

**CANADIAN TREATMENT ACTION COUNCIL  
(CTAC)**

**POSITION PAPER ON**

**DIRECT TO CONSUMER ADVERTISING (DTCA)**

**OF PRESCRIPTION MEDICATIONS**

**November 30, 1999**

**Canadian Treatment Action Council (CTAC)  
Conseil canadien de surveillance et d'accès aux traitements (CCSAT)**



P.O. Box 116, Stn "F" ◆ Toronto, Ontario M4Y 2L4 ◆ Canada  
Phone and Fax (416) 410-6538 ◆ Email [ctac@ctac.ca](mailto:ctac@ctac.ca) ◆ [www.ctac.ca](http://www.ctac.ca)

## **About the Canadian Treatment Action Council (CTAC)**

CTAC is a national not-for-profit organization dealing specifically with HIV/AIDS treatment advocacy issues. The organization was formed out of a growing need for community advocacy on a broad spectrum of treatment-related issues that impact the health and quality of life of people living with HIV/AIDS. CTAC advocates to ensure the research and development of safe and effective HIV/AIDS treatments, a cure for HIV/AIDS, and equitable, affordable and timely access to all HIV treatments.

### Objectives

The Council has three objectives as follows:

- 1) To provide policy development and advocacy on therapies and treatments for persons living with HIV/AIDS, at both the national and provincial/territorial levels, (as appropriate);
- 2) To provide mentoring and skills building regarding treatment advocacy to persons living with HIV/AIDS, at both the national and provincial/territorial levels; and
- 3) To encourage the exchange of relevant HIV/AIDS treatment advocacy information.

### Organization and Governance

The Council consists of 21 representatives, 19 voting members and 2 non-voting members as follows:

- One from each of the provinces,
- One representative for the three territories (currently vacant),
- One from each of the major PWA driven AIDS organizations (Toronto PWA Foundation, B.C.P.W.A. Society, CPAVIH),
- One from each of two treatment or population-specific organizations (in Quebec - COCQ-Sida and in Ontario - AAN!),
- The Aboriginal population (CAAN),
- A women's representative (currently vacant), and
- The hemophiliac population (CHS)

The Canadian AIDS Society (CAS) and the Community AIDS Treatment Information Exchange (CATIE) have non-voting seats on CTAC. The Board of Directors consists of nine members elected by the Council at the Annual General Meeting.

## About HIV/AIDS

HIV (Human Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). HIV disease is a very complex disease that destroys the body's immune system. The virus replicates by infecting certain immune system cells thereby inhibiting the body's ability to fight other infections. As these immune system cells are depleted, the host is susceptible to a wide range of opportunistic infections (OI's) which are infections that occur, or are worsened, as a result of a weakened immune system. There is no cure for HIV.

Current treatments consist of drug combinations that can be selected from three classes of drugs. The three classes are nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors. As well a number of HIV-specific and non HIV-specific drugs may be prescribed for the prophylaxis and/or treatment of OI's. Research has shown a significant amount of cross-resistance across drugs in each class of anti-HIV drugs.

Serious adverse events, both expected and unexpected, are possible with many of these drugs. When used in multiple drug combinations some of the drugs available interact with each other and dose adjustments to one or more drugs may be required. The presence or absence of food can impact the way the drugs are absorbed by the body. Because of a lack of research, very little is known about interactions with other prescription drugs, over-the-counter drugs, street drugs, complementary therapies such as herbal/natural remedies and aboriginal and other traditional healing practices.

Decisions about when to start or change therapies can be difficult. It requires balancing the need for effective and safe treatment today with choosing combinations that allow for maximization of the treatment options available in the future. DTCA would not reflect the complexity of treatments and the amount of information required to make an informed, unbiased decision.

