NB: This document was developed by Legislative Renewal staff as a working document for internal purposes, with a focus on content rather than presentation. It may not be comprehensive or constitute the only information available to Health Canada on issues addressed. However, it is being made available to the public to provide background information.

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EXECUTIVE SUMMARY

The *Food and Drugs Act* substantially prohibits the advertising of prescription drugs to the general public, except to health practitioners. In practice, however, help-seeking messages and reminder messages have exposed the Canadian consumer to some prescription drug "advertising" from Canadian sources. Other sources include the Internet, direct mail and the prescription drug advertising broadcast from the United States which crosses the border. The United States and New Zealand are the only jurisdictions where DTCA of prescription drugs is permitted.

Although there are no Canadian studies which quantify the extent of the effects of DTCA on health care costs, there is a large body of literature which supports the premise that marketing such products creates greater demand. Interested parties are polarized on the issue of whether DTCA should be allowed. Some think that DTCA should be allowed because people should have access to all information and should take part in decision making about their own health. Others believe that DTCA will only increase the burden on the health care system, increase costs, lead to inappropriate prescribing practices, and that consumers can have access to information of better quality through sources other than through advertisements on prescription drugs.

Options to consider include: 1) maintaining the status quo; 2) not imposing any restrictions on advertising; and 3) imposing restrictions on the advertising of health products to consumers by way of regulations. When adopting new regulations, some of the elements to be considered in designing an appropriate scheme could include one or a combination of the various described tools.

1. ISSUE

The purpose of this Issue Paper is to discuss how the advertising of prescription drugs should be controlled.

2. BACKGROUND AND ISSUE ANALYSIS

2.1 The Current Advertising Regulatory Framework Environment

The main provisions governing drug advertising under the current *Food and Drugs Act* and *Regulations* are as follows:

- Section 2 provides that "advertisement includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device".

- Sections 5, 9, 10 and 20 of the Act make it an offence to advertise a food, a drug or a medical device in a deceptive manner.

- Section 3 of the Act prohibits the advertising to the general public of food, drugs, cosmetics or devices as a means to prevent, treat or cure conditions listed in Schedule A to the Act. Schedule A can be amended from time to time by way of regulations. There are 40 diseases currently listed in the schedule, covering a wide range of conditions such as alcoholism, anxiety, appendicitis, asthma, cancer, heart disease, obesity and hernia.

- C.01.044 (1) of the Regulations provides that "where a person advertises to the general public a Schedule F Drug (a prescription drug), the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug".

- Section 14 of the Act prohibits the distribution of a drug as a sample, except in the case of distribution to physicians, dentists, veterinary surgeons or pharmacists.

Advertisement of all drugs to health care professionals is permitted. Voluntary pre-clearance and review activities in relation to this form of advertising for prescription drugs has been delegated to the Pharmaceutical Advertising Advisory Board (PAAB). Voluntary pre-clearance of the advertising of non-prescription drugs to consumers (mainly radio and television ads) has been delegated to Advertising Standards Canada (ASC). Both of these agencies review and clear advertising material, and conduct complaints adjudication. The Therapeutic Products Directorate (TPD) of Health Canada retains ultimate authority for compliance and enforcement in relation to drug advertising, and provides advice and guidance relating to advertising activities to these bodies, as required. The independent agencies are expected to obtain voluntary compliance in the case of some types of advertising violations and where this fails, the issue can be referred to the Therapeutic Products Directorate. Since January 1999, television and radio ads for medical devices have not been subject to any review.

2.1.1 Origin of C.01.044

The Act gives authority to the Governor in Council, in practice a committee of the Cabinet, to make regulations concerning the advertising of drugs. In 1949 a complete prohibition on advertising of prescription drugs to the general public was set out in the *Food and Drugs Act* and *Regulations*. The original purpose of the prohibition on DTCA for prescription drugs was "to protect the purchasing consumer against injury to health and

against deception..."[1] An amendment to this prohibition, section C.01.044 (1), was made in 1978 to limit the advertisement of prescription drugs to the general public to name, price and quantity. This amendment was meant to accommodate price comparisons for consumers, for example in drugstores, but advertising of prescription drugs continued to be otherwise prohibited.

> C.01.044 (1) *Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.*

2.1.2 Distinction Between Advertising and Other Activities

The Therapeutic Products Directorate sets standards for advertising by developing regulations, guidelines and policies. In January 1996 a guideline entitled "The Distinction Between Advertising and Other Activities" (see the Appendix) was issued to help distinguish advertising from other activities which are not advertising. It sets out the Therapeutic Products Directorate's interpretation of when a message is considered advertising, i.e., promotes the sale of a drug, or when it is considered general drug information. The dissemination of information for educative purposes is allowed. Other guidelines on advertising set out the relationship between the Therapeutic Products Directorate, the Pharmaceutical Advertising Advisory Board, and Advertising Standards Canada, and provide broad principles for comparative advertising. The Therapeutic Products Directorate asserts jurisdiction over advertising originating in any country if it is distributed within the boundaries of Canada. However, it has not asserted jurisdiction on advertising originating outside Canada or where all sales and representations are made from a location or agent outside of Canada, e.g., U.S. magazines. This limitation applies to all forms of advertising, including the Internet.

2.1.3 "Help-Seeking" Messages and "Reminder" Ads

"Help-seeking" messages invite consumers to ask their physicians about new, unidentified drug treatments for identified symptoms or disease conditions, e.g. "there are treatments for erectile dysfunction, talk to your doctor". To date, these messages have not been considered advertising but information.

"Reminder" ads which refer to the name of the drug without referring to the intended use are considered to be advertising that does not go beyond C.01.044, i.e. name, price and quantity. If the reminder ad was accompanied by messages (visual or other) that indirectly allude to the intended use, then the advertising would be in violation of C.01.044, because it would go beyond name, price and quantity.

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[1] House of Commons Debates, 1939, Vol.1, page 882 (February 10, 1939)

2.2 The Case For and Against DTCA

Most of the DTCA debate takes the form of arguments and counter arguments rather than being evidence based.

2.2.1 Impact of DTCA on Access to Some Information

Some interested parties argue DTCA does not improve the access to some information because the objective of the drug companies is to sell a product, and that to do this they will show their product in the best possible light, which is incompatible with providing balanced and complete information. This is particularly true with television where the time limitations make it difficult to get balanced information. They also maintain that the vulnerable, who lack knowledge or suffer from a chronic or serious condition, are targeted with emotional rather than essential information and that consumers are provided with too little information to be able to judge whether they really do need a particular drug.

On the other hand, those who think that DTCA improves the access to some information claim that consumers have the right to know about the availability of products, to be able to make informed decisions, and that DTCA helps people seek early diagnosis and treatment.

2.2.2 Impact of DTCA on the Doctor Patient Relationship

Some interested parties contend that DTCA damages the doctor/patient relationship, because as all the relevant information is not conveyed to the patient, significant additional explanation is required from the physician to explain why a particular drug is not suitable for a given situation. It is also reported that some US physicians are concerned that patients lose faith in doctors when DTCA conflicts with professional advice.[2]

But there are those who think DTCA improves the doctor/patient relationship because when patients assist by suggesting treatment, the partnership between the physician and the patient is enhanced.

2.2.3 Impact of DTCA on Medicalisation

Some interested parties maintain that DTCA encourages medicalisation (the tendency for people to think that there is a “pill for any ill” and to seek drug treatment for all conditions) because it makes drugs more acceptable as lifestyle solutions, as opposed to other treatments, such as diet and exercise.

Others claim that DTCA does not encourage medicalisation because there is a prescription barrier, i.e. the patient still needs to get the prescription in order to obtain the drug.

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[2] Steinman, MA, Gifts to physicians in the consumer marketing era, MSJAMA, 284, 2243.

2.2.4 Impact of DTCA on Fiscal Pressures

Some argue that DTCA raises fiscal pressures by increasing the price of drug products and by raising the demand for the new higher-priced drugs (including demand unwarranted by the patient's clinical status). They also allege that there would be an increased number of visits to physicians to get information or to get a prescription for the advertised drug, thereby creating an additional burden on the health care system, particularly if consumers visit a number of physicians until they get the prescription they believe they require.

