbursement under British Columbia's PharmaCare program.

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<sup>3</sup> “Findings of the CSCW Review of PharmaCare”, May 2004.

The Task Force was informed that the PSD is the product of a substantial reorganization of what had been the Ministry of Health's PharmaCare Division. These changes, which have added substantial new human resource capacity to the PSD were, at least in part, responsive to recommendations set out in previous reports of the Auditor General, (see: "Managing PharmaCare: Slow Progress Toward Cost-Effective Drug Use and a Sustainable Program", March, 2006) and the CSCW Review of PharmaCare.

The reorganization of the PharmaCare Division into the substantially more robust PSD has helped to resolve concerns about the level of human resources available to the program and also appears to have diminished the level of senior staff turnover. The reorganization has facilitated the appointment of five executive directors with responsibility for Drug Intelligence, Drug Use Optimization, Policy Outcomes/Evaluation, Business Management/Supplier Relations and the conduct of BC's role as a lead jurisdiction with the National Pharmaceutical Strategy. These additional resources, together with the nature of the reorganization of the entity provides room for optimism<sup>4</sup> that the Ministry of Health will have the human capacity to be able to address the partnership-based engagement strategies that this Task Force views as vital to the longer-

term sustainability of the pharmaceutical management system in British Columbia.

The stated mission of the newly constituted PSD is to "advance the health of British Columbians by supporting optimal drug therapy." This mission is guided by the following core goals:

**Goal One** – Support citizens to have the best possible health;

**Goal Two** – Develop the best pharmaceutical system in the world; and

**Goal Three** – Create the best place to work, with the best people.

Support to patients, the provision of high quality unbiased information to health professionals, access to comprehensive drug benefit programs, acquisition of "the best drugs at the best prices", the importance of sustainability, effective stakeholder engagement, continuous improvement, enhanced patient care and safety were profiled as significant objectives linked to the PSD's core goals.

## 2. Increased Demand and Rising Costs

Much of the PSD presentation to the Task Force focused on the cost and budgeting pressures faced by the PharmaCare program. This is not surprising given the extent to which spending increases within provincial

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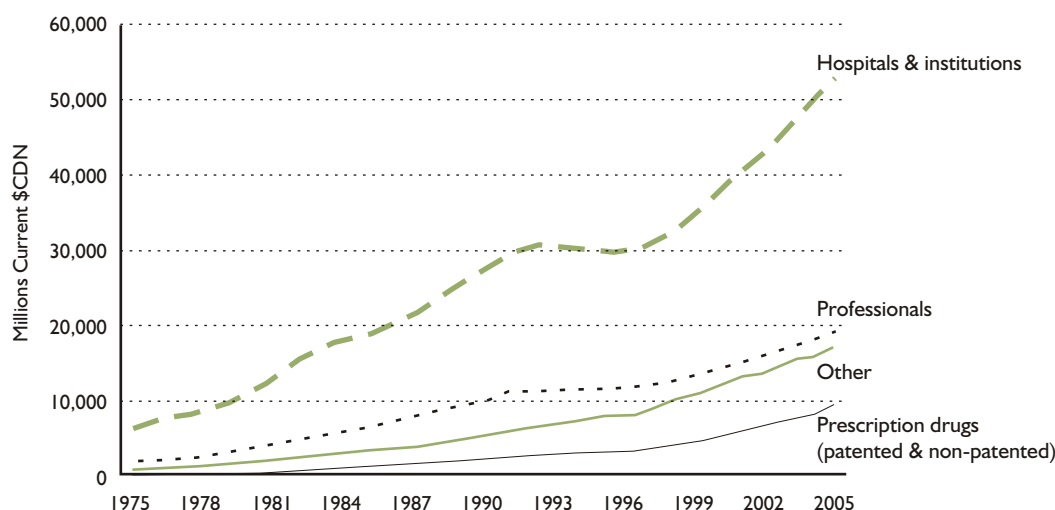
<sup>4</sup> This includes plans for the hiring of further staff to carry out the expanded mandate of the PSD.

pharmaceutical coverage programs have been trending in recent years.<sup>5</sup> At the national level, government-supported expenditures on pharmaceutical products now account for 9.6% of health-related spending (see Figure One).

The numbers in British Columbia are somewhat different. BC continues to spend less, per capita, than the Canadian average on prescription drugs (based on data available from 2006, BC's expenditure level stood at \$466 per person while the national average was \$598). It

is important to note, however, that BC is experiencing the highest growth rate in the number of new prescriptions (11.4% against a national average of 8.6%) and the third highest growth rate in the dollar value of prescriptions. When looked at over the longer term, BC has seen a substantial increase in the cost of prescription drugs over the past decade.<sup>6</sup> In 1996 the province's PharmaCare program spent \$372 million on prescription drugs. The amount increased to \$713 million by 2004 and

**Figure One: Government health expenditure (GHEX) in Canada, 1975 to 2005, by use of funds**



Source: Canadian Institute for Health Information (CIHI), 2005

<sup>5</sup> Some caution may be required when considering, in isolation, increased costs in pharmaceutical coverage programs. It is now well established that increased drug expenditures may simply indicate that drug therapies have been successfully deployed in a manner that may help to alleviate pressures on other aspects of the healthcare system. The British Columbia Medical Association in "A Prescription for Quality; Improving Prescription Drug Policy in British Columbia, (July, 2007 – see p. 14), said this: "As in any area of public policy, increased spending may be a prudent investment, with gains to be realized in the future. For example, clinical guidelines and chronic disease management programs have increasingly emphasized drug therapy as a cornerstone to improving health outcomes and controlling costs. Multiple clinical trials suggest that use of appropriate heart failure drug therapies may be the most effective way to reduce the cost of care while reducing morbidity and mortality: drug therapies can reduce hospitalization by 12% to 35%, depending on the drug (Goldfarb, Weston et. al. 2004). Nonetheless, within finite budgets, increased spending in one area may also offset expenditures elsewhere in the healthcare system. The challenge for healthcare policymakers is to determine if and when the investment in prescription drugs – particularly in light of continued growth – is worth the expected return."

<sup>6</sup> This growth rate is substantially consistent with what has taken place in other provinces and other national jurisdictions.



climbed further to more than \$900 million for the 2006/07 fiscal year (see Figure Two).

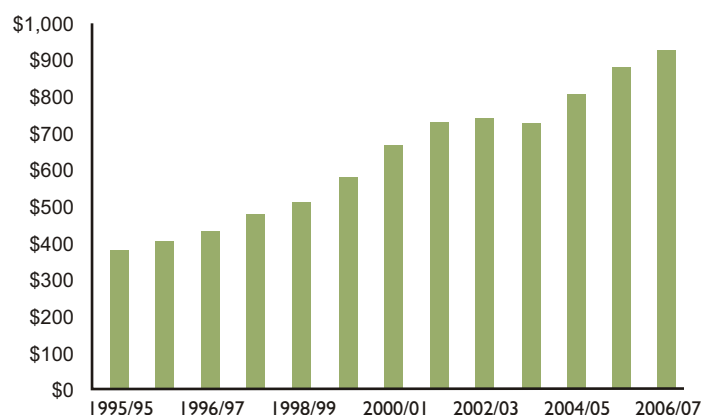
PSD representatives indicated that, faced with these rising cost pressures, they are looking at measures to reduce costs and, thereby, to limit the otherwise predictable trajectory of spending on pharmaceutical products. While PSD representatives were less precise on this point in their discussions with the Task Force, they have indicated in other fora<sup>7</sup> an intention to realize “projected savings” of \$214 million<sup>8</sup> by 2010 through a combination of:

- product agreements with manufacturers of innovative drug therapies that will result in “the negotiation of better terms”;
- cost savings from addressing the link between generic drug rebate programs and retail pharmacies;
- the increased utilization of tendering processes; and
- health promotion initiatives intended to encourage more appropriate and effective drug use by patients.

