Health Canada Santé Canada

Guidance on distinction between advertising and other activities for health products

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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Foreword

Guidance documents provide assistance on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a health product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of other applicable guidance documents and policies. This guidance document supersedes the 2005 policy *The Distinction Between Advertising and Other Activities*.

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Overview

Purpose

Health Canada recognizes that it is important for industry to disseminate non-promotional, accessible information on human and animal health products to health care professionals (HCPs) and the general public. Since advertising is for the purpose of promoting the sale of a health product, it is critical to determine whether the purpose of a message is to promote the sale of a health product or to provide information. This is in accordance with the *Food and Drugs Act* (FDA).

This guidance document outlines the factors that contribute to rendering a message or activity promotional. When deciding if advertising legislative and regulatory provisions apply, one needs to first determine whether a particular message or activity is promotional or non-promotional.

Scope

This guidance document applies to the following health products:

- vaccines
- biologics
    - those regulated under Health Canada
- medical devices
- prescription drugs
    - includes controlled substances
- non-prescription drugs
- animal health products
- natural health products

This document applies to the following messages and activities:

- those involving medical conditions and/or any health-related matters, regardless of the target audience in Canada
- although the target audience is a factor to be considered in assessing the nature of the messages and activities
- those targeting consumers through any messaging media (such as television, radio, print, online, digital platforms) or setting

This document does not constitute part of the FDA, CDSA or their associated regulations. If there is inconsistency or conflict between the acts or regulations and this document, the acts or regulations take precedence. This is an administrative document to help the regulated party comply with the FDA, CDSA, their regulations and applicable administrative policies.

Background

There are numerous provisions within the FDA, CDSA and their respective regulations that apply to health product advertising.

The FDA concerns food, drugs, cosmetics and medical devices. Health products, including controlled substances that are sold in Canada, must meet relevant requirements as set out in this act and its associated regulations. The requirements establish a product's terms of market authorization (TMA), which includes:

- the notice of compliance (NOC)
- drug identification number (DIN)
- natural product number (NPN)
- DIN-homeopathic medicines (DIN-HM)
- veterinary health product (VHP) notification number (NN)
- medical device licence

These in turn authorize the sale of a health product in Canada.

Section 2 of the FDA defines "advertisement" 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." Health Canada will rely, as a general principle, on the ordinary meaning of "promote" as encouraging or inciting the sale of a health product.

The CDSA concerns 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 "including any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of a narcotic."

Section 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* (FDR), which is a regulation under the authority of the CDSA, defines advertisement as "includes any representation by any means whatever for the purpose of promoting, directly or indirectly, the sale or other disposal of a controlled drug".

Promotional messages and activities , as specified in the FDA and CDSA, are considered advertising.

Sections 9(1) and 20(1) of the FDA prohibit advertising any drug or device in a manner that is:

- false, misleading or deceptive or
- likely to create an erroneous impression regarding its character, value, quantity, composition, merit, design, construction, performance, intended use or safety

Section C.08.002 of the FDR for a new drug and section 27(a) of the *Medical Devices Regulations* (MDR) prohibit promoting a health product before market authorization.

If a message about a health product is not considered to promote the sale of a health product, it is not subject to the advertising provisions.

Check out:

- Applicable legislative and regulatory provisions for health product advertising in Canada

General principles

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

- Each message will be evaluated on its own merit in its entirety, with consideration given to the context within which the message is being delivered.
- Any linkages to various materials related to the message will be considered as well.
- As the following list of factors is not exhaustive, other factors or circumstances will also be considered if they provide insight on whether the purpose of the message or activity is to promote the sale of a specific health product.

In general, no single factor will determine if a particular message is promotional.

In addition to this guidance, Health Canada recommends that stakeholders consult advertising preclearance agencies (APAs), where applicable, for assistance in conducting these case-by-case assessments. These agencies will provide advisory opinions on specific messages or activities and can validate that they are either non-promotional or in compliance. Notwithstanding that a manufacturer may seek advice from an APA, there is no legislative or regulatory requirement to use an APA.

Note that Health Canada is the regulatory authority for all health product advertising in Canada.