## Direct to Consumer Advertising

At present, Regulations governing the advertising of prescription drugs fall under the jurisdiction of the Therapeutic Products Program (TPP) of Health Canada, pursuant to the Food and Drugs Act. An amendment to the Act in 1978 limits advertisements to the general public to name, price and quantity. Advertising of all drugs to health care professionals is permitted.<sup>1,2</sup>

In 1996 the Drugs Directorate issued a policy on "The distinction between advertising and other activities."<sup>2</sup> In this policy, if a message is considered non-promotional it is not subject to the provisions of the Food and Drugs Act. Help-seeking ads may be non-promotional and, therefore, permitted where a disease or symptom(s) is mentioned and the patient is asked to call a toll-free (1-800) number for more information or to consult a physician, provided that: no drug name is mentioned; there is no implication that a drug is the sole treatment available for the disease or condition, and no drug manufacturer's name is included. Information given in response to requests from toll-free (1-800) telephone numbers in help-seeking ads is considered non-promotional if: the content is disease-related rather than product-related; the various treatment options (drug and non-drug) and their respective risks and benefits are discussed in an objective manner; no emphasis is placed on one drug product; no reference is made to an unauthorized drug, and no reference is made to the availability of unauthorized drugs through the Emergency Drug Release Program. (Subject to the same requirements are patient support group literature and consumer brochures.)<sup>2</sup>

Responsibility for pre-clearance of advertisements for prescription drugs has been delegated to the Pharmaceutical Advertising Advisory Board (PAAB).<sup>3</sup> Ads are subject to only voluntary pre-clearance and PAAB is the initial avenue of complaint resolution, even for ads that were not originally pre-cleared

by PAAB. Compliance and enforcement of the Regulations remains under the authority of the TPP. Membership in PAAB consists of one ex-officio observer/advisor from the TPP and representatives of the following ten organizations<sup>4</sup>:

Association des médecins de langue français du Canada  
Association of Medical Advertising Agencies  
Canadian Association of Medical Media  
Advertising Standards Canada  
Canadian Drug Manufacturers Association  
Canadian Medical Association  
Canadian Pharmacists Association  
Consumers Association of Canada  
Nonprescription Drug Manufacturers of Canada  
RxD (formerly Pharmaceutical Manufacturers Association of Canada)

### **Canadian Treatment Action Council Position on DTCA**

The Canadian Treatment Action Council firmly believes that health information is for the public good and should not be profit-driven. CTAC fully supports, in principle, the establishment of educational programs, including those funded by industry, and administered by a neutral third party. CTAC does not support any relaxation of the current DTCA Regulations and is strongly opposed to DTCA for medications used to treat HIV/AIDS or associated conditions.

Until the benefits, risks and costs of DTCA are determined, more resources should be put into the provision of consumer-directed objective information. In the meantime tighter controls are required to monitor drug advertisements and enforce the regulations governing them.

### **Issues Considered in the Formation of this Position Paper**

- 1) The scientific evidence with respect to the effects of DTCA on health outcomes.

At present there is no quantified body of scientific evidence on the benefits or risks of DTCA. There is no proof that DTCA has led to improved health outcomes for consumers. If health outcomes do not improve in the presence of DTCA, then its only purpose is to increase industry's profits. Before DTCA can be permitted, independent research must be done to ascertain the risks and benefits.

- 2) The economic evidence with respect to the cost of medications and costs to the health care system.

At present there is no economic evidence on the costs of DTCA. While no evidence exists that the cost of medications has increased as a result of DTCA, the dramatic increase in advertising revenues seen in the United States - \$700 million in 1996 to \$1.2 billion in 1998<sup>5</sup> - gives cause for grave concern with regard to the impact of DTCA on the cost of prescription medications and overall health care.

We can only assume that, ultimately, the price of the drug will be set based on recouping the cost of DTCA, and result in much higher prescription drug prices. The mandate of the TPP must be the health and safety of Canadians, not increased profits to the pharmaceutical industry at the expense and possibly safety of Canadian consumers.

3) The scientific evidence on the effects of DTCA on doctors' prescribing patterns.