These options, and the sensitive implementation issues associated with them, will be addressed in greater detail later in this report.

**Figure Two: PharmaCare Plan Expenditures (\$ millions)**

Includes both Pharmacare plan and program management expenditure



The Ministry of Health and the PSD are right to be concerned about rising pharmaceutical costs. It should be mentioned here, however, that – with few exceptions – all who participated in the Task Force process recognized that affordability and value for money are, and will remain, key factors that those responsible for government's pharmaceutical reimbursement programs must consider in making the difficult decisions regarding whether new drug therapies will be listed for coverage on the provincial formulary. There was also a strong and comprehensive recognition by most presenters that while the cost of pharmaceuticals must be a key factor, so too must be choice, availability, reliability of supply and patient outcomes. Ignoring any of

<sup>7</sup> “Pharmaceutical Policy Reform in British Columbia” (IMS, Provincial Reimbursement Advisor, Vol. 10, Issue 4, November, 2007).

<sup>8</sup> A number of significant patent-protected drug therapies will come off patent in the near term. This factor, of itself, should help to alleviate cost pressures. Encouraging the innovative drug manufacturers to more fully participate in the post-patent context would be prudent.



these factors may potentially result in increased costs to the system in the short and long term and adverse patient outcomes. As you will see from what follows, the key concerns from patient groups, from health care practitioners and from industry focused on what is perceived as an insufficient commitment by the PSD to openness, transparency and meaningful dialogue on matters of shared interest and concern.

**Issue One: *Optimization of the decision-making process for the listing of pharmaceuticals and devices to produce timely, transparent decisions based upon sound science while appropriately protecting the public interest.***

During the course of the submissions process several concerns were raised regarding British Columbia's existing approach to the listing of pharmaceuticals and other health-related products. The Task Force heard repeatedly that, despite the increased administrative capacity within the PSD, the listing process remains cumbersome, unnecessarily insular and less efficient than it should be in providing patients with timely access to coverage for new drug therapies.

Industry, particularly those representing the interests of patented drug manufacturers, enumerated a number of concerns including the following:

- that the current BC process is unreasonably slow, both by national and by international standards;
- that British Columbia provides “full listings” for fewer new therapies than other provincial jurisdictions and generally takes much longer to list;
- that industry believes they have a partnership role to play “as part of the solution” to sustainability but that they have found the PSD to be non-responsive in this regard. The absence of a constructive and transparent environment limits the extent of significant international industry investment in BC<sup>9</sup>;
- that, despite British Columbia's lead role in calling for a national Common Drug Review to improve the quality and efficiency of listing decisions, BC's average “time to listing” increased significantly following CDR implementation<sup>10</sup>;

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<sup>9</sup> For example, it is almost certainly the case that the level of investment by industry in the British Columbia Cancer Agency is more modest than what it would be in a more stable environment that placed greater weight on the importance of innovation.

<sup>10</sup> It must be noted, however, that time to listing decisions, while they remain longer than the national average, have begun to improve over the past year. The Task Force notes that the quality of the available data in this area is modest and it would be useful to have the benefit of a better mechanism to independently assess BC's time-to-listing performance to help facilitate continuous quality improvement.

- the 'silo' approach to PSD budgets does not adequately address, or relate to, the positive impact that effective pharmaceutical treatment and expenditures can have on limiting expenses in other areas of the healthcare system; and
- that the existing process for listing gives insufficient weight to the value of innovation and essentially none to economic development factors.<sup>11</sup>

The Better PharmaCare Coalition (BCP)<sup>12</sup> and the Canadian Diabetes Association (CDA) articulated even stronger views. The BCP made the following observations and recommendations:

- patients believe they are being denied optimal therapy because PharmaCare coverage is restricted to “least expensive” or “best deal” drugs and devices without sufficiently considering the impact on health outcomes of the lowest cost products;
- that the overlap and duplication in national/provincial drug review and listing

processes should be substantially rationalized with the objective of significantly improving “time to listing” decisions;<sup>13</sup>

- BC should establish a quick and effective process at the provincial decision-making level for all drugs/indications that do not fall within the scope of the Common Drug Review (includes 'line extensions' or 'new indications' in respect of previously approved drugs);
- the decision-making processes regarding listing should be open, transparent and inclusive with an increased role for patient engagement and for the participation of disease specialists;
- specific action should be taken to address the disproportionately higher costs paid for generic drugs in British Columbia relative to what is paid in other jurisdictions with “savings” re-directed to investments in new innovative drugs that “merit listing on the BC PharmaCare drug reimbursement

<sup>11</sup> Senior PSD staff confirmed that they do not consider economic development factors to fall within their mandate. This may well be accurate but it must also be understood, given that all listing decisions are ultimately determined through the PSD, that this means broader economic factors beyond cost management of the PSD budget (e.g. prosperity and economic development indicators) are not addressed by anyone.

<sup>12</sup> The Better PharmaCare Coalition represents the interests of Arthritis Consumer Experts, the Arthritis Society (BC/Yukon Division), BC Lung Association, BC Schizophrenia Society, Canadian Arthritis Patients Alliance, Canadian Society of Intestinal Research, Canadian Association of Retired Persons, Heart and Stroke Foundation (BC/Yukon), the Kidney Foundation of Canada (BC), Mood Disorders Association of BC, MS Society (BC Division), Parkinson Society of British Columbia and the Osteoporosis Society of Canada (BC Division).

<sup>13</sup> The BPC proposes that British Columbia should complete formulary listing decisions not more than three months following a “recommendation to list” from the Common Drug Review.

formulary”;<sup>14</sup> and

- BC should benchmark the cost, efficiency and effectiveness of the PharmaCare infrastructure against the performance of other jurisdictions.

The Canadian Diabetes Association's (the CDA) submission made many points similar in nature to those expressed by the BPC but called for PharmaCare to be renewed through legislation that would include the following components:

- stronger transparency and accountability by giving patients a role in formulary listing decisions;
- increased patient access to all safe and effective medications, devices and supplies available for sale in Canada;
- removal of unnecessary paperwork for doctors;
- increased roles for pharmacists and their expertise in medication therapy and chronic disease care;
- inclusion of the relevant disease experts in decisions on disease specific listings;
- responsiveness to the views of British Columbians on the social aspects of drug

policies and priorities; and

- achievement of the greatest savings possible for BC taxpayers by counting all costs and benefits across the BC healthcare system from increasing access to safe and effective medications, devices and supplies.

