Health Canada Santé Canada

The Distinction Between Promotional and Non-promotional Messages and Activities for Health Products

DRAFT Guidance Document

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Canada

Forward

Guidance documents are meant to provide assistance on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada's mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having the force of law and, as such, allow for flexibility in approach. Alternative approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternative approaches should be discussed in advance with the relevant program area to avoid possibly finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the relevant sections of other applicable guidance documents and policies. This guidance document supersedes the policy entitled "The Distinction Between Advertising and Other Activities" (2005).

Table of contents

1 Introduction

1.1 Purpose

Health Canada recognizes that it is important for industry to disseminate non-promotional information regarding human and veterinary health products to health care professionals and for the general public to be able to access such information. Since advertising is defined as a representation for the purpose of promoting the sale of a health product, as per the *Food and Drug Act* (F&DA), it is critical to determine if the purpose of a message is, in fact, to promote the sale of a health product or to provide information.

The purpose of this guidance document is to outline factors that contribute to rendering a message or activity non-promotional. In order to determine the applicability of advertising legislative and regulatory provisions , it is first necessary to determine whether or not a particular message or activity is considered promotional or non-promotional.

1.2 Scope

This guidance document pertains to the following health products: prescription drugs (including controlled substances), non-prescription drugs, medical devices, natural health products, biologics, vaccines, and veterinary health products.

The scope of this document applies to all types of messages and activities involving medical conditions, and/or any health-related matters, regardless of the target audience, such as general public, patient advocacy groups, health care professionals. Moreover, this guidance document applies to all messages and activities targeting Canadians through any advertising medium (e.g., television, radio, print, online, digital platforms, etc.) or setting.

This guidance document is not intended for use in determining whether or not the advertising provisions of the F&DA, the *Controlled Drugs and Substances Act* (CDSA) and their respective regulations are observed. This guidance document applies to messages and activities related to all health products for which the terms of market authorization (TMA) have been granted and the proposed indication(s) for use has (have) been verified under the F&DA and its associated regulations.

This document does not constitute part of the F&DA, CDSA or their associated regulations. In the event of any inconsistency or conflict between the Acts or Regulations and this document, the Acts or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the F&DA, CDSA, the Regulations and the applicable administrative policies.

1.3 Background

There are numerous provisions within the F&DA, CDSA, and their respective regulations that apply to the advertisement of health products.

The F&DA is an Act respecting food, drugs, cosmetics, and medical devices. Health products, including controlled substances that are sold in Canada, must meet relevant requirements as set out in the F&DA and its associated regulations, to establish their TMA, including the Notice of Compliance (NOC), Drug Identification Number (DIN), Natural Product Number (NPN), DIN-Homeopathic Medicines (DIN-HM), and Medical Device Product Licence, which authorize the sale of a health product in Canada.

Section 2 of the F&DA defines “advertisement” as “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.”

The CDSA is an Act respecting the control and sale of controlled substances and their precursors. It is not used to establish the TMA but provides provisions for stakeholders to legally handle and conduct activities with these substances.

Similarly, Section 2(1) of the *Narcotic Control Regulations* (NCR), which is a set of regulations made under the CDSA, defines “advertisement” as “any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a narcotic.”

Section 1(1) of the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR), which is a set of regulations under the CDSA, defines "advertisement" as "in respect of a targeted substance, includes any representation by any means for the purpose of promoting, directly or indirectly, the sale or other disposal of the targeted substance".

Part G of the *Food and Drug Regulations* (F&DR), which is a regulation under the authority of the CDSA, uses the same definition of "advertisement" as in section 2 of the F&DA (see above).

Consistent with the F&DA and the CDSA, promotional messages and activities are considered as advertising. Promotion of a health product prior to market authorization is prohibited by Section 9(1) and 20(1) of the F&DA, as well as Section C.08.002 of the F&DR for a new health product.