Scientific evidence from studies in Canada, the U.S. and other countries indicate that DTCA negatively affects doctors' prescribing patterns. A study by Lipsky and Taylor<sup>6</sup> on "The opinions and experiences of family physicians regarding direct-to-consumer advertising", published in 1997, concluded that "Overall, the study group physicians had negative feelings about DTCA in both print and electronic media." In this study 71% of participants agreed that "DTCA pressures physicians to use drugs that they might not ordinarily use" and the same proportion, 71%, felt that "DTCA was not beneficial".

Doctors are also influenced by patient requests for specific medications<sup>7</sup> and, as a result, can prescribe inappropriately. Dr. Joel Lexchin has written extensively on, and has examined many aspects of, DTCA. In an article titled, "Consequences of direct-to-consumer advertising of prescription drugs"<sup>8</sup>, Dr. Lexchin states that "We know from previously published studies that the more physicians rely on commercial sources of information (information directly from pharmaceutical companies) the less appropriate they are as prescribers." He goes on to say that "This finding has been demonstrated for more than two decades in at least four countries: Belgium, The Netherlands, the United Kingdom and the United States."

A 1999 article in the New York Times by Abigail Zuger<sup>9</sup>, states that "Over the last 20 years, studies have repeatedly shown that doctors who say they rely a great deal on information supplied by pharmaceutical representatives instead of medical journals tend to have more expensive prescribing habits than other doctors, and are somewhat less likely to choose the best drugs for a given job." Since doctors' prescribing habits are negatively affected by advertising, other methods of providing doctors and patients with treatment information need to be explored.

4) Scientific evidence that DTCA will lead to more informed consumers.

Consumers have a fundamental right to information regarding prescription medications. There is no scientific evidence that DTCA will lead to more informed consumers. Prescription drugs, by their very nature, must be administered by a doctor because of safety concerns. DTCA, by definition, is intended to promote a specific product. Information about a cheaper, more efficacious, or less toxic competitor's product, or information on non-drug alternatives does not get included in advertisements.

Balanced, unbiased, objective information is essential for both doctors and patients in decisions regarding prescription medications. DTCA is not an appropriate means of providing this information since it not only informs, it persuades. Advertising is inherently biased in favour of the product being advertised. The health and safety of Canadian consumers must be priority and until there is evidence that consumers' knowledge of medications will improve as a result of DTCA, there should be no relaxation of current Regulations. At question here is not whether consumers have a right to information, but rather what type of information they will receive.

5) The impact of DTCA on doctor/patient relationship.

Studies have shown that the more doctors rely on advertising for information on drugs, the poorer are their prescribing habits.<sup>6, 7, 8, 9, 10</sup> Another conclusion from existing research is that doctors are very likely to prescribe a drug requested by a patient<sup>7</sup>. In a 1988 study of 141 physicians<sup>11</sup>, 110 responded to questions about their prescribing patterns and 51 (46%) cited patient demand as the motivation for their prescribing. "Physicians also frequently attributed their prescribing... to intentional use of placebo effect (24%)."

In a 1999 Canadian study of the "Effects of perceived patient demand on prescribing anti-infective drugs" 260 patient encounters by 20 physicians were analyzed. 124 (48%) were perceived by the family

physician to have expressed or implied a demand for an anti-infective<sup>12</sup>. Where a requested drug is clearly inappropriate, doctors must spend additional time re-educating patients. In busy clinics, doctors may not have the time required for such re-education and this could negatively impact the doctor/patient relationship. Patients who do not get the medication they request from their doctor may change doctors and this would also negatively impact the doctor/patient relationship.

6) The pharmaceutical industry's record on DTCA.

The pharmaceutical industry's record on DTCA is dismal. Marketing currently aimed at physicians and patients is fraught with errors, inaccuracies and omissions which ultimately portray the advertised drug in a more favourable light.<sup>13</sup> The United States Food and Drug Administration (U.S. FDA) continues to face issues such as: lack of fair balance of information e.g., risk/benefit; inadequate communication of indication or efficacy; false and/or misleading information and omission of crucial safety information.<sup>6,13</sup>

Reporter Ross Coulthart of Australia, in an article titled, *The Pharmaceutical Industry Exposed*<sup>14</sup>, presents "an investigation that raises worries about the influence of multi-national drug companies on the body that approves drugs for use in Australia." The report also "raises concerns about the adequacy of current regulatory controls on the advertising of prescription and non-prescription drugs." Even product monographs may contain inaccurate/misleading information, e.g., product monographs may discuss adverse drug reactions but not all possible interactions.

In *Scrip Reports*, 1998, David Gilbert presents a comprehensive review of DTCA. He cites numerous studies, including Canadian studies, of advertising for both prescription and nonprescription drugs, that raise questions about the quality of such advertising<sup>15</sup>. On "Advertising to clinicians", Gilbert says, "It is ...worrying that several studies and reviews highlight inadequacies in the quality of promotional materials that undermine appropriate prescribing." Dr. Lexchin, in a previously cited article<sup>9</sup>, concludes that "There are already problems with the quality of the advertising for nonprescription drugs, and these problems will, in all probability, carry over to DTCA for prescription drugs, even if there is a pre-screening mechanism. Therefore the likely scenario is that consumers will receive misleading information that is difficult to verify through more objective sources."

Given the rise in national spending on prescription drugs in the U.S. - from \$37.7 billion in 1990 to \$78.9 billion in 1997<sup>9</sup> - maintaining market share can be very profitable for drug companies. Barbara Mintzes, in a *Health Action International* article<sup>16</sup>, says that arguments by industry in favour of DTCA, "obscure the fundamental difference between promotion, which aims to sell a product, and the type of information needed to choose how best to treat a health problem. Given the industry's track record on drug promotion to health professionals, and its DTCA track record in the U.S., there is no reason to believe that DTC promotion will lead to any improvement in prescribing or use of medicines. On the contrary, existing evidence points to a likely increase in irrational prescribing and use."

The provision of information on prescription drugs must be based on sound scientific research and not be driven by profits.

7) Effectiveness of the current regulatory system controls.

In 1949 the Food and Drugs Act Regulations completely banned advertising of prescription medicines. In 1978 an amendment to this prohibition, section C.01.044, limits advertising to name, price and quantity.

In Canada, ads are subject to only voluntary pre-clearance by the Pharmaceutical Advertising Advisory Board (PAAB).<sup>1</sup> In its annual report, PAAB reports only the number of complaints and whether those complaints were upheld. In 1998, 11 of 26 complaints were for products on the market less than two

years.<sup>17</sup> Given the pharmaceutical industry's record on DTCA for prescription and nonprescription drugs, voluntary pre-clearance is clearly inadequate.

The PAAB has representation from ten organizations, of which, at least five have a direct financial interest in the production and/or dissemination of advertisements. Pre-clearance by an organization with significant community representation would be preferable. In an abstract titled, "Enforcement of codes governing pharmaceutical promotion: What happens when companies breach advertising guidelines?"<sup>18</sup>, Dr. Joel Lexchin offers some suggestions for improving the current system which include; "proactive ongoing monitoring of a random sample of all promotional activities for violations", a review committee including consumers with a majority of its members from outside the industry and an independent chair, "a wide range of escalating sanctions, up to and including, temporary or permanent suspension of all promotion for the product" and widespread public reporting of all aspects of complaints and violations.

Dr. Martin Shapiro<sup>19</sup> contends that "Lexchin's recommendations make sense only in the hands of an entity that, at the end of the day, is trying to protect the consumer, not increase profits." He states that "regulation will accomplish little unless the manufacturer has something to lose", and suggests penalties for advertising violations could include "a prohibition of the sale of the misrepresented product".

A mandatory, transparent review process for pre-clearance of prescription drug advertising, and a mandatory, transparent reporting system for violations of the Regulations, would address many deficiencies in the current system.

8) The impact of DTCA as it relates to treatments for HIV/AIDS and associated conditions.