Other groups who participated in the Task Force process made recommendations that were focused on strengthening the recognition of health and life sciences research as key drivers of improved health outcomes. This view was strongly articulated by the senior representatives of the Vancouver Coastal Health Authority (VCHA), Providence Health Care (Providence) and Provincial Health Services Authority (PHSA) research institutes who called for the development of what they described as a “healthier climate” for increased engagement of pharmaceutical research and investment in British Columbia and the development of a culture of innovation oriented towards improved health outcomes for patients. These research experts contend that the historical, and current, approaches to listing decisions in BC have been unreasonably restrictive in this regard.<sup>15</sup>

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<sup>14</sup> The high cost of generic drugs in British Columbia, and options to address this, is considered later in this report, (see pages 16-19). It should be observed, however, that some Task Force members were struck by how little attention this area of potentially substantial savings has received compared the province's Reference-Based Pricing program where the level of “savings” is relatively modest. (see: Report of the Reference Drug Program Consultation Panel to the Honourable Sindi Hawkins, Minister of Health Planning, British Columbia, April, 2002)

<sup>15</sup> These research experts were particularly critical of what they regard as a narrow and restrictive approach used by the Therapeutics Initiative. They further suggest that the Therapeutics Initiative has been insulated from robust peer review expected of academic organizations and from the rigours of competitive funding models.

The Task Force agrees and 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. With the process of reorganizing and strengthening the Pharmaceutical Services Division now substantially complete, priority attention should be directed to the revitalization of the drug review listing process<sup>16</sup> and this should be carried out in a manner consistent with government's objective of developing "the best pharmaceutical system in the world." In so doing, a plan needs to be developed with a focus on addressing the timeliness of decision-making, the reduction of unnecessary duplication, improved transparency, the enhanced deployment of a wider array of peer-respected specialized expertise and a meaningful and credible commitment to stakeholder engagement.

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. Experts agree that, in the future, there will be less emphasis on "blockbuster, one-size fits all" therapeutics as a greater number of therapies will be targeted to more specifically meet the needs of particular patient groups. This will require a much more robust approach to evidence-based evaluation, to listing decisions and to the related management of pharmaceutical expenditures. Many of the changes the PSD has made through their recent reorganization have the potential, if managed wisely, to provide the foundation necessary to respond to these anticipated changes.

The Task Force was not persuaded that modifications to the PharmaCare program, or to the listings process, can only be achieved through legislation, nor that reimbursement should be made available in respect of "all safe and effective medications, devices and supplies available for sale in Canada." On the contrary, we believe any necessary changes to the review and listing process can best be achieved through

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<sup>16</sup> This proposal is not new. The March, 2004 CSCW Review of PharmaCare had identified "an urgent need for the implementation of a comprehensive, transparent, administrative system for the generation and ongoing management of the PharmaCare Formulary." That review recommended the development of a new Formulary Management System that would engage the participation of stakeholders and strengthen the role of PharmaCare (now the PSD) as the "system integrator."

meaningful engagement with stakeholders, the use of the very best evidence and through clear policy direction from government.

On the cost side, value for money and sustainability will continue to be core guiding principles. Program administrators with the PSD will be required, as they are now, to make difficult decisions regarding which therapies and products will, or will not, be listed for coverage under the provincial formulary. These decisions, however, can – and should – be informed by a substantially enhanced level of engagement with knowledgeable disease specialists, with other health professionals, with patient representatives and with industry. This increased commitment to engagement of stakeholder interests in the drug review and listing process will also be central to the implementation of more effective strategies to improve drug utilization management. The greatest opportunities for sustainable innovation in the system will likely occur at the intersection of diverse thought that may come from such effective engagement.

### **Proposed Modifications to the Drug Benefit Committee**

At present, one of the most significant roles in BC's listing process is carried out by the Drug Benefit Committee (DBC), an arm's length entity that provides advice to government on whether, and to what extent, drug therapies should be listed for coverage under the

PharmaCare program. The Task Force sees the role of the DBC as key to the management of an effective and respected program but would offer a number of recommendations regarding proposed improvements in respect of the membership, transparency and operations of the DBC.

It is important to note that the Ministry of Health and the PSD have already recognized that changes to the membership of the DBC are both necessary and appropriate. Prior to the initiation of the Task Force process the PSD already had plans to move ahead with the appointment of a public member to the DBC. Action to address this issue was held in abeyance awaiting the outcome of the work of this Task Force.

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<sup>17</sup>, 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.<sup>18</sup> This step would be more compatible with modern governance practices, would provide for increased public and patient engagement and would substantially

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<sup>17</sup> The Board Resourcing Office may be the most appropriate agency to carry out this role.

<sup>18</sup> The appointment process would be different in nature than the one currently in place for the Medical Services Commission.

assist in addressing accountability and transparency expectations. In addition, the Task Force recommends that the DBC should be reconstituted as the “Drug Benefit Council” to more appropriately reflect the arms length position it is expected to play.<sup>19</sup>

The DBC could also benefit from looking more closely at some of the operational reforms which have been implemented by the national Common Drug Review following external reviews conducted in respect of that entity. The CDR has put in place timeline expectations and has increased “feedback loops” with industry regarding their submissions and with clinicians to ensure they have the benefit of the full information necessary to assist them in providing the best possible advice to provinces.

The Task Force also notes that the DBC could be further strengthened if at least one of the public members has broad economic expertise to supplement existing economic capacity currently limited to the more narrow discipline of health economics.<sup>20</sup>

## **A New Approach to Drug Reviews in British Columbia**

During the course of the Task Force process considerable discussion was dedicated to whether British Columbia could – or should – develop a new approach to more effectively support the work of the Drug Benefit Committee.

While the Therapeutics Initiative has served an important role in the past it is now widely regarded as being in need of either substantial revitalization or replacement. The Task Force regards replacement as the better option. The Task Force consistently heard that the existing provincial review processes and, more specifically, the Therapeutics Initiative, confine review to a relatively small community of experts<sup>21</sup> and, as a result, the array of potential expertise that could be deployed to consider the merits of listing submissions is not as broad, nor as deep, as it ought to be.

A session with the senior leadership of the Therapeutics Initiative, despite impressive

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<sup>19</sup> This would also help to better differentiate the roles of the DBC and the DRRC.

<sup>20</sup> One of the three proposed public positions on the DBC could be utilized to add this capacity.

<sup>21</sup> The Therapeutics Initiative has seen relatively modest staffing turnover and several of the newer participants were trained within the program. The existing PSD approach to conflict of interest guidelines are 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.

contributions from Drs. Ken Bassett and Colin Dormuth, did not leave the Task Force with the comfort necessary to suggest that the Therapeutics Initiative is well-positioned to meet the current and future public interest needs of the province. Accordingly, we recommend a new approach that would substantially increase the level of expertise available to support effective and timely drug reviews<sup>22</sup>, increase transparency and improve the quality of information required to properly support the role of the DBC.