Advertisements for all health products, including controlled substances, must comply with the requirements of the F&DA, the CDSA, and their respective regulations where applicable. In the case where advertising is disseminated to health care professionals and the general public, such as when a member of the general public presents at a continuing medical education event, the more restrictive regulatory provisions for advertising apply. Appendix B presents a list of the applicable legislative and regulatory provisions for health product advertising in Canada. If a message regarding a health product is not considered to promote the sale of a health product, it is not subject to the advertising provisions.

1.4 General Principles

It is necessary to determine whether a message or activity is promotional (i.e. considered advertising) in order to determine if the message or activity is subject to the legislative and regulatory requirements on advertising. When making such a determination, the following principles will be upheld:

1. Each message will be evaluated on its own merit in its entirety.
2. The factors described in sections 1.5.1 and 1.5.2 will be taken into consideration.
3. As the list of factors referred to below is not exhaustive, other factors or circumstances will be considered if they provide insight on whether the primary purpose of the message or activity is to promote the sale of a specific health product.
4. Generally, no single factor in itself will determine whether or not a particular message is promotional.
5. Any linkages to various materials within a message will be considered.

It is only after having determined that the primary purpose of a message is promotional that an assessment can be made regarding compliance with the regulations pertaining to health product advertising.

In addition to this guidance, Health Canada recommends that stakeholders consult advertising preclearance agencies, where applicable, for assistance in conducting these case-by-case assessments. These agencies will provide advisory opinions on specific messages or activities to make sure they are either non-promotional or compliant advertising. It is worth noting that Health Canada remains the regulatory authority for all health product advertising in Canada.

1.5 Factors of Messages or Activities that Contribute to a Non-Promotional Determination

There are several factors that may render a message or activity non-promotional. These factors can be divided into two categories: content and context factors, and sponsorship and dissemination factors. The respective factors are presented below:

1.5.1 Content and Context

The following content and contextual factors may contribute towards a determination that a message or activity is non-promotional:

- The content is accurate, objective and is consistent with the terms of market authorization;
- It is not product-focused or does not emphasize the benefits of a health product while minimizing, omitting, or ignoring risks in any way (e.g., editorial comments, opinions, suggestions, etc.);

- It is not influenced by the sponsor or manufacturer or any entity acting on behalf of the sponsor or manufacturer;
- It is presented in a layout and design that cannot be associated with a specific health product; and
- The message or activity is not combined or disseminated concurrently with any promotional messages or activities.

In the case of unauthorized health products, or unauthorized indications:

- the content of the message cautions that the safety and efficacy/effectiveness are still under investigation and that market authorization has not yet been granted by Health Canada;
- for medical devices, the message can only appear in a catalogue; and
- no reference is made suggesting that the health product is available through the Special Access Programme (SAP) for drugs and medical devices, or the Emergency Drug Release (EDR) Program for drugs for veterinary use.

1.5.2 Sponsorship and Dissemination

The following sponsorship and dissemination factors may contribute towards a determination that a message or activity is non-promotional:

- The message or activity is sponsored by a government authority (e.g., the Public Health Agency of Canada, the provincial ministries of health, provincial formularies, etc.);
- A competitor would be willing to fund, sponsor, and deliver the same message;
- The message or activity is delivered by non-sales and/or marketing staff;
- The message or activity is intended for the primary[1] target audience only; and
- The message is not delivered repeatedly or redistributed widely.

[1] Primary audiences are considered as the intended target population of an advertisement, whereas secondary audiences, are the unintended audiences that are also exposed to the advertisement.

2. Examples of Non-promotional Message and Activity Types

In order to provide further guidance as to what may constitute promotional or non-promotional messages or activities, specific examples of non-promotional messages and activities are presented in this section of the guidance document. These are provided to illustrate and apply the general principles and factors outlined in section 1.4 and 1.5. The list of examples presented in sections 2.1 to 2.14 is intended as a guide only and is not all-inclusive. It should be noted that a real-life case might not fall within a specific category, and therefore a combination of factors may be applied to make a determination on promotional versus non-promotional messages or activities.

A message or activity can be promotional where any of the factors under each section are not met, or where circumstances indicate that the primary purpose of the message is to promote the sale of a health product.