Those who think DTCA does not raise fiscal pressures claim that most of the advertised drugs are not reimbursed by the health care system, and that the health interventions that result from DTCA can prevent the more expensive services that would otherwise be required. Others maintain this remains to be demonstrated, as it appears the majority of prescription drugs are paid for by public plans.

2.3 Other Issues to Consider

2.3.1 Nature of the advertised product

One concern with DTCA is that prescription drugs are different from other consumer goods in that they have potential harmful effects as well as potential benefits. Many of the conditions requiring prescription medicines are serious, and those with health conditions have an additional vulnerability. DTCA also differ from other forms of advertising in that a person must go to a physician for a prescription. The individual cannot simply go out and buy the product.

2.3.2 Balanced Information

It is generally accepted that information provided should be balanced and that it should not be possible for sponsors to promote the benefits of therapeutic products to consumers without presenting risk information.

The advertising directed to health professionals is frequently unbalanced because of the presentation (risk information in small print and separated from the rest of the advertisement) or because the information is incomplete or even inaccurate, e.g., exaggeration of the benefits.

Balanced information for drug advertising has for a long time been a concern. A 1963 Justice Canada report by the Restrictive Trade Practices Commission concerning the Manufacture, Distribution and Sale of Drugs states: *"In Canada, deceptive advertising is forbidden. Would it not be appropriate to go one step further and prohibit the dissemination of information which, while accurate, is incomplete with regard to side*

effects, contraindications and effectiveness?" [3]

2.3.3 Data on the Effects of DTCA

The report of a research project to assess the potential effects of DTCA of prescription drugs on the Canadian health system was released in February 2002. Some of the outcomes identified in *Health Transition Fund National Research Proposal: An Assessment of the Health System Impacts of Direct to Consumer Advertising of Prescription Medicines*, are as follows:

Regarding the literature review:

- Regulatory violations are frequent in both the United States and New Zealand (the only two jurisdictions where DTCA is currently allowed), and are most often associated with inadequate information regarding risks and exaggeration of benefits.
- There is a strong association between heavily advertised products and cost increases.
- There is no evidence to support DTCA claims of improvements in health outcomes, appropriateness of care, pharmaceutical use, or the doctor/patient relationship.

Regarding the expert survey (questionnaires sent to drug policy experts):

- Most respondents from government, the health professions, and consumer and patient groups believed that DTCA has a negative effect on appropriateness of care, and on public understanding of drug therapy and disease risks. Advertising, media and pharmaceutical industry respondents generally judged the quality and impact of DTCA positively.
- Nearly all respondents believed that DTCA increases spending on prescription drugs and frequency of physician visits.
- Advertising and pharmaceutical industry respondents strongly supported the introduction of DTCA in Canada. There was some support from patient/disease groups, but little support from other sectors.

Regarding the survey of Vancouver and Sacramento patients and physicians:

- In both sites, patients with higher advertising exposure requested more advertised medicines.
- Patients who requested medicines were nearly nine times as likely to receive one or more new prescriptions than other patients.
- Physicians in both cities were more likely to express ambivalence about treatment choices when prescribing a drug a patient had specifically requested.

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[3] Report concerning the manufacture distribution and sale of drugs, Restrictive Trade Practices Commission, Department of Justice, Ottawa, 1963, p. 501.

Regarding the economic analysis:

- DTCA is a relatively new marketing tool which developed in response to increased drug benefit management by third-party payers.
- There is no convincing theory to predict that brand-specific prescription drug advertising will lead to more competitive pricing or health care savings relative to existing disease awareness campaigns.

One of the components of this research project, the review of the literature on DTCA, concluded that knowledge of DTCA's effects on health and on the quality of health care services remains elusive. [4]

2.3.4 The Cross-border Effects of U.S. DTCA

Despite Canada's current laws, regulations and policies with regard to drug advertising, DTCA still reaches Canadians from the United States via print, television and the Internet in increasing volumes. As mentioned above, the Therapeutic Products Directorate has to date asserted jurisdiction over advertising originating in any country if it is distributed within the boundaries of Canada. However, it has not asserted jurisdiction over advertising originating outside Canada and where all sale and representation is made from a location or agent outside of Canada. Internet advertising is essentially un-vetted.

Some interested parties are of the opinion that the best way to counter this cross-border flow of often inaccurate information is to have in place mechanisms to disseminate Canadian-made independent information.

2.3.5 Right to Objective Information and Partners in Decision Making

The popularity and acceptance of self-medication, self-care and alternative health care is continuously increasing, as is the desire of Canadians to take charge of their own health. Increasingly, consumers are partners with health care practitioners in making treatment choices and consumers are seeking objective information about prescription drugs in order to be able to make choices. When people have to make a decision about a prescription drug, they are usually dealing with a serious health condition and with a substance with potential harmful effects. Some interested parties argue that to participate in informed decisions about care, they need full, unbiased, accurate information about the pros and cons of all treatment choices, both drug and non-drug, as well as the option not to treat, where appropriate. They maintain that this type of information can not be expected to be provided by advertising. Many believe that to ensure lack of bias, information providers should have no financial link to product manufacturers or the health industries. Others maintain that the industry has produced examples of unbiased, well-balanced and

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[4] Direct-to-Consumer Advertising of Prescription Drugs: What do we know thus far about its effects on health and health care services?, Literature Review - An Assessment of the Impact of Direct-to-Consumer Advertising (DTCA) on Health and the Health Care System in Canada, Barbara Mintzes, January 31, 2000, p. 63.

complete information.

To date in Canada, some good sources of drug information have been developed for consumers, but these are not readily accessible or even known to all consumers.

A group of interested parties has taken the view that it is paternalistic to ban DTCA because it implies people cannot decide for themselves whether to trust the information they see in ads and it also implies that doctors know best. On the other hand, others have indicated that if physicians are misled by advertising, it is likely that consumers might be misled even more so.

With reference to the argument against paternalism, it is important to note the existence of two well established legal doctrines under Canadian law: (1) the obligation of physicians to obtain their patient's **informed consent** to proposed medical treatment, meaning that physicians have a legal obligation to advise their patients of the alternative treatments available to them and related risks and benefits; and (2) the **learned intermediary** doctrine, which provides that where specialized expertise and knowledge is required to ensure that patients are fully advised of the risks and benefits of products such as therapeutic drugs for which prescriptions are required, it is appropriate that such information be conveyed through physicians.

2.3.6 Health Professionals and Advertising

Studies have demonstrated that the more physicians rely on commercial sources of information (information from pharmaceutical companies) the less appropriate they are as prescribers, in other words, the less likely they are to prescribe the medication of first choice for the condition the patient presents.[5] While physicians can have access to objective guides on pharmacotherapy to verify independently the claims presented in the commercial material, consumers often cannot, and even if they did have access to objective guides on pharmacotherapy, many may not understand these technical documents. If physicians can be misled by prescription drug advertising, it is reasonable to expect that consumers could also be misled to an even greater extent.

2.3.7 Impact of Patient Demand on Prescribing

In addition to the negative impact of drug advertising on physician's prescribing described above, another reason put forward for inappropriate prescribing is perceived patient demand. DTCA is likely to put greater pressure on physicians to prescribe a particular drug. A 1989 study conducted in the United States identified physicians who were mis-prescribing. Among physicians who readily admitted that their prescribing could not be justified on scientific grounds, the most common cited reason for the inappropriate

[5] Joel Lexchin, Consequences of direct-to-consumer advertising of prescription drugs, Canadian Family Physician, April 1997, Vol. 43, pp. 594-596.

prescribing was perceived patient demand.[6] This study suggested that DTCA may be contributing to inappropriate prescribing.