Factors that contribute to a promotional determination

The following questions will help stakeholders determine whether the message is primarily intended to promote the sale of a drug:

What is the context in which the message is disseminated?

For example, when and how is the message delivered? What is the milieu or medium of dissemination? Is it a science-based message delivered to scientists or health care professionals by an expert, such as a researcher at a conference with a varied agenda. Or is it a product-related message delivered to a group of health care professionals by the sales representative of the product manufacturer at a meeting with a specific agenda?

Who are the primary and secondary audiences?

For example, are the target audiences limited or unlimited in scope? Are the primary and the secondary audiences the same? Where they are different, did the manufacturer or a third party contracted by the manufacturer engage in distribution beyond the primary target audience? Where the message is not limited to the primary audience, it is more likely to be promotional. For example, a subset of patients with a particular medical condition constitutes the primary audience of a message. Should this message appear in a public newspaper, it would be targeting a secondary audience or would be unlimited in scope.

Note: Primary audiences are considered the intended target group. Secondary audiences are “unintended” and are also exposed to the message.

Who delivers the message (the provider)?

For example, is the message delivered by the health product manufacturer, its agent or an independent third party (such as a patient support group)? The message is more likely promotional if it is not delivered by an independent party.

Who sponsors the message and how?

For example, is the sponsor the 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 of an organization or conference? If the message is sponsored by the manufacturer or its agent and the funding is not added to the general operations budget, the message is more likely to make it promotional. A fee that is paid by the manufacturer to have the message disseminated is more likely promotional.

What influence does a health product manufacturer have on the message?

For example, what are the linkages between the information, the provider and the manufacturer, the provider and the writer? Content that is influences by the manufacturer (prepared, edited) is more likely promotional.

What is the content of the message?

For example, are the facts described objectively in a balanced manner or is emphasis placed on a particular health product or its merits? Is the message balanced with respect to describing both risks and benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context (for example, a discussion of disease management, scientific research)? Messages that are not balanced, objective, set in a proper context, scientifically rigorous or that emphasize a particular health product are more likely advertising.

How frequently is the message delivered?

For example, is it delivered once or repeatedly? A message that is repeated is more likely promotional.

Other factors that may render a message or activity promotional can be divided into 2 categories:

- content and context factors
- sponsorship and dissemination factors

Content and context factors

A message or activity may be determined to be promotional if it:

- is mainly product-focused
- emphasizes the benefits of a health product or minimizes, omits or ignores risks in any way
    - through editorial comments, opinions or suggestions
- is affected directly or indirectly by the sponsor or manufacturer or any entity acting on behalf of the sponsor or manufacturer
- is presented in a layout and design that can be associated with a specific health product
    - such as brand colours, logo-like graphics and other visual cues, unique packaging, setting or decor
- is combined or disseminated at the same time as other promotional messages or activities
- includes direct or implied comparative therapeutic claims
    - in terms of ingredients, brands or therapeutic category
- is disseminated in the context of the target medical condition when directed to the general public
    - such as messages about health products in women's magazines for medical problems affecting only women

A message involving unauthorized health products or unauthorized indications, in a context such as educational activities, may be considered promotional if:

- the message does not caution that the product's safety and effectiveness are still under investigation and that Health Canada has not yet granted market authorization
- for medical devices, they are advertised in a way other than in a catalogue that, the message does not include a clear and visible warning that the devices may not have been licensed in accordance with Canadian law
- there's a suggestion the health product is available through the Special Access Program (SAP) for drugs and medical devices or the Emergency Drug Release (EDR) Program for animal health products

Sponsorship* and dissemination factors

A third-party message or activity may be determined to be promotional if it:

- is not disseminated by a government authority
    - such as the Public Health Agency of Canada, provincial ministries of health or provincial formularies
- is not sponsored and delivered by a competitor
- is delivered by sales or marketing staff
- involves distributing samples

* Note: Sponsorship is defined as “support of a third party-owned message or activity”.

Promotional examples

The examples presented in this page illustrate and apply the general principles and factors outlined in the overview page. The examples are a guide and should not be considered exhaustive. As a real-life case may not fall neatly within a single category, stakeholders may rely on a combination of factors to determine if a message or activity is promotional.