The proposed new approach would establish a Drug Review Resource Committee that would be responsible for the maintenance of a much larger open registry<sup>23</sup> of experts to participate in Drug Coverage Review Teams (see Chart One). These DCRT's, 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. This proposed mechanism, which is substantially based upon BC's panel-based utilization of experts similar to what exists in the provincial labour relations context, would also provide for the increased participation of disease-specific experts, a group that the Task Force views as an underutilized asset in the current decision-making process.<sup>24</sup>

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, in addition, to substantially improve budget impact information that the DBC and the PSD will require in order to make the most appropriate recommendations and decisions possible. The introduction of an appeal mechanism would also be a useful addition for Government to consider in working towards an improved process.

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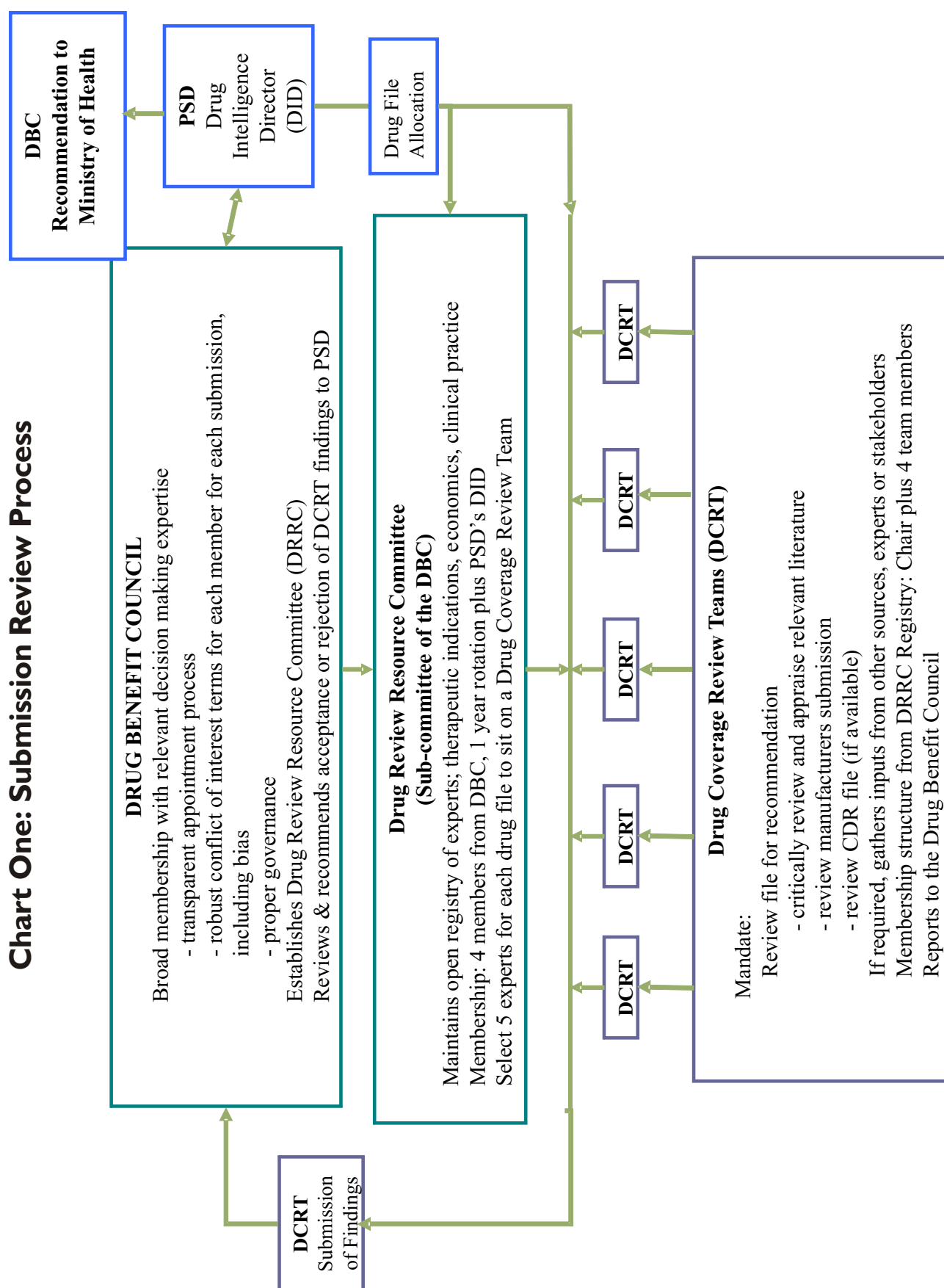
<sup>22</sup> Maintaining the requirement for the input of therapeutic and clinical expertise in the review process will remain important. In this regard, it is anticipated that experts currently involved in work with the Therapeutics Initiative would be encouraged to be active participants in the proposed new process.

<sup>23</sup> The registry could also include participation by experts external to British Columbia.

<sup>24</sup> Participation would be subject to compliance with appropriate conflict of interest guidelines.



**Chart One: Submission Review Process**



## Recommendations for an Improved Listing Process

### **Recommendation One:**

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

### **Recommendation Two:**

The Ministry of Health should act to establish new target review/listing decision guidelines with the goal of substantially improving British Columbia's performance on time-to-listing decisions. Progress on this front must be publicly reported and consistently benchmarked against the performance of other jurisdictions.

### **Recommendation Three:**

The Drug Benefit Committee should be reconstituted as the “Drug Benefit Council” to more appropriately reflect the arms length role it is expected to carry out in the review processes applicable to consideration of new therapies.

### **Recommendation Four:**

The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the Therapeutics Initiative. This new DRRC should also provide for a registry of experts that will substantially widen the array of expertise available to offer advice and recommendations on the therapeutic value and cost-effectiveness of new drug therapies.

### **Recommendation Five:**

The membership of the DBC should be modified to include the participation of at least three public members selected through a process external to the PSD. Government may also wish to consider ensuring that at least one member of the DBC has broad economic expertise to supplement the existing expertise that is focused more narrowly on health economics.

### **Recommendation Six:**

No members of the Therapeutics Initiative or, in the alternative, no participant in a Drug Coverage Review Team should participate as members in the work of the Drug Benefit Council.

**Issue Two: Procurement and service delivery options for pharmaceuticals and medical devices that will achieve and maximize value to patients and value for money objectives.**

It is important to note that all participants in the Task Force process and, for the most part, those who provided submissions to the Task Force, recognize the importance of sustainability pressures facing health care generally. Accordingly, the need for efficient and effective procurement and service delivery options is well understood.

In exploring options for change the Task Force considered:

- the current approach to acquisition and reimbursement policies that apply to generic drug products;
- the fundamental role played by pharmacists and pharmacies and the need to ensure that any new approaches or policies regarding procurement will not produce unintended adverse consequences in the service delivery relationship between patients and pharmacists and also the pharmaceutical supply chain;
- the potential value of more direct engagement and, where applicable, negotiation between the PSD and the manufacturers of patent-protected drug

therapies; and

- the need for a cautious approach in the implementation of possible cost-containment strategies including more robust utilization of tendering processes.