One of the findings of the study funded by Health Canada through the Health Transition Fund and released in February 2002 was that patients who request drugs are much more likely to get prescriptions than patients who don't.[7]

2.3.8 Is it better because it is new?

The most advertised prescription drugs are usually the new ones. But it is not because a drug has just been launched on the market that it necessarily represents the best therapeutic choice. Between 1991 and 1999, 778 new patented drugs were marketed in Canada. Of these, only 54, or 7% were thought to be either breakthrough drugs or substantial improvements over existing treatments. Of the rest, 367, or 47%, were "line extensions", new dosage forms or other modifications of existing products, and 357, or 45%, offered moderate, little or no therapeutic improvement.[8]

Some people also worry about advertising aimed at convincing the public to take recently launched drugs in preference to established therapies. This is especially the case when the new drug's activity is based on new pharmacologic concepts for which the effectiveness outside the context of controlled clinical studies needs to be monitored. The full range of side effects, long-term effects interactions and contraindications of new drugs is less known when they first come on the market. Many serious harmful drug effects occur rarely and they may not all be discovered during the clinical trials. If a new drug is heavily advertised soon after its launch, it may be taken by hundreds of thousands of people in a very short time, which provides less time to react when a problem is identified.

Interested parties have indicated that the use of new drugs has to be approached with caution and that unless new products present major advantages over existing ones, they should not routinely replace standard treatments until extensive experience with the products has been gained and independent assessments are available. For example, the drug Oraflex (benoxaprofen) was approved for marketing in April of 1982 in the U.S. and marketing began in May 1982, accompanied by an unprecedented campaign of DTCA.

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[6] Schwartz RK, Soumerai SB, Avorn J, Physicians motivations for nonscientific drug prescribing, Soc. Sci. Med., 1989; Vol. 28, pp.577-582.

[7] B. Mintzes and all, An Assessment of the Health Impacts of Direct-to-Consumer Advertising of Prescription Medicines (DTCA), Centre for Health Services and Policy Research, University of British Columbia, February 2002.

[8] Patented Medicines Pricing Review Board, Annual Reports, http://www.pmprb-cepmb.gc.ca/english/06_e/06pub_e.htm#Annual Report

As a result of this campaign, within a month or two, half-a-million people had received the drug. Many of these people received Oraflex inappropriately and suffered serious side effects. Had a more cautious approach to prescribing this medication been taken, something that might have occurred without DTCA, many patients might have been able to avoid these side effects. Within five months of its marketing, Oraflex was withdrawn from the market because of severe adverse reactions and reported deaths. [9]

Interested parties have suggested that a way to circumvent this problem would be to allow advertising of prescription drugs to consumers only after formal post marketing studies to define risks have been completed, or after a certain period of time has elapsed, e.g., five years. A strengthened post-market surveillance system to ensure that the safety and effectiveness of products are properly monitored after they have been approved for sale would also serve that purpose.

2.3.9 Independence of Third Parties

The members of the Pharmaceutical Advertising Advisory Board (PAAB), a body which reviews the prescription drug advertising material intended for health professionals, is composed of representatives from the Canadian Medical Association, the Canadian Pharmacists Association, the Consumers Association of Canada, the pharmaceutical industry, advertisers, and Health Canada as ex-officio. Some interested parties are of the opinion that the presence on the Board of pharmaceutical companies and advertisers creates a fundamental conflict of interest and that the Pharmaceutical Advertising Advisory Board has an arm's length relationship to government, but not to Industry. They say that fines are not sufficient and that the pre-clearance of drug advertising is based on low standards. Examples of ads that were approved by the Pharmaceutical Advertising Advisory Board but that were considered misleading with respect to safety and efficacy were described in submissions that were received during the 1998 Legislative Renewal consultations.

Interested parties have expressed concern with the current voluntary pre-clearance mechanism for advertising to health professionals and also with the information and advertising materials directed at consumers. They were also concerned with the lack of a transparent compliance and enforcement mechanism. The Pharmaceutical Advertising Advisory Board has started publishing violations quarterly, though fines are not disclosed.

Third party agencies such as the Pharmaceutical Advertising Advisory Board are viewed by many as not being independent from Industry. Although pre-clearance is seen as a positive feature, they argue if it is based on weak standards and if fines for violations of code standards are not large enough to be a strong disincentive, self-regulation will not

[9] Direct To Consumer Advertising - Impact on Patient Attitudes and Behaviour and Doctor's Responses, Therapeutic Products Programme.

work.

2.3.10 Compliance and Enforcement

In the United States there is no mandatory pre-clearance of drug advertising, but the capabilities in terms of the monitoring and enforcement are stronger than they are currently in Canada. However, the effectiveness of the U.S. system was recently criticized by the U.S. General Accounting Office. Many interested parties believe that since healthcare is recognized as a public responsibility in Canada, the government in this country has an even higher interest in ensuring that the advertising of medicines is appropriate. This leads to the best possible use of health care resources, and contributes to the best overall health outcome for Canadians. Many supported the view that Health Canada should pre-clear the promotional material for all drugs, or that there be no representatives from industry on the boards of third party agencies involved in the pre-clearance of drug ads.

Another point raised is that while professional advertising of prescription drugs is pre-cleared on a voluntary basis by the Pharmaceutical Advertising Advisory Board, there is no body responsible for reviewing the information/ promotional material on prescription drugs that is currently directed at the consumers.

2.3.11 Advertising vs Information

In order to determine the applicability of the advertising provisions of the Act and Regulations, it must be determined whether or not a particular message constitutes advertising. The current definition of "advertisement" in the *Food and Drugs Act* reads as follows:

> *"advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device*."

It has proven difficult to draw the line between advertising and information. Advertisers are resourceful and are quite successful in designing an increasing number of "information" products that, arguably, are promotional in nature. Interested parties have maintained that a definition of advertising that would differentiate advertising from information would be helpful.

2.3.12 Different Legislative Environment

When DTCA is discussed, it is usually within the context of the current legislative reality with its inherent limitations, i.e., low penalties for deception violations; deception violations that are subjective rather than objective, thus leading to interpretation problems, etc. It is difficult when trying to imagine a new framework regarding the advertising of health products, to avoid referring to the current legislative framework, where the disincentives to comply with the regulatory requirements are almost nonexistent and where the potential for prosecution and the levels of penalties are so low that they become an insignificant "cost of

doing business".

A reformed legislative package would need to include higher penalties and stronger deception prohibitions (requirement for supporting data, onus on the supplier to demonstrate the claim of the product, prohibition to publish an ad when advised that it violates the Act, etc.) than what is currently the case. Otherwise, any regime would be of minimal value in the real world.

2.3.13 Products Which Should Not Be Advertised

Among the defenders of DTCA, some believe that there are classes of drugs that should not be advertised directly to the public because they present particular factors of risks. For example, products which may contribute to the development of resistant strains of microorganisms, innovative products which should be the object of strict post-market surveillance before they become more widely used and products which have the potential to create dependency or to be used for non-medical purposes require particular caution in the marketplace.

2.3.14 Controlled Drugs, Narcotics, Restricted Drugs and Benzodiazepines

It is generally agreed even among supporters of DTCA that products that are addictive should not be advertised to the general public. All drugs that are potentially addictive are currently in Schedule F (can only be obtained with a medical prescription), and therefore cannot be advertised under C.01.044. But if C.01.044 was eliminated, there still needs to be a prohibition somewhere to prevent the advertising of these products to the general public.

G.01.007 of the *Controlled Drugs and Substances Regulations* prohibits the advertising of a controlled drug to the general public. G.01.007 is not actually in the text of the *Controlled Drugs and Substances Regulations*, but it is technically part of it. The reason for this is that the authority for Part G of the *Food and Drug Regulations* originally derived from Part III of the *Food and Drugs Act*. When the *Controlled Drugs and Substances Act* was promulgated, Part III of the *Food and Drugs Act* was abrogated, and Part G of the *Food and Drug Regulations* then derived its authority from the *Controlled Drugs and Substances Act*.

Section 70 of the *Narcotic Control Regulations* prohibits the advertising of a narcotic to the general public.

Since restricted drugs are not available or sold to the general public, a specific prohibition on advertising appears to be unnecessary. Should anyone advertise a restricted drug (or other controlled drug/substance for that matter) this individual may be charged with trafficking, which includes "sell", defined in the *Controlled Drugs and Substances Act* as ".....includes offer for sale....".

Section 3(a) of new *Benzodiazepines and other Targeted Substances Regulations* also prohibits advertising to the general public.

Therefore, advertising to the general public is prohibited for drugs or substances regulated under the *Controlled Drugs and Substances Act*, i.e., controlled drugs, narcotics, restricted drugs and benzodiazepines.