A message or activity can be promotional if:

- the factors under each section are met or
- circumstances indicate that the purpose of the message is not to promote the sale of a health product

Clinical trial and investigational testing recruitment material

As defined in the *Food and Drug Regulations* (FDR), a clinical trial is:

"an investigation in respect of a drug for use in humans that involve human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamics 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 a systematic investigation of 1 or more human subjects, undertaken to assess the safety and/or effectiveness of a medical device.

An announcement used to recruit patients or clinical investigators for a clinical trial or investigational test concerning a health product may be considered promotional when the purpose is to promote the sale of the product. For example:

- does not give the manufacturer's name or participant recruitment agency
- does not clearly identify the intent to recruit clinical trial/investigational testing participants or clinical investigators
- does not indicate the patient profile required (for example, the disease/symptoms to be treated, age) and the purpose of the clinical trial or investigational testing
- does not include contact information, such as a telephone number, email address and website link, where people can obtain further information on the clinical trial or investigational test
- makes claims about the product's safety and effectiveness
- makes comparative claims with other treatments
- makes direct or indirect reference to the name of the product under investigation
    - including the study title may not render the message promotional, but including the name of the product under investigation in the title may indicate the purpose is promotional

Corporate messages

A corporate message is a communication (such as a website, brochure, published article, prospectus or annual report) that gives information about a health product manufacturer or organization. This information could be on the philosophy, activities, product range (by name), financial details and/or area of future development or research.

Corporate messages, or information disseminated through corporate messages, may be considered promotional if:

- they seem to provide information about the health products being marketed, developed or researched rather than the manufacturer or organization
- there is far more information about the health product being marketed, developed or researched than simply its name and the therapeutic area
- in the case of unauthorized drugs or an unauthorized indication, there is no mention that the product's safety and efficacy is still under investigation and that Health Canada has not yet granted market authorization

However, a health product manufacturer may give detailed information about the health products being marketed, developed or researched when required by Canadian law (for example, as a requirement of the filing system for Canadian securities).

Medical condition and treatment awareness materials

Medical condition and treatment awareness materials raise awareness and provide information about a medical condition or treatment. They do not accompany a health product or branded health product materials for the same medical condition.

A manufacturer, or another organization, makes these materials available to the public, directly or indirectly. Various means are used, for example:

- by mail
- in retail outlets
- online, such as:
    - email
    - websites
    - social media
    - digital applications
- in waiting rooms of health care professionals

Declaration of sponsorship of such materials, by name or logo, is required and does not in itself render the material promotional.

Medical condition and treatment awareness materials may be considered promotional if:

- they do not emphasize the need for patients to consult a health care professional for complete information on the condition and available treatment options
- they believe they have the symptoms of the disease
- the content is focused on the product rather than the disease
- they do not discuss available treatment options (consistent with the health product's terms of market authorization issued by Health Canada) and the product's risks and benefits fairly and objectively, for example:
    - emphasis is on 1 product or 1 drug class through the use of capital letters, bold text and links
    - risks are minimized and benefits exaggerated
    - there is no discussion about non-health product treatment options
        - all recognized treatment options, including those that don't involve drugs (such as massage and acupuncture) should be discussed
- they make direct or indirect therapeutic or safety comparative claims
- the material refers to an unauthorized health product or indication
- the material refers to the product's availability through the Special Access Program (SAP)

Electronic tools and technology

Social media

Social media encompasses websites and applications that make it possible for health care professionals, patients and/or the public to share, create, discuss and modify content. Examples of social media channels include Facebook, Twitter, Instagram, LinkedIn, blogs and forums. A person or organization and/or its representatives may sponsor the social media activity or message.

information disseminated through social media may be considered promotional if:

- the social media website or platform is branded
- the content, user-generated comments, hyperlinks and/or other interactive features, which are under the sponsor's control, place additional focus or emphasis on a specific health product and its benefits

- the "sharing" options (such as email, "like", "tweet", "re-tweet", "comment") could modify the context by which the content is disseminated
    - for example, reach different audiences, emphasize a specific product
- a person or organization and/or its representatives sponsor the social media activity or message and is engaged in discussions beyond in a monitoring capacity
    - monitoring includes removing inappropriate comments, reporting adverse events and giving a general message such as "thank you for your comment" or "talk to your doctor for more information"

The criteria applicable to social media apply to all types of messages, regardless of the type of message, in addition to the elements outlined for the specific type of message.