2.1 Clinical Trial and Investigational Testing Recruitment Material

A Clinical Trial, as per the *F&DR*, is defined as an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of a drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism, and excretion of the drug, or ascertain the safety or efficacy of the drug.

Investigational Testing is defined as a systematic investigation in one or more human subjects, undertaken to assess the safety and/or effectiveness of a medical device.

Any announcement that is intended to assist in the recruitment of patients or clinical investigators for a clinical trial or investigational test concerning a health product may be considered non-promotional in the following circumstances:

- the announcement states the health product manufacturer's name or participant recruitment agency;
- the intent of the announcement is clearly identified as being for recruitment of clinical trial/investigational testing participants or clinical investigators;
- the announcement indicates the patient profile required (the disease/symptoms to be treated, age, etc.) and the purpose of the clinical trial or investigational testing;
- the announcement includes contact information such as a telephone number, email address, etc. for obtaining further information that is related only to the clinical trial or the investigational test;
- the announcement does not make claims respecting the safety and efficacy/effectiveness of the health product;
- the announcement does not draw a comparison with other treatments; and
- the announcement includes no direct or indirect reference to the name of the health product under investigation.

2.2 Corporate Messages

A corporate message is defined as a communication (e.g., web site, brochure, published article, prospectus, annual report, etc.) that provides information about a health product manufacturer, or organization, concerning its philosophy, activities, product range (by name), financial details, area of future development or research, etc. Corporate messages, or information disseminated through corporate messages, may be considered non-promotional in the following circumstances:

- the purpose of the communication is clearly to provide information about the health product manufacturer or organization rather than about the health products being marketed, developed or researched;
- information about a health product being marketed, developed or researched is included in the “Investor Information” section of the communication and is limited to the name of the health product and the therapeutic area; and
- no emphasis is given to any product or its benefits.

2.3 Medical Condition and Treatment Awareness Related Materials

Medical condition and treatment awareness related materials provide information about a medical condition or treatment and may make reference to, but do not accompany, a health product. These materials are made available directly or indirectly to the general public by a health product manufacturer, or another organization, through various means, such as online (via web sites, social media, digital applications, email, etc.), by mail, in retail outlets, in health care professionals' waiting rooms, etc.

Declaration of sponsorship of such materials by a health product manufacturer does not in itself render the material promotional. Medical condition and treatment awareness related materials may be considered non-promotional in the following circumstances:

- the content is disease-related rather than product-related;
- the material presented describes available treatment options, and their respective risks and benefits are discussed in a fair, balanced and objective manner (e.g. no emphasis on one product or one drug class through the use of capital letters, bold text, and links; minimizing risks; exaggerating benefits; etc.);
- in the case of a disease where there is only one treatment available, the treatment is not alluded to, referred to, or mentioned in any way; and
- the material emphasizes the need for patients to consult a health care professional for complete information on the disease, and the available treatment options, or if they suspect they are experiencing any symptoms related to the disease.

2.4 Electronic Tools and Technology

2.4.1 Social Media

Social media encompasses websites and applications that enable health care professionals, patients and/or the general public, through virtual communities, to share, create, discuss and modify content. A few examples of social media channels include Facebook, Twitter, Instagram, LinkedIn, blogs, and forums.

In addition to the elements outlined in section 2.3 of this guidance document, information disseminated through social media may be considered non-promotional in the following circumstances:

- the social media web site or platform remains unbranded (e.g., no specific product is mentioned);
- the content, user-generated comments, hyperlinks and/or other interactive features do not place additional focus or emphasis on a specific health product and its benefits;
- the available "sharing" options (e.g. email, "like", "tweet", etc.) do not modify the context by which the content is disseminated (e.g. different audience, emphasis on a specific product, etc.); and
- a person or organization and/or its representatives may sponsor the social media activity or message, but is not engaged in discussions except in a monitoring capacity (e.g., removal of inappropriate comments, etc.).