Effectively addressing any – or all – of these areas will require a very substantial degree of direct and meaningful engagement by the PSD with the various stakeholders whose interests will be most deeply impacted by any changes to existing arrangements. Patients must certainly be at the forefront of any engagement processes, but the PSD will also need to undertake direct dialogue and, where applicable, negotiations with other parties including the patent-protected/innovative drug manufacturers, the generic drug companies, community pharmacy and the pharmacist profession.

While effective and meaningful engagement by the PSD will be essential, all parties must understand that the sustainability pressures facing the PharmaCare program, and health care more generally, are very real. Government will be compelled to act with a higher degree of unilateralism unless the interested parties are able to create innovative more sustainable procurement mechanisms and/or achieve a reasonable degree of consensus on modifications to pricing and procurement options within a reasonable period of time.<sup>25</sup>

<sup>25</sup> The previously mentioned Corbett Review had called for this kind of engaged stakeholder negotiation process in May of 2004. It would be regrettable if that fundamental step in an improved process was simply skipped in favour of a unilateral approach driven by budget targets. It must again be mentioned that, to be successful, those stakeholder/PSD negotiations must address price and, as importantly, what each of the stakeholders can do to work effectively with Government to implement more sustainable disease management initiatives.

## Generic Drugs – Call for a Fundamental Shift

The complexity of existing practices in respect of product cost, rebates, allowances and reimbursement strategies associated with generic drugs proved to be an area that occupied a significant amount of the time and attention of the Task Force. There is little doubt that this is an area where significant savings for PharmaCare can be achieved. There will, however, be a clear need for a cautious, thoughtful and stakeholder engaged approach to reduce the likelihood of unintended adverse impact on care delivery on the patient-pharmacist relationship, on the preservation of an effective and efficient supply chain, and with respect to value-added contributions of manufacturers. This will be addressed in greater detail below.

It is first important to state clearly that generic drug products play an essential role in the provision of an effective and sustainable healthcare “eco-system”. All stakeholders, including the innovative drug manufacturers, supported this view. All parties also recognized that generic drug products represent a key

component in effectively managing drug formularies and costs.

Generic drugs have attracted an increasingly significant level of the “market share” of pharmaceutical products. In British Columbia generic drugs represented approximately 26% of all PharmaCare expenditures in 2006. The number is expected to increase to approximately 52% by 2012 resulting, in large measure, from the number of innovative drugs that will “come off patent” during that period of time.

Despite the important role played by generic drugs, there are several areas of concern that warrant attention if the Province is to be successful in generating savings, efficiently redirecting resources and in making certain that appropriate accountabilities have been put in place regarding the provision of services to patients. These concerns include the following:

- the price paid for generic drugs in Canada is significantly higher than in other countries. A report by the Patented Medicines Price Review Board (PMPRB) in June, 2006 concluded that Canadian prices for generic drugs were substantially higher than in 10 of 11 comparator jurisdictions;<sup>26</sup>

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<sup>26</sup> PMPRB, June 2006, “Canadian and Foreign Price Trends”. Other studies finding Canadian generic drugs prices to be high in comparison to other countries include: i) Palmer D'Angelo Consulting Inc, August 2002, “Generic Drug Prices: A Canada US comparison” PDCI Report Series, available at: [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf); ii) PMPRB, November 2002, “A Study Of The Prices Of The Top Selling Multiple Source Medicines In Canada”, available at: [www.pmprb-cepmb.gc.ca/CMFiles/study-e22SHF-8292005-2710.pdf](http://www.pmprb-cepmb.gc.ca/CMFiles/study-e22SHF-8292005-2710.pdf); iii) Brett Skinner, August 2004, “Generic Drugopoly: Why Non-Patented Prescription Drugs Cost More In Canada Than In The United States And Europe”, available at: [www.fraserinstitute.ca/admin/books/files/GenericDrugopoly.pdf](http://www.fraserinstitute.ca/admin/books/files/GenericDrugopoly.pdf); iv) Brett Skinner, February 2005, “Canada's Drug Price Paradox: The Unexpected Losses Caused By Government Interference In Pharmaceutical Markets”, available at: [www.fraserinstitute.ca/admin/books/chapterfiles/Jun05ffparadox.pdf](http://www.fraserinstitute.ca/admin/books/chapterfiles/Jun05ffparadox.pdf); and v) PMPRB, October 2006, “Trends in Canadian Sales and Market Structure”. Both PMPRB reports are available at: [www.pmprb-cepmb.gc.ca/english/view.asp?x=805](http://www.pmprb-cepmb.gc.ca/english/view.asp?x=805).

- the 2006 PMPRB report also estimated that, if Canadian generic prices were adjusted to reflect compatibility with prices paid in comparator jurisdictions, Canadian prices should have been 32.5% lower than what they actually were;<sup>27</sup>
- the procurement relationships between generic drug manufacturers, retail pharmacies and government (as the party responsible for the reimbursement to patients in respect of generic drug costs) is complex and has been distorted by industry practices in relation to rebates and professional allowances;
- reimbursement to pharmacies has generally been based upon invoices which reflect the maximum allowable price for generic products. Rebates appear to be based upon the gap between the net cost of the generic product to pharmacies and the maximum allowable price eligible for reimbursement. The average level of rebate has been estimated to be in the range of 40%.<sup>28</sup>

It is not tenable to maintain practices which result in provincial reimbursement plans, such as PharmaCare, paying an artificially high price for generic drug products particularly in light of the fact that the generic “share” of the market will

soon reach 50% of all prescriptions. As a result, action is clearly necessary to address this issue. The nature of that action will require careful consideration and a thoughtful implementation plan.

In considering how to proceed, Government may wish to consider a range of options from the negotiation of a new, more rational, set of arrangements with generic drug manufacturers and with other interested parties through to a more unilateral legislative response that would make clear the outside limits of government's funding obligations in respect of reimbursement for generic pharmaceuticals.<sup>29</sup>

Ontario and Quebec have both opted for the legislative option with initiatives that limit reimbursement on multi-source generic products to not more than 50 percent of the cost of brand name products in the same class. This action generated immediate and significant savings on the price of generics, but it also caused considerable confusion and uncertainty in other areas including the provision of pharmacy-based cognitive and other direct services to patients, as well as ongoing confusion in respect of the administration of the legislative requirements. It would also appear that the management of the changes also had a significant and adverse impact on community based pharmacies.

<sup>27</sup> In dollar terms, this would equate to \$1.47 billion based upon 2005 expenditures (See: Federal/Provincial/Territorial Ministerial Task Force, June 2006, “National Pharmaceuticals Strategy Progress Report”, available at: [www.hc-sc.gc.ca/hcs-sss/alt\\_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp\\_e.pdf](http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2006-nps-snpp/2006-nps-snpp_e.pdf)).

<sup>28</sup> Canadian Generic Drug Sector Study, Competition Bureau of Canada, October, 2007.

<sup>29</sup> A thirty percent rebate level on generic drugs in British Columbia (and that number is likely conservative given what is known about industry practice) generates approximately \$230 million which could be secured as “savings” or redeployed, in whole or in part, to provide for patient services at the pharmacy level.