Other interactive tools

Electronic interactive tools encompass a wide variety of technologies used to communicate information to a large number of people in a user-friendly manner. These tools may take the form of:

- a quiz
- a chat room
- clinical software
- an online banner ad
- a web-based or mobile application
- a keyword, such as a metadata tag
- a search engine optimization (SEO) tool
- decision-making support tools used by HCPs

In addition to the elements outlined in the previous section, information disseminated through interactive tools and technologies may be considered promotional if the tool and/or technology:

- is branded
- provides links or search results/outputs to material that emphasizes a specific product and its benefits
- makes direct or indirect therapeutic or safety comparative claims

Formulary kits or packages

Formulary kits are packages prepared for formulary committees (public, including hospital formulary, and private payers) to review. These committees then decide whether to include a health product in a formulary.

Formulary kits or information disseminated through these kits may be considered promotional if they:

- exceed that which would normally be required to support such an application (as described by the public and private formularies)<
    - are disseminated, in whole or in part, to a wider audience at the same time or at a later date, except when submitted to health technology assessment agencies
        - submissions to these agencies via patient and health care professional groups would be examined on a case-by-case basis to determine if they are promotional
- involve sample distribution, unless required by the formulary committee

Educational activities

Continuing medical education, scientific/medical exhibits and conferences

Continuing medical education (CME) events are accredited programs for health care professionals or scientific/medical symposia focused on health products. These events are sometimes sponsored by health product manufacturers.

The key factor in determining the status of such an activity is the degree to which the program is independent of the drug manufacturer.

Key aspects of these events include the following:

- They provide a forum for exchanging information on related clinical and scientific issues.
- The intended audience is health care professionals and staff involved in patient care. Patients, patient groups, experts in a given field, sales representatives and other non-health care professionals attend only when their participation is justified and allowed by event organizers. Members of the public should not attend.
- The sponsor or its representatives can present at these events when their participation is allowed by event organizers.
- Commercial exhibits or advertisements must be arranged in a location that is clearly and completely separated from the CME event.

Information distributed at these events may be considered promotional if:

- a health product manufacturer sponsors only specific portions of the agenda or conference that are related to a product
- the sponsor's role and any financial relationships between the sponsor and the speakers and organizers of the event is not clearly disclosed
- the content of the agenda and individual presentations from non-manufacturer/sponsor members are not independently developed and are influenced by the sponsor, manufacturer or any entity acting on behalf of the sponsor or manufacturer
- inducement is provided to participants
- there are direct or indirect promotional activities relating to health products, including sample distribution, during the event
- sales representatives are engaging in promotional activities related to health products during the event
- the limitations of the data and of the health products are not adequately discussed
- reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a health product are disseminated by the sponsor or its agent to a wider audience

For further requirements, please consult:

- national standard for accredited continuing medical education/continuing professional development activities of the Royal College of Physicians and Surgeons of Canada
- code of ethics of the Conseil québécois de développement professionnel continu des médecins

Canadian and international medical/scientific conferences

The factors mentioned in the Overview page apply also to Canadian and international medical/scientific conferences held in Canada. Conference participants may freely exchange information to achieve conference goals. Additional elements that may render these events promotional are:

- display of a drug product prior to market authorization in Canada is not prominently identified as not being authorized for sale in Canada
- there are actions intended to target the Canadian general public directly or indirectly

Other learning activities

Other learning activities (OLAs) are unaccredited programs, events or activities where medical/scientific information is presented to health care professionals by their peers. The main focus of and reason for sponsoring or participating in OLAs is to exchange scientific and clinical information.

The intended audience is health care professionals and staff involved in patient care. Patients, patient groups, experts in a given field, sales representatives and other non-health care professionals attend only when their participation is justified and allowed by event organizers. Members of the public should not attend.