HIV disease is very complex and has many variables. Treatment of HIV disease requires multiple-drug combinations. Complex drug regimens and combinations involving synergies, interactions, resistance and cross-resistance can further complicate treatment decisions. Since HIV medications are generally fast-tracked, long-term safety data is unavailable. Information on serious adverse reactions and adverse drug reactions that occur infrequently or after prolonged exposure may not be known.

Information changes daily regarding drugs as a result of clinical trial information and patient reporting, and new drugs are being developed and marketed on an ongoing basis. Because of the complexity of the disease and its treatments DTCA would clearly be inappropriate for medications used to treat HIV/AIDS and associated conditions.

Community organizations have devoted tremendous resources to providing balanced, unbiased information on treatments to persons infected with HIV. Medical decisions must be individually made based on a complex set of factors in collaboration with health care providers. DTCA would have the potential to undo much of the education that has already been done.

9) Responses from other governments and organizations.

In the provinces' response to the 1996 DTCA consultations they reiterated their preference for a continued ban on DTCA because of concerns about potential increases in drug costs<sup>20</sup>. To date there is no new evidence to allay those fears.

The World Health Organization adopted a resolution in 1988 that discourages DTCA for prescription drugs because of concerns about the effects of this activity on the rational use of drugs.<sup>21</sup>

- 10) Other means of providing crucial information to facilitate informed decision-making on prescription medications.

Educational programs, including those sponsored by industry and administered by a neutral third party, can provide concise, balanced and objective information to consumers. Third parties

- (a) have no vested interest in profit,
- (b) assimilate and compare products,
- (c) interpret information,
- (d) contextualize information for individuals (emphasizing the patients right to choose based on full information), and
- (e) involve consumers.

Across many disease groups there are organizations that exist to provide services including the provision of balanced, objective treatment information. The HIV community has a long standing tradition of doing this well. The Community AIDS Treatment Information Exchange (CATIE) and the Canadian Aboriginal AIDS Network (CAAN) are examples of national HIV/AIDS organizations whose clientele includes the same people that industry would target with DTCA.

There are other national organizations and numerous provincial and local organizations that already have some infrastructure in place to address treatment-related issues. Enhancement of current programs and the establishment and implementation of new initiatives would help to ensure that all consumers, including hard-to-reach populations, could access sound information regarding treatments. DTCA has the potential to marginalize the role of community information and advocacy.

Scientific presentations at conferences and publications in peer-reviewed scientific journals have long been respected sources of information on prescription medications. Current Regulations do not exclude such practices.

- 11) Full DTCA currently reaches Canadians from the United States via print, television and the Internet.

While the TPP has jurisdiction over advertising to Canadians that originates in other countries, it would be difficult, if not impossible, to ensure compliance of the Regulations for advertising that originates outside our borders. The current lack of DTCA regulation in the United States has given rise to an increased incidence of information that is inaccurate and/or misleading in that country.<sup>6, 7, 10, 13, 14</sup>

Canadians should not be subjected to increased DTCA merely because Americans are. At present only the United States and New Zealand permit DTCA and it has become apparent that many problems exist. Until the benefits of DTCA to consumers can be established, Canada should remain in the majority of countries that do not permit full DTCA.

- 12) Prescription drugs must be administered by a doctor, so there is a safety valve in place.

Research has shown that doctors frequently relent to patients' requests for specific medications.<sup>11, 12, 13</sup>

Indeed doctors may not be an effective safety valve at all. In an article, published in the Journal of American Medical Association, Alan Holmer<sup>22</sup> reports that in a 1998 national survey in Prevention Magazine, as many as 12.1 million consumers received a prescription drug as a result of a DTC advertisement. In this survey 53 million patients talked to their doctor about a drug as a result of an advertisement, although only 38% sought additional information from another source.

Patients, intent on receiving a particular medication, may switch doctors when their request is refused. In order to ensure that doctors remain the “safety valve” for potentially dangerous medications, such as anti-HIV medications where still much more research is needed in a post-approval situation to ascertain the frequency and severity of adverse events, DTCA must be tightly regulated. Lack of DTCA does not preclude access to information.

### **Conclusion**

The Canadian Treatment Action Council does not support DTCA of prescription medications generally, and is opposed to any advertising of anti-HIV medications or medications for HIV-specific and HIV-non-specific opportunistic infections. For all other drugs the *status quo* should remain, i.e., Advertising of prescription medications is limited to name, price and quantity. To ensure that advertisements are accurate and contain balanced information, they should be subject to mandatory pre-clearance by a consumer-based/consumer-driven organization with a mandatory, transparent reporting system for violations. Adequate penalties and sanctions for violations must be enacted and enforced.

CTAC supports, in principle, the establishment of industry-sponsored education initiatives for anti-HIV drugs, implemented by HIV-community-based information providers. More industry funding is required to ensure that such initiatives are successful.

## References

- 1 Discussion Document. TPP. Direct-to-consumer advertising of prescription drugs; April 6, 1999; 1
- 2 The distinction between advertising and other activities; Policy issues from the drugs directorate; January 12, 1996
- 3 Discussion Document. TPP, Direct-to-consumer advertising of prescription drugs; April 6, 1999; 1-2
- 4 Chepesiuk R. PAAB: The choice for integrated, independent and balanced review of direct -to-consumer advertising (DTCA) of prescription medicines; *Presentation to multi-stakeholder consultations on DTCA, Aylmer, Quebec, April 14, 1999.* 4
- 5 Koerner C. U.S. FDA, *Presentation to multi-stakeholder consultations on DTCA, Aylmer, Quebec, April 14, 1999*
- 6 Lipsky MS & Taylor CA.. The opinions and experiences of family physicians regarding direct-to-consumer advertising. J Fam Prac, Dec., 1997; 45:6, 495, 495-499
- 7 Mansfield PR. How does pharmaceutical company promotion affect prescribing? International Conference on Improving the Use of Medicines, April 1-4,1997
- 8 Lexchin J. Consequences of direct-to-consumer advertising of prescription drugs. Can Fam Phys J; Apr. 1997; 43, 594-596
- 9 Zuger A. Fever Pitch: Getting doctors to prescribe is big business. New York Times, Jan. 11, 1999
- 10 Haayer F. Rational prescribing and sources of information. Soc Sci Med; 1982; 16:2017-23
- 11 Schwartz RK, Soumerai SB, Avorn J. Physician motivations for non-scientific drug prescribing. Soc Sci Med 1989;28(6):577-82
- 12 Miller E. MacKeigan LD. Rosser W. Marshman J. Effects of perceived patient demand on prescribing anti-infective drugs. CMAJ 1999;161:139-42
- 13 Pear R. Drug concerns get FDA reprimands over advertising; New York Times, Mar. 28, 1999
- 14 Coulthart R. The pharmaceutical industry exposed. Business Sunday; ninemsn Pty Ltd. April 19, 1998
- 15 Gilbert D. Direct-to-consumer advertising of prescription medicines; Scrip reports, industry alert; June 29, 1998, PJB Publications Ltd. 3.2.3-3.2.4
- 16 Mintzes, B. Blurring the boundaries, new trends in drug promotion. Health Action International. 1998; 18
- 17 PAAB 1998 Report: Tabled at PAAB AGM, April 9, 1999: 3
- 18 Lexchin J. Enforcement of codes governing pharmaceutical promotion: What happens when companies breach advertising guidelines? Can Med Assoc J; Feb 1, 1997; 156, (3) 351-356

19 Shapiro M. Regulating pharmaceutical advertising: What will work? Can Med Assoc J; Feb 1, 1997; 156 (3) 359-361

20 Discussion Document, TPP, Direct-to-Consumer Advertising of Prescription Drugs; April 6, 1999; 4

21 World Health Organization. Ethical criteria for medicinal drug promotion. Resolution WHA41.17 adopted by the forty-first World Health Assembly, May 13, 1988

22 Holmer AF. Direct-to-consumer advertising builds bridges between patients and physicians. JAMA; Jan. 27, 1999; 281: 4