Submission to the Standing Committee on Health

Study on Prescription Drugs

The BC Persons With AIDS Society

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The British Columbia Persons with AIDS Society is one of Canada's largest organizations of people living with HIV/AIDS, and has over 4000 HIV-positive members. BCPWA is a consumer driven society. Its volunteer Board of Directors is composed exclusively of people living with HIV/AIDS, and its programs are determined and driven by BCPWA members, including Board members. The mission of BCPWA is to empower its members through mutual support and collective action.

BCPWA wishes to appear before the Standing Committee on Health regarding Prescription Drugs because pharmaceutical products are a key component to staying alive for most HIV-positive people. We have a strong vested interest in what the Standing Committee hears, understands, and recommends.

BCPWA believes in a few key principles that we feel underlie all of the issues related to prescription drugs. These are:

- Our right to make informed choices;
- Our right as consumers to have a voice in all aspects of decision making regarding prescription drugs, from bench to bedside;
- Transparency by both industry and government regarding all aspects of prescription drugs (research, licensing, pricing, public information, etc.);
- The responsibility of the state to create the conditions necessary to permit its citizens to maximize their health;
- The need for safe, effective, and accessible products, recognizing that safety, efficacy, and accessibility may be defined differently depending on the state of one's health.

Rising costs

The rising cost of prescription drugs is a very complex issue and presents some formidable barriers to access to treatment. Canada must play a lead role in addressing prescription drug prices domestically, and on the international stage, in order to ensure that Canadians can benefit from new treatments.

As costs continue to rise, provincial formularies and private insurers have begun to refuse coverage of the higher priced new drugs, limiting treatment options. In other instances, when a new drug is added to a formulary, another drug is removed. For many serious, life-threatening illnesses, access to a broad range of treatment options is essential to customize treatments to individual needs, in order to maximize efficacy and minimize toxicity.

Prescription drug prices are set internationally, largely based on what the market will bear. Canada comprises about 2 % of the international market, so any interference in the setting of prices in Canada is a course fraught with challenges; responses by pharmaceuticals manufacturers may range all the way up to choosing not to sell their products in Canada, creating an even larger barrier to treatment access. Such a move by industry would also have enormous implications for research and development of new treatments in Canada.

As can be seen from the fact that traditionally prices in Canada are lower than elsewhere in the world, notably the United States, it seems that the Patent Medicines Pricing Review Board (PMPRB) has "room to maneuver", possibly considerably greater room than has been explored thus far.

Nonetheless, we cannot ignore the fact that, because of cross-border shopping by Americans seeking to elude the often higher prices charged in the American market-based system, pharmaceutical companies have already begun to charge the same amount for HIV drugs in Canadian dollars that they charge in the United States. This has made the newest HIV drugs recently approved by Health Canada inaccessible to the majority of HIV-infected Canadians, where the cost of one drug may now be up to $30,000 annually.

Part of how provinces are attempting to cope with rising costs is through the newly created Common Drug Review, in which a committee reviews newly approved drugs for their cost-effectiveness before recommending whether they should be put onto provincial formularies. If a drug is found to be 'cost-effective' -- the definition for which has not been made public, it is important to note -- provincial formulary program functionaries will then re-review it for the purpose of determining whether or not to place it on their formularies. If a drug is found by CDR to be not 'cost-effective', provinces will simply not even consider it. There are many issues regarding CDR that need to be addressed, including the lack of transparency regarding review criteria, the lack of consumer participation on the review committee, the duplication of reviews by provinces, and the very mandate of CDR, which is to contain costs rather than to ensure that consumers have the most timely access to safe and effective medicines.

Recommendations:

- That the government of Canada immediately engage with selected potential international partners – Australia and certain members of the European Union, for example -- to explore ways to ensure that prescription drug prices are contained while at the same time not restricting access to new medicines.
- That the federal and provincial/territorial governments collaborate in the bulk purchase of prescription drugs through the creation of a national pharmaceuticals purchasing "pool" to leverage their thus-enhanced purchasing power and market share and so keep prices down, enabling reduced costs and improved patient access; we would recommend that, in the bargaining undertaken by any such "pool", due consideration be given to matters such as research and development costs and a reasonable return on investment.
- That consideration be given to adapting the Common Drug Review such that it may be converted into a national formulary system, which would more or less absorb the bulk purchasing "pool" recommended above.
- In the meantime, it is essential that consumers be active participants on the Patent Medicines Prices Review Board and the Common Drug Review committee.
- Altered only insofar as is necessary to render it consistent with the above recommendations, recommendation #37 of the Romanow report should be implemented immediately.
- That a surcharge be placed on every pharmaceutical sale, the proceeds from which should go directly to the United Nations' Global Fund to Fight HIV, Tuberculosis, and Malaria.

Mechanisms for reviewing and controlling prices of all prescription drugs

Canada's ability to regulate and control prescription drug prices, while considerable, is not unlimited. As noted above, Canada's drug market is approximately 2 per cent of the world total, while that of the U.S. is over 50 per cent. Both generic and brand name drugs should be subject to the same pricing review – or purchasing-and-distribution -- system in Canada. This system needs to prohibit what is known as 'drug re-importation' as this practice is limiting access to drugs in Canada.

When manufacturers are concerned that they may not get a Canadian price in line with the U.S. price for a drug, they are beginning to refuse to market drugs here until PMPRB provides a price review, or they are simply deciding not to market it at all in Canada. They are more concerned about the precedent in the U.S. market place than they are about selling drugs in Canada.

So, any solution to the pricing question is going to have to be a North American solution, not merely a Canadian one. Thus, there must be inter-ministerial and interdepartmental cooperation within Canada, and internationally, to negotiate North American pricing regime for drugs that has the effect of insulating the American market from the Canadian one.

Since this is a long-term proposition, in the meantime, the PMPRB mandate should be strengthened by expanding it to include regulation not only of brand name patented drug prices, but also of generic prices, since Canada has very high generic drug prices (assessed in light of the fact that the generic drug industry does not do the R&D done by brand name companies).

Recommendations:

- The pharmaceuticals manufacturing– industry should consult with affected stakeholders as part of its process for PMPRB review.
- The federal Ministry of Health – should expand the PMPRB mandate to include non-prescription and generic drugs.
- All involved parties should collaborate on the creation of a transparent review process that involves relevant stakeholders' input, including that of consumers and third party payers.
- The Ministry of International Trade should continue to appeal WTO and NAFTA rulings that restrict Canada's ability to direct its own healthcare.
- The Government of Canada should reject international trade agreements that limit the Canadian government's ability to adhere to the Canada Health Act, and should work to ensure that all international trade negotiations place human rights (including the right to health) before private property interests, and that all trade agreements expressly state that, in the event of a conflict between government action intended to fulfill its human rights laws (insofar as these are consistent with United Nations standards) and an obligation placed on it by provisions of the trade agreement, its human rights laws will supercede its trade obligations.
- The PMPRB should ensure that, when comparisons within comparator countries are undertaken, they are fair and thorough.
- Health Canada should take the steps necessary to ensure that PMPRB processes are transparent and that the PMPRB is accountable to Canadians.

Mechanisms for approving new drugs and introducing them onto the market, with respect to their therapeutic value, their side effects, their interactions with other drugs, etc., as well as a focus on clinical trials

The prescription drug review and approval process in Canada continues to present challenges in terms of access to treatments. Canada's system lags woefully in comparison to those of other developed countries, and lacks transparency and accountability.

The review and approval of prescription drugs in Canada can take up to 26 months longer than in countries like the United States. Meanwhile, compassionate and expanded access programs for drugs in development are largely at the discretion of industry. Many Canadians, for whom current therapies

have failed or are intolerable, suffer a diminished quality of life and some die before they can access new treatments.

Recommendation 37 of the Royal Commission on the Future of Health Care in Canada calls for the establishment of a new National Drug Agency. The recommendation states, "A new National Drug Agency should be established to evaluate and approve new drugs, provide ongoing evaluation of existing drugs, negotiate and contain drug prices and provide comprehensive, accurate information to health care providers and the public." At present responsibility for many aspects the work of the proposed new agency are divided among various separate regulatory processes and players. While the establishment of such an agency may have the potential to streamline the approval process and better control drug prices, it also raises enormous concerns about such concentrated authority and speaks to the need for transparency and informed citizen's involvement.

Recommendations:

- The Government of Canada should immediately allocate sufficient resources to enable the implementation and maintenance of the recommendations of the Working Group on HIV/AIDS.
- Health Canada should ensure adequate resourcing of its review divisions with individuals having the necessary qualifications and expertise.
- Health Canada should establish and implement mandatory time frames for review performance, and for the quality of review, with appropriate mechanisms for ensuring accountability. In recognition of the variation in the complexity of drug submissions, there is a need for different time frames depending upon the drug class. Time frames should be reduced over time as long as the quality of review is not compromised.
- Health Canada should change policies and structures to allow for rolling submissions and reviews.
- Health Canada should pursue joint reviews with other jurisdictions, where appropriate and consistent with Canadian standards.
- Health Canada should increase transparency of the review process to include access to non-proprietary information about the status of the review and the rationale for any final decision made by Therapeutic Products Directorate including Notice of Non-compliance (NON), Notice of Compliance (NOC), Notice of Compliance with Conditions (NOCC), and Notice of Deficiency (NOD); it should, as well, develop a meaningful system of external communication to increase the transparency of the review process with all stakeholders.
- Health Canada should consider and explore the advisability and feasibility of including other external stakeholder input on the merits of submissions.
- Health Canada should implement current guidelines to ensure that Chemistry and Manufacturing reviews are carried out concurrently with Safety and Efficacy reviews to improve the overall review times.

Monitoring of adverse effects and prescribing practices

Canada requires a comprehensive, active, consumer-centred post approval surveillance system (PASS) linked internationally.

While it is true that idiosyncratic side effects can occur with prescription drugs, over-the-counter drugs and complementary and alternative medications, the gathering, analysis and dissemination of data to all relevant stakeholders provides an opportunity to reduce the likelihood of inappropriate prescribing by physicians and dissemination by pharmacists. This will also ensure that patients who wish to be informed about medications have relevant data upon which to make decisions prior to

starting medication and after starting, should any adverse event occur. Drug interaction information is also very important in this era of polypharmacy.

While a PASS is important for everyone taking medication, it is of particular importance for people taking medications for life threatening and serious debilitating illnesses. These medications are often fast tracked to make them available to people in desperate need as efficiently as possible. Those people are often on multiple medications for which there have been no clinical trials. They are also the least able to tolerate often potent medications. Thus, they require as much information as possible to make difficult and very important treatment decisions.

Recommendations:
Health Canada should

- Develop a Post-Approval Monitoring System (PAMS), which is consumer-centered and includes effective reporting mechanisms from consumers and health care professionals, including anecdotal evidence;
- Ensure, as a critical first step in the implementation of a Post-Approval Monitoring System (PAMS), that the data management system adopted is robust and will accommodate the increased numbers and timeliness needs of the reports;
- Develop a PAMS which meets Canadian needs, paying particular attention to hard-to-serve populations (e.g. Canadian database, develop Canadian strategies for data collection, etc.);
- Develop a system which is open and transparent, and includes an advisory body that consists of a broad spectrum of stakeholders, including consumer representation, that will provide advice on the activities of the Therapeutic Products Directorate's PAMS; further, steps should be taken to ensure the PAMS process itself will respect individual confidentiality;
- Provide an accounting of yearly Drug Information Number (DIN) renewal fees and ensure that an appropriate percentage of these fees is allocated to the PAMS according to original and ongoing agreements;
- Develop and implement a variety of effective strategies for soliciting adverse and other drug reaction information from consumers (local/regional/national), particularly marginalized individuals;
- Develop and implement a variety of effective strategies for soliciting adverse and other drug reaction information from health care professionals (local/regional/national);
- Ensure an effective mechanism to broadly disseminate adverse drug reaction (ADR) information to all stakeholders, such as through the public media, pharmacists, etc.; and,
- Encourage international liaison on drug safety issues.

Direct-To-Consumer Advertising (DTCA)

DTCA results in unnecessary and inappropriate prescription drug use, overstated benefits and/or minimized risk information and increased prescription drug costs. At the same time, it does not result in better health outcomes and does not result in more informed consumers. Prescription drug information should be funded by industry and delivered by a neutral third-party that has no vested interest in any particular product, but rather can provide accurate, balanced and unbiased information including non-drug alternatives.

Since the government of New Zealand banned DTCA, the US is the only country where DTCA is permitted. The problems which led to the New Zealand government's decision have also been very prominent in the US. Investment in prescription drug advertising in the US has surpassed US$2

billion annually in recent years. Earlier this year the European Union voted to uphold its ban on DTCA.

Accurate, balanced and unbiased information is essential for consumers to make informed choices regarding treatments. There is no evidence that DTCA is the best means to achieve this goal, however there is evidence that DTCA can have detrimental effects. DTCA should continue to be banned in Canada, and regulations should be implemented in the short term to ensure a mandatory, transparent and independent review process for the exceptions currently permitted. A mandatory, transparent reporting process for violations, and appropriate sanctions and penalties, are essential to ensure compliance. In the long-term interest of Canadians, measures must be taken to ban completely any form of prescription drug advertising in Canada.

Recommendations:

- That the Government of Canada retain as its long-term goal with respect to DTCA the complete and total banning of prescription drug advertising in Canada.
- That Health Canada ensures the current legislative renewal process it has undertaken address deficiencies in the Food and Drugs Act & Regulations to ensure that DTCA continues to be banned in Canada.
- In the meantime, regulations should be tightened by the Governor-in-Council to provide a mandatory transparent review process for ads currently permitted.
- Health Canada should implement a mandatory, transparent reporting system for violations, with adequate penalties and sanctions.
- Health Canada should spur and oversee the creation of a regime whereby information on prescription drugs be funded by industry and delivered by neutral third parties who have no vested interest in any product or service.