The Task Force also considered the approach that was adopted in Nova Scotia to address, perhaps more effectively than in Ontario and Quebec, the need for a more rational approach to the cost of generics and the development of more transparent and accountable arrangements with pharmacies regarding the provision of quality cognitive, and other, services to patients. The Nova Scotia approach, which involved a seven month negotiation, provides an example of how a collaborative and effective shared-risk model can be developed by government and by stakeholders resulting in significant cost-savings for the provincial drug program. The Task Force recommends that British Columbia adopt a collaborative approach similar to the process used in Nova Scotia, but we suggest that the process include consideration of options that would increase the level of engagement by innovative drug manufacturers in the post-patent environment. A more effective system may also necessitate the PSD playing a more direct role in procurement/acquisition of generic drugs, but this should not be accomplished in a manner that would negatively impact the level of services provided to patients by pharmacists. If prudently managed, a new negotiated arrangement in BC should result in more significant savings than what was accomplished in Nova Scotia and a more effective arrangement than that which resulted from the legislated approaches in Ontario and Quebec.

It must also be mentioned that, in making their submission to the Task Force, the

Canadian Generic Pharmaceutical Association (CGPA) invited action to lower the reimbursement level for generic drugs and, further, to restrict “trade spend” on rebates and allowances. The CGPA called for increased professional/dispensing fees for pharmacists (this will be addressed in greater detail below) as a critical element of any successful reform equation and also sought “first-to-market” incentives for generic drug manufacturers.

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. Two other key points are offered in this regard:

1. All parties must understand that the Government of British Columbia has a legitimate and pressing interest in achieving the deployment of effective new cost-containment initiatives. If agreement cannot be reached within a reasonable period of time – and the benefit of the experience in Ontario, Quebec and Nova Scotia suggests a period of six months, or less, would be sufficient – then Government would have little choice other than to take unilateral action to address these matters through legislative or other means; and
2. Given that the CSCW Review of PharmaCare had made exactly this kind of



recommendation for a stakeholder negotiation process in 2004 to “ensure that payments...are fair, appropriate and effective”, it would not be reasonable for Government to now act unilaterally without any meaningful effort to negotiate more acceptable arrangements with the impacted stakeholders.

## The Role of Pharmacy

As will be clear from the preceding section, the Task Force is concerned that, while significant changes are required on a number of fronts, it will be important to make certain that the essential role of pharmacy and pharmacists is not compromised through this process of reform. In fact, we believe that with appropriate consultation and effective multi-stakeholder engagement this important role can be enhanced.

In many respects, the fiscal focal point of PharmaCare's relationship with the pharmaceutical supply chain and one of the most important links to effective and accessible service delivery to patients is pharmacy. If the province's goal is to assure optimal drug therapy and improved outcomes for patients, it will be essential for the PSD to fully engage pharmacy (which is widely viewed as one of the most accessible parts of the healthcare system), in informed and transparent processes to develop new and innovative care practices to improve

effective drug utilization and better patient engagement.

The Task Force also shares the view that it will be necessary for the PSD to enter upon negotiations with the representatives of pharmacy to develop and implement a new arrangement for the provision of both dispensing and other patient-centered professional pharmacy services. Both parties have, or ought to have, a significant interest in moving towards a new and more transparent arrangement. For the PSD the goal should be to establish new, more competitive, approaches that will help to contain unreasonably high generic prices. For the pharmacy community, decreasing reliance on rebates in favour of clearer understandings with Government on services provided to patients should be viewed as a much more appropriate outcome.

PharmaCare's reimbursement level has been \$8.60 per prescription for a considerable period of time. The British Columbia Pharmacists' Association takes the position that the real cost is \$13.60 per prescription<sup>30</sup> which is driven by pharmacists spending, on average, one third of their time on professional services over and above dispensing. There are two points that must be made here as well:

- I. The PSD has reasonably resisted increases to the current level of \$8.60 per prescription in an environment where it

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<sup>30</sup> See: The Activity Based Costing Study Final Report, January, 2007, a study jointly sponsored by the BC Ministry of Health, the Canadian Association of Drug Stores and the British Columbia Pharmacy Association.



was understood that the cost of these services were offset by generic rebates and other indirect sources of revenue. In effect, the rebates provided by the generic industry to pharmacy have subsidized the provision of services provided to patients by pharmacy; and

2. If the reimbursement arrangement for generic drugs is to be substantially altered, either through negotiation or through legislation, it will be essential for the PSD to negotiate a new arrangement with pharmacy to ensure that high quality patient services are sustained and, where possible, improved while also ensuring that the compensation for pharmacy in respect of the provision of these services is reasonable and fair.

The Task Force is not indicating that the cost of prescriptions should be \$13.60 per transaction. Clearly some adjustment ought to be put in place but the level should be determined through negotiations between the parties. These negotiations should also address the scope of, and compensation for, professional counseling and other services provided by pharmacy in addition to the dispensing fee. The January 2007 Activity Based Costing Study provides a useful foundation for the commencement of those discussions.

### **More Direct Engagement with Innovative Drug Manufacturers**

As noted earlier, (see p. 5 above), the PSD has indicated that one element of their proposed cost containment initiative

contemplates more direct engagement with manufacturers to secure product agreements with “better terms.” The Task Force believes this proposed approach has considerable potential but that the PSD would be most successful if their concept of “better terms” extends beyond economic arrangements to the shared interest that the PSD and industry have, or ought to have, in substantially improving health outcomes for patients.

The Task Force heard that innovative drug manufacturers have developed, or have been involved with, a number of disease management initiatives in other jurisdictions. From their perspective, improved engagement and a clear and stable operating environment would help to create the conditions necessary for industry to deploy similar programs in British Columbia in partnership with other health care providers. In fact, BC's uniqueness as a platform for improved evidenced-based population health outcomes is considered by industry to be a very valuable asset. The Task Force believes that the province and industry have much to gain by working more closely together to make full and effective use of the resources available to them.

If the right conditions for effective engagement are to be established, it will remain essential for industry to understand that the Province's interest in the containment of pharmaceutical costs is pressing and substantial. All parties, including the manufacturers of innovative drug products, must be prepared to accept new approaches to shared risk. The

Task Force was satisfied that there is sufficient recognition of, and interest in, the shared risk model by these stakeholders to warrant further serious exploration by the PSD of these options.

### **Increased Utilization of Tendering Processes**

This was likely the most contentious issue considered by the Task Force and it was certainly the area that has caused the greatest level of anxiety amongst patient groups and within the broader stakeholder community.

The Canadian Diabetes Association (CDA) expressed particular concern about a memorandum of understanding signed by Alberta and British Columbia which indicates that the two jurisdictions would work together to explore the bulk purchase of glucose test strips with a view towards achieving significant cost savings to the public drug plans in both jurisdictions. The problem, from the CDA perspective, is that this was being done with little or no consultation with the key target patient groups and there was considerable concern that this move would:

- unreasonably limit patient choice;
- potentially result in the required use of test strips that correspond to inferior blood glucose monitors;
- lead to a possible decline in diabetes education currently available at the pharmacy level;
- cause further disruption and inconvenience for a patient group who already experience considerable disruption in their lives; and

- result in increased risk of adverse reactions or declines in quality of care or patient outcomes that would inevitably shift costs to other parts of the healthcare system.