2.4.2 Other Interactive Tools

Electronic interactive tools encompass a wide variety of technologies that are being developed and used to communicate information to a large number of people in a user-friendly manner. These tools may take the form of a keyword (such as a metadata tag), a web-based or mobile application, a chat room, an online banner ad, a search engine optimization (SEO) tool, a quiz, clinical software, decision-making support tools used by health care professionals and/or other technologies.

In addition to the elements outlined in section 2.3 of this guidance document, information disseminated through interactive tools and technologies may be considered non-promotional in the following circumstances:

- the tool and/or technology remains unbranded (e.g., no specific product); and
- the tool does not provide links or search results/outputs to material emphasizing a specific product and its benefits.

2.5 Formulary Kits or Packages

Formulary kits are defined as material prepared for review by formulary committees (e.g., public and private payers), on which a decision to include a health product in a formulary may be based. Formulary kits or information disseminated through formulary kits concerning a health product may be considered non-promotional in the following circumstances:

- the information provided is limited to that which would normally be required to support such an application as described by the public and private formularies; and
- the information package is not disseminated, in whole or in part, to a wider audience simultaneously, or at a later date.

2.6 Educational Activities

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

Continuing Medical Education (CME) events, defined as accredited programs for health care professionals and scientific symposia related to health products, are at times sponsored by health product manufacturers. Attendance at, and participation in, CME events is generally restricted to health care professionals. In the event that members of the public are attending as well, the sponsor or organizer should make every effort to ensure that the event remains non-promotional. Moreover, information disseminated at such events may be considered non-promotional in the following circumstances:

- the event provides a forum for the exchange of information on related clinical and scientific issues;
- a health product manufacturer does not sponsor specific portions of the agenda or conference;
- the sponsor's role and any financial relationships between the sponsor and the speakers and organizers of the event is clearly disclosed;
- the content of the agenda is not influenced by the sponsor or manufacturer or any entity acting on behalf of the sponsor or manufacturer;
- the content of an individual presentation is not influenced by the sponsor where it concerns a health product manufactured by that sponsor;
- there is no inducement provided to participants;
- there are no ancillary commercial or promotional activities relating to health products;
- the limitations of the data and of the health products are adequately discussed; and
- reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific health product are not disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting.

The above-mentioned factors apply to both Canadian and international medical/scientific conferences held in Canada. Conference participants may freely exchange information to achieve conference goals while ensuring that there is no intent to target the Canadian general public directly or indirectly.

2.6.2 Other Learning Activities

Other Learning Activities (OLAs) are defined as unaccredited programs, events or activities where medical/scientific information is presented to health care professionals, by health care professionals. The primary focus of, and the reason for, sponsoring or participating in OLAs is the exchange of scientific and clinical information and issues. Information disseminated at OLAs may be considered non-promotional in the following circumstances:

- the need for such an activity has been clearly and systematically identified through a needs assessment in collaboration with relevant health care professionals;
- the objectives of the program have been clearly outlined and the activities are meant to address an identified gap between the current situation and the desired situation;
- only health care professionals are invited or are in attendance;
- all materials for the program or activity have been developed in accordance with program objectives and are only distributed to health care professional attendees;
- any product discussions are fair and balanced, and consistent with the Canadian terms of market authorization; and
- evaluations are collected to assess whether program objectives have been met.

Additionally, for an OLA event to be considered non-promotional, a speaker/presenter must:

- appropriately disclose any conflict of interest(s) and funding;
- disclose that the safety and efficacy/effectiveness are still under investigation in the case of unauthorized health products and unauthorized uses; and
- have complete editorial control of the content being presented.

2.7 Publication Supplements

Supplements in a publication (such as a magazine and a journal) 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 an addendum to a regular issue, and are funded by sources other than the journal publisher, e.g., by a health product manufacturer.

