Health Canada Santé Canada

Canada

– Meeting With Stakeholders –

The Distinction Between Advertising And Other Activities

January 10, 2023

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Purpose

Consistent with Health Canada's commitment to openness and transparency, this meeting is intended to:

- Share some stakeholders' comments, which Health Canada received during the 2019 consultation on this document.
- Explain how Health Canada addressed these comments.
- Respond to clarification questions.

Proposed Agenda

Time	Item	Lead
13:30 – 13:35	Introductory remarks	Alain Musende
13:35 – 14:55	Review of stakeholders comments and Health Canada's actions	Alain Musende
14:55 – 15:25	Questions and answers • Via the chat function • Verbally	• Alain Musende • All
15:25 – 15:30	• Next steps • Closing remarks	Alain Musende

General Comments

General Comments

1. Why did we change the title of the document?

2. Situations described herein constitute advertising as per the *Food & Drugs Act, as* they would directly or indirectly contribute to increasing sale of health products.

3. Health Canada should demonstrate a clear recognition, understanding and sensitivity towards opioid-dependent patients.

General Comments

Health Canada Santé Canada

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

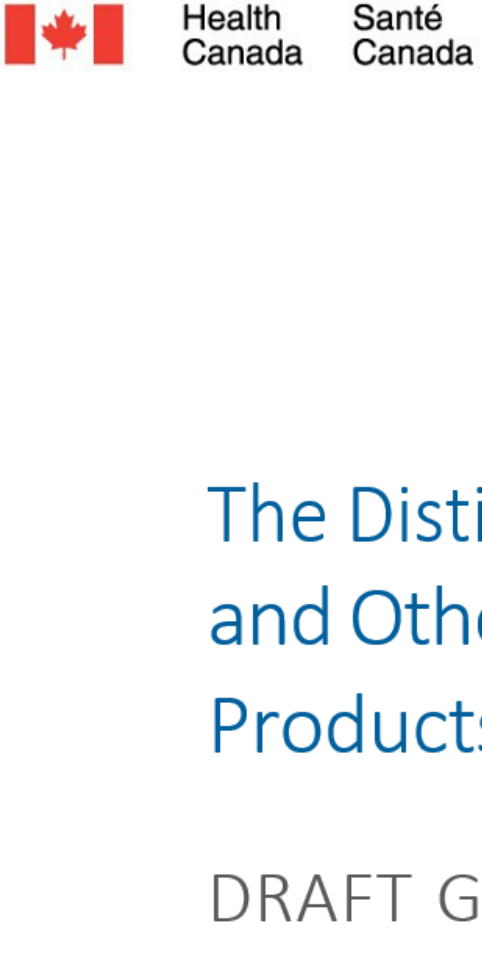
DRAFT Guidance Document

July 2019

Section 2 – *Food and Drugs Act*:

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

General Comments



Comments on the Introduction

1.1 Purpose

48 # 1 Introduction

49 ## 1.1 Purpose

50 Health Canada recognizes that it is important for industry to disseminate non-promotional information regarding
51 human and veterinary health products to health care professionals and for the general public to be able to access
52 such information. Since advertising is defined as a representation for the purpose of promoting the sale of a health
53 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
54 promote the sale of a health product or to provide information.

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

1.1 Purpose

1. Suggest the term “animal health products” instead of “veterinary health products”.

2. To avoid ambiguity and uncertainty, the document should endeavor to provide specific details wherever possible.

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Health Canada recognizes that it is important for industry to disseminate non-promotional information regarding human and animal health products to healthcare professionals (HCPs) 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 whether 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 a particular message or activity is considered promotional or non-promotional.

1.2 Scope

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.

1.2 Scope

1. The scope is for authorized products. However, clinical trials, and Class I medical devices also discussed.

2. Need to better differentiate between “target audiences”.

3. Are ethical products within the scope of this guidance document?

4. The message should be the focal point of the analysis, not whether particular people are viewing the message.

1.2 Scope

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

The scope of this document applies to messages and activities involving medical conditions, and/or any health-related matters, regardless of the target audience in Canada. Moreover, this guidance document applies to all messages and activities targeting Canadians through any messaging media (e.g., television, radio, print, online, digital platforms, etc.) or setting.

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, their Regulations, and the applicable administrative policies.

1.3 Background

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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."

1.3 Background

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.

1.3 Background

1. A Continuing Medical Education event is educational. Thus "advertising" would not be presented by a speaker.

2. Include that promotion of a prescription drug to the general public is limited to name, price and quantity, and mention Section C.01.044 of the *Food & Drug Regulations*.