2.3.15 Advertising Directed to Health Professionals

As discussed above, the Pharmaceutical Advertising Advisory Board (PAAB) reviews the prescription drug advertising submitted by manufacturers on a voluntary basis prior its to dissemination to health professionals. Standards for the Pharmaceutical Advertising Advisory Board are set out in the PAAB Code which conforms with the relevant requirements of the Act and Regulations and various applicable guidelines of the Therapeutic Products Directorate. Some have argued that binding regulatory standards should also apply to the advertising of health products to health professionals to ensure that the information they are provided is not unduly biased.

2.3.16 Health Practitioner Oriented Promotion

Concerns have also been raised with regard to certain practices such as the sponsorship by manufacturers of various conferences, social events, and continuing education events for practitioners.

Pharmaceutical associations, health practitioners associations and some provincial licensing bodies have guidelines regarding the relationship between health professionals and the pharmaceutical industry.

For example, Rx&D, an association representing Canada's Research-Based Pharmaceutical Companies has a detailed guideline entitled "Code of Marketing Practices" which can be found at http://www.canadapharma.org/Industry_Publications/Code/. This Code describes principles that member companies must follow with respect to marketing practices, continuing health education programs, relationships with physicians and other activities.

Rx&D's newsletter, Rx&D Update, published quarterly, reports on the infractions to the Code. It can be found at http://www.canadapharma.org/Industry_Publications/RxD_Update/. The penalties for infractions are set out in the Code.

The Canadian Medical Association also has a policy on the subject entitled "Physicians and the Pharmaceutical Industry which can be found at http://www.cma.ca/staticContent/HTML/N0/l2/where_we_stand/physicians_and_the_pharmaceutical_industry.pdf.

The Canadian Pharmacists Association has a Guideline on the Ethics of Relationships Between Pharmacists and Pharmaceutical Manufacturers which can be found at http://www.pharmacists.ca/content/about_cpha/who_we_are/policy_position/guidelines.cfm

The College of Family Physicians of Canada refers to the Canadian Medical Association Code of Ethics: http://www.cma.ca/cma/common/displayPage.do?pageId=/staticContent/HTML/N0/l2/where_we_stand/1996/10-15.htm and to the Rx&D Code of Marketing Practices.

Most provincial licensing bodies either refer to the CMA or the Rx&D codes, or have their own policy. These policies are not always consistent with one another. In addition, some of these codes or guidelines are broad and often leave room for interpretation. Adherence to the Code of Marketing Practices is voluntary, and the penalties for infractions could be considered insufficient. In addition, the extent to which possible violating situations are reported is not known. A code of conduct established in the regulations could help prevent inappropriate promotional activities from occurring while allowing for legitimate education activities to take place.

2.3.17 The Approach to Drug Advertising Is Not Consistent

The Regulations do not treat all products the same with regard to advertising. They limit consumer-directed advertising of prescription pharmaceutical drugs (Schedule F drugs) to name, price and quantity. By contrast, those biological and radiopharmaceutical drugs (Schedule C and D) which are not designated as prescription-only but are generally prescribed treatments are not subject to the same advertising restriction. For example, a vaccine to prevent the flu can be advertised, while an antiviral prescription drug to treat the flu cannot. Although it might be argued that the need to control the advertising of radiopharmaceuticals and biologics is not an issue at the moment, it is felt that in the new legislative framework, the control of advertising of drug products that present a similar degree of risk should be equivalent.

2.3.18 Injectable Preparations of Vitamins and Minerals

When the daily dose of vitamins exceeds a certain level prescribed in the regulations, or when a product contains certain minerals, the label has to carry a cautionary statement that the drug is ”for therapeutic use only”. The advertising of products carrying this cautionary statement is limited to name, price and quantity, just like for prescription drugs. Although these products are not prescription drugs, the advertising restriction imposed on them by regulation is similar to that of prescription drugs. However, this advertising restriction does not apply to injectable drugs. For example, a “For Therapeutic Use Only” vitamin and mineral oral preparation would not be allowed to be advertised beyond name, price and quantity, while the same preparation, in its injectable version could be advertised freely. This is an anomaly that should be corrected.

2.4 Consultations

2.4.1 Therapeutic Products Directorate Consultations

The Therapeutic Products Directorate initiated a regulatory review process in 1996 to address the issue of DTCA. A multi-stakeholder consultation workshop was held in June 1996, with representatives from the provinces, health practitioners, academia, the pharmaceutical industry, private insurers, consumer advocacy groups, professional associations and the media sector.

The first task for participants at the 1996 workshop was to provide their advice and opinions on the objective for DTCA. Their comments were compiled into the following guiding principles. It should be noted that these principles go beyond advertising in that they also apply to the provision of drug information in general:

1996 Guiding Principles:

- Ensuring consumer safety: information should be evidence-based and balanced with respect to risks and benefits.
- Assisting consumers in making informed choices: information must include a discussion of the disease to be treated, and alternate drug and non-drug therapies.
- Respecting the health care practitioner: information must support and enhance the consumer-practitioner relationship.
- Addressing health care costs: information policies should strive to optimize drug therapy and should not result in increased health care costs.
- Ensuring accountability: information policies should be assessed by measuring their impact in terms of improved health outcomes.
- Acknowledging the Canadian environment: information policies may consider international practices, but they must be made in Canada.

In response to the outcomes from that workshop, the provinces requested an opportunity to study DTCA from their perspective as administrators of the Canadian health care system. A major concern was the possibility of increased inappropriate demand with subsequent direct and indirect cost consequences. The Federal/ Provincial/ Territories (FTP) Task Force on utilization reviewed the matter in course of its ongoing research during 1997 and 1998. The provinces reiterated their preference for a continued ban on DTCA for prescription drugs.

The next phase of the consultative process commenced in the fall of 1998 when the Therapeutic Products Directorate brought together a small group of interested parties to look at the DTCA issue in terms of the spectrum of available policy options and to assist the Therapeutic Products Directorate in the design of a multi-stakeholder consultation workshop.

The last Therapeutic Products Directorate workshop on DTCA was held in April 1999.

Stakeholder opinions have been and continue to be divided on the issue. Some groups have called for a complete ban on drug advertising while others call for a removal of the current restrictions. Others believe some DTCA can be allowed but only if there is significant government scrutiny of the activity.

2.4.2 National Forum on Health

The National Forum on Health recommended against DTCA, although few if any consultations were held on this topic, and the Forum report contains no explanation to support its decision.

2.4.3 Legislative Renewal National Consultations

The Legislative Renewal Secretariat held a first round of national public consultations during the Fall of 1998. The following reflects what was heard regarding DTCA during these consultations:

- *Self-regulation of drug promotion does not work. We should not be talking about deregulating further in Canada. We should be talking about what kind of changes we could make to our current system to bring regulation of drug promotion in line with health priorities.*
- *Advertising of prescription drugs would drive up their cost.*
- *Advertising of prescription drugs should be allowed on the basis of people's right to know.*
- *DTCA of prescription drugs should not be allowed, given the lack of evidence of health benefits and the serious potential for harm.*
- *Existing prohibitions on direct to consumer marketing must be maintained and strengthened.*
- *Regulation of drug promotion is a public responsibility and should not be left to industry self-regulation. It should be carried out directly by Health Canada or by a legislated independent body, at arm's length from both the pharmaceutical and advertising industries, with the legislative authority to actively monitor and enforce compliance, including sanctions and corrective actions, and with full procedures in place for public reporting and for transparency and accountability of decision-making.*
- *DTCA is unlikely to be the same in Canada as it has been in the U.S.. Given our lack of adequate regulation, it will probably be worse. Deregulation of drug promotion should not be disguised as an educational initiative.*
- *Consumers are sophisticated enough to benefit from advertised information without being unduly influenced by it.*
- *Legislation should not restrict DTCA. If government feels it needs to restrict or control marketing activities, it can put in place guidelines and policies designed to clearly delineate permissible and non-permissible activities. Policies for*

nonprescription drug advertising and prescription drug advertising should be separate, recognizing the inherent differences of products deemed suitable for self-treatment.