Where a publication is sponsored, in whole or in part, by a health product manufacturer, it may be considered non-promotional in the following circumstances:

- the content of the supplement comprises unedited symposium proceedings that address a variety of issues relating to different diseases or health products;
- the content of the supplement includes a variety of treatment approaches for the same medical condition;
- the publication is targeted to the publication's customary readership;
- no link is established between promotional materials and the publication (e.g., by proximity within the publication);
- sponsorship by the manufacturer is declared in such a way that there is no obvious link to a health product that is being discussed;
- the supplement is identified in such a way that it is distinct from the regular publication;
- the supplement is not disseminated by the sponsor either in whole or in part; and
- no article of the publication supplement is modified by the sponsor.

2.8 Medical Procedure and Health Service-Related Messages

Health care professionals may promote medical procedures and services (e.g., medical cosmetic services) offered in their clinics to the general public. Such messages relating to medical procedures and services may be considered non-promotional in the following circumstances:

- there is no specific health product being promoted; and
- it does not involve the sale or purchase of a health product, but rather the service itself.

2.9 Patient Information Materials and Packages

Information in the form of a web site, application, leaflet, brochure, or booklet published by the manufacturer concerning a health product is considered to be part of the labelling. Therefore, relevant labelling requirements will apply to this material and it must be consistent with the terms of market authorization. These materials and packages may be considered non-promotional in the following circumstances:

- it pertains only to the health product that is being, or has already been, prescribed to a patient by a health care professional; and
- in the case of a web site, the access is gated to ensure that information is only accessible by patients.

2.10 Patient Support Group Literature

Patient support groups often publish information in the form of web sites and brochures/leaflets that are intended to promote a better understanding of a disease and its treatment among members and potential members of these groups.

Declaration of sponsorship of the brochure by a health product manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on health products may be considered non-promotional in the following circumstances:

- the content is disease-related rather than product-related;
- the various treatment options and their respective risks and benefits are discussed in an objective manner (e.g. no emphasis on one product or one drug class through the use of capital letters, bold text, and links; minimizing risks; exaggerating benefits; etc.);
- no emphasis is placed on one specific health product or its merit, such as excessive use of a brand name or describing the product as a "breakthrough"; and
- no emphasis is accorded to the merits of one health product.

2.11 Press Releases and Press Conferences

It is common practice for a health product manufacturer to release information on new developments in research regarding a health product at the time of launch of a new health product, or when a new indication for use is included in the TMA for a previously authorized product.

A press release or information disseminated at a press conference concerning a health product may be considered non-promotional in the following circumstances:

- the announcement is maintained on the web site of the manufacturer and its subsidiaries and/or the press release distributor web site for no more than 30 calendar days from the initial date of publication;
- the announcement is limited to the name of the health product and its authorized or proposed therapeutic use;
- statements regarding the degree of safety or efficacy and comparison to other treatments are limited to the factual and observed information;
- there is no attempt to influence the pick-up, placement or emphasis given in subsequent publications or broadcasts, e.g., no payment is made by the manufacturer to influence the visibility in the press;
- there is no reference to a health product as being a "breakthrough" product (defined as a health product that is used i) alone or in combination with another health product(s) for the treatment of a disease or condition; and ii) that the health product proves to be therapeutically more beneficial compared to existing therapies based on clinically significant endpoints); and
- no fee is paid by the sponsor to have the message published or broadcasted.

2.12 Risk Management Plans

A Risk Management Plan (RMP) is a dynamic stand-alone document, required or requested by Health Canada, which describes a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to drugs, and the assessment of the effectiveness of those interventions. The document

reflects emerging, known, and unknown clinical and non-clinical safety data that is updated throughout the drug's life-cycle upon discussion and agreement between Health Canada and the sponsors/market authorization holders. An RMP and the information disseminated according to the RMP concerning a drug may be considered non-promotional in the following circumstances:

- the document is scientifically accurate and consistent with the Canadian Product Monograph;
- there are no direct or implied product benefits (regardless of scientific accuracy);
- there are no comparative safety or benefit claims;
- the document has been required or requested by Health Canada;
- the document is disseminated to health care professionals or patients only after it has been accepted by Health Canada;
- there are no product logos or branding on the document; and
- the document is not distributed to health care professionals by sales and/or marketing staff.