3. The sole purpose of this document should be to determine whether the message is promotional, not whether the message conforms to regulations.

1.3 Background

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

Consistent with the F&DA and the CDSA, promotional messages and activities are considered as advertising.

Advertising of a health product prior to market authorization is prohibited by Section 9(1) and 20(1) of the F&DA. In general, Section 9(1) prohibits advertising any drug or device 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) prohibits advertising 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. Advertising prior to market authorization is also prohibited by Section C.08.002 of the F&DR for a new drug, and Section 27(a) of the Medical Devices Regulations (MDR).

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 would not generally be subject to the advertising provisions.

1.4 General Principles

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.

1.4 General Principles

1. The “primary purpose” does not recognize that materials may still be promotional via a secondary purpose.

2. “Primary purpose” and “on its own merit” should be defined.

3. Health Canada should consider promotional campaigns, which may include post-marketing trials, sponsorship and delivery of educational events, payments to researchers and clinicians etc.

1.4 General Principles

1.4 General Principles

Determining whether a message or activity is promotional helps in interpreting whether the legislative and regulatory requirements on advertising applies in a given case. After having determined that the purpose of a message is to promote directly or indirectly the sale of a health product, an assessment can be made regarding compliance with the Acts and Regulations pertaining to health product advertising.

When making such a determination, the following principles will guide the analysis:

1. Each message will be evaluated on its own merit in its entirety, with consideration being given to the context within which the message is being delivered.
2. Any linkages to various materials related to the message will be considered as well.
3. The factors described in section 1.5 will also be taken into consideration. As this list is not exhaustive, other factors or circumstances may also 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.

Generally, no single factor in itself will be determinative of whether the purpose of a particular message is advertising.

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 will validate that 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

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

1. This Guidance should include examples as was provided in the January 12, 1996 Health Canada guidance under the “Considerations” section.

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

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

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

What is the context in which the message is disseminated?
e.g., when and how is the message delivered; what is the milieu or medium of dissemination? Is it a science-

1.5.1 Content and Context

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.

1.5.1 Content and Context

1. Specify that similar color coding, use of logo-like graphics etc. should not be used.

2. Remove “and is consistent with the terms of market authorization”.

3. Add “it is not disproportionately product-focused”.

4. What is meant by “influenced”?

5. What type of message can appear in the catalogue?

1.5.1 Content and Context

1.5.1 Content and Context

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

- It is disproportionally product-focused
- It emphasizes the benefits of a health product while minimizing, omitting, or ignoring risks in any way (e.g., editorial comments, opinions, suggestions, etc.)
- The message is affected directly, indirectly, or in an intangible way 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 can be associated with a specific health product e.g. brand colors, logo like graphics and other visual cues; unique packaging, setting, decor etc.; and
- The message or activity is combined or disseminated concurrently with any promotional messages or activities.
- The message includes direct or implied comparative therapeutic claims e.g. in terms of ingredients, brands, or therapeutic category
- The message is disseminated in the context of the target medical condition e.g. messages about health products in women's magazines for medical problems affecting only women

1.5.2 Sponsorship and Dissemination

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.

1.5.2 *Sponsorship and Dissemination*

1. How "a competitor would be willing to sponsor or fund“?

2. The word sponsorship should be removed from the title of subsection 1.5.2.

3. Need examples of “primary audience”, “secondary audience”, and “target audience”.

4. What is “delivered repeatedly”, “redistributed widely”?

5. A message is not promotional if delivered by sales or marketing staff.

1.5.2 Sponsorship and Dissemination

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

- The message or activity is not disseminated by a government authority (e.g., the Public Health Agency of Canada, the provincial ministries of health, provincial formularies, etc.);
- A competitor would not be willing to sponsor and deliver the same message;
- The message or activity is delivered by sales and/or marketing staff;
- The message or activity involve sample distribution.

Comments Regarding:

Examples of Promotional Messages and Activities

2 Examples of Non-promotional Messages

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 Examples of Non-promotional Messages

1. Confirm that “under each section” refers to section 2.

2 Examples of Non-promotional Messages

2. Examples of promotional Messages and Activities

In order to provide further guidance in terms of what may constitute promotional messages or activities, specific examples are presented in this section. These are provided to illustrate and apply the general principles and guiding 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. There may be other current or future activities that could be considered as advertising as well. It should be noted that a real-life case might not fall within a specific category, therefore a combination of factors may be applied to make a determination on whether the message or activity is promotional.