Information distributed at OLAs may be considered promotional if:

- the need for such an activity has not been identified through a needs assessment, in collaboration with relevant health care professionals or their organizations
- the objective of the program is not clearly outlined and the activities are not meant to address the gaps as identified in the needs assessment
- the purpose of associated activities is unclear
- materials for the program or activity have not been developed in accordance with clear program objectives identified through a needs assessment and are distributed widely beyond those participating in the event
- inducement is provided to participants
- there are direct or indirect promotional activities relating to health products, including sample distribution during the event
- product presentations are not fair and balanced
    - with respect to unauthorized health products and/or unauthorized uses, there is no mention that safety and effectiveness are not established by Health Canada and that market authorization has not been granted in Canada
- sales representatives engage in promotional activities during the event
- evaluations are not collected to assess whether program objectives have been met, as identified in the needs assessment for the activity

An OLA event may also be considered promotional if a speaker/presenter does not:

- disclose any conflict of interest(s) and funding, including with respect to the sponsor
- disclose that Health Canada has not established the safety and effectiveness of an unauthorized health product and that market authorization has not been granted in Canada
    - if the presenter chooses to discuss or present on an unauthorized health product
- have complete editorial control of the content being presented with respect to the sponsor or its agents
    - individual presentation has not been independently developed and is influenced directly or indirectly by the sponsor, manufacturer or any entity acting on behalf of the sponsor or manufacturer

Publication supplements

Supplements in a publication (such as a magazine and a journal, in digital or print form) usually consist of a collection of articles that deal with related issues or topics. They are:

- published as a separate issue of the journal or as an addendum to a regular issue
- funded by sources other than the journal publisher (such as a health product manufacturer)

A publication supplement that is sponsored, in whole or in part, by a health product manufacturer may be considered promotional if:

- the content does not include a variety of treatment approaches for the same medical condition
- it is targeted to an audience beyond the publication's usual readership
- there's a link between promotional materials and the supplement (for example, by proximity within the publication)
- sponsorship by the manufacturer is either not declared or in such a way that there is obvious link to a health product that is being discussed
- it is not clearly identified as being distinct from the regular publication
- it is disseminated by the sponsor in whole
- the sponsor, manufacturer or any entity acting on behalf of the sponsor or manufacturer has modified an article in the supplement
- a supplement consisting of symposium proceedings that address a variety of issues related to different diseases, medical conditions or health products is edited by the sponsor/manufacturer or any entity acting on its behalf

Medical procedure and health service messages

Health care professionals may promote medical procedures and services (such as medical cosmetic services) offered in their clinics to the general public.

These messages may be considered promotional if:

- a specific health product is being promoted
- they do involve the sale or purchase of a health product rather than of the service

Patient information materials

Separate package inserts, prescribing information, fact sheets, consumer/patient medication information (such as patient leaflets), patient diaries or other material that is to be distributed to a patient for whom the health product is prescribed may be considered promotional if:

- it also contains information on a product that is not prescribed to the patient by a health care professional
- it is distributed to consumers to whom the product was not prescribed
- in the case of a website, access is restricted to ensure that information is only accessible by the patient for whom the product was prescribed

Note: Some of these materials may be considered as part of the labelling. Relevant labelling requirements for the type of health product will apply to this material and must be consistent with the terms of the marketing authorization.

Patient support group activities and literature

Patient support group activities

Patient groups play an expanded role in health care, including in participating and contributing to how clinical trials are designed and conducted.

The involvement of patient support groups in clinical trials may be considered promotional if:

- the group does not inform its members or make public the funding it received from the sponsor of the clinical trial/investigational testing for this and previous trials
- the group does not inform its members or make public the full extent of its role, which should be limited to the one described and approved by the Ethical Review Board
- any deviation or change in funding or role is not made public and reported to the members
- the group's role changes depending on the sponsor's funding level for similar study requirements and products

Patient groups and their members are sometimes invited to attend conferences and learning activities sponsored by industry.