2.13 Reference texts, Peer-reviewed Journal Articles

This section discusses the dissemination of 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 manufacturer. These resources or information may be considered non-promotional in the following circumstances:

- the material provided remains as-is and is not accompanied by any form of additional verbal or written information designed by or on behalf of the manufacturer for the purpose of promoting a heath product (e.g., detail aid, a summary or interpretation of the text); and
- the material was not written or edited by an employee or agent of the manufacturer.

2.14 Responses to Inquiries

Information provided to an individual or organization about a health product by a health product manufacturer in response to a request for information, or a request for proposal, may be considered non-promotional in the following circumstances:

- the inquiry has not been encouraged in any way by the manufacturer of the health product; and
- the response to the inquiry is not communicated by sales and/or marketing personnel.

Appendix A: Glossary

Some of the following terms, with the exception of those found in the respective Acts and Regulations, may be defined differently in other contexts; however, for the purpose of this guidance document, they are defined as follows:

Advertisement: 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.

Advertising Preclearance Agencies (APA): Independent entities which review and revise (preclear) advertising material, prior to its use in the marketplace, to help interested parties ensure compliance with the advertising provisions of federal legislation, the various Health Canada guidance documents, as well as their own codes of advertising. The agencies also offer mechanisms to resolve complaints on advertising for authorized health products. The board of directors or advisory bodies of these agencies may include stakeholders from academia, consumer groups, the media, advertising agencies, the pharmaceutical industry, and health care professional associations. Health Canada acts as an ex-officio observer and advisor to these boards and advisory bodies, without relinquishing any part of its authority under the F&DA and its associated Regulations. Although Health Canada works in collaboration with these agencies, it does not endorse them.

Brand/Product Name: The unique name under which the manufacturer of a health product advertises and sells it.

Claim: Any representation made on behalf of a health product, including the indication for use and marketing claims. A marketing claim may be a statement or image that is designed to promote the sale of a health product and which highlights a specific product attribute such as "longer lasting" or "tastes great."

Comparative Claim: A statement that compares an identified attribute of one health product or ingredient to that of another health product(s)/ingredients(s) in terms of comparability or superiority.

Controlled Substance: Any type of substance that the federal government has categorized as having a higher-than-average potential for abuse or addiction. Such substances are divided into categories based on their potential for abuse or addiction and include illegal street drugs and prescription medications.

Cosmetic: Any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving, or altering the complexion, skin, hair, or teeth, and includes deodorants and perfumes.

Device: Please see definition of a Medical Device.

Directions for use: Commonly known as the instructions for use. This refers to full information about the procedures recommended for achieving the optimum performance of the device and includes cautions, warnings, contra-indications and possible adverse effects.

Drug: Includes any substance or mixture of substances manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
(b) restoring, correcting or modifying organic functions in human beings or animals; or
(c) disinfection in premises in which food is manufactured, prepared or kept.

Drug Identification Number (DIN): A computer-generated eight-digit number assigned by Health Canada to a drug product, prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and non-prescription (over-the-counter) drug products that have been evaluated and authorized for sale in Canada.

Emergency Drug Release (EDR): A Health Canada program that considers requests for access to drugs for veterinary use that are unavailable for sale in Canada; and that are submitted by veterinary practitioners, for the purpose of diagnosing or treating a medical emergency in a patient (or group of animals) under their care.

Formulary Committees: A multidisciplinary committee responsible for the decision-making surrounding the list of drugs whose costs are covered by a private or public drug coverage program (formulary).

General public: Ordinary people, especially all the people who are not members of a particular organization or who do not have any special type of medical/scientificknowledge.

Health care professional: A person who is entitled under the laws of a province to provide health services in the province.

Health Product: A prescription (including a controlled substance) or non-prescription drug, a medical device, a natural health product, a veterinary drug, a veterinary health product, and/or a radiopharmaceutical.

Homeopathic Medicine Number (DIN-HM): A computer-generated eight-digit number assigned by Health Canada to each homeopathic medicine authorized to be marketed under the Natural Health Products Regulations.