A message or activity can be considered as advertising where the factors under each section below are 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

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.

2.1 Clinical Trial and Investigational Testing Recruitment Material

1. Consideration of the significantly evolved roles of patients and patient groups.

2. Are the following acceptable: study title, study number, protocol codes, the generic name, etc.?

3. The text suggests that the title of the study would be considered promotional.

4. Referencing the study number or protocol code can inadvertently or indirectly lead to the product name.

2.1 Clinical Trial and Investigational Testing Recruitment Material

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A Clinical Trial, as per the *F&DR*, is defined as an investigation in respect of a drug for use in humans that involve human participants 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 for the purpose of the *Medical Devices Regulations* is understood as being a systematic investigation in one or more human participants, 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 promotional in the following circumstances:

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

2.2 Corporate Messages

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.

2.2 Corporate Messages

1. Publicly traded companies have strict obligations under securities laws that must be respected.

2. Once on SEDAR (System for Electronic Document Analysis and Retrieval), a company cannot remove its filings except in accordance with securities law and regulator policies.

3. Why an “Investor Information” section? Not all company websites contains it.

2.2 Corporate Messages

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A corporate message is understood as being a communication (e.g., website, 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 promotional in the following circumstances:

- the purpose of the communication appears to be about the health products being marketed, developed, or researched rather than to provide information about the manufacturer or organization;
- information about a health product being marketed, developed or researched is not limited to a section intended for current and potential investors e.g. the "Investor Information" section of the communication and exceeds the mention of the name of the health product and the therapeutic area; and
- emphasis is given to a product or its benefits.
- in the case of unauthorized drugs, or unauthorized indication, there is no mention that the safety and efficacy is still under investigation and that market authorization has not yet been granted by Health Canada.

Communication of detailed information about the health products being marketed, developed, or researched is considered non-promotional when the communication is required by Canadian laws e.g., as a requirement of the filing system for provincial and territorial securities regulators.

2.3 Medical Condition and Treatment Awareness Related Materials

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.

2.3 Medical Condition and Treatment Awareness Related Materials

1. The requirement that treatments not be discussed when only one treatment is available, is arbitrary and affects patients.

2. Where are the requirements for 'help-seeking' messages?

3. Can sponsors mention a treatment when there is only one non-prescription treatment but many prescription treatments available.

4. A non-promotional piece must not include comparative therapeutic (safety or efficacy) claims.

2.3 Medical Condition and Treatment Awareness Related Materials

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 or branded health product materials for the same medical condition.

These materials are made available directly or indirectly to the general public by a manufacturer, or another organization, through various means, such as online (via websites, social media, digital applications, email, etc.), by mail, in retail outlets, in HCPs' waiting rooms, etc.
Mention of the sponsor of such materials, by name or logo, is required and does not in itself render the material promotional. Medical condition and treatment awareness related materials may be considered promotional in the following circumstances:

- the content is product-focused rather than disease-focused,
- the material does not discuss available treatment options (including non-health product) and their respective risks and benefits in a fair, balanced and objective manner (e.g. emphasis is placed on one product or one drug class through the use of capital letters, bold text, and links; minimizing risks; exaggerating benefits; etc.);
- the material makes direct or indirect therapeutic or safety comparative claims;
- the material does not emphasize the need for patients to consult a HCP for complete information on the disease, and the available treatment options, or if they suspect they are experiencing any symptoms related to the disease.
- the material makes reference to an unauthorized health product or indication, and
- the material makes reference to availability through SAP

2.4.1 Social Media

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.).

2.4.1 Social Media

1. This guideline seems contradicts our freedom of speech.

2. Electronic tools and technology are a means of distributing messages, not a type of message.

3. Social platforms such as LinkedIn, Twitter etc. do not allow. sponsors to delete users' content.

4. Proposed text: " the content, user-generated comments which are under the sponsor-control, hyperlinks…."

5. Differentiate between pharma-owned and 3rd party owned.

2.4.1 Social Media

2.4 Electronic Tools and Technology

2.4.1 Social Media

Social media encompasses websites and applications that enable HCPs, 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. A person or organization and/or its representatives may sponsor the social media activity or message, but

In addition to the elements outlined in section 2.3 of this guidance document, information about a health product or medical condition disseminated through social media may be considered promotional in the following circumstances:

- the social media website or platform is branded (e.g., a specific product is mentioned);
- 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 available "sharing" options (e.g. email, "like", "tweet", "re-tweet", "comment", etc.) could 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 are engaging in discussions beyond in a monitoring capacity (e.g., removal of inappropriate comments, adverse event reporting, etc.) and the provision of non-material content such as "Thank you for your comment".