The BC Pharmacy Association (BCPhA) also expressed substantial concern about the potential for the increased use of drug tendering. Briefly summarized, their concerns include:

- the reduction in prescribers' options inevitably limits options for effectively meeting the needs of individual patients;
- multi-sourced drugs assist in the maintenance of a secure drug supply and this could be compromised by increased reliance upon single-source tendering mechanisms; and
- the BCPhA shared the concerns of the CDA that single-source tendering could lead to the required use of inferior products and less effective patient outcomes.

Many of these same concerns were articulated by the Canadian Generic Pharmaceutical Association. From their perspective tendering carries the following risks:

- a “winner-take-all” environment which undermines competition;
- the removal of generic “investments” in supporting community pharmacies and patient care initiatives;
- increased vulnerability of product supply shortages.

The Task Force believes this is an area where the PSD will need to proceed with caution<sup>31</sup> but we believe there is a legitimate place for tendering as an option in respect of meeting some of the procurement needs of the Province. 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

## Recommendations Regarding Procurement Options

### **Recommendation Seven:**

The PSD should initiate a negotiation process with drug manufacturers and with representatives of community pharmacy and pharmacists to establish new price and reimbursement arrangements and increased competition in respect of generic pharmaceutical products. If the parties are unable to conclude an acceptable agreement within six months the Government should move unilaterally to address the needs of the Province through legislation or through other means.

### **Recommendation Eight:**

To increase the level of overall funding transparency, negotiations with pharmacists and community pharmacy should provide for a new framework for compensation in respect of dispensing and other professional services provided by pharmacists. The

framework should address those professional services that can be effectively and efficiently provided by pharmacists and should be linked to transparent accountability agreements to maintain and, ideally, improve point-of-care services to patients.

### **Recommendation Nine:**

The PSD should adopt a cautious approach to broadened utilization of tendering processes. The process adopted should mirror tendering processes used in other areas of Government characterized by a process that is transparent, fair, open and includes understandable evaluation criteria. Increased tendering should provide for reasonable levels of patient choice, avoid the deployment of older inferior products and, where possible, arrangements that provide for participation of multiple suppliers.

<sup>31</sup> The Task Force heard that sole source tendering of glucose strips has been used in New Zealand but there has been substantial criticism of the outcomes both with respect to the quality of patient care and in relation to the deployment of inferior technologies.

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).

**Issue Three: *Strengthening patient care and choice and building positive relations between government decision makers and industry to achieve those objectives.***

This aspect of the Task Force mandate has been substantially addressed earlier in this report. Meaningful engagement, transparency in evidence-based decision-making processes and a genuine commitment to a much higher degree of partnership-based shared risk arrangements are viewed as the critical elements of a more constructive, cost-effective and higher quality pharmaceutical management system.

In many respects, the Task Force process itself has been a useful exercise in the development of improved relationships and it would be in the public interest if the PSD and the various stakeholders continued to build upon that foundation after the work of the Task Force is complete. The existing level of engagement and cooperation between the parties is not sufficient and must be improved.

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.

**Recommendation Ten:**

The Deputy Minister of the Ministry of Health should commit to participate in an annual accountability session to hear from patient

groups, from industry and from other key stakeholders regarding improved relations and the strengthening of the common objectives of patient care and choice.

**Issue Four: *The effectiveness of the Common Drug Review and proposals for improvement.***

The Task Force had the benefit of a very useful briefing and dialogue with Michael Teirney of the Common Drug Review who was forthright and helpful in addressing the status of

the work conducted by the CDR.

We were impressed by the responsiveness of the CDR to recently completed reviews of the agency that offered a number of recommendations regarding CDR practices and procedures. It was evident, for example, that the CDR had taken steps to improve public

participation in decision making, to increase transparency, to facilitate “feedback loops” with industry and to accelerate the pace of listing recommendations. In many respects the CDR approach includes several engagement attributes that could be used to inform the positive evolution of the relationship between the PSD and key stakeholders.

This does not mean that the Task Force experienced universal support for the CDR. Industry expressed concerns that the CDR is disproportionately focused on the cost of new therapies rather than on the potential for improved health outcomes and that this has resulted in a situation where approximately one-half (see Chart Two) of new therapies approved by Health Canada receive a “recommendation to list” decision from the CDR. According to industry, this reflects a much lower level of market engagement opportunity for new therapies in Canada when compared to approval and listing decisions in other international jurisdictions.

Similar concerns were expressed by the Canadian Diabetes Association who criticize the CDR's performance in making new drug therapies available to Canadians.

The Task Force notes that the CDR process, including recommendations to list, or not list,

## Chart Two

CDR Activity to December 31, 2008	
<i>Number of submissions</i>	<b>115</b>
<i>Number of final recommendations issued</i>	<b>91</b>
<i>Number of recommendations to "list"</i>	<b>45</b>
<i>Number of recommendations to "not list"</i>	<b>46</b>

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from the CDR's Canadian Expert Drug Advisory Committee (CEDAC) takes 20-26 weeks and that this includes a three week period for manufacturers' comments on CDR review reports. This commitment to openness, transparency, engagement and to much more efficient decision-making should inform similar improvements to the BC process.<sup>32</sup>

The Common Drug Review also could, and should, play a significant role in developing and maintaining a national data set on key performance indicators that would help to facilitate cross-jurisdictional analysis on matters such as time-to-listing, (see: Recommendation Two, p. 14).

<sup>32</sup> See: Report of the Federal Standing Committee on Health, “Prescription Drugs Part I – The Common Drug Review: An F/P/T Process”, December 12, 2007.

### **Recommendation Eleven:**

Given that BC was a lead jurisdiction in calling for the implementation of the CDR, action should be taken to:

1. ensure BC's decision-making processes include similar timelines to those used by the CDR and a

greater level of commitment to openness and transparency; and

2. that any unnecessary overlap between the CDR and BC formulary management system are reduced to the fullest extent possible.

### **Issue Five: *The effectiveness, transparency and future role of the Therapeutics Initiative in supporting the listing process of drugs, or a more viable and cost-effective alternative.***

As will be evident from the section of this report dedicated to the identification of proposed improvements to British Columbia's listing process, the Task Force recommends the replacement of the Therapeutics Initiative with a new process that would provide for a much wider array of expertise to consider the therapeutic value and cost-effectiveness of new drug therapies (see: Recommendation Four, p.12). This approach, we believe, is viewed as being preferable to the option of endeavoring to initiate a reform of the Therapeutics Initiative. The Therapeutics Initiative is regarded by most who participated in this process, other than the

PSD leadership, as narrow, insular and resistant to meaningful stakeholder engagement.

If, in the alternative, the Ministry of Health elects to maintain the existing arrangement(s) substantial reforms will be required to address the need for mechanisms more appropriate to modern concepts of governance and accountability, the expansion of the scope of expertise available to the Therapeutics Initiative and the elimination of direct engagement by Therapeutics Initiative members in the work of the Drug Benefit Committee.

Furthermore, if the Therapeutics Initiative is to continue it will be necessary to take steps to provide it with a level of financial resource appropriate to their continuing functions. The Task Force would also recommend that their public education role should be reassigned to the new Drug Utilization Branch of the PSD.<sup>33</sup>

<sup>33</sup> Recent steps initiated by the Ministry of Health, (see "Province Promotes Best Practices for Drug Prescribing", March 25, 2008), are a positive step in this regard.



**Recommendation Twelve:**

Subject to Recommendation Four, if the Therapeutics Initiative is maintained, action must be taken in the following areas:

- the governance, membership and accountability standards associated with the operation of the Therapeutics Initiative will require substantial improvement;
- steps must also be taken to renew and revitalize the panel of experts the Therapeutics Initiative relies upon to discharge its obligations;
- the function of the Therapeutics Initiative should be focused on therapeutic evaluation. Activities beyond that core mandate such as public education should be reassigned to the PSD's Drug Utilization Unit where an accountable process can be implemented to assure the unbiased and evidence-based practices;
- the practice of having members of the Therapeutics Initiative also participating in the work of the Drug Benefits Committee should be terminated.



## Summary of Recommendations

### ► An Improved Drug Review/Listing Process

**Recommendation One:** Priority attention should be focused on development of an enhanced Formulary Management System together with improved stakeholder engagement and appeal mechanisms. This work should be led by the Pharmaceutical Services Division and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.

**Recommendation Two:** The Ministry of Health should act to establish new target review/listing decision guidelines with the goal of substantially improving British Columbia's performance on time-to-listing decisions. Progress on this front must be publicly reported and consistently benchmarked against the performance of other jurisdictions.

**Recommendation Three:** The Drug Benefit Committee should be reconstituted as the “Drug Benefit Council” to more appropriately reflect the arms length role it is expected to carry out in the review processes applicable to consideration of new therapies.

**Recommendation Four:** The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the Therapeutics Initiative. This new DRRC should also provide for a registry of experts that

will substantially widen the array of expertise available to offer advice and recommendations on the therapeutic value and cost-effectiveness of new drug therapies.

**Recommendation Five:** The membership of the DBC should be modified to include the participation of at least three public members selected through a process external to the PSD. Government may also wish to consider ensuring that at least one member of the DBC has broad economic expertise to supplement the existing expertise that is focused more narrowly on health economics.

**Recommendation Six:** No members of the Therapeutics Initiative or, in the alternative, no participant in a Drug Coverage Review Team should participate as members in the work of the Drug Benefit Council.

### ► Improved Procurement Practices

**Recommendation Seven:** The PSD should initiate a negotiation process with drug manufacturers and with representatives of community pharmacy and pharmacists to establish new price and reimbursement arrangements and increased competition in respect of generic pharmaceutical products. If the parties are unable to conclude an acceptable agreement within six months the Government should move unilaterally to address the needs of the Province through legislation or through other means.

**Recommendation Eight:** To increase the level of overall funding transparency, negotiations with pharmacists and community pharmacy should provide for a new framework for compensation in respect of dispensing and other professional services provided by pharmacists. The framework should address those professional services that can be effectively and efficiently provided by pharmacists and should be linked to transparent accountability agreements to maintain and, ideally, improve point-of-care services to patients.

**Recommendation Nine:** The PSD should adopt a cautious approach to broadened utilization of tendering processes. The process adopted should mirror tendering processes used in other areas of Government characterized by a process that is transparent, fair, open and includes understandable evaluation criteria. Increased tendering should provide for reasonable levels of patient choice, avoid the deployment of older inferior products and, where possible, arrangements that provide for participation of multiple suppliers.

### ► **Building Positive and Productive Relationships**

**Recommendation Ten:** The Deputy Minister of the Ministry of Health should commit to participate in an annual accountability session to hear from patient groups, from industry and from other key stakeholders regarding improved relations and the

strengthening of the common objectives of patient care and choice.

### ► **Improving the Common Drug Review Process**

**Recommendation Eleven:** Given that BC was a lead jurisdiction in calling for the implementation of the CDR, action should be taken to:

1. ensure BC's decision-making processes include similar timelines to those used by the CDR and a greater level of commitment to openness and transparency; and
2. that any unnecessary overlap between the CDR and BC formulary management system are reduced to the fullest extent possible.

### ► **Replacing or Reconstituting the Therapeutics Initiative**

**Recommendation Twelve:** Subject to Recommendation Four, if the Therapeutics Initiative is maintained, action must be taken in the following areas:

- the governance, membership and accountability standards associated with the operation of the Therapeutics Initiative will require substantial improvement;
- steps must also be taken to renew and revitalize the panel of experts the Therapeutics Initiative relies upon to discharge its obligations;

- the function of the Therapeutics Initiative should be focused on therapeutic evaluation. Activities beyond that core mandate such as public education should be reassigned to the PSD's Drug Utilization Unit where an accountable process can be implemented to assure the unbiased and

evidence-based practices;

- the practice of having members of the Therapeutics Initiative also participating in the work of the Drug Benefits Committee should be terminated.

## PHARMACEUTICAL TASK FORCE PROJECT CHARTER

**Project Title:** Pharmaceutical Task Force

The Province and industry have an agreed objective of a pharmaceutical procurement process which delivers quality health care for clients, value for money, innovative approaches and collaborations, and a transparent decision making process that is understandable to all stakeholders.

### MANDATE

The Pharmaceutical Task Force will make recommendations to the Minister of Health by January 31, 2008 on the following:

1. optimize the decision making process for the listing of pharmaceuticals and devices to produce timely, transparent decisions based on sound science while appropriately protecting the public interest.
2. procurement and service delivery options for pharmaceuticals and medical devices that will achieve and maximize value to patients and value for money objectives.
3. identify and strengthen common objectives related to patient care and choice and to build positive relations between government decision makers and industry to achieve those objectives.
4. on the effectiveness of the Common Drug Review process and proposals for improvements.
5. on the effectiveness, transparency and future role of the Therapeutics Initiative in supporting the listing process of drugs, or a more viable and cost effective alternative.

### MEMBERSHIP

Name	Responsibility
Don Avison	Chair
David Hall	Member
Robert Sindelar	Member
George Morfitt	Alternate Chair
Sue Paish	Member
Gord Cross	Member
Paul Gudaitis	Member
Russell Williams	Member
Mark Schonfeld (BCMA)	Member

## TASK FORCE RESOURCES

The Task Force may request limited funding from MoH to assist in the research and development of recommendations back to government. MoH will also provide secretariat services to the task force.

The Task Force will have the ability to, but not be restricted to, adding extra committee members, set rules for meeting quorums, and other decisions necessary in order to fulfill its mandate.

The Task Force will be required to comply with all provincial statute and regulation, including but not limited to the provisions of the Freedom of Information and Protection of Privacy Act.

The Province will provide reasonable access to senior officials from the Ministry of Health, in particular the Pharmacare Branch, and other related Ministries at no charge to the Task Force Budget.

Industry will provide staffing, information and research supports through Rx and D at no charge to the Task Force budget.

Government will provide staffing, information, and other support as required, in addition to the secretariat services, at no charge to the Task Force budget.

## SIGN-OFF

Project Sponsor

  
\_\_\_\_\_  
Gordon Macatee, Deputy Minister  
Ministry of Health

Date:

November 7, 2007