Indication for Use: A statement that describes the limitations for use of a drug, including the disease state, condition(s) or symptom(s) and the target population, if specified, for which the health product is intended and authorized to be used by Health Canada.

Label: Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package.

Manufacturer: A person who fabricates or processes a health product for the purpose of sale, but does not include a pharmacist or other health care professional who, at the request of a patient, compounds a health product for the purpose of sale to that patient.

Marketing: The process or technique of promoting, selling, and distributing a product or service.

Medical Condition: A broad term that includes all diseases, lesions, disorders, or non-pathologic conditions that normally receive medical treatment, such as pregnancy or labour**.**

Medical Device: An instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
(c) diagnosing pregnancy in human beings or animals,
(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
(e) preventing conception in human beings or animals,

however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Medical Device License Number: A computer-generated number assigned by Health Canada to a Medical Device Licence, authorizing the importation/sale of the medical device(s) listed on that licence under the Medical Devices Regulations.

Natural Health Product: A substance set out in Schedule 1 of the *Natural Health Product Regulations,* or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2 of the *Natural Health Product Regulations* or any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Natural Product Number (NPN): A computer-generated eight-digit number assigned to each natural health product approved to be marketed under the *Natural Health Products Regulations*.

New Drug: A drug, other than a veterinary health product:

- that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;
- that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or
- with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration or duration of action, and that has not been sold for that use or condition of use in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

Notification Number (NN): A number generated by the VHP notification system for a VHP, after Health Canada has ensured that the product meets all of the requirements of the VHP Notification Program. It begins with "NN" followed by a combination of four digits and letters.

Notice of Compliance (NOC): A document issued to a manufacturer, from Health Canada, following the satisfactory review of a submission for a new drug, and that signifies compliance with the *Food and Drug Regulations*.

Patient: An individual who has a medical condition and is receiving, or is registered to receive, care.

Promotion:[2] To make, for the purpose of selling a product or service, a representation about a product or service by any means, whether directly or indirectly, that is likely to influence and shape attitudes, beliefs and behaviours about a product or service.

Product Monograph: A factual, scientific document on a health product that, devoid of promotional material, describes the properties, claims, indications and conditions of use of the drug and contains any other information that may be required for optimal, safe and effective use of the health product.

Risk: A measure of both the potential harm to human and animal health that may result from being exposed to a product under specific conditions of use, together with the likelihood that the harm will occur.

[2] This definition should be read in conjunction with the definition of advertisement.

Special Access Program (SAP): Health Canada's program that considers requests from practitioners who wish to have access to drugs that are unavailable for sale in Canada, or to custom-made or unlicensed medical devices, in order to treat patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable to provide appropriate treatment for patients under their care. The SAP authorizes a manufacturer to sell a drug or medical device that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radio-pharmaceutical products not authorized for sale in Canada.

Sponsor: A person or an organization that pays for, plans or carries out the dissemination of a message or activity in relation to a health product, involving a medical condition, and/or any health-related matter.

Terms of Market Authorization (TMA): These are comprised of all labelling information such as the PM, prescribing information, inserts, instructions for use, etc. that accompanies the NOC and/or in the document that assigns a DIN, NPN or DIN-HM, medical device license number, or NN, and any related labelling material for health products. This information is derived from the information on the health product that is submitted for regulatory review and authorization, as required by the F&DA, and its associated regulations, and as interpreted by guidance documents and policies.

Unauthorized Product: Refers to a health product such as a drug, vaccine, natural health product or medical device for which the market authorization has not been granted by Health Canada.

Veterinary Health Product (VHP): Low-risk drugs in dosage form that may contain ingredients such as vitamins, minerals, and traditional medicines, and are used to maintain or promote the health and welfare of companion animals (pets) and food-producing animals.

Appendix B: Relevant Legislative and Regulatory Sections

Stakeholders are advised to consult the full text of the relevant Acts and associated regulations. For convenience, some relevant sections are reproduced below:

1. Sections of the *Food and Drugs Act*:

Section 3(1): No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Exemption: Refer to Sections A.01.067 and A.01.068 of the F&DR, and Sections 103.2 and 103.3 of the Natural Health Products Regulations (NHPR).