Attendance at and participation in these activities may be considered promotional when:

- the content is product-related rather than disease-focused
- the treatment options and their respective risks and benefits are not discussed objectively without emphasis placed on 1 product or drug class

Patient support group literature

Patient support groups often publish information in the form of websites and brochures or leaflets. These are intended to help members (and potential members) better understand a disease and its treatment.

Declaration of sponsorship of the websites and brochures/leaflets by a health product manufacturer does not render the brochure promotional. Patient group publications that include information on health products may be considered promotional if:

- the content is focused on the product rather than on the disease
- the treatment options and their respective risks and benefits are not discussed objectively
    - emphasis is placed on 1 product or drug class (by using capital letters, bold text and links)
    - risks are minimized and benefits exaggerated
    - emphasis is placed on 1 health product or its merit (by overly using a brand name or describing the product as a "breakthrough")

In the case of clinical research or studies, messages disseminated by patient support groups to their members may be considered promotional when the message:

- promises or implies a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document
- coerces, states or implies a certainty of favourable outcome or other benefits beyond what is outlined in the consent document and the protocol
- claims (explicitly or implicitly) that the health product under study is safe or effective for the purposes under investigation, or that the test article is equal or superior to other health products
- uses terms such as "new treatment," "new medication" or "new drug" without explaining that the test is investigational

Press releases and press conferences

Health product manufacturers commonly release information on new research developments about a product when:

- a notice of compliance is issued
- a new drug is launched
- a new indication for use is included in the terms of market authorization for a previously authorized product
- changes are made to reimbursement status or formulary coverage

A press release or information disseminated at a press conference concerning a health product may be considered promotional if:

- the announcement is kept indefinitely on the landing page of a Canadian website of the manufacturer and its subsidiaries and/or the press release distributor's website, although no longer considered as news
    - for example, posted for more than 1 year from the initial date of publication and not archived
- statements about the degree of safety or efficacy and comparisons to other treatments are not factual
- an attempt is made to influence the pick-up or placement of the announcement
    - for example, payment is made by the manufacturer to influence the visibility in the press and for subsequent publications or broadcasts
- reference is made to a health product or its merit by, for example:
    - using a brand name excessively
    - describing the product as a "breakthrough"
        - defined as a health product that is proven to be therapeutically more beneficial compared to existing therapies based on clinically significant endpoints
        - lacks a statement that the product has been granted a breakthrough therapy designation by the U.S. Food and Drug Administration

Risk management plans

A risk management plan (RMP) is required or requested by Health Canada. This document describes a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to a health product and to assess the effectiveness of those interventions. An RMP reflects emerging, known and unknown clinical and non-clinical safety data. It is updated throughout the product's life cycle upon discussion and agreement between Health Canada and the sponsors/market authorization holders.

Risk minimization measures (RMMs) are interventions intended to prevent or reduce the occurrence of adverse reactions associated with being exposed to a health product or to reduce their severity or impact on the patient. Measures may include warnings on the label or providing information in educational materials used by health care professionals. They form part of an RMP.

Risk minimization tools (RMTs) are documents or materials developed for additional RMMs, such as guides for health care professionals or patients. An RMT may be considered promotional if:

- it is not scientifically accurate and inconsistent with the Canadian product monograph
- the product benefits (direct or implied) that are not necessary for defining the risk are included
    - for example, a risk associated with a use or strength
- it contains unauthorized safety or benefit claims and/or comparative claims
- it is inconsistent with the RMM objectives
- it is distributed to health care professionals by sales or marketing staff for the purpose of promoting the sale of a product, such as being used as detailing aids during a sales call

Where RMTs are communicated in a context such as educational activities, they may be considered promotional if:

- the activity is not clearly intended as a risk minimization measure or the need for such an activity has not been clearly and systemically identified through a needs assessment in collaboration with relevant HCPs or their organizations
- the information is distributed in a manner that may be considered promotional according to the section on Educational activities

Reference texts, peer-reviewed journal articles

As a courtesy, a manufacturer may disseminate reference texts (textbooks and chapters of textbooks), government publications or reprints of published, peer-reviewed articles from medical or scientific journals.

These disseminated resources or information may be considered promotional if:

- they are not in their original form and are accompanied by any form of verbal or written information designed by or on behalf of the manufacturer for the purpose of promoting a health product (for example, a detail aid, summary or interpretation of the text)
- they have been solely written or edited by an employee or agent of the manufacturer

Responses to inquiries

Information provided to an individual or organization about a health product by a manufacturer in response to a request for information may be considered promotional if:

- the inquiry has been encouraged in any way by the manufacturer of the health product
- the response to an inquiry regarding unauthorized products or indications (off-label) is communicated by sales or marketing personnel

Definitions

For the purpose of this guidance document, the following terms are defined as follows:

Advertisement:

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.

Advertising preclearance agencies (APA):

Independent entities, which review and 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. Some 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 HCP associations. Health Canada acts as an ex-officio observer and advisor to some of these boards and advisory bodies, without relinquishing any part of its authority under the Food and Drugs Act (FDA) and its associated regulations.

Animal health products:

Include veterinary drugs and veterinary health products (VHPs) but exclude veterinary biologic products not regulated by Health Canada.

Biological drugs (biologics):

Products made from living sources, including vaccines. Biologics come from living organisms or from their cells. They are often made using biotechnology. Examples of biologics include insulin, growth hormones and antibodies. Biologics are generally larger and more complex in composition than chemically produced pharmaceutical drugs.

In Canada, biologic drugs are listed in Schedule D of the *Food and Drugs Act*.

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 highlights a specific product attribute, such as "longer lasting" or "tastes great."

Comparative claim:

A statement that compares an identified attribute of 1 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. They 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. 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.

Disposal:

The power or opportunity to make use of someone or something.

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 8-digit number assigned by Health Canada to a drug product before being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada. It's 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
- submitted by veterinary practitioners, for the purpose of diagnosing or treating a medical emergency in an animal or group of animals under their care

Formulary committees:

A multidisciplinary committee responsible for making decisions about drugs whose costs are covered by a private or public (including hospitals) drug coverage program (formulary).

General public:

Ordinary people, especially all the people who are not members of a particular medical, pharmaceutical or scientific organization or who do not have any special type of medical or scientific knowledge. This excludes persons who have been prescribed a health product by a health care professional (HCP).

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 for human or animal use, a medical device for human use, a natural health product, a VHP and/or a radiopharmaceutical drug for human or animal use.

Homeopathic medicine number (DIN-HM):

A computer-generated 8-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. Does not include a pharmacist or other HCP who, at the request of a patient, compounds a health product for the purpose of sale to that patient.

Market authorization holder (MAH):

Also referred to as sponsor or manufacturer. The MAH is the legal entity that holds the notice of compliance, drug identification number, medical device licence number or product licence number, or has received approval to initiate clinical trials in Canada.

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 human use in:

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

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.

Medical device licence 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 human use in:

- diagnosing, treating, mitigating or preventing 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 maintain or promote health

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 health products pertain to human beings only.

Natural product number (NPN):

A computer-generated 8-digit number assigned to each natural health product authorized to be marketed under the *Natural Health Products Regulations*.

New drug:

A drug, other than a VHP:

- 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 2 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 4 digits and letters.

Notice of compliance (NOC):

A document from Health Canada issued to a manufacturer, 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.

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.

Sale:

Includes offer for sale, expose for sale or have in possession for sale, or distribute to 1 or more persons, whether or not the distribution is made for consideration. Also includes lease, offer for lease, expose for lease or have in possession for lease.

Special Access Program (SAP):

Health Canada's program that considers requests from practitioners who wish to access drugs that are unavailable for sale in Canada or 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. 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, medical devices 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 comprise all labelling information (for example, the product monograph, prescribing information, inserts, instructions for use) that accompanies the NOC and/or in the document that assigns a DIN, NPN or DIN-HM, medical device licence 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 FDA and its associated regulations and as interpreted by guidance documents and policies.

Unauthorized product:

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.

Vaccine:

Complex biologic products designed to induce a protective immune response effectively and safely. Vaccines are classified according to the type of active component (antigen) they contain.

Veterinary health product (VHP):

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

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:

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 *Food and Drug Regulations* (FDR) 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.

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

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

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.

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

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 1 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

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

Section 78: 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: