Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, May 6, 2008 11:36 AM
To: Lun, Eric HLTH:EX
Cc: Gudaitis, Paul HLTH:EX
Subject: RE: Task Force Reporting Out

Sure, I'm fine with that, as long as it is public, which I hope to be true by then. Paul - can you please start working on the high level messaging piece? Thanks,

B

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: Tue, May 6, 2008 8:36 AM
To: Nakagawa, Bob HLTH:EX
Subject: Task Force Reporting Out

Bob - Mike T asked if I could update folks on the TF report at the June 5/6th in-person ACP. I thought it would be ok as long as it is public by then. You ok with that?

It would be quite high level but we should all put our heads together about messaging externally anyway.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Monday, May 12, 2008 5:40 PM
To: Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Taylor, Suzanne C HLTH:EX; Therrien, Darlene HLTH:EX; Mochrie, Paul HLTH:EX
Subject: Re: FOR REVIEW/COMMENT - all comm materials - pharma task force report

Bob,

While I don't agree with the "accept all" approach, I do like the response strategy as the proposed values anchors our potential options we can go forward with. However, to deflect the likely expectation that "accept all" is not really everything word for word, I would like to see stronger wording on that. I'm not sure where that message can be enhanced.

I do agree with what Paul is asking below in that external stakeholders will want more details on what we plan to do so we need to be ready, with what we are ready to do and the potential timelines for each.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

----- Original Message -----
From: Gudaitis, Paul HLTH:EX
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Taylor, Suzanne C HLTH:EX; Therrien, Darlene HLTH:EX; Mochrie, Paul HLTH:EX
Sent: Mon May 12 16:29:43 2008
Subject: RE: FOR REVIEW/COMMENT - all comm materials - pharma task force report

Bob,

In reviewing the recommended option in the comm plan - my main concern is that we need to be able to flesh out the details around the how the response to the report will be addressed from a Ministry and PSD perspective. As soon as the report is released the calls will be coming in to PSD to address/discuss the recommendations and next steps - I will start to work with PAB to put together the PSD response messaging.

I would like to have the release date confirmed in advance so we can get an idea of the timing for the multilateral stakeholder session announcement. We will also need to discuss the objectives and format of the multilateral session to be sure we can optimize the outcome of this session due to its importance. We need to coordinate these efforts at the outset.

The rest of the comm materials align with the responses we have been preparing to the report.

Paul Gudaitis
Executive Director
Stakeholder and Partner Relations
BC Ministry of Health
Tel: 250-952-3017
Cell: 250-588-5513
Fax: 250-952-1391
Paul.Gudaitis@gov.bc.ca

From: Nakagawa, Bob HLTH:EX
Sent: May 12, 2008 12:31 PM
To: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Taylor, Suzanne C HLTH:EX; Therrien, Darlene HLTH:EX; Mochrie, Paul HLTH:EX
Subject: FW: FOR REVIEW/COMMENT - all comm materials - pharma task force report

FYI. Please provide comments to me ASAP.

Best,

<< OLE Object: Picture (Metafile) >>

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

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From: Plank, Sarah A PAB:EX
Sent: Mon, May 12, 2008 11:22 AM
To: Braman, Jamie L HLTH:EX; Macatee, Gordon HLTH:EX; MacDougall, Michael HLTH:EX; Nakagawa, Bob HLTH:EX
Cc: Stewart, Michelle PAB:EX; Porter, Rodney PAB:EX; Somner, Kurstie HLTH:EX; Weiss, Cheryl HLTH:EX; Wheeler, Jan HLTH:EX
Subject: FOR REVIEW/COMMENT - all comm materials - pharma task force report

I have updated the materials based on conversations with all of you on Friday. As discussed, we are aiming to get everything finalized for tomorrow so that it can be presented at Cabinet on Wednesday.

Appreciate any feedback you might have on the tone/direction from a high-level perspective….

Thx!
S.

News Release

<< File: NR_pharma task force report_TAKE 2_May 11_DRAFT.doc >>

Backgrounder

<< File: BG_pharma task force report_TAKE 2_May 11_DRAFT.doc >>

Issues Note

<< File: IN_pharma_task_force_report_release_May 11_3PM DRAFT.doc >>

Questions & Answers

<< File: QA_pharma_task_force_report_May 11_3PM_DRAFT.doc >>

Comm Plan

<< File: CP_pharma_task_force_report_options_for_release_May 11_3pm_DRAFT.doc >>

****

Sarah Plank
Manager, Media Relations & Issues Management B.C. Ministry of Health - Communications

Phone: (250) 952-3387
Cell: (250) 480-6678
Email: Sarah.Plank@gov.bc.ca

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, May 13, 2008 8:18 AM
To: Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Stewart, Michelle PAB:EX
Subject: RE: FOR SIGN OFF - comm materials - task force report

Thanks Eric. Can you and Paul please use our original response as a reference?

B

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

From: Lun, Eric HLTH:EX
Sent: Tue, May 13, 2008 8:06 AM
To: Nakagawa, Bob HLTH:EX; Plank, Sarah A PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Stewart, Michelle PAB:EX
Subject: RE: FOR SIGN OFF - comm materials - task force report

Sure Bob - I'll work with Paul to review and provide comments. I have a meeting I'm chairing this morning so expect to review after that just before lunch.

From: Nakagawa, Bob HLTH:EX
Sent: Tue 13/05/2008 7:00 AM
To: Plank, Sarah A PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Subject: FW: FOR SIGN OFF - comm materials - task force report

Sarah,

Thanks for this. Bill's on holidays now. Eric, can you please assist Paul with the "fine tooth comb" review of the attached?

I'm in meetings all day at the Grand Pacific, but will be watching BB as much as I can get away with. Call if you need my attention. I've scheduled a meeting with the DM at noon to talk about the tf response etc. If you and/or Michelle can attend, that would be great.

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

From: Plank, Sarah A PAB:EX
Sent: Mon, May 12, 2008 11:06 PM
To: Mercer, Bill HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX
Cc: Porter, Rodney PAB:EX; Silver, Matt PAB:EX; Stewart, Michelle PAB:EX
Subject: FOR SIGN OFF - comm materials - task force report

Hi all,

I have received input back from the MO and DMO that the direction and tone of the materials are what they were looking for.

Bob, I have incorporated your feedback - you will notice an additional option under the communications roll-out section that includes your idea for a public comment period. I have also revised the key messaging in both the issues note and comm plan to better align with the language in the news release, as per your suggestion.

I'm hoping now from all three of you to get the technical review for official sign-off, just to make sure everything is accurate and correct… Bill/Paul, I would especially appreciate it if you could go through all these documents tomorrow with a fine-tooth comb to confirm everything is okay from that perspective.

I am aiming to get the materials back to the DMO and MO by early afternoon on Tuesday.

Thanks very much!
Sarah.

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<<QA_pharma_task_force_report_May 13_DRAFT.doc>>

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NEWS RELEASE

For Immediate Release
[release number]
[Date]

Ministry of Health

GOVERNMENT ACCEPTS DRUG PLAN RECOMMENDATIONS

VICTORIA – Government has accepted all of the recommendations from the Pharmaceutical Task Force, announced Health Minister George Abbott today.

"The task force has provided us with insightful analysis on improving patient care and enhancing the quality, safety and value of our world-class PharmaCare program," said Abbott. "Their advice and recommendations will strengthen our significant investments in this vital area of the public health system, so that patients in B.C. continue to benefit from a public drug plan that is based on the best scientific evidence and sustainable for future generations."

In November 2007, the nine-member task force – made up of clinical professionals, academics, pharmaceutical industry leaders and government policy-makers – was charged with advising government on key areas of pharmaceutical policy within the health system. Their report offers recommendations aimed at creating a more streamlined and transparent drug approval process while delivering the best patient outcomes and the best value to British Columbians.

"The Ministry of Health will begin working with stakeholders on some recommendations immediately, while others are more complex and will take some time to plan and implement," said Abbott. "Our work to enhance the province's pharmaceutical policy has the interests of patients as our foremost consideration, while assuring maximum value for taxpayers."

Government's implementation of the recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The B.C. Government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The B.C. Government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

"The Task Force heard from a wide range of stakeholders, whose views were united by the common thread that patients must have access to the best care and treatment possible," said Don Avison, chair of the Pharmaceutical Task Force. "It has been our privilege to undertake this challenging task, and we trust our conclusions will guide the province to a constructive way forward with the evolution of pharmaceutical policy in British Columbia."

B.C. faces increasing demand for prescriptions each year – with a 46-per-cent increase over the past four years from 18.3 claims per patient in 2002 to 26.8 claims per patient in 2006. In the past two years, PharmaCare has added more than 480 individual generic drugs and more than 50 brand drugs to its formulary. Since 2001, PharmaCare's budget has increased by more than 50 per cent, from $654 million to over $1 billion in 2007/08.

PharmaCare subsidizes eligible prescription drugs and designated medical supplies, protecting British Columbians from high drug costs. PharmaCare provides financial assistance to British Columbians under Fair PharmaCare and other specialty plans. More than 23 million prescriptions are now covered each year under the B.C. PharmaCare program.

The Report of the Pharmaceutical Task Force can be found on the Ministry of Health website at www.insertURLhere.gov.bc.ca.

-30-

Contact: Sarah Plank
Manager, Media Relations
Ministry of Health
250 952-1887 (media line)

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BACKGROUNDER

2008HEALTH0047-000615
April 24, 2008

Ministry of Health

PHARMACEUTICAL TASK FORCE REPORT COMPLETE

The Pharmaceutical Task Force's report made 12 recommendations to government regarding PharmaCare's policy, programs, services and drug approval process.

Recommendation 1 – Priority attention should be focused on development of an enhanced Formulary Management System together with improved stakeholder engagement and appeal mechanisms.

Recommendation 2 – The Ministry of Health should act to establish new target review/listing decision guidelines with the goal of substantially improving B.C.'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 3 – The Drug Benefit Committee should be reconstituted as the Drug Benefit Council to more appropriately reflect the arm's-length role it is expected to carry out in the review processes applicable to consideration of new therapies.

Recommendation 4 – 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 review committee 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 5 – The membership of the Drug Benefit Committee should be modified to include the participation of at least three public members selected through process external to the ministry. Government may also wish to consider ensuring that at least one member of the Drug Benefit Committee has broad economic expertise to supplement the existing expertise that is focused more narrowly on health economics.

Recommendation 6 – 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.

Recommendation 7 - The ministry 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.

-more-

Recommendation 8 – 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 9 – The ministry 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.

Recommendation 10 – 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.

Recommendation 11 – Given that B.C. was a lead jurisdiction in calling for the implementation of the Common Drug Review, action should be taken to:

- Ensure B.C.'s decision-making processes include similar timelines to those used by the Common Drug Review and a greater level of commitment to openness and transparency; and
- That any unnecessary overlap between the Common Drug Review and B.C. formulary management system are reduced to the fullest extent possible.

Recommendation 12 – Subject to Recommendation 4, 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 TI will require substantial improvement;
- Steps must also be taken to renew and revitalize the panel of experts the TI relies upon to discharge its obligations;
- The function of the TI should be focused on therapeutic evaluation. Activities beyond that core mandate, such as public education, should be reassigned to the ministry's Drug Utilization Branch where an accountable process can be implemented to assure unbiased and evidence-based practices;
- The practice of having members of the Therapeutics Initiative also participating in the work of the Drug Benefit Committee should be terminated.

-30-

Media contact: Sarah Plank
Manager, Media Relations
Ministry of Health
250 952-3387 (office)
250 480-6678 (cell)

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ADVICE TO MINISTER

CONFIDENTIAL ISSUES NOTE Ministry: Health Date: April 17, 2008 Minister Responsible: George Abbott	**Release of Pharmaceutical Task Force report DRAFT**

KEY FACTS REGARDING THE ISSUE:

- Government will accept the recommendations of the Pharmaceutical Task Force upon release of the final report (date to be determined).
- Pressure from industry and media for release of the report is mounting.
- Completion and submission of the final report analyzing the strengths and areas of improvement for B.C.'s PharmaCare program was delayed beyond the promised timing of early 2008. The final report was received April 10, 2008.
- A number of recommendations may raise concerns among industry, stakeholders, and advocacy groups including: the future of the Therapeutics Initiative at UBC (academic drug policy researchers); drug product tendering (industry, particularly generics), and dispensing fees (pharmacies/pharmacists).
- Their report offers 12 recommendations aimed at creating a more streamlined and transparent drug approval process while delivering the best patient outcomes and the best value to British Columbians. Report recommendations include:
    - **Tendering** – The Ministry should adopt a cautious approach to broadened utilization of tendering processes. 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.
    - **Drug Reviews** - 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.
    - **Generics** - The Ministry 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. The Task Force believes that British Columbia should vigorously pursue an overall reduction in the cost of generic drug products
    - **Dispensing Fees** - The Task Force does not necessarily agree the cost of prescriptions should be $13.60 per transaction as indicated by the BC Pharmacy Association's analysis. The Task Force suggests that there are adjustments that need to be put in place but the level should be determined through negotiations between the parties.
    - **Drug Benefit Committee** - The membership of the committee should be modified to include the participation of at least three public members selected through a process external to the Ministry.

About the Task Force

- In November 2007, the nine-member task force – made up of clinical professionals, academics, pharmaceutical industry leaders and government policy-makers – was charged with advising government on key areas of pharmaceuticals policy within the

health system to best maximize value for patients and taxpayers, while streamlining and improving the transparency of the drug review process.

- The Task Force met on nine occasions from December 2007 through February 2008. Submissions were received from the BC Pharmacists Association, the Canadian Generic Pharmaceutical Association, the Canadian Association of Chain Drug Stores, Rx&D , MEDEC (Canada's Medical Device Technology Companies), the Better PharmaCare Coalition, the Canadian Diabetes Association and the Vancouver Coastal Health Research Institute, the Child and Family Research Institute (Provincial Health Services Authority), the Providence Health Care Research Institute and the Faculty of Medicine at UBC. In addition, the Task Force met with representatives of the National Common Drug Review (video conference) and UBC's Therapeutics Initiative, the ministry's Pharmaceutical Services Division.
- The Task Force was asked to provide advice to government on how to:
    - Achieve and maximize value for patients in procuring pharmaceuticals;
    - Identify and strengthen patient care and choice;
    - Optimize the decision-making process for what drugs are covered under PharmaCare;
    - Improve the effectiveness of the Common Drug Review process; and
    - Enhance the effectiveness, transparency and future role of the Therapeutics Initiative.

ADVICE AND RECOMMENDED RESPONSE:

- **I thank the members of the task force for their time and thoughtful consideration of how to best maximize value for patients and taxpayers and improve our decision-making processes for drug coverage under PharmaCare.**
- **Government has accepted all of the recommendations from the Pharmaceutical Task Force.**
- **The Ministry of Health will begin working with stakeholders on some recommendations immediately, while others are more complex and will take some time to plan and implement**
- **Our work to enhance the province's pharmaceutical policy has the interests of patients as our foremost consideration, while assuring maximum value for taxpayers.**
- **Our work will be guided by principles including: the best interest of patients and taxpayers; an evidence-based drug review process; fair, open, transparent procurement; and a healthy, competitive pharmaceutical industry.**
- **B.C.'s Pharmaceutical Task Force brought together the expertise and experience of government policy makers, clinical professionals, academics and pharmaceutical industry leaders.**
- **This report will help the province build on our efforts to ensure our PharmaCare program is based on the best scientific evidence and is sustainable for future generations.**
- **Increasing drug costs remains one of the greatest challenges to our health care budget, but we are committed to providing British Columbians with effective, sustainable access to the drugs that they need.**
- **Since 2001, the PharmaCare budget has increased by more than 50 per cent – from $654 million to over $1 billion in 2007/08.**

ADVICE TO MINISTER

Communications Contact:	Sarah Plank	952-3387
Program Area Contact:	Bob Nakagawa	
File Created:	April 17, 2008	
File Updated:	May 11, 2008	
File Location:	Z:\Medstrat 2008\Operations\Announcements\Pharma Task Force Report\IN_pharma_task_force_report_release_May 11_3PM DRAFT.doc	

Comm. Dir	Program Area	ADM	Deputy Minister
Marisa Adair *pending*	Bill Mercer/Paul Gudaitis *pending*	Bob Nakagawa *pending*	Gordon Macatee *pending*

Drug strategy for Canadians - Letter by Russell Williams - Globe and Mail, A26 - 13-Nov-2007
Responding to a Nov. 5th, 2007, Report on Business article, Taskforce member Russell Williams writes that Canadians who rely on provincial drug plans have access to only about a fifth of new pharmaceutical treatments. He argues that this must improve if patients are to remain the focus of health care. He also argues that according to CIHI, drug expenditures have grown not because of price, but because of more medicine use and a demographic shift.

Fears over medicine unproven: industry; Children's Remedies - By Craig Offman - National Post, A01 - 07-Dec-2007
When the New England Journal of Medicine called for an immediate removal of children's decongestants, the Non-prescription Drug Manufacturers Association of Canada argued that science would prove that they are more effective than dangerous. If the Taskforce is critical towards non-prescription drugs, this group may speak up.

New rules: life-saver or safety risk? - By Carly Weeks - Globe and Mail, L04 - 11-Apr-2008
Last week, the federal government proposed a new system for approving and monitoring drugs. Shortly after, some advocates, such as the Canadian Organization for Rare Disorders, argued that the new rules will improve access to breakthrough drug treatments, but others, such as Barbara Mintzes, UBC health policy expert, argued that there won't be enough safety checks and the public could be hurt. It's likely the ministry we'll hear from at least UBC regarding the task force report.

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QUESTIONS AND ANSWERS

QUESTIONS AND ANSWERS

PHARMACEUTICAL TASK FORCE REPORT RELEASE

Ministry of Health
Event Date
Draft: 13 May 2008, 9am

Q 1. *Government promised the release of the Task Force report by the end of January - why has it taken such a long time to release the report?*

- **Government received the Task Force's report in April, and in the interest of openness and transparency, we have released the report in full.**
- **The issue of drug coverage is a complex policy area, and the task force wanted to take the time it needed to consider all of the matters before it.**
- **We have now taken the time we needed to consider the recommendations, and our next steps.**
- **Government has accepted the recommendations, and will move forward within guiding principles that include the best interest of patients and taxpayers; an evidence-based drug review process; fair, open, transparent procurement; and a healthy, competitive pharmaceutical industry.**

Q 2. *Is government going to follow all recommendations made by the Task Force?*

- **Government has accepted the recommendations of the Task Force.**
- **Our work as we move forward will be guided by a number of principles, including the best interest of patients and taxpayers; an evidence-based drug review process; fair, open, transparent procurement; and a healthy, competitive pharmaceutical industry.**

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QUESTIONS AND ANSWERS

Q 3. *Isn't government just caving to the interests of pharmaceuticals?*

- **No. We have reviewed the recommendations and feel they offer a renewed path that builds on our efforts to ensure our PharmaCare program is based on the best scientific evidence and is sustainable for future generations.**
- **These changes will help us to best maximize value for patients and taxpayers and improve our decision-making processes for drug coverage under PharmaCare**
- **The Task Force brought together the expertise and experience of government policy makers, clinical professionals, academics and pharmaceutical industry leaders.**
- **Industry, like other participants, had valuable ideas to bring to the discussion.**

Q 4. *What's the timeline for implementing recommendations?*

- **The Ministry will begin working with stakeholders on some of the recommendations immediately, while others are more complex and will take some time to plan and implement.**
- **Our work to enhance the province's pharmaceuticals policy will be in the best interests of patients while maximizing value for taxpayers.**

Q 5. *What are government's next steps?*

- **Our first step will be a multilateral stakeholder consultation focusing on the task force recommendations.**
- **Following these discussions, over the coming months our Pharmaceutical Services Division will develop an implementation plan.**

Q 6. *Will there be any opportunity for comments on the report?*

- **We will be engaging in a stakeholder consultation process in the next few weeks.**
- TBD if a public comment period will also be put in place

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QUESTIONS AND ANSWERS

Q 7. *Is government going to abolish the Therapeutics Initiative?*

- **Government has accepted the recommendation to establish a new Drug Review Resource Committee to carry out drug submission reviews.**
- **Basing our drug coverage decisions on the best scientific evidence available is the foundation of our drug review process. That will not change.**
- **The Dean of the Faculty of Medicine is currently conducting an academic review of the Therapeutics Initiative.**
- **We will consider these results as well as the recommendations of the Task Force as we continue to improve our work in this area.**

Q 8. *Are you going to negotiate with drug manufacturers and pharmacists to deal with price and rebates with respect to generic drugs?*

- **We recognize the a need to examine the generic drug rebates between manufacturers and drug stores and we thank the Task Force for including generic price rebates in their review of PharmaCare.**
- **This is a complex area where public policy and the marketplace intersect, and we will be working with representatives of pharmacies, pharmacists and generic drug companies as we move forward with this recommendation.**

Q 9. *The Task Force report says government should take a cautious approach to tendering. Will government follow this recommendation?*

- **Yes. Increasing drug costs remains one of the greatest challenges to our health care budget.**
- **Tendering is one area the Ministry continues to explore as a way to better control costs of pharmaceuticals and achieve the best value for taxpayers.**

Q 10. *Are you contemplating having the taxpayers pay more for their drugs to offset the rising costs?*

- **No. Government recently restructured PharmaCare coverage to ensure we were helping those who need it most, and we believe our coverage is both fair and comprehensive.**
- **Importantly, every British Columbian is protected under Fair PharmaCare from catastrophic drug costs.**

QUESTIONS AND ANSWERS

Q 11. *How will PharmaCare reconstitute the Drug Benefit Committee to fulfill the recommendation of the Task Force?*

- **The ministry supports the principle of an arms-length advisory committee to make drug listing recommendations.**
- **We will move forward to establish a new independent advisory body of health and other professionals with expertise in drug therapy and drug evaluation that makes recommendations to the ministry's Pharmaceutical Services Division.**
- **The approach will continue to be evidence-based and the advice is expected to reflect medical and scientific knowledge and current clinical practice.**

Q 12. *With three members of the new drug review committee "members of the public" appointed through an independent process outside the ministry, how will you ensure "Big Pharma" doesn't infiltrate the committee?*

- **To ensure independent, arms-length function by the committee, its membership will not include anyone who is in a position to be placed in a conflict of interest (i.e., who may be influenced one way or another or who has any personal financial stake in listing decisions).**

Q 13. *Will PharmaCare speed up its drug reviews?*

- **Yes. We have taken strides in the ministry to improve our processes to make listing decisions faster.**
- **We are absolutely committed to further streamlining this work, and reducing any duplication with the Common Drug Review process.**
- **At the same time, we will ensure the quality of our drug reviews is maintained.**

Q 14. *Have pharmaceutical stakeholders been engaged with the Task Force's report?*

- **Absolutely. We thank all of the pharmaceutical stakeholders and organizations from throughout British Columbia who took the time to present to the Task Force.**
- **We are committed to further multilateral stakeholder consultations as we take our next steps with regard to the recommendations of the task force.**

Q 15. *Will the Ministry of Health participate in regular meetings with stakeholders, as recommended?*

- **Yes, absolutely.**
- **Our Pharmaceutical Services Division has increased its outreach and engagement of various stakeholder groups, including industry and patient advocacy groups, in the last two years.**
- **This has resulted in a number of positive outcomes, and we are looking forward to further expanding these efforts.**
- **In fact, the Pharmaceutical Services Division very recently established a branch dedicated to stakeholder and partner relations, which signals our commitment to increasing stakeholder engagement.**

Q 16. *You ignored the 1998 auditor general report. You received another report in 2006 by the auditor general. Why didn't you just fulfill those recommendations rather than launch yet another review?*

- **Government has taken significant action to implement key initiatives to the PharmaCare program which stemmed from recommendations of both the Auditor General and PharmaCare's own program review.**
- **This includes:**
  - **Additional staff positions to speed up the approval process, and appointing for the first time an Assistant Deputy Minister specifically responsible for Pharmaceutical Services;**
  - **A review of the formulary management system;**
  - **A review of supply chain processes;**
  - **A structured and systematic process for stakeholder engagement;**
  - **Providing physicians with access to PharmaNet in their offices.**
- **In fact, the former Auditor General who wrote the previous reports sat on the Task Force.**
- **We believe in continuous improvement in health care, and PharmaCare is no exception to this.**

About the Task Force

Q 17. *What is the Task Force and its role?*

- **The nine-member Pharmaceutical Task force brought together the expertise and experience of government policy-makers, clinical professionals, academics and pharmaceutical industry leaders.**
- **In November 2007, the Task Force was asked by the Minister of Health to explore some of the complexities of PharmaCare policy and provide advice to government on how best to contain drug costs while providing the best services and choices for patients.**

Q 18. *Why is this Task Force needed?*

- **We have received tremendous input from British Columbians through the Conversation on Health on the values and issues they feel strongly about on pharmaceutical policy. The Task Force provides detailed examination on these and other issues.**
- **Increasing drug costs remains one of the greatest challenges to our health care budget. Since 2001, the PharmaCare budget has increased by more than 50 per cent – from $654 million to over $1 billion in 2007/08.**
- **The Task Force was asked to provide options and advice for government on how best to maximize value for patients and value for money in our public drug plan.**
- **It is important that we take steps now to find ways to ensure the system is sustainable and:**
    - **Continually improve the program;**
    - **Ensure transparency;**
    - **Provide effective access to the drugs people need over the long term.**

Q 19. *How were task force members chosen?*

- **Members of the task force were selected by the Ministry for their experience and expertise in a number of their fields in order to represent a broad cross-section of skills and backgrounds related to pharmaceuticals and public policy.**
- **We want to tackle the challenges of growing pressures on funding for drug coverage, while at the same time providing patients with access to safe and effective drug therapies.**
- **This was an expert advisory group that worked together for a short period of time to provide innovative ideas for government's consideration.**

Q 20. *Will the Task Force do any further work for government in this area?*

- **No. The advisory work of the Task Force is now concluded. This expert advisory group was formed to work together for a short time to provide recommendations and advice to government.**

Q 21. *How much did this initiative cost?*

- **The ministry has covered about $30,000 worth of costs from within our existing budget.**
- **This includes recompense for some participants and meeting room rentals.**

Q 22. *Didn't having two members from pharmaceutical companies on the task force lead to recommendations that are biased toward industry?*

- **The two pharmaceutical industry members had a lot to bring to the table, based on their experiences and knowledge.**
- **We believe that to be successful in moving forward in addressing the challenge of escalating drug costs, we must take an integrated approach that includes perspectives from all stakeholders.**

Q 23. *Why aren't patient or other groups represented on the Task Force?*

- **The Task Force has a wide-ranging mandate, and members sought information from a number of other groups representing patients' views to assist them in exploring these issues.**
- **Additionally, government received tremendous amount of input from British Columbians on their views on the Conversation on Health.**

Q 24. *Didn't the Conversation on Health provide sufficient insight into sustainable drug spending?*

- **The mandate of the Task Force builds on the submissions people made to the Conversation on Health.**
- **For example, submissions to the Conversation on Health include:**
    - **i. Reduce the amount of paper work required when applying for Fair Pharmacare and premium assistance.**
    - **ii. Encourage doctors to prescribe less expensive drugs when appropriate.**
    - **iii. Take action to make the pharmaceutical system more affordable.**

QUESTIONS AND ANSWERS

Q 25. *What other ways is government trying to reduce pharmaceutical costs?*

- **The Ministry has recently created the Drug Use Optimization Branch, which focuses on educating the province's prescribers, patients and public on the optimal use of cost-effective medications to achieve improved health outcomes.**
- **In March 2008, government announced the Provincial Academic Detailing program where health professionals will educate other health professionals on the latest and best prescribing techniques to improve health outcomes for patients and reduce prescription drug costs over time.**
- **Government is also preparing to launch a joint initiative with the BCMA to educate physicians on their prescribing practices compared to recommended best practices, which will help them provide the very best care to their patients.**

Q 26. *With the report now released, what is the current role of the Task Force?*

- **The Task Force has completed its mandate.**

Q 27. *Is the Task Force's report available to the public?*

- **The Task Force's report is posted on the Ministry of Health's website.**

Communications Strategy

DRAFT – MAY 13 – 9 A.M.

Subject: Report of the Pharmaceutical Task Force

Situational Analysis:

Pressure from industry and media for government to release the April 2008 report of the Pharmaceutical Task Force is mounting. Following a review of the 12 recommendations, government is set to announce it will implement all of the Task Force's recommendations.

Background:

In November 2007, government appointed a nine-member task force to advise and make recommendations on the province's pharmaceutical policy, to best maximize value for patients and value for money as well as improve the pharmaceutical approval process.

The Task Force is comprised of clinical professionals, academics, pharmaceutical industry leaders and government policy makers. The team was asked to provide advice to government on how to:

- Achieve and maximize value for patients in procuring pharmaceuticals;
- Identify and strengthen patient care and choice;
- Optimize the decision-making process for what drugs are covered under PharmaCare;
- Improve the effectiveness of the Common Drug Review process; and
- Enhance the effectiveness, transparency and future role of the Therapeutics Initiative.

Government received a final copy of the task force report on April 10, 2008, which contained 12 recommendations, summarized as follows:

1. Enhance the formulary management system and improve stakeholder engagement and appeal mechanisms.
2. Establish new target drug review/listing decision guidelines to substantially improve B.C.'s time to make listing decisions – including reporting out publicly and benchmarking timing against the performance of other jurisdictions.
3. Reconstitute the Drug Benefit Committee as the Drug Benefit Council to reflect the arm's-length role in the drug review processes.
4. Establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the Therapeutics Initiative, and a registry of experts to substantially widen the array of expertise available to offer advice and recommendations on the therapeutic value and cost-effectiveness of new drug therapies.

Communications Strategy

5. Select three public members, through process external to the ministry, to serve on the Drug Benefit Committee, and consider including one member with broad economic expertise to supplement the existing expertise on health economics.
6. Members of the Therapeutics Initiative or, in the alternative, participants in a Drug Coverage Review Team should not participate on the Drug Benefit Council.
7. Negotiate with drug manufacturers and community pharmacies/pharmacists on new price and reimbursement arrangements and increased competition for generic pharmaceuticals. Failing an acceptable agreement within six months, address the needs of the Province in this area through legislation or through other means.
8. Negotiate a new framework for compensation for dispensing and other professional services provided by pharmacists.
9. Adopt a cautious approach to broadened utilization of tendering processes.
10. Participate in an annual accountability session to hear from patient groups, from industry and from other key stakeholders to improve relations and strengthen patient care and choice.
11. Ensure B.C.'s decision-making processes include similar timelines to those used by the Common Drug Review and a greater commitment to openness and transparency, as well as reduce unnecessary overlap between the Common Drug Review and B.C. formulary management system.
12. If the Therapeutics Initiative is maintained:
    - Improve the governance, membership and accountability standards associated with the operation of the TI;
    - Renew and revitalize the panel of experts the TI relies upon;
    - Focus the function of the TI on therapeutic evaluation, and reassign activities beyond that core mandate, such as public education, to the ministry's Drug Utilization Branch;
    - Terminate the practice of having members of the Therapeutics Initiative also participating in the work of the Drug Benefit Committee.

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Communications Strategy

- Concerns from various stakeholders regarding specific recommendations are expected.

Communication Goals/Objectives:

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Audiences:

- Media
- Patients and the public
- Pharmaceutical industry
- Pharmaceutical stakeholders/organizations in B.C. (pharmacists, pharmacies, patient advocacy groups, etc.)
- Pharmaceutical Task Force members
- Government (including other provinces/territories)

Options for communications approach:

s.13

Communications Strategy

s.13

Key Spokespersons:

George Abbott, Minister of Health
Don Avison, Chair, Pharmaceutical Task Force

Communications Strategy

Key Messages:

- **I thank the members of the task force for their time and thoughtful consideration of how to best maximize value for patients and taxpayers and improve our decision-making processes for drug coverage under PharmaCare.**
- **Government has accepted all of the recommendations from the Pharmaceutical Task Force.**
- **The Ministry of Health will begin working with stakeholders on some recommendations immediately, while others are more complex and will take some time to plan and implement**
- **Our work to enhance the province's pharmaceutical policy has the interests of patients as our foremost consideration, while assuring maximum value for taxpayers.**
- **Our work will be guided by principles including: the best interest of patients and taxpayers; an evidence-based drug review process; fair, open, transparent procurement; and a healthy, competitive pharmaceutical industry.**
- **B.C.'s Pharmaceutical Task Force brought together the expertise and experience of government policy makers, clinical professionals, academics and pharmaceutical industry leaders.**
- **This report will help the province build on our efforts to ensure our PharmaCare program is based on the best scientific evidence and is sustainable for future generations.**
- **Increasing drug costs remains one of the greatest challenges to our health care budget, but we are committed to providing British Columbians with effective, sustainable access to the drugs that they need.**
- **Since 2001, the PharmaCare budget has increased by more than 50 per cent – from $654 million to over $1 billion in 2007/08.**

Contacts:

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(250) 812-5571 (cell)
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Sarah Plank
Manager, Media Relations
Ministry of Health
(250) 480-6678 (cell)
(250) 952-3387 (office)

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Tuesday, May 13, 2008 12:49 PM
To: Nakagawa, Bob HLTH:EX; Stewart, Michelle PAB:EX; Gudaitis, Paul HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - comm materials - task force report

Categories: Red Category

Michelle and Sarah - I have proposed two suggestions to Bob. Awaiting for his opportunity to review. Will advise asap.
Thanks,
Eric

-----Original Message-----
From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, May 13, 2008 8:39 AM
To: Stewart, Michelle PAB:EX; Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - comm materials - task force report

Agreed.

B

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Stewart, Michelle PAB:EX
Sent: Tue, May 13, 2008 8:19 AM
To: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Nakagawa, Bob HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - comm materials - task force report

Just to be clear...we were given very specific direction with respect to the tone and content ...so we're looking for errors in fact at this point....

Michelle Stewart
Communications Director
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-----Original Message-----
From: Gudaitis, Paul HLTH:EX
Sent: Tuesday, May 13, 2008 8:18 AM
To: Lun, Eric HLTH:EX; Nakagawa, Bob HLTH:EX; Plank, Sarah A PAB:EX
Cc: Stewart, Michelle PAB:EX

Subject: Re: FOR SIGN OFF - comm materials - task force report

Bob,

I will review first thing this morning and will work with Eric to track changes.
I am available if you need me to attend the meeting with the DM.

----- Original Message -----
From: Lun, Eric HLTH:EX
To: Nakagawa, Bob HLTH:EX; Plank, Sarah A PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Stewart, Michelle PAB:EX
Sent: Tue May 13 08:05:51 2008
Subject: RE: FOR SIGN OFF - comm materials - task force report

Sure Bob - I'll work with Paul to review and provide comments. I have a meeting I'm chairing this morning so expect to review after that just before lunch.

From: Nakagawa, Bob HLTH:EX
Sent: Tue 13/05/2008 7:00 AM
To: Plank, Sarah A PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Subject: FW: FOR SIGN OFF - comm materials - task force report

Sarah,

Thanks for this. Bill's on holidays now. Eric, can you please assist Paul with the "fine tooth comb" review of the attached?

I'm in meetings all day at the Grand Pacific, but will be watching BB as much as I can get away with. Call if you need my attention. I've scheduled a meeting with the DM at noon to talk about the tf response etc. If you and/or Michelle can attend, that would be great.

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

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From: Plank, Sarah A PAB:EX
Sent: Mon, May 12, 2008 11:06 PM
To: Mercer, Bill HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX
Cc: Porter, Rodney PAB:EX; Silver, Matt PAB:EX; Stewart, Michelle PAB:EX
Subject: FOR SIGN OFF - comm materials - task force report

Hi all,

I have received input back from the MO and DMO that the direction and tone of the materials are what they were looking for.

Bob, I have incorporated your feedback - you will notice an additional option under the communications roll-out section that includes your idea for a public comment period. I have also revised the key messaging in both the issues note and comm plan to better align with the language in the news release, as per your suggestion.

I'm hoping now from all three of you to get the technical review for official sign-off, just to make sure everything is accurate and correct… Bill/Paul, I would especially appreciate it if you could go through all these documents tomorrow with a fine-tooth comb to confirm everything is okay from that perspective.

I am aiming to get the materials back to the DMO and MO by early afternoon on Tuesday.

Thanks very much!
Sarah.

<<NR_pharma task force report_May 13_DRAFT.doc>>

<<BG_pharma task force report_May 13_DRAFT.doc>>

<<IN_pharma_task_force_report_release_May 13_DRAFT.doc>>

<<QA_pharma_task_force_report_May 13_DRAFT.doc>>

<<CP_pharma_task_force_report_options_for_release_May 13_DRAFT.doc>>

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Tuesday, May 13, 2008 1:37 PM
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX
Subject: RE: Review of TF materials

Categories: Red Category

Bob - Sarah Plank called me about this so she wanted something right away. We talked about my Q&A suggestion; Rather than my suggestion below, the proposal was to revise the Q&A to add "...on new drug submissions received".

ORIGINAL: Yes. We have taken strides in the ministry to improve our processes to make listing decisions faster.

UPDATED (may not be exact wording but you should get the gist): Yes. We have taken strides in the ministry to improve our processes to make listing decisions faster on new drug submissions received

Hope that is ok.

From: Lun, Eric HLTH:EX
Sent: Tuesday, May 13, 2008 12:27 PM
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX
Subject: RE: Review of TF materials
Importance: High

Bob - Two suggestions - Let me know what you think of these two so I can provide feedback to PAB.

1. 1. NR: Ordering of principles. I realize that these are not necessarily meant to be in order of priority but they will be read that way so I wanted to move "The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process" after the first one, "The best interests of the patient are paramount". Currently, "The B.C. Government is obliged to seek the best value possible for taxpayer dollars in its expenditures", is listed 2nd.

2. Q&A: *Will PharmaCare speed up its drug reviews?*

I wanted to add the following bullet to the ones already there to reduce expectation that this will happen immediately: PSD will be applying the process changes to improve efficiency on a go-forward basis this year so the expected improvement will not be seen immediately.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
BC Ministry of Health, Pharmaceutical Services Division

From: Gudaitis, Paul HLTH:EX
Sent: Tuesday, May 13, 2008 11:24 AM
To: Lun, Eric HLTH:EX; Nakagawa, Bob HLTH:EX
Subject: Review of TF materials

Eric,

I have completed by review of the Pharm TF materials - I am okay with the materials, the messaging is consistent and appropriate, so I have nothing to add at this time.

Bob,

The only issue I would flag for caution is that in setting out the initial timeline for a multilateral stakeholder session that we would need about 6 - 7 weeks at a minimum as we would need to include such key steps (aside from the usual meeting logistics) as:
- providing time for stakeholders to compile their comments and submit them to PSD
- a PSD review of stakeholder comments prior to meeting
- drafting PSD responses and materials
- obtaining appropriate MOH approvals for materials

This timeline is based on the assumption that we would go with Option 2 from the comm plan as I recommend that we use the multilateral as opportunity to engage the stakeholders in a dialogue on the report recommendations, stakeholders perspectives on the recommendations and the way forward. It would be detrimental to our stakeholder relations if the multilateral was just used as an opportunity to walk through the report (an info out session).

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BC Ministry of Health
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Paul.Gudaitis@gov.bc.ca

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Wednesday, May 21, 2008 1:01 PM
To: Gudaitis, Paul HLTH:EX
Cc: Nakagawa, Bob HLTH:EX
Subject: RE: B.C. Government drug policy task force accused of harbouring "big pharma" big wig - CBC 12:02 pm – May 21-08

Thanks - I don't mind the tone push back.

From: Gudaitis, Paul HLTH:EX
Sent: Wednesday, May 21, 2008 12:55 PM
To: Lun, Eric HLTH:EX
Cc: Nakagawa, Bob HLTH:EX
Subject: FW: B.C. Government drug policy task force accused of harbouring "big pharma" big wig - CBC 12:02 pm – May 21-08

Eric,

I thought it would beneficial if you were kept in the loop on these media bits.

Paul Gudaitis
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BC Ministry of Health
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Fax: 250-952-1391
Paul.Gudaitis@gov.bc.ca

From: Stewart, Michelle PAB:EX
Sent: May 21, 2008 12:52 PM
To: Macatee, Gordon HLTH:EX; MacDougall, Michael HLTH:EX; Nakagawa, Bob HLTH:EX; Gudaitis, Paul HLTH:EX
Cc: Plank, Sarah A PAB:EX; Silver, Matt PAB:EX
Subject: FW: B.C. Government drug policy task force accused of harbouring "big pharma" big wig - CBC 12:02 pm – May 21-08

fyi

Michelle Stewart
Communications Director
Ministry of Health
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Mailto: michelle.stewart@gov.bc.ca

From: PAB Media Monitoring PAB:EX
Sent: Wednesday, May 21, 2008 12:50 PM
Subject: B.C. Government drug policy task force accused of harbouring "big pharma" big wig - CBC 12:02 pm – May 21-08

Media Monitoring – Radio

B.C. Government drug policy task force accused of harbouring "big pharma" big wig - CBC 12:02 pm – May 21-08

Anchor: The B.C. Government has just announced it has accepted all the recommendations of its controversial pharmaceutical task force. Late last year, the nine-member task force was created to advise the Government on drug policy and its PharmaCare program. Critics say the committed (sic) was dominated by big pharma and drug industry lobbyists. But, today, Health Minister George Abbott said the task force and its recommendations have the full confidence of Government.

George Abbott: They, and the, the rest of the task force, I think, did a very comprehensive and very thoughtful job in terms of looking at the issues around ah, pharmaceuticals and brining together a dozen recommendations which I think ah, are going to be the basis for, for ah, continuing ah, improvement in the, in the area of pharmaceutical management.

Anchor: A government press release provided few details today. But, Abbott confirmed that the Government will move on the forces profit, prompt (*I think she wanted to say, the task forces' prompt) to do away with the UBC therapeutics initiative. The UBC group is an independent drug policy group at arms length from Government and drug companies. The NDP's Adrian Dix – reacting to today's decision charges the head of the task force is a well know drug lobbyist and that the task force and its recommendations are putting the interests, in his opinion, of big pharma, over the interests of the public.

Adrian Dix: You've gotta ask yourself, who asked for that? And, how it could be that the main Canadian lobbyist for big pharma was put in a private room with Government officials and allowed to negotiate the end of ah, of an independent, evidence-based review of the affects of pharmaceutical products in British Columbia. How could that have happened?

Anchor: The NDP's Adrian Dix.

(Not for redistribution)

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24/7 Line: (250) 356-0881

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Thursday, May 22, 2008 6:57 AM
To: Jim Wright; Alan Cassels
Cc: Lun, Eric HLTH:EX
Subject: Hansard

Jim, Alan -

Thought you might be interested in the Hansard from the estimates debate yesterday.

B

A. Dix: The minister referred to the report of the Pharmaceutical Task Force which was released today by the ministry. I want to ask the minister, first of all, about the composition of the task force. I think most people would say that it's unusual that the chief lobbyist for one part of the pharmaceutical industry was included; that a whole bunch of other people, including other parts of the industry, I guess you could argue, were excluded; and that in fact the task force had a very different makeup on the issue of conflict of interest, shall we say, than the therapeutics initiative that it proposes to replace. [DRAFT TRANSCRIPT ONLY]

I wanted to ask the minister why the position was taken to make the task force such an industry-dominated thing. When I saw the list of task force recipients, I said to myself and to the media, I think, that they're going to get rid of the therapeutics initiative, because this is a list of people that don't like the therapeutics initiative — that never liked the therapeutics initiative. The representatives of pharmaceutical companies have consistently for years attacked the evidence-based approach of the therapeutics initiative, which is known for, amongst other things, its very strict rules around conflict of interest — rules that will be weakened if this report is implemented. [DRAFT TRANSCRIPT ONLY]

So I want to ask the minister, and we'll have a chance to talk about some other aspects of it as well, why he chose this composition of a panel. If you're going to open it up wide, and you're going to say, "Well, we want industry on the panel," why just Mr. Williams's group? [DRAFT TRANSCRIPT ONLY]

Hon. G. Abbott: I would disagree fundamentally with the member's assertion that this was an industry-dominated task force. It clearly was not. The object of the task force and of the composition of the task force was to get a range of perspectives around the table. Legitimately, that range of perspectives would include industry, but by no means was this committee in any way dominated by industry. [DRAFT TRANSCRIPT ONLY]

For example, it is, I think, useful to note that the chair was Don Avison, who is the widely respected former Deputy Minister of Advanced Education and former Deputy Minister of Health, now the president of the University Presidents Council. I'm sure the member would agree with me that Dr. Avison is just a widely respected individual in this province. [DRAFT TRANSCRIPT ONLY]

I suspect that the member would share my assessment that George Morfitt, the vice-chair, the former Auditor General of British Columbia, brings a huge, huge range of experience and expertise to the table — certainly a professional, non-biased view. I hope the member would agree with me that George Morfitt and Don Avison were excellent choices for this task force. [DRAFT TRANSCRIPT ONLY]

[1555]

I should also point out to the member that additionally we had two members of the committee who are prominent executive directors in the ministry — Gordon Cross, who has done just a terrific job in the ministry as executive director for regional grants and decision support with the finance and corporate services division, and Paul Gudaitis, who has been executive director for the National Pharmaceutical Strategy Secretariat. Both of those are members of the Ministry of Health. They took, I think, a perspective broader than the Ministry of

Health's to the table, but certainly they're both excellent, competent and well-qualified members of the task force as well. [DRAFT TRANSCRIPT ONLY]

David Hall is, arguably, a representative of pharmaceutical business as chief compliance officer and senior vice-president of community relations with Angiotech Pharmaceuticals. It's arguable that he, along with Russell Williams, who's president of Canada's Research-Based Pharmaceutical Companies — they were members — are two, certainly, that were business. [DRAFT TRANSCRIPT ONLY]

Sue Paish is the chief executive officer of Pharmasave Drugs (National) Ltd. Sue Paish, QC, is very well-respected in this province and brings the pharmacy perspective to the task force. I think that's a positive thing, but it's a much different thing than what might be argued were the interests of the larger pharmaceutical firms in this province. [DRAFT TRANSCRIPT ONLY]

Dr. Mark Schonfeld, chief executive director of the B.C. Medical Association, is, I'm sure again, a widely respected individual who brought a world of knowledge both from a medical perspective and a pharmaceutical perspective to the table. Dr. Robert Sindelar, a professor and dean of the University of B.C. faculty of pharmaceutical sciences, again, is widely, widely respected in this province and brings an important perspective to the table. [DRAFT TRANSCRIPT ONLY]

To me, that's nine members of that committee, and I think it was a very well structured committee. It brought a range of perspectives and expertise, and that is exactly what we wanted to do — ensure that we had some dynamics on the committee. It ensured that if the committee could move together to a consensus, it would be an important consensus in that it would be a reconciliation of a number of perspectives. [DRAFT TRANSCRIPT ONLY]

I am enormously appreciative of the work that the Pharmaceutical Task Force has undertaken. I am very respectful and supportive of the recommendations that they have made. I understand it was a very interesting process to be a part of. I wasn't a part of it, but as you can imagine, with that range of perspectives around the table, they worked through, and there were probably not a lot of assumptions that went unquestioned as the task force moved forward with their work. [DRAFT TRANSCRIPT ONLY]

Nevertheless, under the leadership of Mr. Morfitt and Mr. Avison, they were able to complete what I thought was a very thoughtful, balanced, professional, thorough, unbiased report which I think will be a very sound road map for us moving forward in the future. [DRAFT TRANSCRIPT ONLY]

A. Dix: The minister missed one member. Can he explain why the chief lobbyist for big pharma in Canada, not the generics but the other side.... The generics were within the report, but they weren't part of that. I'm not suggesting necessarily that they should be. I'm just asking: why was the principal lobbyist of big pharma put on a committee whose role it was, essentially, to judge — in part, anyway; there are other issues — the therapeutics initiative, which is the opposite of that, which was the *bête noire* of big pharma? [DRAFT TRANSCRIPT ONLY]

You go to the meeting.... They met with the therapeutics initiative. They had, for a report, moderately disparaging things to say about the initiative, considering what it's contributed to our Pharmacare system and our public health system over its many years. I'd be interested to hear the minister's thoughts on that. [DRAFT TRANSCRIPT ONLY]

[1600]

The therapeutics initiative has, I think it's pretty clear, saved lives in this province, saved hundreds of millions of dollars. Part of the initiative was to save hundreds of millions of dollars. They've got to go there, and they've got to explain themselves to a government task force, a special task force whose recommendations were all agreed to today by the minister, and they've got to go and explain themselves to Mr. Williams. [DRAFT TRANSCRIPT ONLY]

Mr. Williams has every right to take part in this debate, but he should have been a witness like the other witnesses to this and contributed that way. He shouldn't have a special role at the table. In my view, it is really

surprising and disappointing when you consider that the recommendations were exactly what people in the industry wanted. [DRAFT TRANSCRIPT ONLY]

I also think the same about the research side of it. Absolutely, it should be part of the discussion. Professor Sindelar is an absolutely excellent professor and has a point of view. His point of view is promoting research and R and D and everything else, which is part of the debate — right? We have a report. One of the major things driving pharmaceutical costs is, I think at times, the rapacious behaviour of big pharma. [DRAFT TRANSCRIPT ONLY]

We have a report. One of the things driving pharmaceutical costs in Canada were changes to patent laws like the very changes to patent laws we just discussed. In all those cases it's not mentioned in the report. It's like it wasn't there. That's what happens, I think, in fairness, when one extremely powerful group, the Canadian research-based pharmaceutical companies, has all the means in the world to make its presence felt — all the effort in the world. They're not lacking in support. They're not lacking in access. [DRAFT TRANSCRIPT ONLY]

You know, all the advocacy groups that the government has cut.... They say they can't advocate. You can't do anything. You can't get government funding and advocate. Here we have one of the most highly paid, supported advocates and lobbyists in the country, and he gets put on the task force to decide the future of his industry. [DRAFT TRANSCRIPT ONLY]

I just disagree with the minister that that's appropriate. I think that it's absolutely bizarre that the therapeutics initiative.... I have not heard — I may be wrong on this — that the problem with the Pharmacare program is the therapeutics initiative. I haven't heard that. If it was, if there were resources questioned, I haven't heard the government coming forward and saying that we should give them more money to do their task. [DRAFT TRANSCRIPT ONLY]

They were essentially, if the minister is true to what his press release said in accepting the recommendations.... The therapeutics initiative was toasted by this report. After all their good work, after the support they get from many people in the Ministry of Health itself who know about this and know about the work they do, they were toasted. Who were they toasted by? A committee made up of people who are on the research side of it — and that's fair enough; they should be heard from — and representatives of large pharmaceutical companies. Not local pharmacies but a national pharmacy chain. That's who they were toasted by. [DRAFT TRANSCRIPT ONLY]

All those people have a right to be part of this debate. Of course they do; it's a democratic country. Big pharma has the same rights as anybody else, but it shouldn't have more rights. They were given a privileged place in this debate, in this task force. Some of that is reflected in the recommendations of the task force. The minister goes through the list and doesn't mention that he also put the principal lobbyist for big pharma in Canada on the committee. I disagree, and I'm asking the minister whether, I guess, he can defend and justify that decision. [DRAFT TRANSCRIPT ONLY]

Hon. G. Abbott: Well, let's begin by advising the member that I didn't miss anyone. I mentioned Russell Williams. He is the president of Canada's research-based pharmaceutical companies — Rx&D, as they are known. If the member wishes to disparage Mr. Williams by characterizing him as the chief lobbyist for some group or other.... I guess if he wants to bring the debate down to that level and, you know, exhibit that sort of offensiveness towards an industry leader, he's welcome to do that. [DRAFT TRANSCRIPT ONLY]

But if he wants to check *Hansard* he will find that, in fact, I did mention Mr. Williams. The sort of cheap attempt to suggest somehow that I was not including Mr. Williams in the rundown of the nine members of the committee is false and inappropriate. [DRAFT TRANSCRIPT ONLY]

[1605]

So in terms of the structure of the committee, again, the object here was not to have a group that was homogeneous of view or of interests. The attempt was to have a group that brought a variety of perspectives and expertise to the table. If it is the member's view, inappropriate and ill-supported as may be the case, that

somehow Mr. Williams's presence sullied or drove the other members of the committee in a particular direction, then I would have to say that the member does not know Dr. Robert Sindelar very well. He doesn't know Dr. Mark Schonfeld very well. He doesn't know Sue Paish very well. He doesn't know Paul Gudaitis very well. He doesn't know Gordon Cross very well. [DRAFT TRANSCRIPT ONLY]

He certainly doesn't know George Morfitt and Don Avison very well if he thinks that having the presence of someone with an industry perspective at the table totally sullied the process. The member can have that view of the world if he wishes. All I can say is that it is an unfortunate view indeed. [DRAFT TRANSCRIPT ONLY]

It's an unconstructive view which, again, I guess goes to remind the people of British Columbia that the New Democratic Party may not yet be ready for prime-time play. They may just be falling short of having sufficient political maturity to manage the issues of government. That's what I would conclude from a rant of that character, because I think it's insulting to the members of this committee for him to disparage their work in that way. [DRAFT TRANSCRIPT ONLY]

Further, the therapeutics initiative was not, as the member characterized it, toasted in this report. I think that is unfair. I think there were some thoughtful suggestions with respect to the therapeutics initiative. There were some suggestions that the therapeutics initiative could be more transparent in terms of how its decisions are made. In fact, they don't make decisions. They provide technical advice to the people that make decisions. But the task force felt that there could be more transparency around that. I presume — because we often hear from members opposite that transparency is a good thing — that they would think that transparency for the therapeutics initiative would be a good idea as well. [DRAFT TRANSCRIPT ONLY]

I presume, also, that the suggestion that the therapeutics initiative should be structured in a way through a registry to ensure that qualified people are available to do that work within the bounds of the therapeutic initiative.... I presume that that greater inclusiveness would be something the member would be supportive of as well. [DRAFT TRANSCRIPT ONLY]

Again, I don't see any of what the member has read, and I've read, in the Pharmaceutical Task Force to indicate that the therapeutics initiative was toasted. The task force said — and I think they said it in a most thoughtful and constructive way — that the TI can be improved, that it can be made more inclusive, that it can be made more transparent, that government may wish to phase in to a little different model or that they may leave the TI in place and just see it evolve towards greater transparency and greater inclusiveness. None of that, it strikes me, is unthoughtful or unconstructive. I think that in fact the recommendations that have been made are precisely that — thoughtful and constructive. [DRAFT TRANSCRIPT ONLY]

A. Dix: Well, since I'd mentioned Mr. Williams in my first question, I think what I said was: why was he put on the committee? Again, I presume.... I take it from the minister that he was trying to balance all of the views from researchers to the industry to the ministry. There are, presumably, other views and other concerns to be represented. [DRAFT TRANSCRIPT ONLY]

What the report says, referring to the therapeutics initiative, is: "It is now widely regarded" — widely regarded by whom? — "as being in need of either substantial revitalization or replacement." And it recommends in recommendation 4, a recommendation that I gather — maybe the minister can correct me — the minister has accepted. It says: "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." [DRAFT TRANSCRIPT ONLY]

[1610]

So I guess the question is.... I mean, the statements about the therapeutics initiative in the report are, I think, given the reality of the situation, disrespectful. It may be very research-based, but the view, the opinion expressed here that the therapeutics initiative is widely regarded as anything but excellent, would be interesting. I'd love to see that note footnoted. [DRAFT TRANSCRIPT ONLY]

I guess I wanted to ask the minister — because I think that my time is shortly to expire, and my colleague from Vancouver-Kensington will take over — whether recommendation 4, which is the replacement of the

therapeutics initiative, has been accepted by the government and if the government is proceeding. Because if it's not, that's an interesting note. That's recommendation 4. [DRAFT TRANSCRIPT ONLY]

I gather that I may not have understood the complexity of the minister's view when his press release said today: "'Government has accepted all of the recommendations from the Pharmaceutical Task Force,' announced Health Minister" — the member for Shuswap — "today." There may have been nuance in that, which I missed, that applies to everything but recommendation 4, but if that's not the case, maybe the minister can correct the record. [DRAFT TRANSCRIPT ONLY]

Hon. G. Abbott: The task force report contains 12 recommendations. Recommendation 4 is: [DRAFT TRANSCRIPT ONLY]

"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. The new DRRC should also provide 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."

That's recommendation 4. [DRAFT TRANSCRIPT ONLY]

Recommendation 12 is: [DRAFT TRANSCRIPT ONLY]

"Subject to recommendation 4, 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 the core mandate, such as public education, should be reassigned to the PSD's drug utilization unit, where an accountable process can be implemented to ensure the unbiased and evidence-based practice. The practice of having members of the therapeutics initiative also participating in the work of the drug benefits committee should be terminated."

That is recommendation 12, which says that if TI is maintained, they are recommending some changes with respect to how it is done. [DRAFT TRANSCRIPT ONLY]

I can advise the member that we have not made a decision with respect to whether TI will be maintained or not, whether the term "therapeutics initiative" will be maintained or not. We are consulting with, among others, the dean of medicine at UBC to think about those things. [DRAFT TRANSCRIPT ONLY]

We are endorsing all 12 of the recommendations, so if the decision is to maintain therapeutics initiative, it will be maintained in an enhanced form that does speak to the issues of inclusiveness — that is, the expanded registry of qualified scientists who can deal with this and having additional transparency around the evidence base for the decisions that it makes. [DRAFT TRANSCRIPT ONLY]

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Thursday, May 22, 2008 5:04 PM
To: Therrien, Darlene HLTH:EX; Taylor, Suzanne C HLTH:EX; Silver, Matt PAB:EX; Nakagawa, Bob HLTH:EX; Wilmer, Brett D HLTH:EX; Mochrie, Paul HLTH:EX
Cc: Plank, Sarah A PAB:EX
Subject: Re: FOR SIGN OFF - MEDIA REQUEST: Pharmacy Post - Dispensing Fees, Legislation and Task Force Report

Matt. I'm fine with responses related to drug review process and transparency.

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

----- Original Message -----
From: Therrien, Darlene HLTH:EX
To: Taylor, Suzanne C HLTH:EX; Silver, Matt PAB:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Wilmer, Brett D HLTH:EX; Mochrie, Paul HLTH:EX
Cc: Plank, Sarah A PAB:EX
Sent: Thu May 22 16:48:33 2008
Subject: RE: FOR SIGN OFF - MEDIA REQUEST: Pharmacy Post - Dispensing Fees, Legislation and Task Force Report

Hi Matt,

This one on the May 13 Forum needs fixing.

* The Prescription Renewal Forum on May 13 brought the Province's pharmacists and physicians together to discuss the implementation of the Throne Speech commitment to have pharmacists authorize routine prescription renewals, making it easier for patients with chronic illnesses to manage their conditions. Renewal of routine prescriptions is not the same as pharmacist prescribing, which was not a topic at the Forum.

We brought pharmacists and prescribers together… nurse practioners, podiatrists attended, while dentists and midwives were invited but did not attend and of course the physicians… so I used prescriber on purpose… which I realize is not a word…

As for next steps we are in the process of reporting the notes from the meeting out to the attendees for their comment and then we will be discussing the results with the College of Pharmacists. Nothing definitive I would report in the media at this time, except for a successful dialogue on how to implement the renewal of prescriptions by pharmacists.

Darlene C. Therrien
Executive Director
Policy, Outcomes Evaluation and Research Pharmaceutical Services BC Ministry of Health Phone (250) 952-1149

From: Taylor, Suzanne C HLTH:EX
Sent: May 22, 2008 4:36 PM
To: Silver, Matt PAB:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Therrien, Darlene HLTH:EX; Wilmer, Brett D HLTH:EX; Mochrie, Paul HLTH:EX
Cc: Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - MEDIA REQUEST: Pharmacy Post - Dispensing Fees, Legislation and Task Force Report

The academic detailing answer looks fine.
thanks, Suzanne

Suzanne C. Malfair Taylor,
BSc(Pharm), PharmD, BCPS, FCSHP
Executive Director, Drug Use Optimization BC Ministry of Health, Pharmaceutical Services Division 303-960 Quayside Drive New Westminster, BC V3M 6G2
t: 604-660-1217
c: 604-760-5962
f: 604-660-2108
e-mail: suzanne.taylor@gov.bc.ca

From: Silver, Matt PAB:EX
Sent: May 22, 2008 3:26 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Therrien, Darlene HLTH:EX; Taylor, Suzanne C HLTH:EX; Wilmer, Brett D HLTH:EX; Mochrie, Paul HLTH:EX
Cc: Plank, Sarah A PAB:EX
Subject: FOR SIGN OFF - MEDIA REQUEST: Pharmacy Post - Dispensing Fees, Legislation and Task Force Report

Hi everyone,

Thank you very much for the detailed information you provided yesterday in the Pharmacy Post media request. We've tweaked and edited the answers for the reporter. Can you please do a final review so Bob can approve.

Darlene - was curious if you or anyone knows about the outcome of question #5 (what was decisions were made or for next steps etc. resulting from the health professionals forum).

It would be great to have approval by A.M. on Friday as Sarah needs to send to the reporter.

Thanks,

Matt
<< File: 042108 Ann Graham Walker - Pharmacy Post - Dispesnsing Fees Legislation Detailing.doc >> << Message: RE: MEDIA REQUEST - Pharmacy Post - Dispensing fees, detailing, RFP >>
NEWS MEDIA REQUEST
Ministry of Health

Date: May 21, 2008 Time: 12 a.m.
Reporter: Ann Graham Walker
Media: Pharmacy Post
Phone: FAX:
Page/Cell: E-MAIL:
Deadline: May 22 – noon
Topic area: Dispensing fees, detailing, legislation

o/s

Any report from the Pharmacy Task force yet?

* The Task Force's report was released on May 21, 2008. Government has accepted all of the recommendations from the Pharmaceutical Task Force's report. This report will help the Province build on our efforts to ensure our PharmaCare program is based on the best scientific evidence and is sustainable for future generations.

Which Task Force report recommendations will be implemented immediately?

* Government has already begun the process to appoint members of the public to our drug review committee, and will begin immediate work to reconstitute it into a drug benefit council, included ensuring no cross-membership with the body that carries out the technical review of evidence for drug submissions (currently the Therapeutics Initiative). (#5, #6). We have taken a number of steps already to streamline our drug review process and improve the time it takes to reach a listing decision – we expect to make further enhancements to these processes and set target timelines very shortly. (#1, #2, #11). We will also begin immediately to enhance our stakeholder engagement through the work of the newly established Stakeholder and Partner relations branch, which will include stakeholder engagement sessions throughout the year (#10). We will continue our planning related to tendering for drug therapies.

Task Force News Release - http://www2.news.gov.bc.ca/news_releases_2005-2009/2008HEALTH0047-000615.htm

Task Force Backgrounder - http://www2.news.gov.bc.ca/news_releases_2005-2009/2008HEALTH0047-000615-Attachment1.htm

Task Force Report - http://www.health.gov.bc.ca/library/publications/year/2008/PharmaceuticalTaskForceReport.pdf

Communications Contact:

Sarah Plank, Communications Manager, Ministry of Health
250 952.3387
250 480.6678

Insert name of Public Affairs Officer overseeing preparation of IN/materials:
Matt Silver

s14

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Friday, May 23, 2008 8:32 AM
To: Walsh, Sara M HLTH:EX
Cc: Gavin Stuart (gstuart@medd.med.ubc.ca); Lun, Eric HLTH:EX; Gudaitis, Paul HLTH:EX; brian.warriner@vch.ca; Jim Wright
Subject: Meeting with Faculty of Medicine

Sara,

Can you please work with Dean Stuart's admin to set up a meeting with Gavin, Brian Warriner, Jim Wright, Eric Lun, Paul Gudaitis and me to discuss the Pharmaceutical Task Force report as it relates to the Therapeutics Initiative? 2 hours please, at UBC, in the morning if possible.

Thanks,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Friday, May 23, 2008 1:07 PM
To: Letwin, Shallen Dr.; Lun, Eric HLTH:EX
Cc: Pelletier, Marc; Vojt, Anne (Pharmacy); Millin, Bruce; Virani, Adil; XT:HLTH Morris, L; Miyata, Mits; Callin, Mary-Jane; Gudaitis, Paul HLTH:EX
Subject: RE: Report on Pharmaceutical Task Force

Thanks Shallen. We'll make note of this as we consider changes to our process that result from the task force implementation. On that note, I've copied Paul Gudaitis who is leading this work for us.

Best,

B

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

From: Letwin, Shallen Dr. [mailto:Shallen.Letwin@fraserhealth.ca]
Sent: Thu, May 22, 2008 8:47 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX
Cc: Pelletier, Marc; Vojt, Anne (Pharmacy); Millin, Bruce; Virani, Adil; XT:HLTH Morris, L; Miyata, Mits; Callin, Mary-Jane
Subject: Report on Pharmaceutical Task Force

Hi Bob and Eric,

I have reviewed the task force report and there are many things in the report that are encouraging to see.....

However, one issue that I can see is the lack of specific language linking Health Authorities to the Drug Review/Listing Process.

As previously discussed, I think a greater partnership with the Health Authorities in the decision making process would help move us towards formulary alignment

I would like you to consider specific membership from the health authorities pharmacy services on the Drug Benefits Council or the Drug Review Resource Committee or the Drug Coverage
Review Teams

I know Mits sits on the Drug Benefits Committee, but not as a Health Authority Rep.

Further discussion should continue on "adopting" the decision by the Drug Benefits Council by health authorities in order to minimize duplication in work, with potential different outcomes.

Look forward to speaking with you more on this

Thanks

Shallen

Dr. Shallen Letwin
Regional Director-Pharmacy Services
Fraser Health
Pharmacy Administration
Support Services Facility
8521-198 A St, Langley BC V2Y 0A1
Bus: (604) 455-1328 ext 741295
Cell: (604) 897-3554
shallen.r.letwin@fraserhealth.ca
www.fraserhealth.ca

Assistant: mary-jane.callin@fraserhealth.ca

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Wednesday, May 28, 2008 12:51 PM
To: Macatee, Gordon HLTH:EX; Stewart, Michelle PAB:EX; Plank, Sarah A PAB:EX; Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; de Faye, Bob HLTH:EX
Subject: FW: letter to Minister re: government task force report
Attachments: MinisterAbbotLetter2008.pdf

FYI. Interesting letter that is making its way through the system, and apparently is being circulated amongst the academics.

B

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Morris Barer [mailto:mbarer@chspr.ubc.ca]
Sent: Tue, May 27, 2008 6:49 AM
To: Nakagawa, Bob HLTH:EX
Subject: letter to Minister re: government task force report

Hi Bob:

You may already have seen this (attached). If not, probably good for you to be aware of it. There may be more....

Cheers.

Morris

Faculty of Law UNIVERSITY OF TORONTO
78 Queen's Park Toronto Canada M5S 2C5

The Honourable George Abbott MLA
Minister of Health
Room 337
Parliament Buildings
Victoria, BC
V8V 1X4

May 26, 2008

Re: Pharmaceutical Task Force and Therapeutics Initiative

Dear Minister,

As a Professor of Health Law and Policy, I have followed with much interest the debate surrounding the 2008 Report of the Pharmaceutical Task Force, which you established. While this is a laudable initiative and while several of the Task Force's findings are interesting, I am troubled by some of the comments in the report, as well as by a procedural issue related to the Task Force itself.

First, I note that the report is very critical of the Therapeutic Initiative (TI). This must come as a total surprise to many experts. The TI has an enviable reputation and is nationally and internationally regarded as an exemplary independent drug review body. Just very recently, as a panel member at a session of the International Conference of the American Thoracic Society (Toronto, May 16, 2008), I witnessed Dr. Jerome P. Kassirer, Distinguished Professor at Tufts University School of Medicine and former editor-in-chief of the New England Journal of Medicine, lauding the TI and comparing it very favourably to a prestigious US expert panel. Similar comments are frequently made at other national and international venues. The rigorous approach of the TI may irritate those who have a significant interest in more widespread and indiscriminate consumption of pharmaceuticals, and those who believe that faster access to drugs is inherently good for health care. The reality is that the TI's review process and its recommendations have saved numerous lives in British Columbia and elsewhere.

It is surprising, particularly in light of the strong recommendation to abolish the TI, that there is little discussion of where the TI is failing. We learn that the review processes in BC "confine review to a relatively small community of experts" and reference is thereby made to the PSD conflict of interest guidelines as "too restrictive." Expanding the pool of reviewers can obviously improve review times and may contribute to the review process. However, the Panel's suggestion to become more lenient with respect to conflict of interest guidelines is troubling, particularly at a time when it is widely accepted in medicine that conflict of interest rules ought to be strengthened, not weakened.

1/..

 Tel 416-978-3725 Fax 416-978-7899 (Falconer) 416-978-2648 (Flavelle)

UNIVERSITY OF
TORONTO
FACULTY OF LAW

Finally, I want to comment briefly on a procedural issue. In the Report, general reference is made to the fact that Task Force members included representatives from the pharmaceutical industry. Unfortunately, no detailed disclosure is made of specific conflicts of interest of Task Force Members. I learned that five of the nine members of the Task Force have sufficient ties with the pharmaceutical industry to be considered having a conflict of interest. While it is obviously important to involve all stakeholders in this initiative, it seems quite unique that the majority of members of an important governmental task force have direct or indirect financial interests associated with the recommendations made.

In the scientific community, it is now widely accepted that researchers who have a conflict of interest have to disclose that very clearly in all public presentations or publications. It is also increasingly recommended that they are to be excluded from some aspects of medical research and that they should not be involved in review processes or in the establishment of clinical practice guidelines (see for example various reports of the Association of American Medical Colleges). Appropriate conflict of interest rules seem even more important in the context of the drafting of a policy report which seems to rely heavily on members' individual expertise and integrity, and contains only limited publicly verifiable data and analyses. The existence of conflicts of interests of Task Force Members is particularly worth noting in light of its recommendation that the Province should become more lenient with conflict of interests in the context of pharmaceutical review. It is well-established and understandable that those with conflicts of interest like to believe that these do not affect people's judgment. The available evidence points to exactly the opposite.

For all of these reasons, I urge you to evaluate the recommendations made by the Task Force Panel very critically, particularly as they relate to the future of the Therapeutics Initiative. Experts and policy makers in other provinces and in other countries envy the fact that British Columbia has an independent body such as the TI as a pillar of its health care policy. I strongly believe that BC has everything to gain from strengthening the TI, rather than abolishing it.

Yours sincerely,

Trudo Lemmens, Lic.Jur, LLM, DCL
Associate Professor
Faculties of Law and Medicine
University of Toronto

E=mail: Trudo.lemmens@utoronto.ca
Phone: 416 978 4201
Fax: 416 946 3744

TRANSITORY COPY

BRITISH COLUMBIA
The Best Place on Earth

To: Honourable George Abbott
Minister of Health

Date: May 22, 2008

CONFIDENTIAL

Following is an excerpt from the minute of the Cabinet meeting of May 14, 2008, for your attention:

11. Pharmaceutical Task Force

Cabinet reviewed a report entitled "Report of the Pharmaceutical Task Force to the Honourable George Abbott, Minister of Health, Province of British Columbia," dated April, 2008. Cabinet indicated support for the recommendations of the task force.

o/s

Rob Lapper
Deputy Cabinet Secretary

pc: Gord Macatee

)a

TRANSITORY COPY

BRITISH COLUMBIA
The Best Place on Earth

To: Honourable George Abbott
Minister of Health

Date: May 9, 2008

CONFIDENTIAL

Following is an excerpt from the minute of the Cabinet meeting of May 7, 2008, for your attention:

8. Pharmaceutical Task Force Report

Cabinet reviewed a document entitled "Draft Response to Release of TF Report," dated April 28, 2008. Cabinet directed the Minister of Health to return to Cabinet after Cabinet members have had an opportunity to review the "Report of the Pharmaceutical Task Force".

o/s

FOR Rob Lapper
Deputy Cabinet Secretary

pc: Gord Macatee

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Sunday, June 1, 2008 8:40 PM
To: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: Pharm TF Rec Implementation Planning

Thanks Paul. I'll look forward to reviewing this with you.

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

From: Gudaitis, Paul HLTH:EX
Sent: May 30, 2008 4:05 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: Pharm TF Rec Implementation Planning

Bob,

As discussed earlier.
Over the last week, I have been working with Eric and Paul on developing the draft cut of the Pharm TF implementation plan. The first of the attached documents provides the context for this work and includes an overview of activities, risks, mitigation strategies and next steps required to further develop the implementation plan and start work on meeting the 6 month deadline for those issues that have been identified to be immediate priorities. The second document contains a workbook that provides further detail on the primary activates that need to be actioned and their associated timelines - note this is a high level work plan that will require additional work to identify the required approvals and additional activities that need to be considered in order to meet the 6 month timeframe. Note Eric is going to provide some additional info on the rationale for the timelines and the assumptions put forward under his respective recommendations.

When you are back in the office next week we can review the attached and discuss next steps.

Thank you Eric and Paul for working to get this info together in such a short timeframe.

<< File: Task Force Rec Imp Plan DRAFT 30 May 08.doc >> << File: Copy of DRAFT Project Plans Rec 4 and 7_27 May 08-PM_EL edits (2).xls >>

Paul Gudaitis
Executive Director
Stakeholder and Partner Relations
BC Ministry of Health
Tel: 250-952-3017
Cell: 250-588-5513
Fax: 250-952-1391

Paul.Gudaitis@gov.bc.ca

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Tuesday, June 3, 2008 10:07 AM
To: Nakagawa, Bob HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Lun, Eric HLTH:EX; Zimmerman, Janine HLTH:EX
Subject: RE: Meeting to Discuss the Pharm TF Imp Plan
Attachments: TF Drug Review Issues Note DRAFT 3Jun08.doc

Hi Bob - I would like to discuss the attached with you at our monthly meeting later this morning. After our meeting, I will update the document for our meeting this aft.
Thanks,
Eric

From: Walsh, Sara M HLTH:EX
Sent: Tue 03/06/2008 8:20 AM
To: Gudaitis, Paul HLTH:EX; Manning, Marie HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX; Zimmerman, Janine HLTH:EX; Prosser, Sarah HLTH:EX
Cc: Nakagawa, Bob HLTH:EX
Subject: RE: Meeting to Discuss the Pharm TF Imp Plan

Hi Marie,

Eric I believe is in Vancouver all week, therefore please update meeting invite with Bob's polycom number, so he can dial-in. 952-1592

Sincere Regards,
Sara Walsh, EAA
Office of the Assistant Deputy Minister
Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard St
Victoria, BC, V8W 3C8
Tel: 250 952-1464 Fax: 250 952-1584
Email: Sara.Walsh@gov.bc.ca

From: Gudaitis, Paul HLTH:EX
Sent: Mon, June 2, 2008 3:43 PM
To: Walsh, Sara M HLTH:EX; Manning, Marie HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX; Zimmerman, Janine HLTH:EX; Prosser, Sarah HLTH:EX

Cc: Nakagawa, Bob HLTH:EX
Subject: Meeting to Discuss the Pharm TF Imp Plan

Marie / Sara,

Can you both please work to find a time that would work for Bob, Eric, and Paul M. and I to get together to review the Draft Pharmaceutical Task Force Implementation plan that was prepared last week for Bob's review.

We would need to conduct this meeting as early as possible this week (1 hour meeting).

Thanks.

Paul Gudaitis
Executive Director
Stakeholder and Partner Relations
BC Ministry of Health
Tel: 250-952-3017
Cell: 250-588-5513
Fax: 250-952-1391
Paul.Gudaitis@gov.bc.ca

Task Force Response – Drug Review Structure and Process

DRAFT - Issues / Decision Note (Last Updated June 3, 2008)

Background:

Government's implementation of the recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The B.C. government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The B.C. government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

Component	Current	TF Recommendation	Proposed
Structure			
PSD	Formulary Management: ▪ 10 FTE: 1 director, 3 pharmacists, 3 analysts, 1 admin, 2 clerks (currently 2 vacancies) ▪ responsible for all key aspects of drug review process including managing TI Other Support: ▪ SA – LC drugs ▪ POER – BIA, communication ▪ BSDM - PLA	▪ No comment on PSD staffing but assumed to be fully staffed ▪ Recommended increased governance of TI or equivalent (DRRC/T)	Formulary Management: ▪ 11 FTE: add 1 FTE Manager to manage operations of DBC and DRRC and to track submission reviews and support implementation Other Support: ▪ New Clinical Decision Support unit (3 FTE) to support FM and SA to improve clinical input into processes, lead drug class reviews and to play key role for newly proposed clinician submission pathway
Independent Review Body	1. CDR 2. TI for non-CDR sub-dedicated and centralized review team 3. Clinical consultation as needed (e.g., expert opinion for DBC; LC criteria development)	1. CDR: No changes proposed; emulate where possible 2. Either: a. Disassemble TI to create DRRC and DRRT; DRRT to have increased clinician input and decentralized review expertise b. OR Significantly increase governance of TI 3. Increase stakeholder consultation	New model to meet key principles: 1. Transparent, standardized evidence-based review process 2. Reviewers meet COI rules 3. Improve opportunities for more clinician input 4. PSD governance maintained Drug Review Resource Collaboration: ▪ Reports to DBC and PSD ▪ Centralized expertise for the following: (1) evidence-based clinical review, (2) cost-effectiveness review, (3) budget impact analysis ▪ Maintains registry of clinician experts from varied disciplines to provide input into above at established points during review process Proposal to establish DRRT was not adopted as this model has higher risk of bias, inconsistent application of evidence-based review, and inability to support due to unavailability of limited critical appraisal expertise and clinician expertise
Advisory Independent Body	Drug Benefits Committee ▪ 13 members	1. Rename to council 2. Add 3 public members, one as general economist 3. No members on review team should be member of DBC	Accept all (need to confirm number of public members with MO)

Process			
Submission			
Review			CDR Non- CDR
DBC			
Implementation			

Implementation:

Count of Deliverables						Yr	Mth						
						2008						2011	Grand
Task Force	Div Plan Code	Key Step	Deliverables	Status	Approval	6	7	8	9	10	11	3	
TF1 Improve Stakeholder Engagement	1.1 A2	Plain Language Review Process	Plain Language Review Process posted on web	Green	Eric				1				1
	1.3 B4	Clinician submissions	Clinician submissions process developed	Green	Eric						1		1
	2.3 B1	Enhance FM Webpage Info	Post PSD Decisions, DBC Recommend	Green	Eric		1						1
TF2 Review Timeliness	1.3 B1	Fast Track Review	Fast Track Review Process Estab	Green	Eric			1					1
	2.1 A1	Improve PSD Review	Establish target review times	Green	Bob / Eric			1					1
	(blank)	Improve PSD Review	Initiate review time tracking	Green	Eric				1				1
			Report annual review times	Green	Eric							1	1
TF3 Rename DBC to Council	(blank)	Rename DBC to Drug Benefit Council	Renamed	Green	Eric		1						1
TF4 Establish DRRC / DRRT	(blank)	Improve review process, including rebirth of TI as DRRC, ensuring sound DRRC governance, and enhancing clinician input and	1 - Strategy: Determine strategic role of TI in drug review process wrt current drug review, research and education	Green	DMO / Bob / Eric	1							1
			2 - Strategy: Establish new drug review structure and process, including determining new resource needs	Green	DMO / Bob / Eric	1							1
			3 - Preparation: Finalize new TOR for DBC and DRRC, Establish PSD governance resources; draft and finalize new contracts for DRRC; develop recruitment plan to resource DRRC	Green	Bob / Eric		1						1
			4 - Implement: Post TOR for DBC and DRRC; Begin recruitment for DRRC	Green	Eric		1						1
			5 - Implement: New members of DRRC recruited, all PSD, DBC, and DRRC resources in place	Green	Eric					1			1
			6 - Implement: Launch new DBC and DRRC	Green	DMO / Bob / Eric						1		1
TF5 Public Member	1.3 B2	DBC - public members	1 - Finalize and approve # of new public members and initiate recruitment	Green	MO or DMO	1							1
			2 - Recruited and placed 2 or 3 new DBC public members	Green	Eric				1				1
			3 - DBC public member training binder developed and member trained	Green	Eric					1			1
TF6 DBC Membership	(blank)	Ensure no members on TI or DRRC are members of DBC	Request membership change; include in DBC TOR	Green	Eric		1						1
Grand Total						3	5	2	3	2	2	1	18

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, June 3, 2008 1:21 PM
To: Gudaitis, Paul HLTH:EX; Mochrie, Paul HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: Competition bureau - task force report follow up

Paul and Paul - just had a conversation with Mark Ronayne from the Competition Bureau about the task force report and recommendations. He would like to be asked (Gudaitis- please follow up) to provide a competition policy perspective on the issues identified in recommendation #7. I said that I would welcome that, as we are trying to encourage and stimulate competition in our marketplace. We also talked a little bit about the possibility of inviting them to the multilateral stakeholder meeting in July where we will be discussing the TF report. I want to give that a bit of thought, as they really aren't stakeholders per se, but on the otherhand, it might be good to have them there.

Eric, this is FYI, as we may talk about this on our call this afternoon.

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

O/S

O/S

O/S

Education

- Patients (cited in the recommendation)
- MDs
- Pharmacists
- Therapeutics Letter – review process

Research

- Distinguish from the TI

Bob to call David Henry to reconsider not doing the external review.
Reestablishing the advisory board – Jim to pull the terms of reference
Next meeting – July – Brian and Bob's office to coordinate.

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Friday, June 6, 2008 9:36 PM
To: Silver, Matt PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

I think that is fine Matt. I'll let you know if I think of anything else.

B

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Silver, Matt PAB:EX
Sent: June 6, 2008 8:30 PM
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

Thanks Bob - new messaging for TI looks good and I broke up messaging bullet two into two bullets. My accepted track-changed document with very minor tweaks is attached.

We really appreciate everyone looking at this on short notice and will consider it approved unless you have further comments or anyone else has something to add/change.

Matt

-----Original Message-----
From: Nakagawa, Bob HLTH:EX
Sent: Fri 6/6/2008 8:02 PM
To: Silver, Matt PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

Matt,

I've made some comments and suggestions for changes in the attached. Let me know what you think.

<<IS_Palmer_Task_Force_interview_June_6_430pm_DRAFT.doc>>

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP Assistant Deputy Minister - Pharmaceutical Services
BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

---

From: Silver, Matt PAB:EX
Sent: June 6, 2008 4:51 PM
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

Hi Bob,

I've attached the scan with the information on media inaccuracies and those who have jumped to conclusions on recommendations etc. I met today with Paul/Woody/Vivian to go over this and have since added to it..

As discussed, we want to provide the Minister with info before his interview with Vaughn Palmer on Monday, June 9. I've made a couple changes from Sarah's review, but can you please review and approve and send back to Sarah/myself by Saturday? I've also attached our media clips collection since the Task Force report was released on May 21.

Thanks,

Matt
<< File: IS_Palmer_Task_Force_interview_June_6_430pm_DRAFT.doc >> << File: Media coverage - May 21 to June 5 2008.doc >> << Message: RE: MEDIA RESPONSE - Task Force - Vaughn Palmer >>

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Friday, June 6, 2008 8:03 PM
To: Silver, Matt PAB:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: RE: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

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IS_Palmer_Task_Force_interview...

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

From: Silver, Matt PAB:EX
Sent: June 6, 2008 4:51 PM
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX; Turnquist, Woodrow HLTH:EX; Ip, Vivian HLTH:EX; Lun, Eric HLTH:EX; Plank, Sarah A PAB:EX
Subject: FOR SIGN OFF - Task Force Issues Scan - Minister's Interview with Vaughn Palmer on Monday, June 9

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Task Force - Media Coverage Inaccuracies
June 6, 2008

Since the Pharmaceutical Task Force's report was released on May 21, 2008, several media reports have contained inaccuracies and jumped to conclusions. s.13

s.13

Therapeutics Initiative
The largest inaccuracy reported by media is that government is going to abolish the Therapeutics Initiative, which provides research on medications.

- **CKNW, May 21, 2008** – The opposition health critic told media that "this government went and disbanded it [Therapeutics Initiative] today."

- **Strategic Thoughts, May 21, 2008** - The Campbell government shouldn't get away with rewarding the drug companies by re-organizing the Therapeutics Initiative out of existence.

- **CBC Early Edition, May 22, 2008** – Reporter states to Alan Cassels in an interview, "Now, the pharmaceutical task force recommended that a group called the Therapeutics Initiative be dissolved, and the government has accepted that recommendation."

- **CBC Radio, May 22, 2008** – Host says one of the task force's recommendations: To fire an independent group of academics at UBC which has been providing doctors and the government advice about drug safety and efficacy for more than a decade.

- **Georgia Straight, May 29, 2008** – Author Alan Cassels states "at about the time the new Victoria Cross was launched, the Therapeutics Initiative was being torpedoed by the provincial government's endorsement of its own Pharmaceutical Task Force report."

- **Vancouver Sun, May 29, 2008** – "From that moment on, supporters of the Therapeutics Initiative feared the program was being put on the chopping block. Their suspicions were based primarily on the makeup of the panel, which included representatives of the prescription drug industry. It looks like they were right."

- **Salmon Arm Observer, June 4, 2008** – A local doctor is interviewed in a story where he makes several comments about his dislike of the task force report. The doctor says "the Ministry of Health has dispensed with the TI, on the grounds that it's too slow to approve drugs and has too strict conflict of interest guidelines and isn't "transparent enough" – all industry based complaints."

Messaging:

s.13

s.13

s.13 **our government supports the need for independent, scientific reviews of new drug products.**

- **PharmaCare bases drug coverage on the best available clinical evidence, and that will not change – but we also see opportunities to improve this process, including increased transparency and engagement of a wider range of experts for reviews.**

Task Force members

Many media reports have questioned government about the membership of the Task Force committee and their connection to the pharmaceutical industry.

- **Vancouver Sun, May 22, 2008** – The opposition health critic said the make-up of the committee heavily favoured pharmaceutical industry interests.

- **CBC early morning, May 22, 2008** – Alan Cassels said "You're stacking a task force to look at drug policy in British Columbia, and you put the head lobbyist of the pharmaceutical industry in Canada on the committee, as well as others who are involved with chain drug stores and other aspects of the drug industry. That struck us as almost laughable."

- **The Tyee, May 23, 2008** – Reporter said "At least five of the task force's nine members had close connections to the industry, as documented by The Tyee in November.

- **Georgia Straight – May 29, 2008** - Cassels says "This nine-member task force—which had a mandate to find ways to "maximize value" for patients and money and to "improve the pharmaceutical approval process"—included the top Canadian lobbyist for industry association Canada's Research-Based Pharmaceutical Companies (Rx&;D), plus five other people with ties to the drug industry."

Messaging:

- **Members of the task force were selected by the Ministry for their experience and expertise in a number of their fields in order to represent a broad cross-section of skills and backgrounds related to pharmaceuticals and public policy.**

- **Task Force members represented a wide range of stakeholders in the pharmaceutical industry and is brought together by expertise and experience of:**
  - **Government policy makers:**
  - **Clinical professionals;** s.13
    s.13
  - **Academics;**
  - **Pharmaceutical industry leaders.**

- **All participants involved had valuable ideas to bring to the task force.**

Task Force report recommendations will lead to higher drug costs
A Vancouver Sun story said that it's hard to see how the panel recommendations won't lead to higher costs since new drugs can be vastly more expensive than the ones they replace.

- **Vancouver Sun, May 29, 2008** – "The right drug, according to companies bringing new drugs to market, is their latest product. Occasionally they represent genuine breakthroughs, miracle drugs that save lives and reduce suffering. More often they are either me-too drugs, i.e. versions of a breakthrough drug from competing manufacturers, or slight variations on existing products that are more expensive than generic alternatives."

Messaging:

- **Task Force recommendations are guided by six principles, one of which is to get the best drug prices for B.C. taxpayers.**
- **All drug benefit decisions in B.C. are based on scientific evidence-based, transparent reviews – and this will not change.**
- **Government restructured PharmaCare coverage in 2005 to ensure we were helping those who need it most, and we believe our coverage is both fair and comprehensive.**
- **Increasing drug costs remains one of the greatest challenges to our health care budget. Tendering is one area the Ministry continues to explore as a way to better control costs of pharmaceuticals and achieve the best value for taxpayers.**
- **We will continue to negotiate with manufacturers to get the best price as we've been doing – none of the recommendations from the Task Force prevents us from doing that.**
- **Importantly, every British Columbian is protected under Fair PharmaCare from catastrophic drug costs.**

Task Force consultation with stakeholders and organizations

Questions could be asked about stakeholder engagement with the Task Force when they conducted presentations with organizations. Media have reported that the majority of stakeholder consultation was done with organizations that represent Big Pharma, such as the Better PharmaCare Coalition.

- **Salmon Arm Observer, June 4, 2008** – "The Better PharmaCare Coalition, which includes groups such as Heart & Stroke Foundation of BC & Yukon, Canadian Diabetes Association, the Kidney Foundation of Canada, the BC Schizophrenia Society, and the BC Lung Association, was one of several stakeholders who presented to the task force."

Messaging:

- **The Task Force heard from a wide range of stakeholders, whose views were united by the common thread that patients must have access to the best care and treatment possible.**
- **Many different stakeholders, organizations and advocacy groups presented to the Task Force, including:**
    - **The Therapeutics Initiative;**
    - **Canadian Generic Pharmaceutical Association;**
    - **Better PharmaCare Coalition;**
    - **Canadian Diabetes Association;**
    - **Canadian Association of Chain Drug Stores;**
    - **Child and Family Research Institute;**
    - **Providence Health Care Research Institute.**
- **No organization was given preferential treatment during stakeholder consultations.**
- **Every stakeholder who asked to present to the Task Force was allowed to do so.**

Drug Review Process

There has been discussion about speeding up drug approvals and whether this will be beneficial to B.C. patients.

- **Vancouver Sun, May 22, 2008** – The opposition health critic said he's concerned that speeding up the drug-approval process, as recommended by the committee, will bring about potential harm to patients.

- **CBC, May 29, 2008** – In an interview, Dr. Brian Warriner said that a number of Task Force recommendations relate to speeding up approvals for drugs in British Columbia, and some of them may be quite sensible.

Messaging:

- **I believe** s.13 **that we can improve drug approval timelines and do it appropriately** s.13 s.13

- **We have taken strides in the Ministry to improve our processes to make listing decisions faster and we are absolutely committed to further streamlining our review for new drugs submitted, and reducing any duplication with the Common Drug Review process.**

- **If we speeded reviews excessively, then that would be a concern.** s.13

s.13

- **While we** s.13 **speed up the drug approval process, we will continue to ensure that all drug benefit decisions are based on scientific evidence-based, transparent reviews – this will not change.**

- **By improving B.C.'s drug approval process, we can:**

    - **Get our timelines comparable to other jurisdictions;**

- **Ensure that in every case a full and comprehensive assessment is made of a drug, both in terms of its safety, its efficacy, and its value in terms of its addition to the formulary.**

Accepting Task Force recommendations
Many media reports have not mentioned that government's acceptance of task force recommendations will be guided by six principles that include seeking best value for taxpayers and working in the best interests of patients.

- **CBC, May 21, 2008** – Reporter does not go into detail about accepting recommendations, just says "The B.C. Government has just announced it has accepted all the recommendations of its controversial pharmaceutical task force.

- **Strategic Thoughts, May 21, 2008** – Author says "Nowhere in the Task Force's report can you find any indication of how full implementation of its recommendations will impact costs for the Pharmacare program, not even so much as to say whether costs would go up or down under the recommendations."

Messaging:

- **Government has accepted all recommendations by the task force, and will be guided by six principles:**

    1. **The best interests of the patient are paramount.**

    2. **The B.C. government is obliged to seek the best value possible for taxpayer dollars in its expenditures.**

    3. **The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.**

    4. **The B.C. government is committed to fair, open and transparent procurement processes.**

5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.

6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

- We will implement task force recommendations and work with stakeholders on some of them immediately. Others are more complex and will take some time to plan and implement.

- We are committed to further multilateral stakeholder consultations as we take our next steps with regard to the recommendations of the task force.

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Saturday, June 7, 2008 1:03 PM
To: Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX
Cc: Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX
Subject: RE: TF Abbreviated Responses - Drug Review Process DRAFT
Attachments: TF Abbrev Responses - Drug Review 1-6 11 12 DRAFT Updated.doc

Sorry, please use this updated version which corrects some grammatical errors in the first one sent.

Eric
-----Original Message-----
From: Gudaitis, Paul HLTH:EX
Sent: Sat 07/06/2008 12:05 PM
To: Lun, Eric HLTH:EX; Nakagawa, Bob HLTH:EX
Cc: Mochrie, Paul HLTH:EX
Subject: Re: TF Abbreviated Responses - Drug Review Process DRAFT

Thanks for the info Eric/Paul.
I will review and compile into a complete doc for review and comment.
Bob - I will work on this info this weekend and provide a draft on Monday - as we do not meet the DM until the 16th.

----- Original Message -----
From: Lun, Eric HLTH:EX
To: Nakagawa, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX; Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX
Sent: Sat Jun 07 12:00:45 2008
Subject: TF Abbreviated Responses - Drug Review Process DRAFT

Hi there,

Here are my draft abbreviated responses to each of the recommendations related to the drug review process. Please review and if you need me to rework anything, please advise.

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, BC Ministry of Health

Recommendation	Ministry Response
1. 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 PSD and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.	Guided by the six principles listed in the government response, the Ministry will focus on enhancing the provincial Formulary Management System—the system for selecting drugs and developing policy for coverage under the province's drug insurance program. By November, 2008, PSD will implement several initiatives to improve stakeholder engagement, including establishing a dedicated Stakeholders and Partner Relations branch. Other stakeholder engagement and drug review transparency initiatives include establishing a formal pathway for clinicians to make submissions for drug reviews, and making available on the PSD website more detailed information on the drug review process and drug review decisions. PSD will also establish an evidence-based appeal mechanism for manufacture and clinician submissions. Additional details on other initiatives to enhance the provincial Formulary Management system are outlined in the other Ministry responses.
2. The Ministry of Health should act to establish new target review/listing decision guidelines with the goal of substantially improving B.C.'s performance on time-to-listing decisions. Progress on this front must be publicly reported and consistently benchmarked against the performance of other jurisdictions.	The Ministry is fully committed to a robust evidence-based evaluation of drug submissions—there is also, a need for timely patient access to pharmaceutical therapy that have objectively demonstrated advantages to existing available therapies. By August 2008, the Ministry will establish target time-to-review timelines (to be applied on a go-forward basis) and introduce a criteria-based fast track capability to the drug submission review process to accelerate reviews of drugs that have demonstrated superior therapeutic or substantial cost-effectiveness advantages compared to available alternatives. Actual time-to-review timelines for individual submissions will be publicly reported on the PSD website in the drug review status tracking section and review times will be summarized annually in the PSD Annual Report. Where possible, this information will also be benchmarked against other jurisdictions (currently, this information is not available from other jurisdictions).
3. 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.	By November 2008, the Ministry will reconstitute the committee as a Drug Benefit Council (DBC) - an independent arms length advisory body to make recommendations to the Ministry of Health's Pharmaceutical Services Division (PSD) regarding the listing of drugs on its formulary to improve and maintain the health and well-being of British Columbians. The DBC will consist of health care professions, other professionals with expertise in drug evaluation, and members of the public. When required, additional experts will be accessible to the DBC to assist with completing their mandate. The approach of the DBC will be evidence-based and the advice is expected to reflect current medical and scientific knowledge and current clinical practice. To ensure independent, arms-length function by the committee, all persons involved on the DBC must comply with established conflict of interest policies.
4. The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the TI. 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.	By November 2008, the Ministry will establish a Drug Review Resource Committee (DRRC) that will report to the Drug Benefit Council. The DRRC will consist of experts who will review drug submissions by completing clinical evidence reviews and pharmacoeconomic reviews, as required. The DRRC will also include a registry of clinician expert members to advise and participate in the drug review process. As with the DBC, members of the DRRC will be required to comply with established conflict of interest policies.

5. The membership of the DBC should be modified to include the participation of at least three public members selected through 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 focussed more narrowly on health economics.	The Ministry will appoint three public members to the DBC. The public member appointment process will begin in June 2008 and is expected to be completed by November 2008. To ensure an open, transparent and consistent appointment process, the Ministry will work in consultation with the Board Resourcing and Development Office. The Ministry recognizes there is an interest and movement towards public participation in all areas of health policy as a means of incorporating public values into health care decision making to enhance transparency, equity and fairness and will take the necessary final steps to include public participation in its drug review process.
6. 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.	By July, 2008, the Terms of References for the DRRC and DBC will be prepared and will stipulate that no DRRC members will participate on the DBC as members.
11. 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.	The Common Drug Review is an example of an efficient working relationship between federal, provincial and territorial governments. PSD will emulate CDR processes, wherever possible, including establishing similar target time-to-review timelines and introducing appeal mechanisms (see government response #1). Where evidence of unnecessary overlap are demonstrated and brought to the attention of the Ministry, every effort will be made to eliminate unnecessary overlap.
12. Subject to recommendation four, if the TI is maintained, action must be taken in the following areas: • the governance, membership and accountability standards associated with the operation of the TI will require substantial improvement; • steps must also be taken to renew and revitalize the panel of experts the TI relies upon to discharge its obligations; • the function of the TI 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 unbiased and evidence-based practices; • the practice of having members of the TI also participating in the work of the DBC should be terminated.	The Ministry is supportive and appreciative of the many valuable contributions made by the Therapeutics Initiative (TI) thus far. Over the next 6 months and concluding by November 2008, the Ministry will work with the Faculty of Medicine to define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework. The Faculty of Medicine is ultimately responsible for overseeing the governance of the TI. The Dean of the Faculty of Medicine is currently conducting an academic review of the TI and is expected to complete its review by October, 2008. Within PSD, the Drug Use Optimization Branch is responsible for public education on drug-use issues. The new Terms of References for the DRRC and DBC will stipulate that no DRRC members will participate on the DBC as members (See government response # 6)..

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Friday, June 13, 2008 2:23 PM
To: Mochrie, Paul HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX
Subject: Re: FOR REVIEW - Draft of Pharm TF Implementation Doc

For my section, I'll be requesting a telecon next week to review the DRRC set up, how the TI fits in and target timelines. Prior to that, I'll be sending flow charts.

Paul and Bob - will work around your schedule since you are in PEI.

Thanks,
Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

----- Original Message -----
From: Mochrie, Paul HLTH:EX
To: Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX
Sent: Fri Jun 13 14:07:16 2008
Subject: RE: FOR REVIEW - Draft of Pharm TF Implementation Doc

Thanks Paul.

As I understand, the timeline in question pertains only to the development of a policy framework for tendering. We will have a draft completed by the end of this month. Thus, including time for review and approval, July is a workable deadline. August is even more so. I will defer to you and Bob on the implications of identifying a shorter/longer timeframe.

Particularly if this document will be circulated or referenced outside the Ministry, we will want to avoid any inference that we are committing to actually issue one or more tenders by the above-referenced deadline.

Please let me know if you need anything further at this point.

Cheers,
Paul

From: Gudaitis, Paul HLTH:EX
Sent: Friday, June 13, 2008 1:42 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: FOR REVIEW - Draft of Pharm TF Implementation Doc
Importance: High

Bob,

In working with Eric and Paul (thanks for providing the info), I have put together the implementation approach document to address the Pharm Task Force Report recommendations. Please review the attached - I can edit the doc over the weekend to ensure that we have a copy for the briefing with Gord on Monday.

Paul - in reviewing the materials I noticed that we do not have a deadline for the activities for recommendation #9 - can you please suggest a deadline date (I would propose that this work could be completed by July/Aug 2008 - due to the urgency of completing the work reduce the impact on the ability to tender).

<< File: Pharm TF Rpt Rec Implementation Approach DRAFT 13 June 08.doc >>

Paul Gudaitis
Executive Director
Stakeholder and Partner Relations
BC Ministry of Health
Tel: 250-952-3017
Cell: 250-588-5513
Fax: 250-952-1391
Paul.Gudaitis@gov.bc.ca

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Saturday, June 14, 2008 4:52 PM
To: Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: FOR REVIEW - Draft of Pharm TF Implementation Doc

Hi guys,

I've made some revisions/ comments on the attached. Can you please take a look at it and make sure that it is still OK. I've asked Eric to attend the DM meeting in Victoria to be able to answer some of the TI/ DRRC questions that may come up.

Thanks to all of you for your work in pulling this together. The real challenge is now to advance the big chunks (rebates/ pharmacy compensation and the formulary process redesign) in a timely way.

Best,

Pharm TF Rpt Rec Implementatio...

Best,

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC V8W 3C8

250-952-1705

Please consider the environment before printing this e-mail

From: Gudaitis, Paul HLTH:EX
Sent: June 13, 2008 1:42 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: FOR REVIEW - Draft of Pharm TF Implementation Doc
Importance: High

Bob,

In working with Eric and Paul (thanks for providing the info), I have put together the implementation approach document to address the Pharm Task Force Report recommendations.
Please review the attached - I can edit the doc over the weekend to ensure that we have a copy for the briefing with Gord on Monday.

Paul - in reviewing the materials I noticed that we do not have a deadline for the activities for recommendation #9 - can you please suggest a deadline date (I would propose that this work could be completed by July/Aug 2008 - due to the urgency of completing the work reduce the impact on the ability to tender).

<< File: Pharm TF Rpt Rec Implementation Approach DRAFT 13 June 08.doc >>

Paul Gudaitis
Executive Director
Stakeholder and Partner Relations
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Cell: 250-588-5513
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Paul.Gudaitis@gov.bc.ca

PHARMACEUTICAL TASK FORCE RECOMMENDATIONS IMPLEMENTATION APPROACH

INTRODUCTION:

In November, 2007 the Pharmaceutical Task Force was established and invited to make 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 decision 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; and
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 report from the Pharmaceutical Task Force was released in April 2008, and the recommendations contained within were accepted by the Minister of Health.

PURPOSE

- ~~With the acceptance of the recommendations by the Minister of Health, there is a need to develop and introduce an accelerated implementation approach that would address each of the recommendations put forward in the report.~~

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- ~~The following approach~~To provides an overview of the activities and ~~dead~~timelines ~~associated with~~for implementing the recommendations contained within the Pharmaceutical Task Force Report.

GUIDING PRINCIPLES FOR RECOMMENDATIONS IMPLEMENTATION

The ~~Government's~~ implementation of the Pharmaceutical Task Force recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The B.C. Government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The B.C. Government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

TASK FORCE RECOMMENDATIONS – ACTIVITIES AND PROJECTED COMPLETION TIMELINES

- The following approach describes the proposed activities that will be initiated to address the Pharmaceutical Task Force recommendations. ~~In addition the proposed deadline(s)~~The timelines for the completion of these activities is also included.

- ~~Note the corresponding recommendations and activities do not include details on funding or resourcing matters.~~ Upon approval a more detailed workplan will be developed to address the sub-activities, resources, and funding required in order to successful meet the projected completion dates.

Recommendation 1:

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 PSD and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.

Activities

- Guided by the six principles listed above, the Ministry will focus on enhancing the provincial Formulary Management System—the system for selecting drugs and developing policy for coverage under the province's drug insurance program.

- The Pharmaceutical Services Division (PSD) will implement initiatives to improve stakeholder engagement, including establishing a dedicated Stakeholders and Partner Relations (SPR) branch.
- Other stakeholder engagement and drug review transparency initiatives include establishing a formal pathway for clinicians to make submissions for drug reviews, and making ~~available on the PSD website~~ more detailed information on the drug review process and drug review decisions available on the PSD website.
- PSD will also establish an evidence-based appeal mechanism for manufacturer and clinician submissions.
- Additional details on other initiatives to enhance the provincial Formulary Management system are outlined in the response to later recommendations.~~other Ministry responses~~.

Projected Date of Completion

- **May 2008 – Stakeholder and Partner Relations branch established**
- **November, 2008 – ~~Complete remaining activities indicated~~Stakeholder engagement and drug review transparency initiatives established; evidence-based appeal mechanism established.**

Recommendation 2:

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

Activities

- The Ministry will establish target time-to-review timelines ~~(to be applied on a go-forward basis)~~ and introduce a criteria-based fast track capability to the drug submission review process to accelerate reviews of drugs that have demonstrated superior therapeutic or substantial cost-effectiveness advantages compared to available alternatives.
- Actual time-to-review timelines for individual submissions will be publicly reported on the PSD website in the drug review status tracking section and review times will be summarized annually in the PSD Annual Report. Where possible, this information will also be benchmarked against other jurisdictions (currently, this information is not available from other jurisdictions).

Projected Date of Completion

- **August 2008 – Establish target time-to-review timelines and introduce a criteria-based fast track capability**

Recommendation 3:

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.

Activities

- The Ministry will reconstitute the committee as a Drug Benefit Council (DBC) - an independent arms length advisory body to make recommendations to the Ministry of Health's PSD regarding the listing of drugs on its formulary to improve and maintain the health and well-being of British Columbians.
- The DBC will consist of health care professions, other professionals with expertise in drug evaluation, and members of the public. When required, additional experts will be accessible to the DBC to assist with completing their mandate. The approach of the DBC will be evidence-based with the advice reflecting current medical and scientific knowledge and current clinical practice.
- To ensure independent, arms-length function by the committee, all persons involved on the DBC must comply with established conflict of interest policies.

Projected Date of Completion

- **November 2008**

Comment [BN1]: Why will this take so long?

Recommendation 4:

The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the TI. 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.

Activities

- The Ministry will establish a Drug Review Resource Committee (DRRC) that will report to the Drug Benefit Council. The DRRC will consist of experts who will review drug submissions by completing clinical evidence reviews and pharmacoeconomic reviews, as required. The DRRC will also include a registry of clinician expert members to advise and participate in the drug review process. The DRRC will collaborate with the TI to develop clinically relevant questions to guide the evidence review and to assess the clinical relevance of the appraisal results
- ~~As with the DBC,~~ members of the DRRC will be required to comply with established conflict of interest policies.

Projected Date of Completion

- **November 2008**

Recommendation 5:

The membership of the DBC should be modified to include the participation of at least three public members selected through 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 focussed more narrowly on health economics.

Activities

- The Ministry will appoint three public members to the DBC. The Ministry recognizes there is an interest and movement towards public participation in all areas of health policy as a means of incorporating public values into health care decision making to enhance transparency, equity and fairness and will take the necessary final steps to include public participation in its drug review process.
- To ensure an open, transparent and consistent appointment process, the Ministry will work in consultation with the Board Resourcing and Development Office.

Projected Date of Completion

- **November 2008 – Completion of public member appointment process (initiated in June 2008)**

Recommendation 6:

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.

Activities

- The Terms of References for the DRRC and DBC will be prepared/ revised and will stipulate that no DRRC members will participate on the DBC as members.

Projected Date of Completion

- **July 2008**

Recommendation 7:

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.

Activities

- PSD and the BC Pharmacy Association (BCPhA) have established a process for dialogue regarding the economic relationship between the Province and community pharmacies. Using this process mechanism, PSD and BCPhA have agreed to undertake discussions about a new framework for generic drug pricing and pharmacy compensation. A strategy for these discussions will be brought forward for approval.

- PSD will also solicit and discuss proposals from pharmaceutical manufacturers and other interested parties regarding possible alternatives to enhance price competition or otherwise moderate retail prices for generic drugs.

Projected Date of Completion

- **November 2008**

Recommendation 8:

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.

Activities

- PSD will advance and discuss options to evolve the current model of PharmaCare reimbursement for pharmacy services.
- Operating within the funds allocated to the PharmaCare program, PSD will work with the BCPhA and other stakeholders on the development of a compensation framework that is equitable, transparent and provides a return for professional pharmacy services that represent material added value to the health care system.

Projected Date of Completion

- **November 2008**

Recommendation 9:

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.

Activities

- PSD will develop a policy framework to guide future competitive tendering initiatives. While preserving appropriate patient care and promoting fair competition between suppliers, PSD will ensure that the tendering process is open and well-communicated.
- Insofar as is practicable, PSD will rely on Government's established principles and processes for procurement, including BC Bid, and will work with Government's Common Business Services to conduct such processes. This

policy framework will be articulated before any additional tendering is undertaken.

Projected Date of Completion

- **August 2008~~TIMELINE TO BE DETERMINED~~**

Recommendation 10:

The Deputy Minister of the Ministry of Health should commit to participate in a 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.

Activities

- The newly established Stakeholder and Partner Relations (SPR) branch of the PSD will ~~work toward establishing~~hold ~~the initial~~a multi-lateral stakeholder engagement session to present the Pharmaceutical Task Force recommendations and request that stakeholders provide their ~~corresponding~~ perspectives ~~on how they can be engaged in the implementation of the report recommendations~~.

Projected Date of Completion

- **July 2008**

Recommendation 11:

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.*

Activities

- The Common Drug Review is an example of an efficient working relationship between Federal/Provincial/Territorial governments. PSD will emulate CDR processes~~,~~ wherever possible, including establishing similar target time-to-review timelines and introducing appeal mechanisms (see government response #1).
- ~~Where evidence of unnecessary overlap are demonstrated and brought to the attention of the Ministry, every effort will be made to eliminate unnecessary overlap.~~

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Projected Date of Completion

- ~~Ongoing~~**August 2008**

Recommendation 12:

Subject to recommendation four, if the TI is maintained, action must be taken in the following areas:

- *the governance, membership and accountability standards associated with the operation of the TI will require substantial improvement;*
- *steps must also be taken to renew and revitalize the panel of experts the TI relies upon to discharge its obligations;*
- *the function of the TI 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 unbiased and evidence-based practices; and*
- *the practice of having members of the TI also participating in the work of the DBC should be terminated.*

Activities

- The Ministry is supportive and appreciative of the many valuable contributions made by the Therapeutics Initiative (TI)~~ thus far~~. The Ministry will work with the University of British Columbia (UBC) Faculty of Medicine to define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework.
- The UBC Faculty of Medicine is ultimately responsible for overseeing the governance of the TI. The Dean of the Faculty of Medicine ~~is currently conductinghas~~ requested a formal~~n~~ academic review of the TI.
- Within PSD, the Drug Use Optimization (DUO) Branch is responsible for public education on drug-use issues.
- The new Terms of References for both the DRRC and DBC will stipulate that no DRRC members will participate on the DBC as members (See government response # 6).

Projected Date of Completion

- **October 2008 – Academic review of the TI ~~is to be~~ completed**
- **November 2008** – define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework. ~~**Conclusion of six-month process to define and enhance how the TI contributes to DRRC framework**~~

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Monday, June 16, 2008 6:03 AM
To: Lun, Eric HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Gudaitis, Paul HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: Pharm TF response overview

Thanks Eric. Agreed.

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

From: Lun, Eric HLTH:EX
Sent: June 16, 2008 12:28 AM
To: Nakagawa, Bob HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Gudaitis, Paul HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: Pharm TF response overview

Bob - For Recommendation 2 (target review/listing decision guidelines)

Based on our discussion on Friday, what is worded as "time-to-review" in our draft activities should be changed to "time-to-decision". We still need to talk about what the best options are in those circumstances when we hit the target time and we are still in negotiations with the manufacturer.

Thanks,

Eric

From: Nakagawa, Bob HLTH:EX
Sent: Sun 15/06/2008 1:15 PM
To: Macatee, Gordon HLTH:EX; de Faye, Bob HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Wheeler, Jan HLTH:EX; Boomer, Joanne HLTH:EX
Subject: Pharm TF response overview

Gord and Bob,

Hope you are having a relaxing Father's day....

Please find attached an overview of our proposed approach to implementation of the Pharmaceutical Task Force Recommendations that we will be reviewing with you tomorrow.

Best,

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

PHARMACEUTICAL TASK FORCE RECOMMENDATIONS IMPLEMENTATION APPROACH

INTRODUCTION:

In November, 2007 the Pharmaceutical Task Force was established and invited to make 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 decision 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; and
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 report from the Pharmaceutical Task Force was released in April 2008, and the recommendations contained within were accepted by the Minister of Health.

PURPOSE

- To provide an overview of the activities and timelines for implementing the recommendations contained within the Pharmaceutical Task Force Report.

GUIDING PRINCIPLES FOR RECOMMENDATIONS IMPLEMENTATION

The implementation of the Pharmaceutical Task Force recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The B.C. Government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The B.C. Government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

TASK FORCE RECOMMENDATIONS – ACTIVITIES AND PROJECTED COMPLETION TIMELINES

- The following approach describes the proposed activities that will be initiated to address the Pharmaceutical Task Force recommendations. The timelines for the completion of these activities is also included.

- Upon approval a more detailed workplan will be developed to address the sub-activities, resources, and funding required in order to successful meet the projected completion dates.

Recommendation 1:

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 PSD and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.

Activities

- Guided by the six principles listed above, the Ministry will focus on enhancing the provincial Formulary Management System—the system for selecting drugs and developing policy for coverage under the province's drug insurance program.
- The Pharmaceutical Services Division (PSD) will implement initiatives to improve stakeholder engagement, including establishing a dedicated Stakeholders and Partner Relations (SPR) branch.

- Other stakeholder engagement and drug review transparency initiatives include establishing a formal pathway for clinicians to make submissions for drug reviews, and making more detailed information on the drug review process and drug review decisions available on the PSD website.
- PSD will also establish an evidence-based appeal mechanism for manufacturer and clinician submissions.
- Additional details on other initiatives to enhance the provincial Formulary Management system are outlined in the response to later recommendations..

Projected Date of Completion

- **May 2008 – Stakeholder and Partner Relations branch established**
- **November, 2008 – Stakeholder engagement and drug review transparency initiatives established; evidence-based appeal mechanism established.**

Recommendation 2:

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

Activities

- The Ministry will establish target time-to-review timelines and introduce a criteria-based fast track capability to the drug submission review process to accelerate reviews of drugs that have demonstrated superior therapeutic or substantial cost-effectiveness advantages compared to available alternatives.
- Actual time-to-review timelines for individual submissions will be publicly reported on the PSD website in the drug review status tracking section and review times will be summarized annually in the PSD Annual Report. Where possible, this information will also be benchmarked against other jurisdictions (currently, this information is not available from other jurisdictions).

Projected Date of Completion

- **August 2008 – Establish target time-to-review timelines and introduce a criteria-based fast track capability**

Recommendation 3:

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.

Activities

- The Ministry will reconstitute the committee as a Drug Benefit Council (DBC) - an independent arms length advisory body to make recommendations to the

Ministry of Health's PSD regarding the listing of drugs on its formulary to improve and maintain the health and well-being of British Columbians.

- The DBC will consist of health care professions, other professionals with expertise in drug evaluation, and members of the public. When required, additional experts will be accessible to the DBC to assist with completing their mandate. The approach of the DBC will be evidence-based with the advice reflecting current medical and scientific knowledge and current clinical practice.
- To ensure independent, arms-length function by the committee, all persons involved on the DBC must comply with established conflict of interest policies.

Projected Date of Completion

- **November 2008**

Comment [BN1]: Why will this take so long?

Recommendation 4:

The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the TI. 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.

Activities

- The Ministry will establish a Drug Review Resource Committee (DRRC) that will report to the Drug Benefit Council. The DRRC will consist of experts who will review drug submissions by completing clinical evidence reviews and pharmacoeconomic reviews, as required. The DRRC will also include a registry of clinician expert members to advise and participate in the drug review process. The DRRC will collaborate with the TI to develop clinically relevant questions to guide the evidence review and to assess the clinical relevance of the appraisal results
- members of the DRRC will be required to comply with established conflict of interest policies.

Projected Date of Completion

- **November 2008**

Recommendation 5:

The membership of the DBC should be modified to include the participation of at least three public members selected through 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 focussed more narrowly on health economics.

Activities

- The Ministry will appoint three public members to the DBC. The Ministry recognizes there is an interest and movement towards public participation in all

areas of health policy as a means of incorporating public values into health care decision making to enhance transparency, equity and fairness and will take the necessary final steps to include public participation in its drug review process.
- To ensure an open, transparent and consistent appointment process, the Ministry will work in consultation with the Board Resourcing and Development Office.

Projected Date of Completion

- **November 2008 – Completion of public member appointment process (initiated in June 2008)**

Recommendation 6:

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.

Activities

- The Terms of References for the DRRC and DBC will be prepared/ revised and will stipulate that no DRRC members will participate on the DBC as members.

Projected Date of Completion

- **July 2008**

Recommendation 7:

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.

Activities

- PSD and the BC Pharmacy Association (BCPhA) have established a process for dialogue regarding the economic relationship between the Province and community pharmacies. Using this process mechanism, PSD and BCPhA have agreed to undertake discussions about a new framework for generic drug pricing and pharmacy compensation. A strategy for these discussions will be brought forward for approval.
- PSD will also solicit and discuss proposals from pharmaceutical manufacturers and other interested parties regarding possible alternatives to enhance price competition or otherwise moderate retail prices for generic drugs.

Projected Date of Completion

- **November 2008**

Recommendation 8:

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.

Activities

- PSD will advance and discuss options to evolve the current model of PharmaCare reimbursement for pharmacy services.
- Operating within the funds allocated to the PharmaCare program, PSD will work with the BCPhA and other stakeholders on the development of a compensation framework that is equitable, transparent and provides a return for professional pharmacy services that represent material added value to the health care system.

Projected Date of Completion

- **November 2008**

Recommendation 9:

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.

Activities

- PSD will develop a policy framework to guide future competitive tendering initiatives. While preserving appropriate patient care and promoting fair competition between suppliers, PSD will ensure that the tendering process is open and well-communicated.
- Insofar as is practicable, PSD will rely on Government's established principles and processes for procurement, including BC Bid, and will work with Government's Common Business Services to conduct such processes. This policy framework will be articulated before any additional tendering is undertaken.

Projected Date of Completion

- **August 2008**

Recommendation 10:

The Deputy Minister of the Ministry of Health should commit to participate in a 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.

Activities

- The newly established Stakeholder and Partner Relations (SPR) branch of the PSD will hold a multi-lateral stakeholder engagement session to present the Pharmaceutical Task Force recommendations and request that stakeholders provide their perspectives.

Projected Date of Completion

- **July 2008**

Recommendation 11:

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.*

Activities

- The Common Drug Review is an example of an efficient working relationship between Federal/Provincial/Territorial governments. PSD will emulate CDR processes wherever possible, including establishing similar target time-to-review timelines and introducing appeal mechanisms (see government response #1).

Projected Date of Completion

- **August 2008**

Recommendation 12:

Subject to recommendation four, if the TI is maintained, action must be taken in the following areas:

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

- *the function of the TI 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 unbiased and evidence-based practices; and*
- *the practice of having members of the TI also participating in the work of the DBC should be terminated.*

Activities

- The Ministry is supportive and appreciative of the many valuable contributions made by the Therapeutics Initiative (TI). The Ministry will work with the University of British Columbia (UBC) Faculty of Medicine to define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework.
- The UBC Faculty of Medicine is ultimately responsible for overseeing the governance of the TI. The Dean of the Faculty of Medicine has requested a formal academic review of the TI.
- Within PSD, the Drug Use Optimization (DUO) Branch is responsible for public education on drug-use issues.
- The new Terms of References for both the DRRC and DBC will stipulate that no DRRC members will participate on the DBC as members (See government response # 6).

Projected Date of Completion

- **October 2008 – Academic review of the TI completed**
- **November 2008** – define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework.

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, June 17, 2008 9:03 PM
To: Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX; Gudaitis, Paul HLTH:EX
Subject: RE: IMPORTANT - Outcomes of DM brief re: Pharm TF Rec Implementation

Yes, we should definitely get together soon via phone this week, or in person early next week. I'll discuss with Paul G tomorrow and set something up. Paul M – since you weren't at the meeting, can I give you a call sometime tomorrow to bring you up to speed? What time works for you?

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

From: Mochrie, Paul HLTH:EX
Sent: June 17, 2008 6:44 PM
To: Lun, Eric HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX
Subject: RE: IMPORTANT - Outcomes of DM brief re: Pharm TF Rec Implementation

Thanks for copying me on the notes, Paul.

I am definitely in favour of a further conversation re our go-forward plan. Specifically in relation to Rec. 7 and 8, I would benefit from a better understanding of Gord's perspective. Some of the concepts noted in relation to the economic model for pharmacy compensation are quite different from the general direction suggested by the Task Force.

Cheers,
Paul

From: Lun, Eric HLTH:EX
Sent: Tuesday, June 17, 2008 6:33 PM
To: Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: IMPORTANT - Outcomes of DM brief re: Pharm TF Rec Implementation

Thanks for the notes. Can we meet to discuss this because there are some complex issues here wrt Recommendations 4, and 7-9. Would like to meet to brain storm and develop strategy together.

Eric

From: Gudaitis, Paul HLTH:EX
Sent: Tuesday, June 17, 2008 5:38 PM
To: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX; Gudaitis, Paul HLTH:EX
Subject: IMPORTANT - Outcomes of DM brief re: Pharm TF Rec Implementation
Importance: High

Bob / Eric / Paul,

I have put together my notes from the meeting with Gord (I have included his notes in the process).
Please review the attached - Bob / Eric let me know if I missed anything.

The four of us should discuss next steps as an outcome of this meeting.
We will need to put together the next version of the implementation timeline to outline critical decision points and where and when we need to brief Gord and the Minister.

As our discussion with Gord demonstrated - we do not have much time and we need to accomplish critical goals in the time afforded.

Please redline any additions/edits.

Thanks.

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Thursday, June 19, 2008 1:12 PM
To: Manning, Marie HLTH:EX; Rich, Adrienne HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Scott, Pam HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; McClymont, Brenda HLTH:EX; Mochrie, Paul HLTH:EX; Stewart, Michelle PAB:EX; Lun, Eric HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA
Attachments: Pharm TF Rpt Rec Implementation Approach REVISED DRAFT v5 19 June 2008 REDLINED EL Edit.doc

Marie and/or Adrienne,

My comments are in the attached document. This draft includes comments by Paul M. My understanding is that you will 'clean up' so that it can be reviewed and approved by Bob Nakagawa BEFORE it goes further.

Thanks,

Eric

-----Original Message-----
From: Nakagawa, Bob HLTH:EX
Sent: Thursday, June 19, 2008 11:35 AM
To: Lun, Eric HLTH:EX; Gudaitis, Paul HLTH:EX; McClymont, Brenda HLTH:EX; Mochrie, Paul HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; Scott, Pam HLTH:EX; Rich, Adrienne HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

I'll want to sign off on this prior to forwarding to the MO.

Tx

B

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: June 19, 2008 11:31 AM
To: Gudaitis, Paul HLTH:EX; McClymont, Brenda HLTH:EX; Mochrie, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; Scott, Pam HLTH:EX; Rich, Adrienne HLTH:EX
Subject: Re: PTF Communications Plan Briefing for MGA

I am also reviewing now and will provide comments back shortly.

Eric Lun, Pharm.D.

Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

----- Original Message -----
From: Gudaitis, Paul HLTH:EX
To: McClymont, Brenda HLTH:EX; Mochrie, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; Scott, Pam HLTH:EX; Rich, Adrienne HLTH:EX
Sent: Thu Jun 19 10:59:32 2008
Subject: RE: PTF Communications Plan Briefing for MGA

Brenda / Marie,

Can the two of you please clean up the document for the MO.
Please use the attached version and provide a clean copy (without redlined edits).

Once the doc has been cleaned up please email it back to me and I will review the document and then we can send it forward to the MO as requested.

When providing the doc to the MO please be sure to include - Bob, Eric, Paul M, Michelle Stewart and myself on the email.

Thanks.

From: McClymont, Brenda HLTH:EX
Sent: Thu 19/06/2008 10:40 AM
To: Mochrie, Paul HLTH:EX; Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; Scott, Pam HLTH:EX; Rich, Adrienne HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

The DMO has just advised that the Minister's Office has requested this material before end of day today, as staff will not be back in the office prior to briefing.
Can you please advise if this is doable so I can let them know. We will need to forward this on to the Minister's office without DM approval due to the urgency.

Thanks,
Brenda

Brenda McClymont
Documents Coordinator
Assistant Deputy Minister's Office, Pharmaceutical Services
3-2 1515 Blanshard St
Victoria BC V8W 3C8
Telephone 952-1969
brenda.mcclymont@gov.bc.ca

From: Mochrie, Paul HLTH:EX
Sent: Thursday, June 19, 2008 8:18 AM
To: Gudaitis, Paul HLTH:EX; Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX; Scott, Pam HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Thanks Paul.

Building on the recent changes made by you and Bob, I have suggested a few additional revisions to Recommendations 7, 8 and 9, as attached. I have also included a couple of explanatory comments regarding the thinking behind my suggestions.

Please let me know if further clarification is required.

Cheers,
Paul

From: Gudaitis, Paul HLTH:EX
Sent: Thursday, June 19, 2008 6:23 AM
To: Nakagawa, Bob HLTH:EX; Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX; Stewart, Michelle PAB:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX; Scott, Pam HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

All,

I have revised the document based on Bob's edits and further edits integrating these changes with ones that I have just completed.

We can use the attached as the basis of our dicussion regarding the Pharm TF Recommendations next steps and as part of the briefing for the Minister.

Michelle - the attached document outlines the planned activities and timelines that we are putting together to act on the recommendations contained in the Pharm TF report - we are planning to brief MGA on this and we also need to work on the communications around these items (Gord and Bob D. have been briefed on the last version of this document).

Paul M. and Eric - please review to ensure that the contents of the activities reflect the intent of the work and timelines.

Thanks.

From: Nakagawa, Bob HLTH:EX
Sent: Thu 19/06/2008 5:49 AM
To: Gudaitis, Paul HLTH:EX; Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX; Scott, Pam HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Paul Gudaitis. As discussed, I've taken a crack at the first bullets for each of the recommendations to align them with the words that were used. I'm fine with the sub-bullets describing more of the detail, but want to start the response to each of the recommendations very directly and explicitly. The sub-bullets will need to be adjusted. Please pull PAB into this discussion and get their input.

Paul Mochrie and Eric, please review and improve….

Thanks

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

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From: Gudaitis, Paul HLTH:EX
Sent: June 18, 2008 1:40 PM
To: Nakagawa, Bob HLTH:EX; Mochrie, Paul HLTH:EX; Lun, Eric HLTH:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX; Scott, Pam HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Bob / Paul / Eric,

I have taken the first attempt at updating the Pharm TF Implementation document based on the outcomes of our discussion with the DM.

Please see attached redlined document for comment.

Thanks.

From: Nakagawa, Bob HLTH:EX
Sent: Wed 18/06/2008 10:16 AM
To: Scott, Pam HLTH:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX; Gudaitis, Paul HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

That document will need to be updated to reflect the discussion with the DM. Gudaitis will work with Mochrie, Lun and me to pull it together.

Thanks,

B

Bob Nakagawa,
Assistant Deputy Minister - Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

-----Original Message-----
From: Scott, Pam HLTH:EX
Sent: June 18, 2008 10:09 AM
To: Nakagawa, Bob HLTH:EX
Cc: Walsh, Sara M HLTH:EX; McClymont, Brenda HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Hi Bob,

Will the PTF Recommendations Implementation Approach document that you signed off on this weekend and forwarded to the DMO be adequate information to be provided to the MO for the briefing that will be set up early next week? Could we put this information into an Information BN for the MO?

Thanks,
Pam

Pam Scott
Executive Coordinator to the
Assistant Deputy Minister
Pharmaceutical Services
Ministry of Health
250 952-2643

-----Original Message-----
From: Nakagawa, Bob HLTH:EX
Sent: Wednesday, June 18, 2008 9:07 AM

To: Morris, Amanda V HLTH:EX; de Faye, Bob HLTH:EX; Stewart, Michelle PAB:EX; Gudaitis, Paul HLTH:EX
Cc: Somner, Kurstie HLTH:EX; Scott, Pam HLTH:EX; Obee, Sarah F PAB:EX; Manning, Marie HLTH:EX; Walsh, Sara M HLTH:EX
Subject: Re: PTF Communications Plan Briefing for MGA

Sounds good to me Amanda.

B
Bob Nakagawa-ADM Pharmaceutical Services BC Ministry of Health

----- Original Message -----
From: Morris, Amanda V HLTH:EX
To: de Faye, Bob HLTH:EX; Nakagawa, Bob HLTH:EX; Stewart, Michelle PAB:EX; Gudaitis, Paul HLTH:EX
Cc: Somner, Kurstie HLTH:EX; Scott, Pam HLTH:EX; Obee, Sarah F PAB:EX; Manning, Marie HLTH:EX
Sent: Wed Jun 18 08:41:09 2008
Subject: FW: PTF Communications Plan Briefing for MGA

Hello,
Tim Woolfrey has checked in with the Minister's office and the MO would prefer not to wait until early July and would still like to proceed with a Minister briefing early next week (with the understanding that a further briefing in early July will likely also be necessary). Tim will be in touch with your offices once the MO has provided us with an exact date/time for the briefing next week.

Thank you.
Amanda

From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, June 17, 2008 4:02 PM
To: de Faye, Bob HLTH:EX
Cc: Gudaitis, Paul HLTH:EX; Walsh, Sara M HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Agreed.

Paul - can you please set up a meeting for us to get together with Michelle on this next week, or via phone while we are in PEI?

Best,

<< OLE Object: Picture (Metafile) >>

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP Assistant Deputy Minister - Pharmaceutical Services
BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

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From: de Faye, Bob HLTH:EX
Sent: June 17, 2008 3:50 PM

To: Nakagawa, Bob HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

I'd suggest that we start to get Michelle rolling on developing a strategy. She can start to get her head around the issues and our positioning.

I think we need to do this sooner rather than later as the editorials on the T.I. seem to be continuing unabated…….and this being the case, we'll find the Minister coming under more pressure from a communications perspective.

Regards,

Bob

Bob de Faye
Chief Administrative Officer
Ministry of Health

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From: Nakagawa, Bob HLTH:EX
Sent: Tuesday, June 17, 2008 3:42 PM
To: de Faye, Bob HLTH:EX
Subject: RE: PTF Communications Plan Briefing for MGA

Thanks for this Bob. We have not connected with PAB on this yet. We wanted to have a better sense of the direction that we were going in before we did. I'll talk to Paul Gudaitis about the briefing. We can certainly brief the Minister on where we are right now, but we do not have anything close to a communications strategy to present. Perhaps we should brief the Minister on where we are now and follow up with the communications strategy in July. Or do you think that we should just delay until July and present the whole thing?

Best,

<< OLE Object: Picture (Metafile) >>

Bob Nakagawa, B.Sc.(Pharm.), ACPR, FCSHP Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705
P Please consider the environment before printing this e-mail

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From: de Faye, Bob HLTH:EX
Sent: June 17, 2008 3:02 PM
To: Nakagawa, Bob HLTH:EX
Subject: PTF Communications Plan Briefing for MGA

Hi Bob:

Just thought I'd pass on a note that the DMs Office had recently received from our Minister's Office seeking an MGA briefing on the communications plan coming from the Implementation Plan for the Pharmacautical Task Force (and also to go through the steps and timing for the implementation activities surrounding the 12 recommendations). Sounds like they want this to happen sooner rather than later……

With regard to the communications strategy…….do you already have Michelle Stewart and her PAB folks in the loop on this one?

Regards,

Bob

Bob de Faye
Chief Administrative Officer
Ministry of Health

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From: Woolfrey, Tim J HLTH:EX
Sent: Monday, June 16, 2008 12:02 PM
To: Morris, Amanda V HLTH:EX
Cc: Somner, Kurstie HLTH:EX
Subject: FW: PTF Report

Hi Amanda,

MO has asked that Minister be briefed re the roll out of the PTF recommendations, and they were hoping to do so early next week. Can you please check in with Bob and/or PAB and let me know if this timing will work? Just for your info, looks like Minister would be available for this briefing on the am of Monday June 23, however after that he likely wouldn't be available again until the week of July 8.

Thanks!
Tim.

From: Richards, Joanna D HLTH:EX
Sent: Monday, June 16, 2008 11:54 AM
To: Woolfrey, Tim J HLTH:EX
Cc: Braman, Jamie L HLTH:EX
Subject: PTF Report

Hey Tim,

We need staff to brief the minister on the comm plan coming out of the recommendations from the Pharmaceutical Task Force. Can you check with Bob's shop and make sure that PAB has been looped into the process? If possible, it would be good to get the minister up to speed early

next week on how implementation of the recommendations is going to roll out over the coming months.

Thanks Tim,
Joanna

PHARMACEUTICAL TASK FORCE RECOMMENDATIONS IMPLEMENTATION APPROACH

INTRODUCTION:

In November, 2007 the Pharmaceutical Task Force was established and invited to make 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 decision 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; and
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 report from the Pharmaceutical Task Force was released in April 2008, and the recommendations contained within were accepted by the Minister of Health.

PURPOSE

- To provide an overview of the activities and timelines for implementing the recommendations contained within the Pharmaceutical Task Force Report.

GUIDING PRINCIPLES FOR RECOMMENDATIONS IMPLEMENTATION

The implementation of the Pharmaceutical Task Force recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The B.C. Government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The B.C. Government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The B.C. government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in B.C.

TASK FORCE RECOMMENDATIONS – ACTIVITIES AND PROJECTED COMPLETION TIMELINES

- The following approach describes the proposed activities that will be initiated to address the Pharmaceutical Task Force recommendations. The timelines for the completion of these activities is also included.

- Upon approval a more detailed workplan will be developed to address the sub-activities, resources, and funding required in order to successful meet the projected completion dates.

Recommendation 1:

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 PSD and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.

Activities

- Guided by the six principles listed above, the Ministry will focus on enhancing the provincial Formulary Management System—the system for selecting drugs and developing policy for coverage under the province's drug insurance program.
- The Pharmaceutical Services Division (PSD) will implement initiatives to improve stakeholder engagement, including establishing a dedicated Stakeholders and Partner Relations (SPR) branch.

- Other stakeholder engagement and drug review transparency initiatives include establishing a formal pathway for clinicians to make submissions for drug reviews, and making more detailed information on the drug review process and drug review decisions available on the PSD website.
- PSD will also establish an evidence-based appeal mechanism for manufacturer and clinician submissions.
- Additional details on other initiatives to enhance the provincial Formulary Management system are outlined in the response to later recommendations..

Projected Date of Completion

- **May 2008 – Stakeholder and Partner Relations branch established**
- **November, 2008 – Stakeholder engagement and drug review transparency initiatives established; evidence-based appeal mechanism established.**

Recommendation 2:

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

Activities

- New target review/ listing decision guidelines will be established. These guidelines and our performance against them will be publicly reported via the internet. August 2008.
- The Ministry will establish target time-to-decision~~review~~ timelines and introduce a criteria-based fast track capability to the drug submission review process to accelerate reviews of drugs that have demonstrated superior therapeutic or substantial cost-effectiveness advantages compared to available alternatives.
- Actual time-to-~~review~~ decision timelines for individual submissions will be publicly reported on the PSD website in the drug review status tracking section and review times will be summarized annually in the PSD Annual Report. Where possible, this information will also be benchmarked against other jurisdictions (currently, this information is not available from other jurisdictions).

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Projected Date of Completion

- **~~August~~ July 2008 – Draft preliminary ~~Establish~~ target time-to-~~review~~ decision timelines and introduce concept of a~~a~~ criteria-based fast track capability**
- **July 2008 – Request stakeholder feedback on draft preliminary target time-to-decision and the concept of a criteria-based fast track capability**
- **August 2008 – Implement target time-to-decision timelines and criteria-based fast track capability**

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Recommendation 3:

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.

Activities

- The Ministry will reconstitute the Drug Benefit ~~e~~Committee as ~~a~~ the Drug Benefit Council (DBC). Members of the DBC will be approved by the Minister. August 2008.

- - an independent arms length advisory body to make recommendations to the Ministry of Health's PSD regarding the listing of drugs on its formulary to improve and maintain the health and well-being of British Columbians.
- The DBC will consist of health care professions, other professionals with expertise in drug evaluation, and members of the public. When required, additional experts will be accessible to the DBC to assist with completing their mandate. The approach of the DBC will be evidence-based with the advice reflecting current medical and scientific knowledge and current clinical practice.
- To ensure independent, arms-length function by the committee, all persons involved on the DBC must comply with established conflict of interest policies.

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Projected Date of Completion

- ~~November 2008~~**August 2008**

Recommendation 4:

The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the TI. 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.

Activities

- A new Drug Review Resource Committee will be established as part of the new enhanced Formulary Management Process. Members of the DRRC will be approved by the Minister. November 2008.

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- PSD will bring forward a decision note for Ministerial approval regarding the establishment of the Drug Review Resource Committee (DRRD) – options and recommendations on suggested approach (including governance, composition, terms of membership, etc)
- Upon approval ~~t~~The ~~h~~e Ministry will establish a ~~Drug Review Resource Committee (~~DRRC~~)~~ that will report to the Drug Benefit Council. The DRRC will consist of experts who will review drug submissions by completing clinical evidence reviews and pharmacoeconomic reviews, as required. The DRRC will also include a registry of clinician expert members to advise and participate in the drug review process. The DRRC will ~~collaborate with the TI to~~ develop clinically

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relevant questions to guide the evidence review and to assess the clinical relevance of the appraisal results

- Develop a list of potential candidates/members including suggestions regarding the chair of the DRRC
- The members of the DRRC will be required to comply with established conflict of interest policies.

Comment [PG1]: Eric – we need some additional clarification around how the DRRC will be developed and function

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Projected Date of Completion

- **July/August 2008 – Decision note brought forward for Ministerial consideration and approval**
- **August 2008 – Potential list of candidates/members and possible chair brought forward for discussion/consideration**
- **November 2008 – implement DRRC framework**

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Recommendation 5:

The membership of the DBC should be modified to include the participation of at least three public members selected through 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 focussed more narrowly on health economics.

Activities

- The Ministry will appoint a minimum of two ~~three~~ public members (one of which should be an economist) to the DBC. The Ministry recognizes there is an interest and movement towards public participation in all areas of health policy as a means of incorporating public values into health care decision making to enhance transparency, equity and fairness and will take the necessary final steps to include public participation in its drug review process.
- Implement approach to seek potential public representatives for membership in the DBC.
- ~~To ensure an open, transparent and consistent appointment process, the Ministry will~~ Wwork in consultation with the Board Resourcing and Development Office to review potential candidates for membership.

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Projected Date of Completion

- **June 2008 – initiate search for public member candidates for consideration**
- **November 2008 – Completion of public member appointment process ~~(initiated in June 2008)~~**

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Recommendation 6:

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.

Activities

- The Terms of References for the DRRC and DBC will be prepared/ revised and will stipulate that no DRRC members will participate on the DBC as members.

Projected Date of Completion

- **July 2008**

Recommendation 7:

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.

Activities

- A negotiation process with drug manufacturers and representatives of community pharmacy will be initiated. August 2008. Formatted: Bullets and Numbering
- Obtain clear mandate from ~~Cabinet and/or PMO~~the Minister in order to define parameters of negotiations with manufactures, pharmacy and pharmacists. Formatted: Bullets and Numbering
- Develop and seek approval for options to be brought forward for consideration as part of the negotiation process (i.e., current jurisdictional alternatives)
- PSD and the BC Pharmacy Association (BCPhA) have established a process for dialogue regarding the economic relationship between the Province and community pharmacies. Using this process mechanism, PSD and BCPhA have agreed to undertake discussions about a new framework for generic drug pricing and pharmacy compensation. A strategy for these discussions will be brought forward for approval.
- PSD will also solicit and discuss proposals from pharmaceutical manufacturers and other interested parties regarding possible alternatives to enhance price competition or otherwise moderate retail prices for generic drugs – while being cognizant of the need to retain the right to utilize tendering as required.

Projected Date of Completion

- **July 2008 – request clear mandate from ~~Cabinet or PMO~~the Minister regarding negotiation approach** Formatted: Bullets and Numbering
- **August 2008 – develop options for consideration**
- **November 2008 – conclusion of negotiation process**

Recommendation 8:

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.

Activities

- A new framework for community pharmacy compensation will be developed. November 2008.
- PSD will advance and discuss options to evolve the current model of PharmaCare reimbursement for pharmacy services.
- Operating within the funds allocated to the PharmaCare program, PSD will work with the BCPhA and other stakeholders on the development of a compensation framework that is equitable, transparent and provides a return for professional pharmacy services that represent material added value to the health care system.
- Alternative delivery models will also be explored/developed, to address the matter of pharmacy reimbursement and business concerns.

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Projected Date of Completion

- **August 2008 – declare intentions for endpoint of negotiations with pharmacy**
- **November 2008 – conclusion of negotiation process (i.e., mutually established agreement or decision on government policy considerations)**

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Recommendation 9:

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.

Activities

- A cautious approach to broadened utilization of tendering processes will be developed. August 2008.
- PSD will declare intentions regarding tendering and develop a policy framework to guide future competitive tendering initiatives. While preserving appropriate patient care and promoting fair competition between suppliers (including a consideration for multiple winners in tendering process), PSD will ensure that the tendering process is open and well-communicated.
- Insofar as is practicable, PSD will rely on Government's established principles and processes for procurement, including BC Bid, and will work with Government's Common Business Services to conduct such processes. This policy framework will be articulated before any additional tendering is undertaken.

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Projected Date of Completion

- **July/August 2008 – declare intentions for the next 6-12 months as they pertain to tendering**
- **August/September 2008 – bring forward policy framework for consideration and approval**

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Recommendation 10:

The Deputy Minister of the Ministry of Health should commit to participate in a 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.

Activities

- The Deputy Minister will participate in an annual accountability session in November 2008.
- The newly established Stakeholder and Partner Relations (SPR) branch of the PSD will hold a multi-lateral stakeholder engagement session to present the Pharmaceutical Task Force recommendations and request that stakeholders provide their perspectives.

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Projected Date of Completion

- **July 2008 – conduct multilateral stakeholder session and introduce concept of Fall DM accountability stakeholder session**
- **November 2008 – conduct DM accountability session**

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Recommendation 11:

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.*

Activities

- BC's decision-making processes will be reviewed. Similar timelines will be adopted and overlap will be minimized.
- The Common Drug Review is an example of an efficient working relationship between Federal/Provincial/Territorial governments. PSD will emulate CDR processes wherever possible, including establishing similar target time-to-review timelines and introducing appeal mechanisms (see government response #1).

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Projected Date of Completion

- **August 2008**

Recommendation 12:

Subject to recommendation four, if the TI is maintained, action must be taken in the following areas:

- *the governance, membership and accountability standards associated with the operation of the TI will require substantial improvement;*
- *steps must also be taken to renew and revitalize the panel of experts the TI relies upon to discharge its obligations;*
- *the function of the TI 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 unbiased and evidence-based practices; and*
- *the practice of having members of the TI also participating in the work of the DBC should be terminated.*

Activities

- The governance, membership and accountability standards associated with the TI will be improved
- Steps will be taken to renew and revitalize the panel of experts the TI relies upon to discharge its obligations
- The focus of the TI will be therapeutic evaluation.
- The Ministry is supportive and appreciative of the many valuable contributions made by the Therapeutics Initiative (TI). The Ministry will work with the University of British Columbia (UBC) Faculty of Medicine to define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework.
- The Ministry will work with UBC Faculty of Medicine to determine ~~is ultimately responsible fo~~the oversight and ~~r overseeing~~ the governance of the TI. The Dean of the Faculty of Medicine has requested a formal academic review of the TI.
- Within PSD, the Drug Use Optimization (DUO) Branch is responsible for public education on drug-use issues.
- The new Terms of References for both the DRRC and DBC will stipulate that no DRRC members will participate on the DBC as members (See government response # 6).

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Projected Date of Completion

- **October 2008 – Academic review of the TI completed**
- **November 2008** – ~~define and enhance how the TI contributes to the clinical evidential review component of the drug review process within the newly established DRRC framework~~Implement the recommendations put forward and

approved for overseeing the governance of the TI (or the group providing the functional responsibilities of the TI).

Scott, Pam HLTH:EX

From: Nakagawa, Bob HLTH:EX
Sent: Friday, June 20, 2008 1:05 PM
To: Lun, Eric HLTH:EX
Subject: RE: 732913 - PTF Communications Plan Briefing for MGA

Let's talk about this some more before we commit. "collaboration" seems a bit cumbersome.

Tx

B

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services BC Ministry of Health 3-2, 1515 Blanshard Street Victoria, BC V8W 3C8

250-952-1705

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: June 19, 2008 9:01 PM
To: Rich, Adrienne HLTH:EX; Somner, Kurstie HLTH:EX
Cc: Nakagawa, Bob HLTH:EX; Mochrie, Paul HLTH:EX; Stewart, Michelle PAB:EX; Scott, Pam HLTH:EX; McClymont, Brenda HLTH:EX
Subject: Re: 732913 - PTF Communications Plan Briefing for MGA

Noticed a small but important point - When the acronym "DRRC" was converted to text during formatting, the "C" should have been converted to "Collaboration" rather than "Committee". We can adjust for next iteration.

Thanks,
Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

----- Original Message -----
From: Rich, Adrienne HLTH:EX
To: Somner, Kurstie HLTH:EX
Cc: Nakagawa, Bob HLTH:EX; Lun, Eric HLTH:EX; Mochrie, Paul HLTH:EX; Stewart, Michelle PAB:EX; Scott, Pam HLTH:EX; McClymont, Brenda HLTH:EX
Sent: Thu Jun 19 16:05:29 2008
Subject: 732913 - PTF Communications Plan Briefing for MGA

Approved by Bob Nakagawa. For Bob de Faye's approval.

<<732913 Pharm TF Rpt Rec Implementation Approach 06-19-08.doc>>

Adrienne Rich

Scott, Pam HLTH:EX

From: Lun, Eric HLTH:EX
Sent: Friday, June 27, 2008 2:31 AM
To: Nakagawa, Bob HLTH:EX
Cc: Walsh, Sara M HLTH:EX; Lun, Eric HLTH:EX
Subject: RE: TF - Drug Review Changes
Attachments: DRRC Costing Projection 2008 06 26.xls; TI Contract-Activities-Proposal 2008 06 27.doc; PSD Drug Review Process Overview_v1_Jun27_08.doc; 732913 Pharm TF Rpt Rec Implementation Approach 06-19-08.doc

Hi Bob - pls see attached for our meeting at 10-11
Decision Points:
1. Process - Target timelines
2. DRRC: Naming, Budget, Process (CDR Subs)
3. DBC: Budget expansion (new members, more meetings)
4. TI: contract, leadership
5. Next Steps / Other: Decisions for MGA, DBC recruitment

Thanks,
Eric

From: Nakagawa, Bob HLTH:EX
Sent: Mon 23/06/2008 8:02 PM
To: Lun, Eric HLTH:EX; Fowler, Sherrill HLTH:EX
Cc: Walsh, Sara M HLTH:EX
Subject: RE: TF - Drug Review Changes

Thanks Eric. Maybe we can work something out for Friday.....Sara, please discuss.

B

Bob Nakagawa,
Assistant Deputy Minister – Pharmaceutical Services
BC Ministry of Health
3-2, 1515 Blanshard Street
Victoria, BC
V8W 3C8

250-952-1705

-----Original Message-----
From: Lun, Eric HLTH:EX
Sent: Mon, June 23, 2008 5:27 PM
To: Fowler, Sherrill HLTH:EX
Cc: Nakagawa, Bob HLTH:EX; Walsh, Sara M HLTH:EX
Subject: TF - Drug Review Changes

Hi Sherrill

Pls set up a 1 hour meeting with Bob to review this. Some time this week pls.

Thanks,

Eric

Eric Lun, Pharm.D.
Executive Director, Drug Intelligence
Pharmaceutical Services Division, Ministry of Health

DRRC Costing Projection

	Submission Type			Total
	CDR	Non-CDR Standard	Non-CDR Complex	
Submission / Yr	35	15	10	**60**
Subs Reviewed by Team				
Evidence	0	15	10	25
Clinicians	35	15	10	60
Pharmacoecon	10	15	10	35
Members per Team				
Evidence	1	1	1	
Clinicians	2	2	2	
Pharmacoecon	1	1	1	
Reports - Billable Hrs per member per Sub				
Evidence	0	0	0	
Clinicians	8	10	12	
Pharmacoecon	10	14	40	
Meetings - Billable Hrs per member per Sub				
Evidence	0	0	0	
Clinicians	3	4	4	
Pharmacoecon	3	4	4	
Rate				
Evidence	$0	$0	$0	
Clinicians	$127	$127	$127	
Pharmacoecon	$127	$127	$127	
Cost Projection				
Evidence	$0	$0	$0	$0
Clinicians	$97,790	$53,340	$40,640	$191,770
Pharmacoecon	$16,510	$34,290	$55,880	$106,680
	$114,300	**$87,630**	**$96,520**	**$298,450**

Last updated June 27, 2008

Notes

10 DBC meetings / yr (6 subs/DBC)

1 = group
2 members = GP plus Specialist
1 = group

Reports includes critique, rebuttal

3 Report Levels: (1) critique-based, (2) Lit review + critique; (3) new model

UBC TI paid through separate contract

DRRCCosting Structure for Industry Driven Non-CDR Reviews

		Preparation and Review of Reports					Collaboration 'Meetings'				Attending DBC Meetings if Required					Total
Body	Participants	Reports	Hr/Memb	Hrs/Report	$/Report	Cost	DCCR	Hrs/meet	$/Meeting	Cost	DBC	# attend	Hrs/meet	$/Meeting	Cost	Costs
CER	1	10	0	0	$ -	$ -	0	3	381	$ -	10	1	4	$ -	$ -	$ -
CPR	2	10	3	6	$ 762	$ 7,620	10	3	762	$ 15,240	0	0	0	$ -	$ -	$ 33,020
PER	1	10	10	10	$ 1,270	$ 12,700	10	3	381	$ 3,810	10	1	4	$ 508	$ 5,080	$ 24,130
Total Non-CDR Costs						$ 20,320				$ 19,050					$ 5,080	$ 57,150

DRRC Costing Structure for Physician Driven Non-CDR Reviews

		Preparation and Review of Reports					Collaboration 'Meetings'				Attending DBC Meetings if Required					Total
Body	Participants	Reports	Hr/Memb	Hrs/Report	$/Report	Cost	DCCR	Hrs/meet	$/Meeting	Cost	DBC	# attend	Hrs/meet	$/Meeting	Cost	Costs
CER	1	15	0	0	$ -	$ -	0	3	381	$ -						$ -
CPR	2	15	3	6	$ 762	$ 11,430	15	3	762	$ 22,860						$ 49,530
PER	1	15	25	25	$ 3,175	$ 47,625	15	3	381	$ 5,715						$ 57,150
Total Non-CDR Costs						$ 59,055				$ 28,575					$ -	$ 106,680

DRRC Costing Structure for CDR Reviews

		Preparation and Review of Reports					Collaboration 'Meetings'				Attending DBC Meetings if Required					Total
Body	Participants	Reports	Hr/Memb	Hrs/Report	$/Report	Cost	DCCR	Hrs/meet	$/Meeting	Cost	DBC	# attend	Hrs/meet	$/Meeting	Cost	Costs
CER	0	0	0	0	$ -	$ -	0	0	0	$ -						$ -
CPR	2	35	6	12	$ 1,524	$ 53,340	5	3	762	$ 7,620						$ 63,500
PER	1	5	15	15	$ 1,905	$ 9,525	5	3	381	$ 1,905						$ 12,700
Total CDR Costs						$ 62,865				$ 9,525					$ -	$ 76,200

Total DRRC Costs $ 240,030

Total DRRC Costs				
	Reports	Meetings		Total
		Colaborat	DBC	
CER	$ -	$ -	$ -	$ -
CPR	$ 72,390	$ 45,720	$ 27,940	$ -	$146,050
PER	$ 69,850	$ 11,430	$ 7,620	$ 5,080	$ 93,980
Total	$ 142,240	$ 57,150	$ 35,560	$ 5,080	$240,030

ASSUMPTIONS

			Formula	
- Physician Rate			$ 127	
- No. of CDR Reviews			35	
- 'No. of Non-CDR Drug Reviews	- Industry Requested		10	
	- Physician Requested		15	
- % of DBC Meetings Attended	- CER and PER attend all 10 meetings			
	- CPR doesn't attend any meetings			
	- CER doesn't get paid to attend DBC meetings			
- CER is not involved in CDR Drug Reviews				
- TI member would be paid for participating in Collaborating meeting and in preparing rebuttals to CPR critiques				
Participants of Industry Requested Non-CDR reviews will:				
- hours of attendance per person at colloboration meetings:		All	3	
- hours per person preparing reports:		- CPR	3	- varies by type of report
		- PER	10	- varies by type of report
		- CER	0	- CER reports already funded through TI contract
Participants of Physician Requested Non-CDR reviews will:				
- hours per person at colloboration meetings:		- CER	3	
		- CPR	3	
		- PER	3	
- hours spent per person preparing reports:		- CER	0	- CER reports already funded through TI contract
		- CPR	3	
		- PER	25	
Participants of Industry Requested CDR Drug Listing Request Reviews will:				
(PER only involved in 5 of these reviews.)				
- hours spent per person preparing reports:		- CPR	6	
		- PER	15	

Appendix 1:

Comparison of the major components (TI Organization, TI Objectives - deliverables, and Budget) of the current contract to the changes proposed under Options 1a, 1b and 1c		
TI ORGANIZATION		
Current Wording	**Overview**	**Proposed Change**
An Advisory Committee with experts and members from the professions, the University, the public and government oversees the activities of the Therapeutic Initiative (TI). The Advisory Committee also acts in an advisory capacity to the Province's Executive Director, Drug Intelligence, Pharmaceutical Services Division (PSD), and Ministry of Health. The Advisory Committee shall follow the Terms of Reference as stated in Appendix 1. The main working committee of the Therapeutics Initiative is the Scientific Information and Education Committee (SIEC). The SIEC shall follow the Terms of Reference as stated in Appendix 2. The ongoing day-to-day operations of the Therapeutics Initiative are directed by the Managing Director(s) who is/are the Principal Investigator(s) of Contributory Agreement. The Managing Director(s) will be responsible for managing the budget of the Therapeutics Initiative as well as the development of an annual work plan consisting of an educational and communications strategy, and priorities for therapeutic review. The SIEC will approve this work plan. The Executive Committee supports the day-to-day decisions of the Managing Director(s).	Describes structure of various components of IT and mentions appended Terms of Reference for: Advisory Committee; Scientific Information and Education Committee. No mention of the Pharmaco-Epidemiology Group (PEG).	O/S

TI OBJECTIVES		
Current Wording	**Activities as Reported in 2006/7 Annual Report**	**Proposed Change**
The Contractor will provide the services of a Managing Director(s) who will provide support for the day-to-day operations of the Therapeutics Initiative under the direction of the Advisory Committee, the Executive Committee and the SIEC in order to achieve the following objectives.	No breakdown of expenditures between TI objectives; main expenditures are salaries and benefits (59%) consulting fees (22%), and honoraria/services rendered (6%) – remaining expenditures are for administration (13%).	
(a) Critically appraise the relevant literature and provide advice to the Province regarding industry drug submissions and other submissions as requested by the Province.	DAWG reviewed: 34 new drugs for PSD; drugs for CADTH (received $60,000 from CADTH in research grants); 3 blood reviews (received $200,000 in research grants over 2 years from Canadian Agency for Drug and Technologies in Health.)	O/S

(b)	Review possibilities for expanding the categories for therapeutic substitutions, maximum allowable costs, delisting, appropriate prescribing education and other innovative utilization management opportunities.	DAWG: prepares therapeutic evidence from clinical trials PEG: prepares utilization/observational analysis of Ministry databases	O/S
(c)	Enhance population therapeutics/post marketing surveillance to inform policy post-listing by measuring drug utilization patterns in BC (by patient and doctor) and identifying population health benefits or harms of individual drugs or drug categories. These analyses will assist the Province in refining funding policy for drugs by providing relevant "real-world" information that is not available through published clinical trials.	PEG prepares a minimum of 5 studies per year. PEG is also developing better methods around post-market surveillance and observation analysis that use prescription claims data.	
(d)	Maintain and distribute the Therapeutics Letter and website. There shall be a minimum of six letters per year.	Completed 6 information Therapeutic Letters – letters published in Canadian Family Physicians Journal, and are also available on TI website. TI web site averages 12,129 hits per day in March 2007; an increase of 35% over the January 2006. Therapeutics Letter Working Group: produces TI Letters DAWG: prepares synopses of their work that is included in the	

	Letters. PEG: provides data included in the letters (e.g. costs of drugs in BC)	
(e) Provide multi-pronged direct interactive dissemination of educational messages by providing clinicians with specific practical ways to ensure more effective and cost-effective prescribing.	TI Website: registered users are entitled to access exclusive premium content. All issues of Therapeutic Letter available on web site. DAWG developing format for short executive summaries of all their reports to be posted on web site. Education Working Group uses the web site for posting information on upcoming education sessions. And will produce multimedia content (podcasts) from edited recording of past TI educational events. Website administration is a central function and one that I don't think can be assigned to any one working group. -Therapeutics Letter Group provides educational content by having the Therapeutics Letter available online, -the Education Working Group provided educational content by having Podcasts, -PEG, will soon have its studies online. -Other prongs of dissemination are the roadshows and annual course (Education Working Group), the Therapeutics Letter (TL Group) and peer-reviewed publications in medical journals (PEG).	
(f) Audit and provide feedback to physicians of individual and group prescribing linked to best available evidence as demonstrated by the Better Prescribing Project Health Transition Fund Project.	<u>This is not currently being done</u> but it could require all of the working groups and certainly DAWG and PEG because therapeutic evidence would be paired with physician-specific data from the Ministry in prescribing portraits. I and one other person prepared the prescribing portraits used in the	

		Better Prescribing Project, which was funded in the first round of the federal Health Transition Fund. The EQIP project is providing this service now with the added aspect of reinvestment of savings.	
(g)	Analyze PharmaCare payment data to identify inappropriate patterns of drug prescribing, dispensing and consumption.	PEG	
(h)	Evaluate existing drug therapies by the standards of the best evidence in the scientific literature. Use this evaluation to establish cost-effective first choice drugs and advice for their optimal clinical use.	DAWG: undertakes evaluations. PEG: would provide data analysis for observational studies (such as cost-effectiveness studies) and does analysis for RCT data.	
(i)	Provide to the Province and the practicing physicians and pharmacists of British Columbia, evaluations of the benefit and harm evidence of drug classes and put this evidence into context for their optimal clinical use.	EWG: Provide community based program for clinicians – over 30 sessions per year (at hospitals throughout BC). TI offers an annual two-day drug therapy course to physicians and pharmacists. The course held April 21-22, 2006, was attended by 358 physicians and pharmacists, while March 30-31, 2007 course was attended by 376 physicians and pharmacists. (Course has met accreditation criteria for College of Family Physicians.) All working groups, but mainly the Education Working Group and TI Letter Group. Keep in mind the education function relies on data from the DAWG and to a lesser degree the PEG.	
(j)	Continue with physician and pharmacist education programs to support optimal prescribing/dispensing based on the best available evidence.	EWG: Undergraduate and postgraduate medical/pharmacy education: Members of TI involved in teaching evidence-based medicine to medical students, and Pharm D students.	
(k)	Monitor the effect of the education on the	PEG: TI measures the impact the Therapeutics Letter has on	

	physician prescribing patterns using the PharmaNet database.	prescribing practices of physicians who receive the letter – 88% trust information and 95% of GPs reported they changed their prescribing.	
(l)	Utilize the feedback obtained to improve the physician and pharmacist educational interventions.	Evaluation methods used to assess recognition of TI include focus group, telephone interviews with clinicians and participants of teleconferences an, courses and committees. PEG: has provided the evaluation role. EWG and TL Group: produce educational messages. EWG: also collects audience feedback which it uses to refine its interventions.	
(m)	Build and implement a communications strategy to enhance the profile of the Therapeutics Initiative generally within the health professional community as well as the public. An experienced communications professional should be hired to draft the communications strategy. A draft strategy should be delivered to the Province for approval before proceeding no later than April 1, 2007. The strategy should be implemented no later than September 1, 2007 (pending approval from the Province to proceed).	This is new. The TI has recently (last year or so) hired a communications/IT person	
(n)	N/A	N/A	

O/S

		O/S

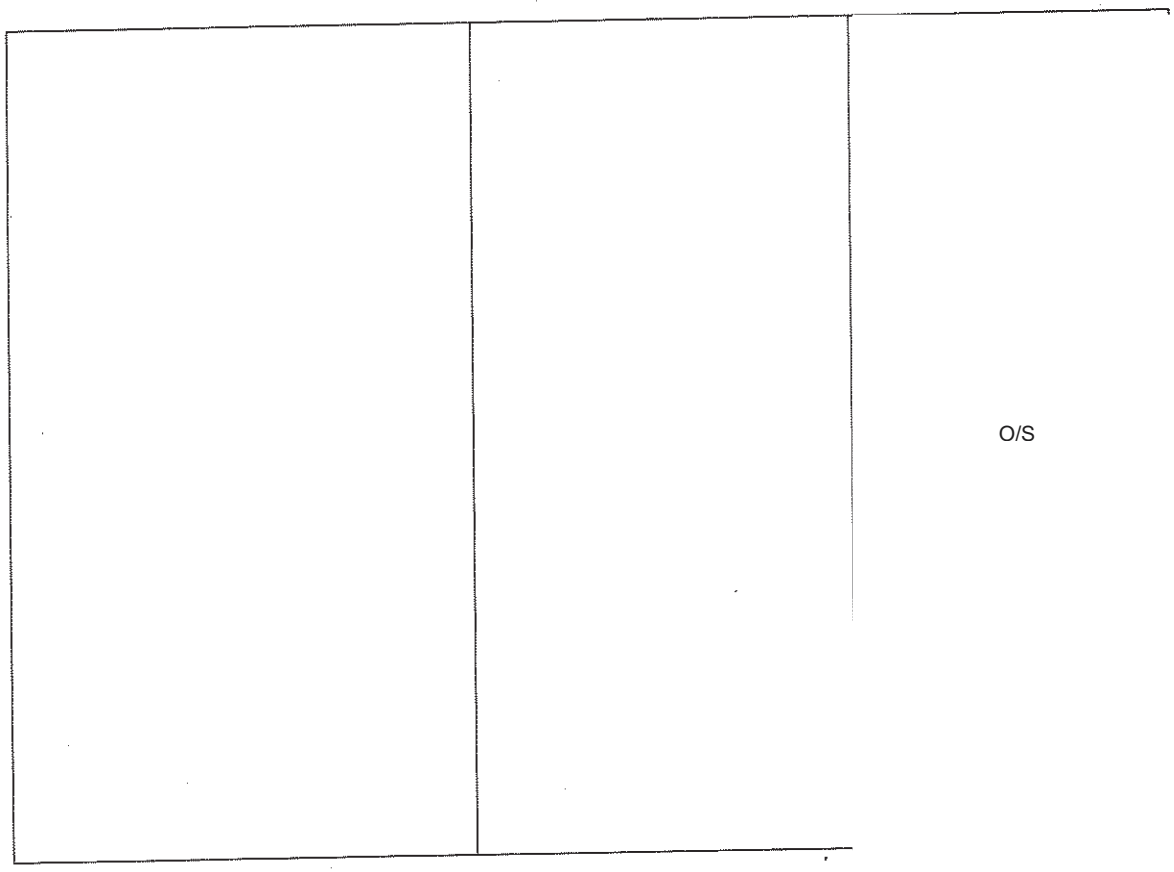
TI REPORTS

Current Wording	Overview of Proposed Change	Proposed Wording Change
The Contractor will submit annual reports on or before October 1 each year summarizing the activities that took place during the twelve-month period ending on the previous March 31. The report shall cover the following terms: a) Progress towards meeting the mandate of the program and, as appropriate, progress towards achieving the specific goals for the year as described in the previous year's report. b) Financial statements prepared in accordance with the generally accepted accounting principles; and c) Goals for the year ending on the following March 31.	PEG will also submit a separate annual report and financial statement by October 1st.	O/S

		following March 31.

BUDGET

Current Budget	Overview of current Budget Proposed Changes	Proposed Wording Change
1. **Quarterly Payment:** During the Term of the Agreement, the Province will forward to the Contractor quarterly payments of $250,000 of the 1st of April, July, October, and January of each year. 2. **Payments for Deliverables under Schedule A - Services, Section C:** (a) The Province will provide the Contractor with $300,000 for the Pharmacosurveillance Report(s) on Thiazolidinedione (TZD). A $200,000 payment will be issued upon signing of this amendment. An additional payment of $100,000 for fiscal year 2007/08 will be issued upon receipt of financial statements as per paragraph 6 of this schedule. **3. Contract Maximum Amounts:** Notwithstanding paragraph 1, the total payments made with respect to expenditures incurred during the term of this Agreement, shall **not be greater than the following:** 2004/2005 – Not to exceed: $1,000,000 2005/2006 – Not to exceed: $1,000,000 2006/2007 – Not to exceed: $1,000,000 2007/2008 – Not to exceed: $1,300,000 2008/2009 – Not to exceed: $1,000,000 2009/2010 – Not to exceed: $1,000,000 2010/2011 – Not to exceed: $1,000,000 2011/2012 – Not to exceed: $1,000,000 $8,300,000 is the Maximum amount the Province must pay to the Contractor during the term of this Agreement.	1. Allocated the TI's quarterly payments of $250,000 between the TI (55%) and the PEG (45%). 2. Increased the Budget by $150,000 for work on the biologics project ($75,000 in each of 2008/9 and 2009/10).	O/S


O/S

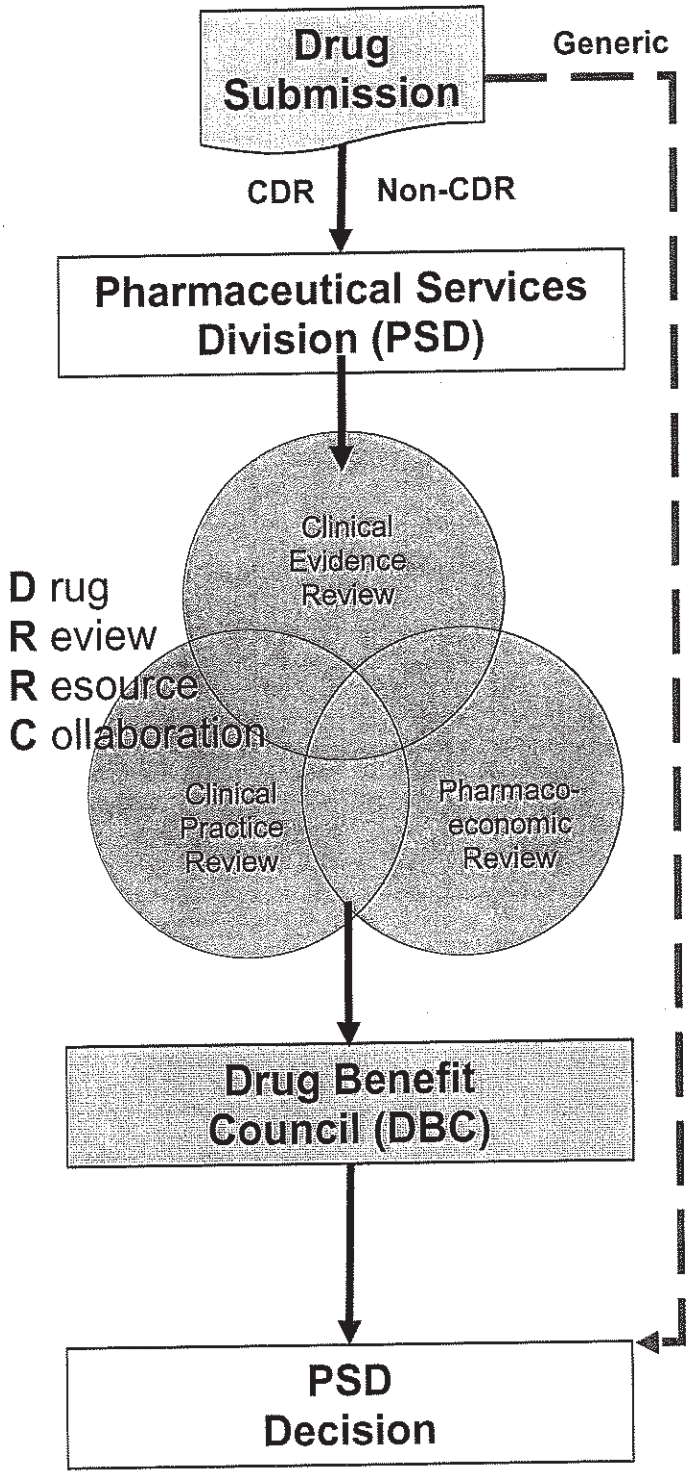
Definition:

Submission – A submission consists of:

- a written application made by a manufacturer, together with supporting documentation, to have a drug listed on the PSD formulary; or
- a written, peer supported, application made by a clinician, together with supporting documentation; or
- a written request for advice made by the PSD, together with supporting documentation; or
- Any other therapeutic reviews made by PSD as required.

Pharmaceutical Services Drug Review Process

v2 - Last Updated June 26, 2008



Drug Submissions may be submitted by manufactures or clinicians and are grouped into three general types: Common Drug Review (CDR), Non-CDR and generic submissions. Generic drug submissions generally follow an abbreviated review pathway. Priority review may be granted to submissions that meet established criteria.

Drug Review Resource Collaboration consists of three expert teams who specialize in completing clinical evidence reviews, clinical practice reviews, and pharmacoeconomic reviews for drug submission, as required. The teams work collaboratively to produce reports for the Drug Benefit Council to consider. CDR Submissions do not usually require another evidence review or pharmacoeconomic review since these would have already been prepared by CDR.

Drug Benefit Council makes a listing recommendation to PSD based on a synthesis of applicable information from the submission, DRRC reports, CDR reports and recommendation, budget impact analyses, existing PSD policies, etc.

PSD Decision

PSD Target Time-to-Decision:

CDR	9 months
Non-CDR	12 months
Generic	2 months

If decision is not to list, submitters may resubmit if new information becomes available.

PHARMACEUTICAL TASK FORCE RECOMMENDATIONS IMPLEMENTATION APPROACH

INTRODUCTION:

In November, 2007 the Pharmaceutical Task Force was established and invited to make 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; and
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 report from the Pharmaceutical Task Force was released in April 2008, and the recommendations contained within were accepted by the Minister of Health.

PURPOSE

- To provide an overview of the activities and timelines for implementing the recommendations contained within the Pharmaceutical Task Force Report.

GUIDING PRINCIPLES FOR RECOMMENDATIONS IMPLEMENTATION

The implementation of the Pharmaceutical Task Force recommendations will be guided by six principles:

1. The best interests of the patient are paramount.
2. The British Columbia (BC) Government is obliged to seek the best value possible for taxpayer dollars in its expenditures.
3. The foundation of all drug benefit decisions will be predicated upon a transparent evidence-based review process.
4. The BC Government is committed to fair, open and transparent procurement processes.
5. All persons involved in making decisions respecting the procurement of goods and services by government must be free from conflict of interest, both real and perceived.
6. The BC government values a healthy, competitive pharmaceutical industry that will continue to provide both financial and human resource investments in BC.

TASK FORCE RECOMMENDATIONS – ACTIVITIES AND PROJECTED COMPLETION TIMELINES

- The following approach describes the proposed activities that will be initiated to address the Pharmaceutical Task Force recommendations. The timelines for the completion of these activities is also included.

- Upon approval a more detailed work plan will be developed to address the sub-activities, resources, and funding required in order to successful meet the projected completion dates.

Recommendation 1:

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 (PSD) and include meaningful engagement with stakeholders, including patients, healthcare professionals, disease specialists, research leaders and industry.

Activities

- Enhance the provincial Formulary Management System—the system for selecting drugs and developing policy for coverage under the province's drug insurance program.
- Implement initiatives to improve stakeholder engagement, including establishing a dedicated Stakeholder and Partner Relations branch.

- Implement other stakeholder engagement and drug review transparency initiatives include establishing a formal pathway for clinicians to make submissions for drug reviews, and making more detailed information on the drug review process and drug review decisions available on the PSD website.
- Establish an evidence-based appeal mechanism for manufacturer and clinician submissions.

Projected Date of Completion

- **May 2008 – Stakeholder and Partner Relations branch established**
- **November, 2008 – Stakeholder engagement and transparency initiatives established for the drug review process**
- **November 2008 – Evidence-based appeal mechanism established for the drug review process**

Recommendation 2:

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

Activities

- Establish target time-to-decision timelines and introduce a criteria-based fast track capability to the drug submission review process to accelerate reviews of drugs with demonstrated superior therapeutic and/or substantial cost-effectiveness advantages compared to available alternatives.
- Publicly report on actual time-to-decision timelines for individual submissions via the PSD website. Performance measures on the drug review process will be developed and reported in the divisional Annual Report. Where possible, this information will also be benchmarked against other jurisdictions (currently, this information is not available from other jurisdictions).

Projected Date of Completion

- **July 2008 – Prepare proposals for target time-to-decision timelines, performance measures, and submission criteria for fast track review pathway**
- **July 2008 - Solicit stakeholder feedback on above and other proposed Formulary Management initiatives to improve the drug review process as needed**
- **August 2008 – Implement target time-to-decision timelines, reporting commitments, and criteria-based fast track capability**

Recommendation 3:

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.

Activities

- The Ministry will reconstitute 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 PSD.
- Members of the Drug Benefit Council will be approved by the Minister.
- The Drug Benefit Council will consist of health care professions, other professionals with expertise in drug evaluation, and members of the public (all who will be required to comply with conflict of interest guidelines). When required, additional experts will be accessible to the Drug Benefit Council to assist with completing their mandate.

Projected Date of Completion

- **July 2008 –Finalize Terms of Reference of reconstituted Drug Benefit Council**
- **November 2008 – Planned first meeting of Drug Benefit Council**

Recommendation 4:

The Ministry of Health should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the TI. This new Drug Review Resource Committee 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.

Activities

- A new Drug Review Resource Collaboration will be established as part of the new enhanced drug review process.
- PSD will bring forward a decision note for the Minister's approval regarding the proposed role, composition, governance, etc. of the Drug Review Resource Committee.
- It is envisioned that the Drug Review Resource Committee will collect and evaluate information from the following three areas of consideration for each drug submission under review, as required: (1) clinical evidence data, (2) clinical practice input, and (3) cost-effectiveness data. The Drug Review Resource Committee will report to the Drug Benefit Council to which all the Drug Review Resource Committee work will be provided to help the Drug Benefit Council carry out their mandate of making drug listing recommendations to the Ministry. The envisioned make up of the Drug Review Resource Committee will consist of experts from three main groups: (1) clinical evidence evaluation experts, (2) practicing clinician experts, and (3) pharmacoeconomic experts. This proposed role and make-up of the Drug Review Resource Committee will represent a significant enhancement as currently the primarily utilizes only the clinical evidence evaluation component provided by the Therapeutics Initiative.
- The members of the Drug Review Resource Committee will be required to comply with conflict of interest guidelines and will be appointed by the Ministry.
- The Ministry will develop a list of potential candidates/members for consideration.

Projected Date of Completion

- **July 2008 – Decision note brought forward for Ministerial consideration and approval**
- **August 2008 – Draft Terms of Reference for Drug Review Resource Committee , develop list of potential members for consideration, and initiate recruitment**
- **November 2008 – Implement Drug Review Resource Committee framework into Ministry drug review process**

Recommendation 5:

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

Activities

- The Ministry will appoint a minimum of two and up to three public members to the Drug Benefit Council (one of which may be an economist).
- Implement approach to seek potential public representatives for membership in the Drug Benefit Council.
- Work in consultation with the Board Resourcing and Development Office to review potential candidates for membership.

Projected Date of Completion

- **June 2008 – Initiate search for public member candidates for consideration**
- **November 2008 – Target to complete public member appointment and have member attend first Drug Benefit Council meeting.**

Recommendation 6:

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.

Activities

- The Terms of References for the Drug Review Resource Committee and Drug Benefit Council will be prepared / revised and will stipulate that no Drug Review Resource Committee members will participate on the Drug Benefit Council as members.

Projected Date of Completion

- **July 2008**

Recommendation 7:

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.

Activities

- A negotiation process with drug manufacturers and representatives of community pharmacy will be initiated.
- Obtain clear mandate from the Minister in order to define parameters of negotiations with manufacturers and pharmacy.
- PSD and BC Pharmacy Association have agreed to undertake discussions about a new framework for generic drug pricing and pharmacy compensation. A strategy for these discussions will be brought forward for approval.
- PSD will solicit and discuss proposals from manufacturers and other interested parties regarding possible alternatives to enhance price competition or otherwise moderate retail prices for generic drugs – while being cognizant of the need to retain the right to utilize tendering as required.

Projected Date of Completion

- **June 2008 – initiate discussions with BC Pharmacy Association and Canadian Generic Pharmaceuticals Association**
- **July 2008 – request clear mandate from Minister regarding objectives for negotiation process**
- **November 2008 – conclusion of negotiation process (i.e., consensus with one or more stakeholder groups and/or decision on implementation of government policy alternatives)**

Recommendation 8:

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.

Activities

- A new framework for community pharmacy compensation will be developed.
- PSD will advance and discuss options to evolve the current model of pharmacy services reimbursement.

- Operating within the funds allocated, PSD will work with the BC Pharmacy Association and other stakeholders on the development of a compensation framework that is equitable, transparent and represents added value to the health care system.
- Alternative delivery models will also be explored/developed, to address the matter of pharmacy reimbursement and business concerns.

Projected Date of Completion

- **June 2008 – initiate discussions with BC Pharmacy Association and Canadian Generic Pharmaceuticals Association**
- **July 2008 – request clear mandate from Minister regarding objectives for negotiation process**
- **November 2008 – conclusion of negotiation process (i.e., consensus with one or more stakeholder groups and/or decision on implementation of government policy alternatives)**

Comment [PM1]: Since Recommendations 7 and 8 pertain to the same subject (i.e. discussions with industry and pharmacy), I suggest we identify the same deliverables in respect of both recommendations.

Recommendation 9:

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.

Activities

- PSD will maintain a cautious approach to broadened utilization of tendering processes.
- PSD will declare their intentions regarding tendering and develop a policy framework to guide future competitive tendering initiatives (including an analysis of the costs and benefits of tenders resulting in contracts with multiple suppliers).
- PSD will ensure that the tendering process is open and well-communicated.
- The Government's established principles and processes for procurement will be utilized (i.e., use of BC Bid, reliance on support from Government's Common Business Services).

Comment [PM2]: If appropriate, I would like to reinforce the message that, notwithstanding the Task Force, our approach to tendering has been very cautious.

Projected Date of Completion

- **July 2008 – request clear mandate from Minister regarding tendering activity over the next 6 months**
- **July/August 2008 – declare intentions for the next 6-12 months as they pertain to tendering**
- **August/September 2008 – bring forward policy framework for consideration and approval**

Recommendation 10:

The Deputy Minister of the Ministry of Health should commit to participate in a 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.

Activities

- The Deputy Minister (DM) will participate in an annual accountability session.
- The newly established Stakeholder and Partner Relations branch of the PSD will hold a multi-lateral stakeholder engagement session.

Projected Date of Completion

- **July 2008 – Conduct multilateral stakeholder session and introduce concept of Fall DM accountability stakeholder session**
- **November 2008 – conduct DM accountability session**

Recommendation 11:

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

1. *ensure BC's decision-making processes include similar timelines to those used by the Common Drug Review and a greater level of commitment to openness and transparency; and*

2. *that any unnecessary overlap between the Common Drug Review and BC formulary management system are reduced to the fullest extent possible.*

Activities

- BC's decision-making processes will be continuously reviewed and any overlap identified will be eliminated..
- PSD will emulate Common Drug Review processes wherever possible, including establishing similar target time-to-review timelines and introducing appeal mechanisms (Note: time-to-review is a different time marker and performance measure than "time-to decision", noted in Recommendation 2).

Projected Date of Completion

- **August 2008**

Recommendation 12:

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 unbiased and evidence-based practices; and*
- *the practice of having members of the Therapeutics Initiative also participating in the work of the Drug Benefit Council should be terminated.*

Activities

- The Ministry will work with the University of British Columbia (UBC) Faculty of Medicine to review the purpose and function of the Therapeutics Initiative. The Dean of the Faculty of Medicine has requested a formal academic review of the Therapeutics Initiative.
- The Ministry will also work with the UBC Faculty of Medicine to determine the future oversight and governance structure of the Therapeutics Initiative and revitalization of the panel of experts Therapeutics Initiative relies upon for its clinical evidence evaluations.
- The new Terms of References for both the Drug Review Resource Committee and Drug Benefit Council will stipulate that no Drug Review Resource Committee members will participate on the Drug Benefit Council as members.

Projected Date of Completion

- **October 2008 – Academic review of the Therapeutics Initiative completed (by UBC Faculty of Medicine)**
- **November 2008 – Implement the recommendations put forward and approved for the oversight and governance of the Therapeutics Initiative (or the group providing the functional responsibilities of the Therapeutics Initiative)**