Section 9(1): No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Section 20 (1): No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

2. Sections of the Food and Drug Regulations under the Food and Drugs Act:

Section A.01.067: A drug is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Section A.01.068: A drug is exempt from subsection 3(2) of the Act with respect to its sale by a person where the drug is represented by label or is advertised by that person to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Section C.01.007: No reference, direct or indirect, to the Act or to these Regulations shall be made upon any label of or in any advertisement for a drug unless such reference is a specific requirement of the Act or these Regulations.

Section C.01.044: If a person advertises a prescription drug to the general public, the person shall not make any representation other than with respect to the brand name, the proper name, the common name and the price and quantity of the drug.

Section C.08.002: No person shall sell or advertise a new drug unless

(a) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;
(b) the Minister has issued, under section C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission; and
(c) the notice of compliance in respect of the submission has not been suspended under section C.08.006.

Section G.01.007: No person shall

(a) advertise a controlled drug to the general public; or
(b) issue or publish any other written advertisement respecting a controlled drug unless that advertisement carries the symbol (◈) in a clear and conspicuous colour and size in the upper left quarter of the first page of the advertisement.

3. Sections of the Medical Device Regulations under the Food and Drugs Act:

Section 24 (1): For the purposes of subsections 3(1) and (2) of the Act and subject to section 27, a condom may be advertised and sold to the general public for the purpose of preventing the transmission of sexually transmitted diseases if the advertisement and the label of the condom claim only that the condom reduces the risk of transmitting sexually transmitted diseases.

Section 24(2): For the purpose of subsection 3(3) of the Act and subject to section 27, contraceptive devices, other than intrauterine devices, may be advertised to the general public by any means other than by the distribution of samples of the devices door-to-door or through the mail.

Section 27: No person shall advertise a Class II, III or IV medical device for the purpose of sale unless

(a) the manufacturer of the device holds a licence in respect of that device or, if the device has been subjected to a change described in section 34, an amended medical device licence; or
(b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.

4. Sections of the Natural Health Products Regulations under the Food and Drugs Act:

Section 92: No reference, direct or indirect, to the Act, the Food and Drug Regulations or to these Regulations shall be made on any label of or in any advertisement for a natural health product unless the reference is specifically required by law.

Section 103.2: A natural health product is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

Section 103.3: A natural health product is exempt from subsection 3(2) of the Act with respect to its sale by a person where the drug is represented by label or is advertised by that person to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

5. Section of the Controlled Drugs and Substances Act:

Section 55 (1)(l) The Governor in Council may make regulations for carrying out the purposes and provisions of this Act, including the regulation of the medical, scientific and industrial applications and distribution of controlled substances and precursors and the enforcement of this Act, as well as the regulation of designated devices and, without restricting the generality of the foregoing, may make regulations controlling and limiting the advertising for sale of any controlled substance or precursor or any class thereof

6. Sections of the Narcotic Control Regulations under Controlled Drugs and Substances Act:

Section 70: No person shall

(a) publish or cause to be published or furnish any advertisement respecting a narcotic unless the symbol “N” is clearly and conspicuously displayed in the upper left-hand quarter thereof or, if the advertisement consists of more than one page, on the first page thereof;
(b) publish or cause to be published or furnish any advertisement to the general public respecting a narcotic; or
(c) advertise in a pharmacy a preparation referred to in section 36.

7. Section of the Benzodiazepines and Other Targeted Substances Regulations under Controlled Drugs and Substances Act:

Section 3: A person must not

(a) advertise a targeted substance to the general public; or
(b) issue or publish an advertisement for a targeted substance unless the advertisement
    (i) is published in literature distributed to, or in a trade publication for, licensed dealers, pharmacists, practitioners or hospitals, and
    (ii) displays in the upper left quarter of its first page, in a clear manner and in a conspicuous colour and size, the following symbol: