

# CANADIAN TREATMENT ACTION COUNCIL



Canadian Treatment Action Council

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## Common Drug Review says:



## We're Not Worth It

Patients testify in Standing Committee on Health

*by Paulette Eddy, Executive Director, Best Medicines Coalition*

**N**umerous systemic barriers to treatment access exist both nationally and provincially, but the Common Drug Review has emerged as the focus of significant concerns among patient advocates across a full range of disease areas. These concerns formed the basis of testimony by the Best Medicines Coalition (BMC) — of which CTAC is a member organization — to the federal Standing Committee on Health as part of its recent review of the performance of the Common Drug Review (CDR).

CTAC's Chair, Louise Binder, also serves as Chair of BMC. She and fellow BMC operations committee member Linda Wilhelm, who suffers from rheumatoid arthritis, appeared before the Standing Committee on May 9, 2007.

As a national body that makes recommendations to participating public drug plans on whether specific treatments should be reimbursed, the CDR is seen as a major roadblock to appropriate access. This message was communicated strongly by a range of stakeholders over the weeks of committee hearings, including patient organizations like the BMC.



## Common Drug Review says we're not worth it

*continued from page 1*

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"I submit that the Common Drug Review has failed in fundamental ways to meet its stated goals or to carry out its mandate with a process that meets even the most rudimentary rules of natural justice," explained Binder in her testimony.

"In general, it is not providing cost-effective decision-making to the participating provinces. It does poor, short sighted pharmaco-economic analyses. It unnecessarily duplicates the work of many provincial review processes. It duplicates costs. It has processes that are not transparent, inclusive, or patient-friendly, thus missing much relevant data in making its decisions. And it has no appeals process," Binder added.

Binder went on to walk the committee through the process of one drug, Viread (tenofovir), through its journey from clinical trial through reimbursement coverage, graphically demonstrating the CDR's shortcomings.

Likewise Wilhelm, who has suffered from debilitating rheumatoid arthritis for more than twenty years, at times confined to a wheelchair and unable to care for herself or her family, describes a long journey of ineffective treatments, surgeries, and hospital stays.

"Finally, in 1999 came a breakthrough biologic. I walked out of a three month hospital stay on my own steam and have never looked back," said Wilhelm. "A recent CADTH (the body which manages CDR) report concluded that this drug is not cost effective. According to them, I am not worth it. I disagree with this conclusion and know that there are thousands of Canadians with inflammatory arthritis who would agree with me."

In its submission, the BMC outlines specific minimum standards which a vastly reformed CDR, or, if dismantled, provincial drug review committees must meet:

- The CDR's narrow cost containment approach must be revised to incorporate comprehensive and progressive data analysis models which are broader and inclusive in nature. These models must be designed to incorporate a wider definition of costs, including hospitalizations, surgeries, and universal healthcare costs. In addition, post

approval surveillance activities must be incorporated and enhanced.

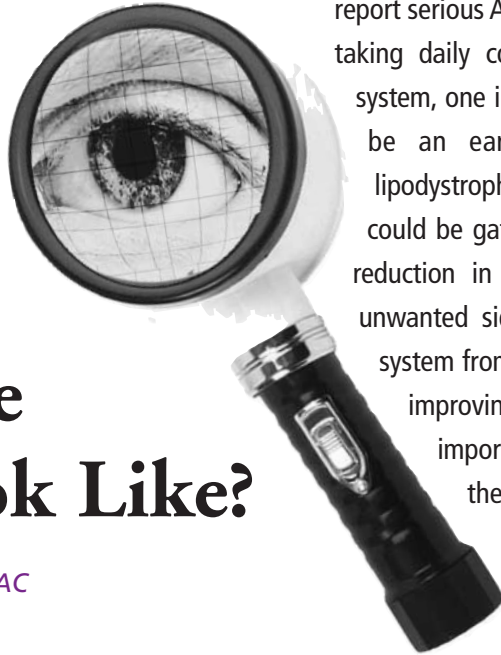
- Models of pharmaceutical review must be flexible enough to facilitate, where appropriate, novel and innovative medicines, including those designed for rare disorders, those for previously unmet needs, and those where significant therapeutic advance is offered.
- Review processes must be further expedited and improved by involving thorough consultation of national and international experts in each therapeutic area.
- Patients, who are most impacted by decisions, must be significantly involved and consulted. In addition, broader stakeholder groups must participate in the process in a meaningful advisory capacity.
- Transparency and fairness must be integrated, allowing patients and other stakeholders a greater understanding of processes and rationale for actions. An appeal process must allow recourse on all decisions.