- *DTCA of prescription drugs could have implications to the cost of the Canadian health care system. It could result in an increase in the use of prescription medications and unnecessary visits to the doctor's office. This could, in turn, lead to increased costs to the provincial government for health care. Awareness of these potentials is a provincial matter. The role of the federal government is to ensure in the legislation that advertising is truthful, not misleading nor deceptive and does not make unfair comparisons with other products.*
- *Yes, there should be restrictions on advertising of prescription drugs to the general public. It is not possible for one drug company to list all the information necessary to make a valid decision for the treatment of a serious disease or condition and do you think they will also list the competitors product for that condition? Certainly not.*
- *Group agreed that there should be no consumer advertising of prescription drugs.*
- *No promotion of prescription drugs, but clinical information should be included with prepackaged prescription drugs, as it is done in most European countries. This would reduce the chance of misunderstanding along the way from the physician to the consumer.*
- *As you know, the Act in its current form fails to address access to new technologies such as the Internet or constantly expanding foreign (primarily American) advertising. It is also clear that Canadians should be protected from unregulated, potentially inaccurate information.*
- *The issue of advertising was discussed and it was agreed that there would be criteria established for advertising of products as a function of their prescription/nonprescription status, which again, would most likely be closely linked to the claim a product was making.*
- *The information rights of users of medicines are inadequately addressed by current legislation in Canada. Unlike Europe and Australia, Canada has no legally mandated patient leaflets accompanying prescription drugs. Such provisions could minimally ensure that users of medicines have access to information in lay language on approved uses, warnings, risks, interactions, contraindications etc. for each medicine they take. This is especially crucial for pregnant and breast-feeding women and women facing multiple medicine use because of chronic illness.*
- *The Canadian public has inadequate information on the safety and effectiveness of new drugs, because Health Canada considers all studies of a drug's safety and effectiveness which are submitted as part of an application for a marketing license to be proprietary information belonging to the manufacturer. Typically,*

most are unpublished studies. Sometimes as little as 1% of the information on a newly approved drug is public.

2.5 International Comparison

2.5.1 United States

The advertising of prescription drugs to the general public has never been prohibited in the United States, however, the requirements for the information to be communicated were such that print ads were possible, but broadcast ads presented more difficulties. In August, 1997, the Food and Drug Administration (USFDA) issued a draft guidance document to relax some of these requirements, thereby facilitating DTCA on television. The USFDA recently announced plans to evaluate this new policy by conducting a consumer impact survey. Preliminary survey results can be found at http://www.fda.gov/cder/ddmac/dtctitle.htm.

DTCA originating in the United States is freely transmitted via print and television into Canada. Also, extensive, unregulated DTCA occurs via the Internet.

It is interesting to note that most American health care professionals and major payers for drugs surveyed in 1991 did not support the more relaxed regulatory regime that was instituted in 1997. A more recent consumer survey showed that the general public welcomes access to more prescription drug information.

DTCA expenditures in the United States for prescription drugs were about $90 million in 1990. (Marketing News) That figure had exceeded $200 million by 1994. By 1996 U.S. marketing expenditures on DTCA, including television and print ads, totaled $791 million. In 1998, for the first time, the amount spent on television advertising ($664 million) exceeded the amount spent on print advertising ($652 million) for a total of over $1.3 billion. In 2000, the amount spent on DTCA was almost $2.5 billion. In spite of the increase, it has to be kept in mind that DTCA expenditures account for only 15% of the money spent on drug promotion, the rest being spent on drug samples (50%), office-based promotion (25%), medical journal advertising (5%), and hospital based promotion (less than 5%). Some consider the guidelines issued in 1997 by the USFDA responsible for the increased in DTCA. However, the initial surge in DTCA preceded the USFDA guidelines, and therefore, they might not have been the most important factor for the overall increase[10]

In the United States, there is no pre-clearance of prescription drug advertising, except for accelerated approval products. However, companies can discuss proposed promotional

[10] Rosenthal, Meredith B. and all, Promotion of Prescription Drugs to Consumers, New England Journal of Medicine, Vol.346, No. 7, February 14, 2002, p. 498-505.

material for prescription drugs with the Division of Drug Marketing, Advertising and Communication (DDMAC) prior to a new drug application, at launch of the product and after it has been marketed. The USFDA does not have time to review all promotional material, so they rely heavily on competitor's complaints and encourage health professional complaints. Although there is no mandatory pre-clearance of drug advertising in the United States, they have strong monitoring and enforcement capabilities. Nevertheless, and as mentioned above, the U.S. General Accounting Office has been critical of the U.S. regime.

The advertising for prescription drugs and veterinary drugs is regulated by the FDA, while the advertising for over- the-counter drugs and dietary supplements is regulated by the Federal Trade Commission.

2.5.2 European Union

DTCA is not allowed in any of the European Union (EU) Member States. While demand for more consumer-oriented information in the EU has not resulted in loosening of restriction on prescription drug advertising, there has been a call for the formation of a Working Group within the European Commission to study this issue. Of particular concern in the EU is the Internet; a research study has been conducted for the EU market to provide information for the development of policies with respect to the market and sale of medicines on the Internet and other information technologies.[11]

In 2001, the European Commission proposed changes to the pharmaceutical legislation to allow a 5 year "pilot project" permitting the advertising of prescription drugs for three health conditions: AIDS, asthma and diabetes. In October 2002, the European Parliament overwhelmingly rejected the Commission's proposal. On June 2, 2003, the EU Health Ministers also rejected the Commission's proposal. The European Parliament's Committee on Environment, Public Health and Consumer Policy called on the Commission to outline a comprehensive consumer/patient information strategy ensuring good quality, objective, reliable and non-promotional information about medicines and other treatments.

2.5.3 Other Countries

The only country other than the U.S.A. that allows DTCA for prescription drugs is New Zealand. The laws that govern DTCA there include: the *Commerce Act*, the *Fair Trading Act*, the *Consumer Guarantees Act*, and the *Medicines Act and Regulations*. In addition, the Advertising Standards Authority Code for Therapeutic Advertising is the principal check on medicine advertising to the public in New Zealand.

Public consultations on the discussion paper "DTCA of Prescription Medicines in New Zealand" were held between November 2000 and February 2001. It was later announced

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[11] Impact of Electronic Commerce on the EU Drug Sector, Ashurst, Morris Crisp, 1998.

that DTCA would continue to be allowed, but with tighter rules.

In April 2003, the New Zealand Medical Association announced that it was calling on the government to prohibit DTCA of prescription medicines in New Zealand:*"We no longer have confidence that self-regulation is sufficient to protect the interests of either patients or doctors, nor do we feel that greater government regulation would provide adequate protection. We have therefore come to the conclusion that DTCA of prescription medicines should be prohibited."* [12]

It is interesting to note that in Denmark, the advertising of over the counter medicines on television is forbidden, and in Ireland, not all classes of non-prescription drugs can be advertised.

With the aim of operating in numerous countries, Healthy Skepticism formerly the Medical Lobby for Appropriate Marketing (MaLAM) was established in 1983. Healthy Skepticism is an international non-profit organization for health professionals which aims to defend appropriate compassionate scientific medical care from marketing practices which may be detrimental to health. Initially Healthy Skepticism concentrated on misleading promotion in developing countries where the consequences may be worse because of a lack of regulatory controls and independent information. Healthy Skepticism has continued this work and expanded it to include inappropriate promotion from any country. More information can be found at: www.healthyskepticism.org

2.6 World Health Organization

The World Health Organization, convinced that observance of ethical criteria for medicinal drug promotion by all parties concerned will contribute to a more rational use of drugs, has adopted a policy that discourages the practice of DTCA for prescription drugs. Most other countries in the world continue to limit the audience for advertising of prescription drugs to health professionals

3. OPTION ANALYSIS

The opinions of interested parties have been and continue to be divided on the issue of DTCA. Some groups have called for a complete ban on drug advertising while others favour a removal of the current restrictions. Others believe some DTCA can be allowed but only if there is significant government scrutiny of the activity.

