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September 30, 2010

As we enter the fall of this very busy year I thought it may be a good time to update you on the significant work undertaken in the area of pharmaceuticals management in British Columbia. In addition, I want to take this opportunity to inform you of the dates for our annual Multi-lateral Stakeholder Engagement Session.

Since our last Multi-lateral Stakeholder Engagement Session in December 2009, our focus has been in four key areas:

Enhanced Drug Review Process

Acting on Task Force recommendations, the Ministry of Health Services (the Ministry) has substantively increased inputs, sponsor contact points and transparency within the drug review process, while reducing historic review timelines.

Full details of our enhanced process are available through the links and Appendix at the end of this letter; however, allow me to provide some highlights:

Increased Sponsor Engagement

There are now four separate sponsor engagement points within the enhanced review process, including an opportunity to comment both pre-and-post Drug Benefit Council recommendation and pre-and-post Ministry decision.

Reduced Timelines

New Time to Listing Decision timelines began with submissions received February 2010, and represent significant improvement from historical timelines.

- 6 months for priority reviews (Common Drug Review priority review drugs)
- 9 months for non-complex (most Common Drug Review submissions)
- 12 months for complex reviews (most non-Common Drug Review)

Review timelines are publicly reported for each drug submission and a review of the process and timelines will be completed within 9 months of implementation (November 2010).

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Greater Transparency

In keeping with the Ministry's commitment to greater transparency, drug review decisions and process details are now publicly posted to our PharmaCare website, including:

- Drug Review Results and Rationale
- Drug Submission Requirements for Patented Drug Products
- Sponsor Engagement in the Drug Review Process
- Conflict of Interest Guidelines
- Drug Benefit Council membership

Patient Input Mechanism

BC has gone beyond the recommendations of the Pharmaceutical Task Force and as of this fall will be one of the few jurisdictions in Canada to have a formal process to consider patient perspectives as part of the drug review process. Individual patients, caregivers and patient groups will have the opportunity to provide their perspective regarding a drug under review, and this input will be considered by the Drug Benefit Council as they formulate their listing recommendations.

Independence and Expansion of Expert Opinion

The Ministry's approach to building rosters of experts to perform needed drug reviews has increased the depth and breadth of available expertise.

The Drug Benefit Council, an independent body appointed by the Minister, oversees the drug review process and provides listing recommendations and rationale to government. The nine Professional members with expertise in drug evaluation have been augmented with three Public members selected through an external process, conducted by the Board Resourcing Development Office.

The Drug Review Resource Committee, a sub-committee of the Drug Benefit Council determines individual review requirements, maintains the rosters of expert reviewers and assigns the actual review work. As part of the process for assigning reviews, the Drug Review Resource Committee makes Conflict of Interest determinations.

In the area of Clinical Practice Review, there are 18 rosters of General Practitioners and specialists that can be called upon for reviews in their areas of expertise. Participation is open to all qualified BC physicians.

Regarding Clinical Evidence Reviews; due to concerns over the low response rate to our 2009 Request for Proposals, we have undertaken a new procurement process to establish this roster. When that process is complete the existing contract with the University of British Columbia (UBC) Faculty of Medicine to conduct Clinical Evidence Reviews will end. We will continue to work with UBC in the areas of health professional education and real world safety and effectiveness; neither of which is related to the drug review process or decisions. Should UBC

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prove to be one of the successful proponents to the revised Clinical Evidence Reviews procurement process then we will manage that relationship in the same manner as all other successful proponents for this work.

Pharmacy Services Agreement

On July 9, 2010, following extensive negotiation, we announced that an agreement on generic drug pricing and pharmacy services had been reached with the BC Pharmacy Association and the Canadian Association of Chain Drug Stores. Under the *Pharmacy Services Agreement* the price of generic drugs in BC will drop to 35 percent of the brand price, resulting in an estimated $380 million a year in total savings to government and private payers. In addition, the Province will reinvest $35 million annually to provide enhanced pharmacy services that will benefit all British Columbians.

Stakeholder Engagement Focus

In December 2009, we announced the creation of a dedicated Stakeholder Engagement Division, under the leadership of Mr. John Bethel, Assistant Deputy Minister. Working in close conjunction with Mr. Bob Nakagawa, Assistant Deputy Minister, Pharmaceutical Services Division, John Bethel and the Stakeholder Relations Division team have held more than 100 personal meetings with stakeholders to consult on pharmaceuticals issues in BC.

Stakeholders' collective response and willingness to engage has been welcome and I am pleased with the constructive dialogue, discussions and results that have ensued. To me, this demonstrates a strong commitment from all concerned to work toward solutions for the benefit of all British Columbians.

2010 Deputy Minister's Multi-lateral Stakeholder Session

As you can see, it has been a busy and productive time for us. With September upon us, we are also looking forward to another important event - our (third annual) Deputy Minister's Multi-lateral Stakeholder Engagement Session, scheduled this year for November 24 in Vancouver.

While we will certainly provide detail and follow up on the work I have noted, we would also like to take advantage of the experience and expertise at the November 24 session to discuss and consider new priorities as we move beyond implementation of the Pharmaceutical Task Force recommendations.

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We would be happy to hear any thoughts or suggestions you may have regarding this annual event. Please forward comments you may have to John at: john.bethel@gov.bc.ca.

Thank you for your time and interest.

Yours truly,

John Dyble
Deputy Minister

Attachments (2)

pc: Mr. John Bethel
Mr. Bob Nakagawa

Links

- The enhanced drug review process in BC
  http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc.pdf
- Drug sponsor engagement within the review process
  http://www.health.gov.bc.ca/pharmacare/formulary/drugsubsponsor.html
- Drug review results
  http://www.health.gov.bc.ca/pharmacare/formulary/index.html
- Drug review timelines
  http://www.health.gov.bc.ca/pharmacare/formulary/drugsub.htm
- Drug Benefit Council
  http://www.health.gov.bc.ca/pharmacare/formulary/dbc_info.html.
- Pharmacy Services Agreement
  http://www.health.gov.bc.ca/pharmacare/suppliers/psa.pdf

Appendix A
Pharmaceutical Task Force: Implementation status table

British Columbia Ministry of Health Services
Pharmaceutical Task Force – Implementation Summary

Task Force Recommendation	Implementation Status

Recommendation 1 – Priority attention should be focused on development of an enhanced Formulary Management System together with improved stakeholder engagement and appeal mechanisms.	**COMPLETE**
	• Enhanced process in place February 2010
	  o 4 points of Sponsor Engagement
	  o Opportunity to re-submit with new information in case of do-not-list decision or request to modify existing coverage status
	http://www.health.gov.bc.ca/pharmacare/formulary/drugsub.htm

Recommendation 2 – The Ministry of Health Services (the Ministry) 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.	**COMPLETE**
	• New Time to Listing Decision target timelines implemented Feb. 2010 and applied on a go-forward basis
	• Review of process and timelines will be completed within 9 months of implementation (November 2010)
	• Significant improvement from historical timelines
	  o 6 months for priority reviews (CDR priority review drugs)
	  o 9 months for non-complex (most CDR submissions)
	  o 12 months for complex reviews (most non-CDR)
	http://www.health.gov.bc.ca/pharmacare/formulary/drugsub.htm
	• Review timelines are publicly reported for each drug submission under review.
	http://www.health.gov.bc.ca/pharmacare/formulary/index.html

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.	**COMPLETE** • Re-constituted as Drug Benefit Council November 2008

Recommendation 4 – The Ministry should establish a new Drug Review Resource Committee to carry out the drug submission review role currently performed by the Therapeutics Initiative (TI). 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.	**SUBSTANTIALLY COMPLETE**
	Drug Review Resource Committee established Feb. 2010
	• DRRC determines drug review requirements of submission
	• DRRC makes Conflict of Interest determinations
	• Plain language description of drug review process, including COI process, posted July 2010
	http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc.pdf
	
	Drug Review Resource Teams:
	• Clinical Practice Review
	  o Managed by UBC Faculty of Continuing Professional Development
	  o Open to all physicians, faculty and non-faculty
	  o Roster is being continually populated by experts and GPs, guided by therapeutic areas from past and expected submissions
	• Pharmacoeconomic Review
	  o Roster established through 2009 RFP
	• Clinical Evidence Review
	  o RFP process completed in 2009 but Ministry committed to re-procurement process
	  o Draft RFQ posted with widespread notice July 12 2010
	  o Final RFQ posted with widespread notice August 10, 2010 and closed October 5, 2010

British Columbia Ministry of Health Services
Pharmaceutical Task Force – Implementation Summary

Task Force Recommendation	Implementation Status
	Patient Input Mechanism • Expected completion October 2010
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.	**COMPLETE** • Public members selected through an external process led by the Board Development and Resourcing Office • Public members of Drug Benefit Council appointed by Minister November 26th, 2009. • Members oriented/trained January 2010 http://www.health.gov.bc.ca/pharmacare/formulary/dbc_info.html
Recommendation 6 – No members of the TI or, in the alternative, no participant in a Drug Coverage Review Team should participate as members in the work of the Drug Benefit Council	**COMPLETE** • No members of TI serve on Drug Benefit Council or Drug Review Resource Teams
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.	**COMPLETE** • Agreement announced July 9, 2010 • Generic drug pricing will reduce to 35% of brand • Generic drug pricing applies to both public and private payers • Re-investment in pharmacy clinical services - $35 M • Projected savings of $380 M per year on generic drugs • Agreement negotiated with the British Columbia Pharmacy Association and the Canadian Association of Chain Drug Stores. http://www.health.gov.bc.ca/pharmacare/suppliers/psa.pdf
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.	**COMPLETE** • Dispensing fees to increase to $10.50 (from $8.60) over the term of the agreement • Retail pharmacy mark-up to increase to 8% for all products (from 7%) • Re-investment in pharmacy clinical services - $35 M o Ministry and BC Pharmacy Association Working Group to determine services • October 15, 2010: residential care monthly dispensing fee to increase to $43.75 (from $35)
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	**COMPLETE** • Discontinued prohibition on tendering in new Pharmacy Services Agreement • Exceptions policy for generic drug listings includes a market test

Task Force Recommendation	Implementation Status
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 Health Services 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.	**COMPLETE** • Deputy Minister's multi-lateral stakeholder engagement sessions conducted in July and Nov/ 2008 and Dec/ 2009 • 3rd annual DM multi-lateral stakeholder engagement session planned for November 2010. o Revised and expanded program in planning stages o Key stakeholders consulted for input September 2010
Recommendation 11 – Given that BC was a lead jurisdiction in calling for the implementation of the Common Drug Review, action should be taken to: • 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 • That any unnecessary overlap between the Common Drug Review and BC formulary management system are reduced to the fullest extent possible.	**COMPLETE** • Reviews of CDR-recommended drugs do not replicate CDR actions. o Only required supplemental reviews are conducted to contextualize the CDR recommendation to BC o No Clinical Evidence Review or Pharmacoeconomic Review for CDR submissions • BC does not start review prior to CEDAC recommendation as CEDAC information considered as part of BC process • Target Review Timelines – see Recommendation #2 • Ministry's commitment to openness and transparency includes posting of key drug review process detail and decisions to PharmaCare website, including: o Drug Submission Requirements for Patented Drug Products o Drug Benefit Council o Conflict of Interest Guidelines o Sponsor Engagement in the Drug Review Process o Drug Review Results http://www.health.gov.bc.ca/pharmacare/formulary/dbc_info.html
Recommendation 12 – Subject to Recommendation 4, 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 Ministry's Drug Utilization Branch where an accountable process can be implemented to assure unbiased and evidence-based practices;	**SUBSTANTIALLY COMPLETE** • Existing arrangement with UBC Faculty of Medicine to conduct Clinical Evidence Reviews will end with completion of new CER procurement (*see Recommendation # 4).* • As with any government procurement, the procurement is open to all interested, including the Faculty if they choose to participate. • Once new CER procurement is complete, the existing UBC contract will be limited to health professional education (not "public education") and real world safety and effectiveness; neither of which are related to the drug review process or decisions.

Task Force Recommendation	Implementation Status
• The practice of having members of the TI also participating in the work of the Drug Benefit Committee should be terminated.	