"We have concluded that the Common Drug Review is a good idea gone very wrong. We have also concluded that the Common Drug Review, in its present configuration, cannot be fixed," Binder told the Committee in summarizing the BMC's recommendations. Copies of the BMC's submission and accompanying media release are available online at [www.bestmedicines.ca](http://www.bestmedicines.ca).

The Standing Committee on Health has since completed its report and recommendations on the CDR, although that report won't be made public until September or October, when Parliament resumes sitting following its summer recess. ■

**Formed in 2002, the BMC is a national alliance of organizations and individuals, representing those living with or affected by chronic disease or illness, who are concerned about drug review reform, treatment access, patient safety and general health policy development.**

# What Does a Vibrant Post-Approval Surveillance System Look Like?



By Ron Rosenes, Vice-Chair, CTAC

**CTAC'S POSITION ON** the need to improve the post-approval surveillance system for drugs and natural health products (NHPs) should be familiar by now. Since publishing the results of the community-based research completed in 2004 on the most appropriate methods to collect post market data from consumers, CTAC has continued to advocate for ways to make the system more active and to make consumers a vital part of the collection of data on drugs and NHPs that have been approved for sale in Canada. Now that Health Canada has proposed a Progressive Licensing Framework which would set the stage for an ongoing and continuous review of licensed therapies at every step of the way — from the laboratory to the pharmacy, and from the pharmacy to the patient — the time is ideal to offer suggestions on consumer input that would bring vibrancy to the system, increase the evidence base for formulary listing decisions, and contribute to improved health outcomes.

The present system for data collection works passively in the sense that it depends on health care providers and pharmaceutical companies to report serious adverse events (AEs), events that may lead to hospitalization or death. Consumers may report directly but the system is little known and little used. As those affected with HIV/AIDS found, it took a very long time for the ravages of lipodystrophy and lipoatrophy to be recognized as serious and debilitating side effects of combination antiretroviral therapy, even though we were well aware of it in our community.

CTAC's vision is of a system that does more than just report serious AEs. It would look at the longer term impact of taking daily combination drug regimens. A more vibrant system, one in which consumers act as "sentinels", would be an early warning system for syndromes like lipodystrophy. A richer and more complex set of data could be gathered and analyzed. It could even lead to a reduction in the need to take other meds to counter unwanted side effects. It has the potential to shift the system from its narrow focus on adverse events towards improving quality of life and health outcomes. Of equal importance, though not the subject of this article, is the data that should be collected through Phase IV clinical trials, those that are or ought to be conducted after market approval.

The CTAC PASS study focussed on the methods used to collect data, not on the data itself. Participants preferred sharing information either in focus groups or one on one with a sympathetic and knowledgeable data collector. The PASS study found that such methods made possible "...a detailed human portrait that might not be easily captured in the existing reporting system." Data collected in this manner included the ways people living with HIV/AIDS manage both the medical and social aspects of medications and their side effects. Still, there remain many challenges in the collection of relevant data that need to be addressed. Participants were often challenged to identify AEs that happened a long time ago and to identify a single causative agent. However, it can be difficult to distinguish among AEs, longer term side effects, and symptoms of the illness itself.

There is little doubt that a consumer-centred system would collect and analyze a richer set of data that could be used to better inform the decision to list medications for reimbursement, de-list or list with restrictions. In the present system, the Common Drug Review (CDR) makes recommendations to the provinces and territories (except Quebec) regarding which drugs to list on formularies but there is no opportunity for re-review after a certain period on the market. Much information could be used from a vibrant PASS system that could impact on the original CDR decision.

If the intent of the Progressive Licensing Framework is to

*continued on page 11*



# GENERIC DRUGS IN CANADA: A POLICY PAPER

CTAC has recently published a policy paper on generic drugs in Canada. To view the full paper please visit [www.ctac.ca/en/resources/position\\_papers](http://www.ctac.ca/en/resources/position_papers) or contact our main office to request a hard copy.

*Prepared by Ward Health Strategies for CTAC*

## EXECUTIVE SUMMARY

Many recent studies have found the price of generic drugs in Canada to be higher than the price of such drugs in comparator countries. This is especially significant to people living with HIV/AIDS as many of the drugs used to treat their condition will be genericized in the next few years. Ensuring the lowest possible price for these drugs will help ensure access for all who need them.

This report provides an overview of background information related to the pharmaceutical market, both globally and within Canada, followed by a summary of the regulatory mechanisms related to pharmaceutical review in Canada. Reimbursement of pharmaceuticals in general and generic drugs in particular within Canada and in various international jurisdictions is discussed, and models for

possible emulation are highlighted. The report then offers suggestions for possible mechanisms to reduce the price of generic drugs, discussing both the pros and cons of each option, and concludes with CTAC's recommendations.

## BACKGROUND

Generic pharmaceutical sales accounted for 17.7% of the total Canadian prescription drug market in 2003, totalling nearly \$3.0 billion of drugstore and hospital sales. Generic share of retail prescriptions was 44%, equating to almost 173 million generic prescriptions.<sup>1</sup> While every Canadian province and territory encourages the use of generic drugs through a variety of regulatory mechanisms, each province varies in their share of spending on generic drugs. For instance, British Columbia has the highest share of generic prescriptions at 50.6%, while Quebec has the lowest at 39.1%.

Generic drugs are less expensive than brand name drugs due to a number of factors: generic manufacturers' development costs are a fraction of those of the developer of a new drug; the time required to create a "copy" is significantly less; regulatory hurdles are diminished for a generic manufacturer; and generic manufacturers have greater flexibility in pricing their products.

## CANADIAN ACCESS TO PRESCRIPTION DRUGS

The majority of Canadians pay for their prescription drugs through private and employer sponsored insurance. The public sector finances 46% of expenditures on prescription drugs. The HIV/AIDS community is slightly different in that a greater proportion of people living with HIV/AIDS have access to public funding.

Each Canadian province has differing rules and regulations surrounding the reimbursement of generic drugs. Ontario and Quebec's generic drug reimbursement require special mention as some studies have suggested that the policies of these two provinces have had a direct impact on the price of generic drugs in all of Canada.

In 1993, the Ontario government implemented a policy aimed at controlling the prices of generic drugs as a condition for listing them on its drug plan formulary (the list of products covered for reimbursement). That process was



called the 75/90 rule and stipulated that the maximum price for the first interchangeable generic drug could only be 75% of the price of the brand name drug, and the maximum price for the second listed generic drug must be no more than 90% of the first generic drug. This policy has continued since then, in spite of numerous legal challenges by generic drug companies.<sup>2</sup> Ontario's recent Bill 102 amends the "75% rule" and now requires a first interchangeable generic drug be priced at no more than 50% of the brand name drug. This regulation came into effect on March 1, 2007.

Unlike Ontario, Québec does not have a "75% rule." However, the government does insist on receiving the lowest or best available price in Canada. Many other provinces follow this policy, and therefore, for the most part, prices of generic drugs in Canada are the same across the country.<sup>3</sup>

### INTERNATIONAL REGULATION

Most developed countries are grappling with the escalating importance of drugs to their health systems and many use some form of a cost containment strategy to contain pharmaceutical expenditures. "The challenge of managing prescription drug costs, the approaches being tried, and the responses are surprisingly similar around the world."<sup>4</sup> The reimbursement systems in Australia, Finland, Germany, New Zealand, Switzerland, the United Kingdom and the United States are described in the main body of the paper.

### CANADIAN GENERIC DRUG PRICES COMPARED

There have been a number of studies published which have investigated the price of generic drugs in Canada versus other jurisdictions. The majority of these studies found that the prices of generic drugs in Canada are significantly higher than those found in comparator countries. Based on a review of the studies above, three main reasons for the relatively high price of generic drugs in Canada emerge: lack of competition (the generic drug landscape in Canada is

dominated by two large players), government policies (generic drug reimbursement policies in Ontario and Quebec), and, to a lesser degree, exchange rate fluctuations.

### POSSIBLE MECHANISMS TO LOWER THE PRICE OF GENERIC DRUGS

A number of possible policy options aimed at curbing the price of generic drugs in Canada are examined. The options under discussion include:

- Expansion of the mandate of the PMPRB
- Promotion of competition in the generic manufacturing Sector
- Elimination of government "interference"
- Monosponist model with international competition
- Profit controls for generic companies
- International reference based pricing for generic drugs
- Reduction of the 50% rule to a "reasonable" level
- Cross border importation of generic drugs from the US
- Bulk buying of generic drugs

### CONCLUSION

It is apparent that some of the models suggested above may be more appropriate and feasible than others, such as expanding the mandate of the PMPRB, reducing the "50% rule", bulk buying, and cross border importation.