Depending on how one looks at it, the current regime may appear to be very restrictive or very permissive. For example:

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[12] http://www.scoop.co.nz/mason/stories/GE0304/S00011.htm

- The definition of "advertisement" is very broad. On the other hand, it does not clearly draw the line between what constitutes promotion for sale and what is the communication of information for educational, professional or scientific purposes. For example, "help-seeking" messages inviting consumers to ask their doctors about new drug treatments for a given condition, is not currently treated as advertising, as long as there is no emphasis on a specific product.

- C.01.044 (1) of the Regulations appears at first glance to constitute a total ban on the advertising of prescription drugs but the exception regarding "name, price and quantity" allows, for example, the promotion of a product by its name, provided that the condition it is supposed to treat is not explicitly mentioned, and without any obligation being imposed on the manufacturer to indicate possible side effects and other information of that nature.

- Add to this the fact that almost all of these provisions were adopted before the development of television and internet and are not well adapted to deal with modern reality and one can understand why there is frustration on the part of some about the current situation. However, the reasons for this frustration can vary greatly from one person to the next:

    - Many people feel that the primary purpose of drug advertising is to increase sales rather than to serve public health, and consequently there is a significant risk that the public will be manipulated. They consider that advertising does not constitute a reliable source of information and can contribute to inappropriate prescribing, over-consumption of therapeutic products and rising health care costs. They would want to see a more stringent regime to govern drug advertising.

    - Others consider that consumers should not be deprived from having access to information which could help them make better informed decisions concerning their own health, particularly if proper safeguards are put in place to prevent misleading or unbalanced advertising.

First, to address the issue of the broad definition of advertisement that does not clearly draw the line between what constitutes promotion for sale and the communication of information for educational, professional or scientific purposes, "promote" could be defined to mean:

- to make a representation, by any means, whether direct or indirect;
- that is intended, or is likely to, influence and shape attitudes, beliefs and behaviours so as to further the marketing of a product or activity;
- given the general context in which the representation is made;
- but would not include the expression of an opinion or a scientific,

> educational, or artistic work, production or performance, by a person who does not stand to gain a financial benefit from the promotion or marketing of the product or activity, or for a purpose other than to further directly or indirectly the marketing of a product or activity.

It is believed that the proposed new definition would allow a better control over advertising activities conducted by people who may have a financial interest in overstating the value of a product (e.g. producer or distributor), while not restricting the free flow of information when in the best interest of public health, e.g. information provided by patient groups to their members or discussions within the health scientific community. This new definition would be used with any of the following options regarding DTCA.

> *During the consultations, interested parties will be asked whether the proposed Act should include special provisions to control the promotion of products that takes place on the Internet. If so, what should these provisions be? Is it realistic to attempt to control the information that circulates on Internet? Should governments rather focus on public education as to the risk of relying on information obtained on the net? What about the advertising which takes place on American television and is picked up in Canada?*

3.1 Option 1: Status Quo: Prohibit Advertising for Prescription Drugs, Allow Name/ Price/ Quantity.

Many respondents were in favor of this option at the Therapeutic Products Directorate workshop held in April 1999.

Pros:

- Status quo considered as a prudent alternative in the absence of data on the consequences.

Cons:

- Prevents access to information for consumers.
- Current advertising practices have been developed to circumvent the Regulations.
- Difficult to enforce re: cross border effects.
- Consumers are already bombarded by DTCA from the United States television, print and also from the Internet.

3.2 Option 2: Not Impose Any Restriction on the Advertising of Health Products

With this option, there would be no restrictions on the advertising of health products except for the provisions of the Act dealing with deception and the advertising of Schedule A diseases. (See other Issue Papers on Deception and Schedule A.)

Pros:

- Allows the advertising of some prescription drugs.
- Limitation in Schedule A.
- Controls to prevent deception.

Cons:

- Potential for biased information.
- Potentially increased health care costs.
- Potential adverse effects.

3.3 Option 3: Allow for the Advertising of Health Products but Establish General Criteria

Aside from the discussion on Schedule A (see Issue Paper on Schedule A), the proposed Act would provide that restrictions could be imposed on the advertising of health products to consumers, by way of regulations. When adopting new regulations, some of the tools or elements to be considered in designing an appropriate scheme could include one or a combination of the following tools:

Tool 1 <u>Prohibiting the promotion of prescription health products</u>

The regulations could prohibit the promotion of prescription health products to any member of the general public.

> *Many people feel that the primary purpose of drug advertising is to increase sales, instead of serving public health and consequently there is a significant risk that the public will be manipulated. They consider that advertising does not constitute a reliable source of information and can contribute to inappropriate prescribing, over-consumption of therapeutic products and raising health care costs.*
>
> *In this scenario, should the exception allowing suppliers to advertise the name price and quantity of a product (without any other representation) be maintained?*
>
> *Should "help seeking" messages inviting consumers to ask their doctors about new health products for a given condition (without emphasis on a specific product) be permitted?*
>
> *Is it appropriate to maintain the distinction between over-the-counter and prescription health products in this regard?*
>
> *Regardless of whether the distinction is maintained, would it be appropriate to have special rules for those products that pose a particular risk, e.g. products*

which may contribute to the development of resistant strains of micro-organisms, or innovative new health products after they are first marketed to allow for the collection and evaluation of data about how they perform outside the context of controlled clinical studies before they become more widely used?

Tool 2 Dissemination of consumer health product information

Health Canada would focus its efforts on ensuring that the public has easier access to objective information regarding health products and other means of treatment.

This could be done for example, by posting product monographs and other information regarding health products on the web.

In the same vein, in Australia, government funding is provided to the National Prescribing Service (NPS), an independent body composed of organizations representing health professionals, consumer and research bodies, government, the healthcare and pharmaceutical industries. Among other things, NPS offers a national telephone service where a consumer can call to obtain balanced information on medicines. For more information, you can go to: http://www.nps.org.au/main.html.

Tool 3 Controlling the content of the promotion

In situations where the promotion of a health product is allowed, the regulations could establish principles to help prevent the public from being misled, such as:

- The representations must not directly or indirectly include claims which go beyond the conditions of Health Canada's pre-market approval (assuming a pre-market approval was required).
- Information provided to the consumer must be based on valid data.
- The representations must be balanced. They must not directly or indirectly exaggerate the benefits of or the need for the product and the risks attached to its use must be fairly stated.
- Statements as to the risks and advantages of the product must be expressed, be it text or statistics, in such a way that the targeted audience can reasonably be expected to truly understand them.

E.g. they should be expressed in plain language and statistics should be stated in absolute as opposed to relative numbers.

- Any comparison between health products must comply with guidelines developed by Health Canada.

  Should such representations be allowed at all?

- The consumer must be informed of the existence of alternative treatments and the representations made must not directly or indirectly exaggerate the relative advantages of using the product when compared with other available therapies.

  Is it realistic to expect the supplier to inform the consumer of alternative treatments, particularly considering the time and space limitations in certain circumstances? Would it be sufficient to inform the consumer as to where such information is available?

- The consumer must be reminded that the treating physician is well positioned to determine whether another form of treatment would be more appropriate in the circumstances.

- The representations must not directly or indirectly encourage the consumer to self-diagnose or self-treat where failure to do so correctly could cause important bodily harm or death particularly if not diagnosed, treated or monitored in due time by a qualified health practitioner.

- As determined more specifically in the regulations, certain information must be included in the promotion (e.g. company or organization paying directly or indirectly for the advertisement) while some other information must be excluded (e.g. comparative statements with specific competing products).

- The product monograph (including a summary drafted in plain language) must be made readily available to the public.

  This would allow any member of the public to get complete information on the conditions of use of the product and its adverse side effects.

- The potential adverse health effects caused by the product must be monitored on an ongoing basis and information provided to the public must be adjusted accordingly.

This is consistent with the responsibilities of the manufacturer, as described in the section on Supply Chain.

- Each advertisement must include a "drug facts box", that provides a limited amount of key information in a format pre-determined by Health Canada.

  For example, this standardized synopsis could indicate which patients would benefit from the drug; the expected outcome in the short, medium and long term; the chance of achieving the same outcome without the drug; the side effects listed by frequency and severity; and the contraindications.

  For any promotion activity of health products by a manufacturer, should consideration be given to establishing a licencing system, whereby only those holding a licence would be authorized to promote a health product, and where that licence could be restricted, suspended or removed, if circumstances warrant?