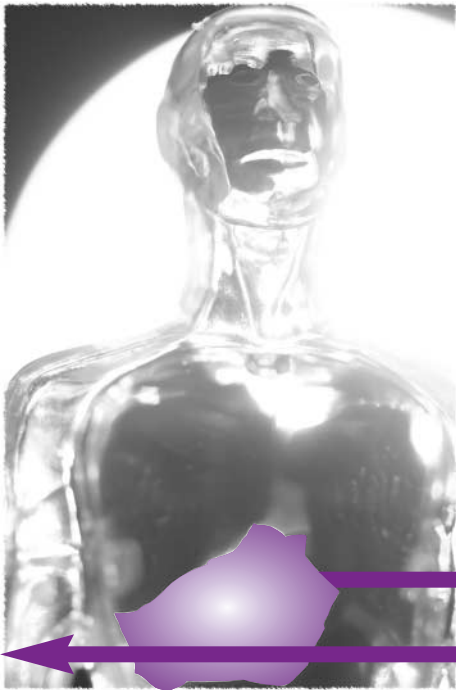
CTAC recommends that funding be provided in order to convene a focus group of experts and other appropriate individuals to discuss these options in more detail. Experts to be recruited include federal, provincial and territorial (FPT) representatives, pharmaco-economic experts, health science industry members (representatives from both brand and generic manufacturers), physicians, patients, and pharmacists. These individuals would be charged with examining the issue and providing expanded recommendations to the government. ■

<sup>1</sup> Canadian Generic Pharmaceutical Association, Accessed March 5, 2007 [www.canadiangenerics.ca/en/resource/market\\_trends.shtml](http://www.canadiangenerics.ca/en/resource/market_trends.shtml)

<sup>2</sup> Canada: Challenge to Pricing Policies for Generic Pharmaceuticals, *Apotex Inc v Minister of Health*, Court of Appeal for Ontario, 28 October 2004.

<sup>3</sup> Palmer D'Angelo Consulting, Inc. (2002). *Generic Drug Prices: A Canada US Comparison*. [www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf](http://www.pdci.on.ca/pdf/Generic%20Pricing%20Study%20Final%20Report.pdf)

<sup>4</sup> Currie, Gillian, Nielson, N. *Models of Funding Prescription Drug Programs*, Working Paper 2002-16. [scholar.google.com/scholar?hl=en&lr=&q=cache:Cxd-vFN0xs4J:www.ucalgary.ca/mg/research/media/2002\\_16.pdf+alternative%2B reimbursement%2Bdrug%2Bmodel](http://scholar.google.com/scholar?hl=en&lr=&q=cache:Cxd-vFN0xs4J:www.ucalgary.ca/mg/research/media/2002_16.pdf+alternative%2B reimbursement%2Bdrug%2Bmodel)



# Canadian HIV Trials Network Tackles HIV/HCV Co-infection

*by Jennifer Chung, Information and Communications Coordinator, Canadian HIV Trials Network*

**W**ith liver disease becoming one of the major complications related to HIV infection, researchers at the Canadian HIV Trials Network (CTN) are leading innovative studies that will help improve the lives of people co-infected with HIV and hepatitis C (HCV). From access to liver transplantation and the development of new treatments for side effects caused by HCV therapy to exploring the underlying factors of concurrent liver disease, Network researchers across the country are working to find new and better methods in the prevention, diagnoses, and treatment of this condition.

## **STRIVING FOR EQUAL ACCESS TO TRANSPLANTATION**

Canadians living with HIV face an uphill battle when it comes to access to liver organ transplantation. To change that, CTN researcher Dr. Curtis Cooper of the University of Ottawa surveyed CTN clinical trial sites across Canada between August to November 2005 to gain a national perspective on the needs and obstacles to this life-saving procedure.

Results indicated that between 20 to 30 per cent of the more than 12,400 HIV positive people followed at these sites were co-infected with HIV/hepatitis C or HIV/hepatitis B. Obstacles to transplantations were identified as organ supply, risk of HCV re-infection, resistance of surgical teams to perform the operation due to fear of HIV infection during

surgery, concerns about success rates, and funding issues.

“We need to determine how to increase the organ supply overall and how to better manage hepatitis C after the transplant,” says Dr. Cooper. “We must also ensure our surgical colleagues are aware that most HIV patients seeking transplantations now are on antiretroviral therapy with undetectable viral loads — so the risk of HIV transmission during surgery is very low.”

Currently, Dr. Cooper sits on a provincial ministry committee that examines ways to increase access to organ transplantation for those living with HIV. He is also working with transplant centres in Ontario to identify patients who are good candidates for the procedure and ensuring that they receive the assessment they deserve.

“We know liver transplantation is effective for most people living with HIV and it is important that our patients get access to this procedure just like everyone else,” explains Dr. Cooper. “Organ supply is the biggest obstacle, and we should focus on trying to increase the overall supply so that everyone, including those with HIV, will benefit.”

## **TAKING AIM AT CO-INFECTION SIDE EFFECTS**

Anxiety and depression can be devastating side effects for people undergoing treatments for both HIV and hepatitis C (HCV). But this might not be the case for much longer. The innovative research of CTN investigator Dr. Marina Klein of the Montreal Chest Institute is transforming treatments for co-infection.

The Peg-Interferon and Citalopram in Co-infection study (PICCO, CTN 194) will test whether the prevention of depression can improve adherence to HCV treatment.



Currently, the most common course of treatment for those co-infected with HIV and HCV is with a pegylated interferon/ribavirin combination for their HIV and HCV. However, this mix of therapies has been shown to negatively affect the mental health of patients, thereby reducing the effectiveness of their HCV treatment. The PICCO trial will add an anti-depressant called citalopram to standard treatment.

Enrolment for this clinical trial will target people co-infected with HIV and HCV who are about to begin HCV treatment for the first time. Researchers will evaluate the use of citalopram before, and during, treatment for HCV. Nearly 80 participants at sites across the country will be randomly assigned to receive either citalopram or a placebo in this trial. The study will compare adherence to HCV treatment and symptoms of depression between participants who receive citalopram and those who receive a placebo.

According to Dr. Klein, what makes this study particularly cutting-edge is the use of telemedicine for evaluating the mental health of participants from across the country. Participants will complete questionnaires and take part in video conferencing with a psychiatric nurse.

PICCO is enrolling participants at sites in Ottawa, Hamilton, Toronto, Vancouver, Winnipeg, Sherbrooke, and Montreal. Researchers are eager to see this trial go ahead across the country, particularly in provinces like British Columbia, which has the highest rates of co-infection in the country. "The population we study and care for could really benefit from this kind of study," says Dr. Marianne Harris, Pacific Regional Director of the CTN and clinical researcher at the BC Centre for Excellence in HIV/AIDS in Vancouver. "New approaches for treating hepatitis C that take mental health into account could greatly improve the overall health status of our co-infected patients."

## SEEKING LONG TERM SOLUTIONS TO HIV/HCV CO-INFECTION

Liver disease progresses more rapidly in people infected with HIV despite the use of highly active antiretroviral therapy (HAART). To uncover the reasons behind this complex problem, Dr. Marina Klein is leading a longer-term study to examine the effect of HAART on liver disease progression in HIV/HCV co-infection (CTN 222).

This new observational study will follow 950 participants over five years and is currently enrolling at sites in Alberta, British Columbia, Ontario, and Quebec. Dr. Klein says a long-term cohort involving such a large number of participants will allow researchers to make better recommendations on the treatment of HCV and develop services which meet the particular health needs of co-infected people.

"Our current treatments for hepatitis C are quite limited because of their toxicity and degree of effectiveness," says Dr. Klein. "With the large number of people involved in the study, we might be able to determine who we need to target for early hepatitis C treatment to prevent liver disease."

While the progression of liver disease is partly due to immune dysfunction from HIV infection, it remains unclear why, unlike other opportunistic infections, hepatitis C liver infection progression is not slowed down by HAART. Dr. Klein says this study will provide researchers with needed information on rates of liver disease according to type and duration of HAART regimen. Her team will also study the role of other factors that may contribute to liver disease progression like alcohol and drug use and rates of chronic toxicities related to HAART.

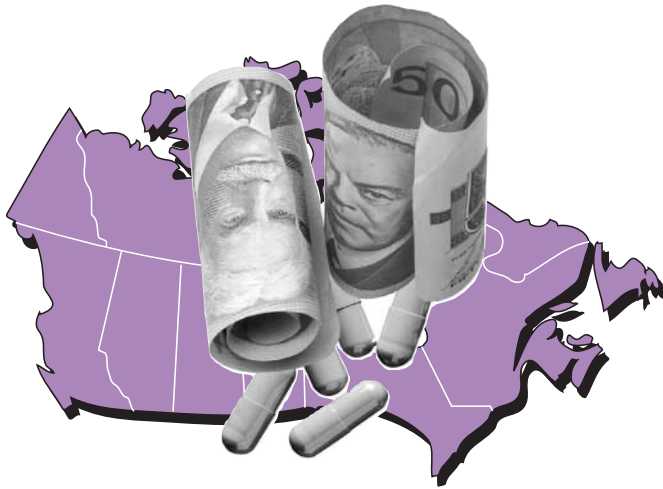
People who access services such as specialty clinics and outreach programmes will be recruited for the study. As well, at-risk individuals, including active and former drug users, women, Aboriginal people, and hemophiliacs, will be sought out to reflect the demographic of the epidemic in the country.

Researchers for this study have received very positive responses from participants who feel they are contributing to a project that advances the knowledge of HIV/HCV co-infection. "The community that is co-infected is very concerned about liver disease. They have seen friends who have died from this illness, so they want answers on how best to treat it," says Dr. Klein. "This type of work can help move the field forward in terms of access and effectiveness of treatment." ■

*For more information about these and other CTN studies, please visit our website at [www.hivnet.ubc.ca](http://www.hivnet.ubc.ca), or call 1-800-661-4664.*

# Federal, Provincial, Territorial (FPT) Initiatives

By Brian Finch,  
Secretary, CTAC



## COMMON DRUG REVIEW

**P**rior to March 2002, the provincial, territorial, and federal drug plans each had their own decision making process by which they approved medications for public reimbursement.

In an effort to streamline this process, the Common Drug Review (CDR) was created in 2002 under the auspices of the Canadian Agency for Drugs and Technologies for Health (CADTH), then called the Canadian Coordinating Office for Health Technologies Assessment (COHTA). In theory, the CDR is one central body to review clinical evidence and cost-effectiveness of new and existing drugs in order to make formulary listing recommendations to the various participating public reimbursement plans.

The federal, provincial and territorial governments (FPT)

### QUICK FACT

Ontario has decided to review breakthrough drugs on their own, thus circumventing the CDR process. Atlantic Canada has their own separate CDR, and Quebec does not participate.

made a commitment to share the costs of this process. Every province but Quebec is participating in the CDR. Submissions began being accepted in September 2003.

Pharmaceutical companies, drug plans and the Advisory Committee on

Pharmaceuticals (the body providing advice on pharmaceutical issues to CADTH's Board, the Common Drug Review program, and the Health Technology Assessment program) now file submissions for new drugs to the CDR for review once Health Canada has approved the drug for sale in Canada.

Once submitted, the reimbursement file moves on to the Canadian Expert Drug Advisory Committee (CEDAC) where input from the CDR and possibly outside experts are considered. A recommendation is sent back to the CDR and is communicated through the CDR to the public drug plans for formulary listing. Public drug plans take into consideration these recommendations when making formulary listing decisions in their respective jurisdictions. The time line for CDR to make these recommendations is approximately 19 to 25 weeks.

## AREAS OF CONCERN

At present, the CDR is an added layer of bureaucracy and is only duplicating and slowing down the process by which the provinces and territories make their formulary listing decisions. The CDR more often than not declines new breakthrough drugs on the basis of very narrow pharmacoeconomical analysis. Counter to their claims, there is very little public input and the process still remains opaque despite the addition of two places for "patient representatives," as these representatives have no formal accountability to the larger patient group community.

## NATIONAL PHARMACEUTICALS STRATEGY

In September 2004, when the First Ministers met to discuss health care reform, another FPT initiative created a Ministerial Task Force (co-chaired by Health Canada and British Columbia's Minister of Health) to develop and implement a National Pharmaceuticals Strategy (NPS). Its first progress report was published in 2006.

This National Pharmaceuticals Strategy is prioritized from nine action points:

- Develop, assess, and cost options for catastrophic pharmaceutical coverage
- Establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness



- Accelerate access to breakthrough drugs for gaps in health needs through improvements to the drug approval process
- Strengthen evaluation of real-world safety and effectiveness
- Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines
- Enhance action to influence the prescribing behaviour of healthcare professionals so that drugs are used only when needed and the right drug is used for the right problem
- Broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record
- Accelerate access to non-patent drugs and achieve international parity of prices of non-patented drugs
- Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies

The FPT governments then identified five areas upon which to focus in order to move forward these nine priority action points. These are the following:

1. "Real world" drug safety and effectiveness
2. Expensive drugs for rare diseases (orphan drugs)
3. Drug pricing and purchasing
4. Catastrophic drug coverage
5. Common drug formulary

## AREAS OF CONCERN

The NPS, as far as it stands, is based on the CDR and their recommendations to create a national formulary. This initiative is very troublesome. There is no agreement on what the pay threshold should be, this threshold being the ratio made between the deductible and the patient's ability to pay. (Many agree that the threshold is, at this point, set far too high.) The stakeholder consultation process has been non-existent, and there is serious concern regarding lack of accountability. Last year, patient group meetings were organized but there were no consultations. Instead, presenters explained how the process would operate without soliciting patient input; in effect, telling patient groups how it was going to be. In light of these developments, patient advocacy groups have raised the concern that the NPS initiative will end up hurting those who are most in need, causing them even more distress than what they are experiencing under our current patchwork-quilt approach to public drug funding in Canada. ■

## QUICK FACT

When the first NPS progress report came out in the summer of 2006, the first ministers of the Atlantic Provinces, regions with the least drug coverage in Canada, were the only ones to publicly express their support of the NPS.



Louise Binder, Chair of CTAC, spoke on Women and AIDS at the "Glimmers of Hope" event organized by the Mennonite Central Committee Alberta at MacEwan Hall, University of Calgary, Alberta, May 27, 2007.

Pictured, from left to right:

Louise Binder; Marry Tumbo, from Mugumu, Tanzania; Kerril McKay, from Kingston, Jamaica; and Cindy Klassen, Calgary, Alberta, Olympic speed skater, gold medalist

## CHAIR'S REPORT

Summer 2007

by Louise Binder



### DEAR READERS,

In all the years that I have done this advocacy work for our community, I have maintained integrity and professionalism in my work. It must always be about the issue — and that issue is getting safe and effective medicines into people's hands. Period. Facts and figures that support arguments to protect people's lives are what count. If those factors will not win the day, then the day should not be won.

This is the approach I have taken in advocating for profound changes to the Common Drug Review (CDR) process, i.e. the federal/provincial/territorial drug review process that makes recommendations to provinces about public reimbursement coverage. This is what I did when I presented recently before the federal Standing Committee on Health about why and how CDR is inefficient, ineffective and lacking in transparency with stakeholders. So what did I get for my trouble? I was not faced with logical counter-arguments about why my facts and figures were wrong. Rather, I was dismissed by one member of the Committee as being, in effect, irrelevant because the effect of my argument was that drug companies would have an easier time of getting drugs covered on reimbursement plans.

It is not exactly rocket science that if CDR is a barrier to patients getting drugs we need, and we remove that barrier so we get those drugs, the company, being the

supplier of those drugs, gets to sell them. We did not set up the system that way. We just live (hopefully) with it. The relevant factors are whether the arguments being made about systemic problems are accurate and whether they are keeping needed drugs from sick people.

I also argue against high drug prices, direct to consumer advertising and cross border internet pharmacies. I argue for compassionate and expanded access by pharmaceutical companies for drugs in trials and to keep people on those programmes as long as they need them. I argue for post approval surveillance of drugs and for effective, safe drug trials and drug reviews for marketing. I believe all of these are barriers to drug access. They each also have a positive and negative effect on different stakeholders in the drug supply process. So be it.

Of course when I use the term "I", it does not mean me personally, but it means me or another representative of CTAC on behalf of the HIV + community members needing drugs.

So, here is what I say to politicians who try to shut me down for fighting for this community by trying to insult me. You do not frighten me nor embarrass me. It is you who should be ashamed. I do not report to you nor do I care what you think of me. I care solely about my community — people living with HIV and AIDS — and their needs. I will fight you fairly on the merits of my arguments anywhere, anytime, and let the best argument win.

Yours truly,

HIV Community Advocate and Activist, Louise Binder



Canadian Treatment Action Council

**Annual General Meeting**

CTAC's **Annual General Meeting and Skills Building Day** will be held in Toronto, Ontario, **October 13 and 14**. Everyone is invited to attend.

For information, please visit

**[www.ctac.ca](http://www.ctac.ca)**

## What does a vibrant post-approval surveillance system look like?

*continued from page 3*

create transparency, flexibility, and increase safety in the system, then the opportunity to incorporate the data gathered from consumers acting as "sentinels" in the system must be part of the planning. At a recent consultation on the framework with Health Canada, CTAC representatives contributed suggestions about the need for TPD (Therapeutic Products Directorate, which approves drugs for sale in Canada) and MHPD (Marketed Health Products Directorate, which is responsible for Post Market Surveillance) to collaborate on enhancements to the present system.

Let's look at some examples. One of the best known is the safety issue of Vioxx®. It was approved by TPD and recommended for reimbursement by CDR before studies showed it could precipitate heart attack or stroke in certain at risk populations. Ongoing data collection might reveal it to be safe enough to be reinstated if used under doctor's care in certain populations, or, conversely, that it should be removed from the market permanently. Presently, the system has no way of making an informed decision. CTAC supports the Progressive Licensing Framework as it seeks to improve the post market environment.

A different example is the decision by CDR not to recommend listing Hepsera® (Adefovir Dipivoxil) for chronic Hepatitis B on the basis that it is a "me-too" therapy and carries a higher price than older drugs in the class. This may seem reasonable until the individual develops resistance to the older drugs and could benefit from the newer alternative. Conversely, negative data could result in the de-listing of a drug or setting new conditions to guide prescribing it. Longer term data could reveal safety and efficacy problems that don't show up in the first few years the drug is on on the market. Conversely, previously unknown advantages may become apparent; for example, the reduced need for concomitant medications to deal with side effects, or an overall improvement to quality of life.

CTAC will continue to participate in consultations with Health Canada to improve and ensure the vibrancy of the system, particularly in the post market environment. While we continue to emphasize the role of consumers in contributing to the system, we will also advocate for sufficient resources for Health Canada to do its work effectively. ■

## CALENDAR OF EVENTS

SUMMER/FALL 2007

### ► AUGUST

**BCPWA Annual General Meeting** .....18  
Vancouver, British Columbia  
Contact: Tel: (604) 893-2200  
Toll Free 1 800 994-2437  
[www.bcpwa.org/evagm.php](http://www.bcpwa.org/evagm.php)

### ► SEPTEMBER

**Interscience Conference on** .....17-20  
**Antimicrobial Agents and Chemotherapy (ICAAC)**  
Chicago, Illinois  
[www.icaac.org](http://www.icaac.org)

**Canadian Aboriginal AIDS Network** .....17-20  
**9<sup>th</sup> Annual General Meeting and Skills Building Forum**  
**1<sup>st</sup> Annual Aboriginal HIV/AIDS Policy Forum**  
Montreal, Quebec  
[www.caan.ca/english/agm.htm](http://www.caan.ca/english/agm.htm)

**Ottawa Coalition on HIV/AIDS and** .....18  
**the HIV Education Committee:**  
**How to Make Your Voice Heard**  
Ottawa, Ontario  
Contact: Michelle Ball at (613) 238-5013 x235 or  
[connect@aco-cso.ca](mailto:connect@aco-cso.ca)

### ► OCTOBER

**CTAC Annual General Meeting** .....13-14  
**and Skills Building Day**  
Toronto, Ontario  
Contact: (416) 410-6538 or  
[ctac@ctac.ca](mailto:ctac@ctac.ca)  
[www.ctac.ca/en/action/agm](http://www.ctac.ca/en/action/agm)

**CATIE's Annual General Meeting** .....13-14  
**and Educational Conference**  
Toronto, Ontario  
Contact: Andrew MacDonald at  
1-800-263-1638 x254 or  
[amacdonald@catie.ca](mailto:amacdonald@catie.ca)

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## 2006/07 FUNDERS

Public Health Agency of Canada (PHAC)

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Ward Health Strategies

## CTAC POSITION PAPERS

### Papers

- 2007 – “Generic Drugs in Canada : A Policy Paper”. Authors: CTAC and Ward Health Strategies.
- 2006 – “Timeliness and Transparency: Assessing the Review Process for HIV Drugs.” Revised April 2006. Author: David Garmaise.
- 2004 – “Roadmap for Addressing the Epidemic of HIV and Hepatitis C Co-Infection in Canada.” Author: Paula Braitstein.
- 2001 – “Improving our Health: The Need to Enhance the Post-Approval Surveillance System for HIV/AIDS Drugs in Canada.” Author: David Garmaise.
- 2001 – “Making Treatments Accessible: A Policy Paper on Determining Appropriate Pricing for Brand-name Pharmaceutical Treatments for HIV/AIDS in Canada.” Author: Glen Brown.
- 2000 – “Position Paper on Direct to Consumer Advertising (DTCA) of Prescription Medications.” Author: Philip Lundrigan.

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## MEMBERSHIP

Membership applications are available by contacting the CTAC office or by visiting the CTAC web site at [www.ctac.ca/en/membership](http://www.ctac.ca/en/membership).

### Full Membership is reserved for

- Persons living with HIV/AIDS
- Groups, organizations and/or projects with a substantial HIV/AIDS mandate

### Associate Membership is open to

- Any individual, group, organization or project that supports CTAC’s mandate and objectives

## CONTACT US

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**Website:** [www.ctac.ca](http://www.ctac.ca)

## CTAC’s Mandate

*To secure and ensure access to therapies and treatments for people living with HIV/AIDS by working with the public, private and not-for-profit sectors.*

### CTAC...

- Informs research and public policy, and promotes public awareness;
- Provides mentoring and skills building in these areas to people living with HIV/AIDS;
- Encourages and facilitates the exchange of related information to stakeholders;
- Builds and works with coalitions to address broader health care issues impacting access to therapies and treatments.

position\_papers or on hard copy from the CTAC office (see contact information below).

## PUBLICATION

**This newsletter is a quarterly publication.**

**Editorial Board:** Ken Monteith / Ron Rosenes / Marco Gomes

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**Printing:** The Printing House

**On-line:** [www.ctac.ca/en/newsletter](http://www.ctac.ca/en/newsletter)

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