Tool 4 Pre-clearance

The regulations could require that any proposed promotion of a health product be subject to pre-clearance by Health Canada or by a body other than Health Canada, in accordance with Health Canada's directives and regulations.

This could be administered in many different ways. For example, it could be that no promotion can take place unless it has been expressly authorized by the Department. Another way to proceed would be to require that Health Canada be notified beforehand of any new proposed promotion and the Department would have so many days to object.

If a separate body were to perform the pre-clearance function:

- *Should the Minister determine what organization(s) will be entitled to pre-clear promotional activities or should the accreditation of such organizations come from the Standards Council of Canada (SCC)?*

- *(SCC) is a federal Crown corporation established by the Standards Council of Canada Act, adopted in 1970. One of its main function is to accredit standards setting organizations and conformity assessment bodies. It comprises representatives from the federal and provincial*

governments as well as from a wide range of public and private interests. For more information, one can consult the document entitled "Standards Systems - A Guide to Canadian Regulators" available at http://strategis.ic.gc.ca./stdsguide or visit the SCC website at http://www.scc.ca

- *What should be the composition of the board of directors and the ruling committee? How should these people be appointed?*

- *Should this body have the power to make decisions or should it only have the power to provide advice to Health Canada?*

- *Should it also be mandated to receive complaints from the public?*

- *Should the Act require that the proceedings and decisions of the organization be made readily accessible to the public subject to protecting confidential information (e.g. website)?*

- *Who should pay for the cost of the review?*

Currently, on a voluntary basis, the Advertising Standards of Canada (ASC) reviews advertising material for non-prescription drugs directed to consumers while the Pharmaceutical Advertising Advisory Board (PAAB) reviews advertisements for all drugs directed to health professionals. The two organizations work in collaboration with Health Canada. More information on these two organizations can be obtained at: http://www.adstandards.com/ and http://www.paab.ca/.

APPENDIX

POLICY

Issued: January 12, 1996

From the Therapeutic Products Programme

Updated: November 3, 2000

The Distinction Between Advertising and Other Activities

Issue

The Therapeutic Products Programme (TPP) recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access nonpromotional information regarding drugs for human use. The purpose of this policy is to clarify the distinction between advertising to promote the sale of a drug and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labelling, shareholder's report, etc.).

This policy is NOT intended for use in determining whether or not the drug advertising provisions of the *Food and Drugs Act* and *Regulations* are observed.

Scope

This policy applies to all types of information disseminated in relation to drugs for use in humans.

Background

There are numerous provisions within the *Food and Drugs Act* and *Regulations* that apply to drug advertising. In order to determine the applicability of those provisions it is first necessary to determine whether or not a particular message can be considered to be advertising. For the purposes of the Act, advertising is defined as including "any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device". If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the *Food and Drugs Act* and *Regulations*.

There is a particular need to distinguish between advertising and nonpromotional information in the following situations:

I) **Prior to market authorization:**

- promotion of a drug prior to market authorization is not permitted (Section 9(1) of the Act, Section C.08 002 of the Regulations) because the terms of such authorization have not been established and the proposed indication(s) for use have not been verified.

ii) **After market authorization when information on a drug is disseminated to the general public:**

- promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).

- a drug (prescription or nonprescription) may not be advertised to the general public for the treatment, preventative or cure for any Schedule A disease (Section 3 of the Act).

Considerations

In determining whether a message falls within the definition of advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information. Where the primary purpose is not clear, the following factors should be considered in determining whether the message is primarily intended to promote the sale of a drug:

- **What is the context in which the message is disseminated?**

  e.g., when and how is the message delivered; what is the milieu or medium of dissemination? Is it a science-based message delivered to scientists/healthcare professionals by an expert, e.g., researcher at a conference with a varied agenda, or is it a product-related message delivered to a group of practicing physicians by the pharmaceutical manufacturers sales representative at a meeting with a limited agenda?

- **Who are the primary and secondary audiences?**

  e.g., are the target audiences limited or unlimited in scope; are the primary and the secondary audiences the same? Where they are different, the message to the secondary audience is more likely to be advertising.

- **Who delivers the message (the provider)?**

  e.g., the drug manufacturer/its agent or an independent third party (e.g., patient support group). Where delivered by an independent party, the message is less likely to be considered as advertising.

- **Who sponsors the message and how?**

  e.g., the drug manufacturer/its agent or an independent third party; is the sponsorship funding targeted to a specific message, or is it added to the general operating budget for an organization, conference etc.? If the message is sponsored by an independent third party and the funding is added to the general operations budget, the message is less likely to be advertising. Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.

- **What influence does a drug manufacturer have on the message content?**

  e.g., what are the linkages between the information, the provider and the manufacturer, the provider and the writer, etc.? Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.

- **What is the content of the message?**

  eg., are the facts described objectively in a balanced manner, or is emphasis placed on a particular drug or its merits; is the message balanced with respect to description of risks as well as benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?

- **With what frequency is the message delivered?**

  e.g., is it delivered once or repeatedly? Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.

No one factor in itself will determine whether or not a particular message is advertising. Each message must be evaluated on its own merit and other factors may apply.

Examples of messages delivered in different contexts are discussed in Appendix I. The list of examples is intended as a guide only and is not all inclusive. The same factors for consideration will be applied to other types of messages not listed here.

This clarification should assist in distinguishing between advertising and nonpromotional information. **It is only after having determined that the primary purpose of a message is advertising that an assessment can be made regarding compliance with the regulations pertaining to drug advertising.**

Implementation:

Since this policy serves to clarify and expand upon the current interpretation of the definition of advertising within the Food and Drugs Act, it is effective immediately upon publication, and replaces the Drugs Directorate Policy, Distinctions between Advertising and Educational Activity, dated October 7, 1991.

Dann M. Michols
Director General
Therapeutic Products Programme

APPENDIX I

Examples of Message Types in the Context of Advertising and Nonpromotional Information

INDEX:

Examples of Message Types in the Context of Advertising and Nonpromotional Information

Press Releases/Press Conferences:

It is common practice for a pharmaceutical manufacturer to release information on new developments in research and at the time of launch of a new drug or a new indication for use of a previously authorized product.

A press release or information disseminated at a press conference concerning a drug may be a nonpromotional activity in the following circumstances:

- the announcement is directed to shareholders or potential shareholders,
- the announcement is limited to the name of the drug and its authorized or proposed therapeutic use,
- no statement is made regarding the degree of safety or efficacy expected,
- no comparison is drawn with other treatments,
- in the case of unauthorized drugs, or unauthorized indications, the message cautions that the safety and efficacy are still under investigation and that market authorization has not yet been obtained, and
- there is no attempt to influence the pick-up, placement or emphasis given in subsequent publication or broadcast, e.g., no payment is made by the manufacturer to influence the visibility (e.g., section) in the press.

In contrast, a press release or information disseminated at a press conference may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the message is to promote the sale of a drug, for example:

- undue emphasis is placed on the drug being a "breakthrough",
- the press release is subsequently sent or provided to another audience, e.g., mailed to physicians,
- a fee is paid by the sponsor to have the message published or broadcast, or
- in the case of an unauthorized drug, it is indicated that the drug is available through the Special Access Programme.

Patient Support Group Literature

Patient support groups often publish information in the form of brochures/leaflets that are intended to promote a better understanding of a disease and its treatment among members and potential members. It can be difficult to distinguish between advertising and nonpromotional information in this context.

Declaration of sponsorship of the brochure by a drug manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on drugs may be a nonpromotional activity in the following circumstances:

- the content is disease related rather than product related,
- the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a " breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Patient support group publications may be advertising where any of the aforementioned conditions are not met, and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

Patient Information Booklets

Information in the form of a leaflet, brochure, or booklet published by the manufacturer about a drug product is not advertising if it pertains only to the drug which it accompanies, and is given to a patient for whom the drug is being, or already has been, prescribed. In these circumstances, the information is considered to be part of the labelling and is, therefore, subject to the relevant regulatory and policy requirements relating to labelling rather than advertising.

By contrast, such information packages about a specific product that are distributed independently of the product to consumers for whom the drug has not been prescribed, fall within the definition of advertising.

Consumer Brochures:

I) Consumer brochures include leaflets/brochures that may make reference to but do not accompany a drug product, and are made available directly or indirectly to the consumer by a drug manufacturer, or other organization, by various means, e.g., by mail, in retail outlets, in health professionals waiting rooms, etc.

Declaration of sponsorship of such a brochure by a drug manufacturer does not in itself render the information promotional. Consumer brochures may be nonpromotional information in the following circumstances:

- 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, e.g., excessive use of a brand name or description of a product as a "breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Consumer brochures may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

ii) Consumer brochures also include leaflets/brochures that are not product-specific but expound on the pharmacological properties/actions of an ingredient, e.g., herb, vitamin, mineral, etc., and are made available in retail outlets selling products containing the same ingredients.

Such information packages may be considered to be advertising for a drug product when displayed in close proximity to or distributed with products containing the same ingredient, in the same retail outlet.

Videos and Interactive Electronic Databases

Videos are defined as messages recorded on videotape that make reference to drug products and that may be played, with or without a request, e.g., in healthcare professional waiting rooms, pharmacies etc.

Interactive electronic databases are defined as electronic information systems that provide menus through which the consumer can control the level of information detail accessed upon request, e.g., drug store kiosks, Internet.

The circumstances under which information about drugs disseminated by videos and interactive electronic databases may or may not be advertising are similar to those specified for consumer brochures and Patient Support Group literature.

Continuing Medical Education (CME)/Scientific Symposia/Exhibits

CME events and scientific symposia related to drugs are sometimes sponsored by pharmaceutical manufacturers. Such activities may not be advertising when they provide a forum for exchange of information on related clinical and scientific issues. The key factor in determining the status of such an activity is the degree to which the programme is independent of the drug manufacturer. The information may be nonpromotional in the following circumstances:

- sponsorship by a drug manufacturer is not targeted to specific aspects of the agenda,
- the sponsor's role is adequately disclosed,
- the programme is directed to scientists and/or health professionals,
- the programme allows for exchange of information/debate,
- the content of the agenda is not influenced by the sponsor,
- the content of an individual presentation is not influenced by the sponsor where it concerns a drug manufactured by that sponsor,
- there is no inducement provided to participants,
- there are no ancillary commercial or promotional activities relating to drug products,
- the limitations of the data and of the drug are adequately discussed,
- discussion of an unauthorized drug or indication for use includes a statement indicating that the

drug/indication has not been authorized for marketing in Canada, and

- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Such an activity may be advertising where any of the aforementioned conditions are not met or where other factors indicate that the primary purpose of the activity is to promote the sale of a specific drug.

Moreover, reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific drug may be advertising if they are disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting.

International Conferences

The considerations described above for scientific symposia also apply to international medical/scientific conferences held in Canada. However, in the context of an international conference, display of a drug product prior to market authorization in Canada, or a product that is labelled for a use that has not been authorized in Canada, may be a nonpromotional activity in the following circumstances:

- the conference must clearly be an international event, e.g., a significant proportion of the conference delegates are from other jurisdictions,
- the material must emanate from the parent company of the manufacturer,
- the material must only be for use within the confines of the conference, and
- the material is prominently identified as not being authorized for sale in Canada.

Help Seeking Announcements

Help seeking announcements are defined as announcements that ask patients among the general public having a particular medical disorder, or that experience a given set of symptoms, to consult a physician for discussion of treatment, or to call a 1-800 telephone number for further information.

Such an announcement may be a nonpromotional activity in the following circumstances:

- no specific drug is identified,
- 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.

Such an activity may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose is to promote the sale or disposal of a drug.

1-800 Telephone Numbers

Information provided by the sponsor to a member of the general public in response to a call placed on a 1-800 line set out in a help-seeking announcement may be a nonpromotional activity, in the following circumstances:

- the content is disease related rather than product related,
- the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a " breakthrough", and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorized drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorized drugs through the Special Access Programme.

Information supplied pursuant to a call placed on the 1-800 telephone line may be advertising where any of the aforementioned conditions are not met or where other factors indicate that the primary purpose is to promote the sale of a drug.

Unsolicited Requests for Information

Information provided to an individual about a drug treatment(s) by a pharmaceutical manufacturer in response to a request for information that has not been solicited in any way (by the manufacturer of the drug) is not considered to be advertising for the sale of a drug.

Journal Supplements/Inserts

Journal supplements are usually comprised of a collection of articles that deal with related issues

or topics, are published as a separate issue of the journal, or as a second part of a regular issue, and are funded by sources other than the journal publisher, e.g., by the pharmaceutical manufacturer.

Where publication is sponsored, in whole or in part, by a drug manufacturer, it may be a nonpromotional activity in the following circumstances:

- the content of the insert comprises unedited symposium proceedings that address a variety of issues relating to different disease entities or drug treatments,
- the content of the insert reports on a variety of treatment approaches for the same medical condition,
- the publication is targeted to its customary readership,
- no link is established between conventional advertising and the articles, e.g., by proximity,
- sponsorship by the pharmaceutical manufacturer is declared in such a way that there is no obvious link to a drug discussed, and
- the supplement is identified in such a way that it is distinct from the regular journal edition.

In contrast, a journal supplement may be advertising where the aforementioned conditions are not met and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug, for example:

- the supplement, in whole or part, is disseminated by the sponsor rather than by the publisher of the journal itself,
- the publication or an article contained in it is edited by the sponsor, or
- a conventional advertisement is placed in close proximity to an article discussing an unauthorized use for the same chemical entity/drug product.

Clinical Trial Recruitment

An announcement that is intended to assist in the recruitment of patients or clinical investigators for a clinical trial, including an Open-label or Treatment IND, may be a nonpromotional activity in the following circumstances:

- the intent of the announcement is clearly identified as being for recruitment of clinical trial participants,

- the announcement indicates the patient profile required (the disease/symptoms to be treated, age, etc.),

- the announcement includes a telephone number for obtaining further information that is related only to the clinical trial, and

- in the case of patient recruitment, no reference is made to the drug manufacturer's name, or to the name of the drug under investigation.

In contrast, an announcement used in the recruitment of clinical trial participants (patient and investigator) may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary intent of the announcement is to promote the sale of a drug, for example:

- the announcement makes claims respecting the safety and efficacy of the drug, or

- the announcement draws a comparison with other treatments.

Formulary Kits

Formulary kits are defined as material prepared for review by pharmaceutics and therapeutics and formulary committees, on which a decision to include a drug product in a formulary may be based. Such information may not be advertising provided the information is limited to that which would normally be required to support such an application.

Where such an information package is disseminated, in whole or part, to a wider audience simultaneously, or at a later date, it may be advertising to promote the sale of the drug concerned.

Institutional Messages

An institutional message is defined as a communication (e.g., brochure, published article, prospectus, annual report, etc.), which provides information about a pharmaceutical manufacturer, or other institution, concerning its philosophy, activities, product range (by name), financial details, area of future development or research, etc. Such a message may be a nonpromotional activity in the following circumstances:

- the purpose of the communication is clearly to provide information about the institution rather than about the drugs being marketed, developed or researched,

- information about the drugs being marketed, developed or researched is limited to the name and therapeutic use of the drug, and

- no emphasis is given to any one or more products, or their benefits.

Reference texts, Peer-reviewed Journal Articles

Dissemination of full, unedited reference texts (textbooks, chapters of textbooks), government publications or reprints of published, peer-reviewed articles
from medical or scientific journals, that are identified as being provided courtesy of a pharmaceutical manufacturer, may be a nonpromotional activity provided that:

- no link between the text and promotion of a drug is established by the manufacturer.

Such material may be considered to be advertising where the aforementioned condition is not met or where other factors indicate that the primary purpose is to promote the sale of a drug, for example:

- the material is accompanied by any form of additional information (e.g., printed, word of mouth) designed by or on behalf of the manufacturer for the purpose
  of promoting a drug (e.g., detail aid),

- the material was written or edited by an employee or agent of the pharmaceutical manufacturer,

- a summary or interpretation of the text prepared by the pharmaceutical manufacturer or his agent accompanies the material,

- reference is made to the availability of an unauthorized drug through the Special Access Programme.