2.5 Formulary Kits or Packages

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.

2.5 *Formulary Kits or Packages*

1. Is Hospital Formulary covered under the public formulary committee listed?

2. Sometimes contain free samples, which are clearly promotional.

3. “In part” in this criteria could make reusing data and content that happens to be in a formulary kit promotional.

2.5 Formulary Kits or Packages

2.5 Formulary Kits or Packages

Formulary kits are defined as material prepared for review by formulary committees (i.e., public (including hospital formulary) 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 promotional in the following circumstances:

- the information provided exceeds that which would normally be required to support such an application as described by the public and private formularies;
- the information package is disseminated to a wider audience simultaneously, or at a later date, except when it is submitted to health technology assessment agencies.
- the kit involves sample distribution, when not required by the formulary committee.

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

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.

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

1. Members of the general public often register and would be exposed to any promotion.

2. Requirements for non-Canadian companies presenting at Canadian International conferences are missing.

3. Does this allow discussion of unauthorized drugs by a Canadian manufacturer?

4. Health Canada should consider accredited CME as non-promotional given the National Standards.

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

5. Do we no longer can have a booth outside the meeting room?

6. A manufacturer should be able to present in these events.

7. A member of the public attending the event should not render it promotional.

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

2.6.1 Continuing Medical Education, Scientific/Medical Symposia/Exhibits and Conferences

Continuing Medical Education (CME) events, defined as accredited programs for HCPs and Scientific/Medical symposia related to health products, are at times 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:

- they provide a forum for the exchange of information on related clinical and scientific issues;
- the intended audience is HCPs and staff involved in patient care. Non-HCPs and staff e.g. patients, representative of patient groups, and sales representatives attend only when their participation is allowed by event organizers
- 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 disseminated at such events may be considered promotional in the following circumstances:

- a health product manufacturer sponsors only specific portions of the agenda or conference that are related to a specific 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 affected directly, indirectly, or in an intangible way by the sponsor or manufacturer or any entity acting on behalf of the sponsor or manufacturer;
- there is inducement provided to participants;
- there are no direct or indirect promotional activities relating to health products, including sample

2.6.1 Continuing Medical Education, Scientific Symposia/Exhibits and Conferences

distribution;

- sales representatives are engaging in promotional activities related to health products,
- the limitations of the data and of the health products are not adequately discussed; and
- reports, edited scripts, or recorded videos of the proceedings, in whole or in part, that concern a specific health product are disseminated by the sponsor or its agent to a wider audience.

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. Additional elements, which 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

For CMEs, further requirements could be found in the National standard for support of accredited Continuing Medical Education/Continuing Professional Development activities of the Royal College of Physicians and Surgeons of Canada[3] and, for Quebec, the Code of Ethics of the Conseil québécois de développement professionnel continu des médecins (CQDPCM)[4].

2.6.2 Other Learning Activities

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.

2.6.2 Other Learning Activities

1. What level of oversight does the sponsor have on the speaker?

2. Is product discussion limited to be consistent with market authorizations, or unauthorized products can also be discussed.

3. Consider adding an additional “Learning Activity” as a category of educational programs directed at patient organizations.

4. Need flexibility in how a “needs assessment” is conducted.

2.6.2 Other Learning Activities

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 HCPs by their peers. The primary focus of, and the reason for, sponsoring or participating in OLAs is the exchange of scientific and clinical information and issues. The intended audience is HCPs and staff involved in patient care. Non-HCPs e.g. patients, patient groups, and sales representatives attend only when their participation is allowed by event organizers.

Information disseminated at OLAs may be considered promotional in the following circumstances:

- the need for such an activity has not been identified through a needs assessment, in collaboration with relevant HCPs or their organizations;
- the objective of the program is not clearly outlined and the purpose of associated activities remain unclear
- materials for the program or activity have not been developed in accordance with clear program objectives and are distributed beyond event participants;
- there is inducement provided to participants;
- there are direct or indirect promotional activities relating to health products, including sample distribution
- product discussions are not fair and balanced and, when inconsistent with the Canadian terms of market authorization, such as discussion on unauthorized health products and/or unauthorized uses; there is no mention that the safety and efficacy/effectiveness are not established by Health Canada and market authorization is not granted in Canada.
- sales representatives engage in promotional activities, and
- evaluations are not collected to assess whether program objectives have been met, in collaboration with the relevant HCPs or their organizations, which would have identified the need for the activity.

Additionally, an OLA could be considered promotional when a speaker/presenter/organizer:

- does not appropriately disclose all conflict of interest(s) and funding, including with respect to the sponsor.
- does not have complete editorial control of the content being presented, with respect to the sponsor or its agents. Individual presentations are not independently developed and are affected directly, indirectly, or in an intangible way by the sponsor or manufacturer or any entity acting on behalf of the sponsor or manufacturer

2.7 Publication Supplements

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.

2.7 Publication Supplements

1. Disconnect between publications and conferences, where it is considered promotional activity if a manufacturer sponsors portions of an agenda for a conference.

2. Many supplements are not based solely on symposium proceedings.

2.7 Publication Supplements

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. They are funded by sources other than the journal publisher, e.g., by a health product manufacturer.

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

- the content of the supplement does not include a variety of treatment approaches for the same medical condition;
- the publication is targeting an audience beyond the publication's customary readership;
- A link is established between promotional materials and the publication supplement (e.g., 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;
- the difference between the supplement and the regular publication remains unclear;
- the supplement is disseminated as a whole by the sponsor; and
- an article of the publication supplement is modified by the sponsor/manufacturer or any entity acting on its behalf.
- a supplement comprised 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;

2.9 Patient Information Materials and Packages

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.

2.9 Patient Information Materials and Packages

1. Are websites, apps, leaflets, etc.. part of the label?

2. Remove “prescribed to a patient by a healthcare professional”.

3. How to ‘gate’ a site so that only a patient can access it?

4. This section is not relevant to self-care products.

5. Information provided in these materials should be equivalent to the information provided on the label.

2.10 Patient Support Group Literature

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.

2.10 Patient Support Group Literature

1. Patient voices need to be heard by industry and in the activities they support, such as continuing medical education. The roles of patients groups have considerably evolved.

2. Ensure Patient Support Groups (large or small) are made aware of these requirements and assist with compliance.

3. A wealth of evidence shows that these materials often are promotional and that pharmaceutical companies spend substantial sums to support “patient information” and “patient awareness” campaigns.

2.10 Patient Support Group Literature

4. Clarify that this applies to all health products.

2.10 Patient Support Group Literature

2.10 Patient Support Group Activities and Literature

2.10.1 Patient Support Group Activities

Patient advocacy groups play an expanded role in healthcare, including in participating and contributing to the design and conduct of clinical trials. Patient support group involvement in clinical trials may be considered promotional in the following circumstances, where the patient group:

- does not disclose to its members or the public the funding it received from the sponsor of the clinical trial/investigational testing for this participation and prior participations
- does not inform its members or the public on the full extent of its role, which should be limited to the one described and approved by the Ethical Review Board
- does not report to its membership and make public any deviation or change in funding or its role
- would perform its role differently for competitors' comparable products, especially depending on the sponsors' funding level

Patient support groups and their members are sometimes invited to attend conferences and learning activities sponsored by industry. In addition to the above elements, attendance and participation at these activities may be considered promotional when:

- the content of these activities is product-focused rather than disease-focused;
- the various treatment options and their respective risks and benefits are not discussed in an objective manner, including emphasizing a specific product or drug class

2.10 Patient Support Group Literature

2.10.2 Patient Support Group Literature

Patient support groups often publish information in the form of websites 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 websites and brochures/leaflets by a health product manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on any health products may be considered promotional in the following circumstances, or where other factors indicate that the primary purpose of publication is to promote the sale of the drug:

- the content is product-focused rather than disease-focused;
- the various treatment options and their respective risks and benefits are not discussed in an objective manner (e.g. emphasis is placed on one specific product or drug class through the use of capital letters, bold text, and links; minimizing risks; exaggerating benefits; etc.);
- Referring to a health product or its merit with excessive use of a brand name or unduly describing the product as a "breakthrough[5]"

In the context 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 favorable 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 known to be equivalent or superior to any other health products
- Uses terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational

2.11 Press Releases and Press Conferences

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.

2.11 Press Releases and Press Conferences

1. There are many more occasions for news releases. Allow more information in the announcement.

2. Why remove it after 30 days? We recommend one year.

3. For a publicly traded company, dissemination of press release is critical for compliance with disclosure obligations under securities law.

4. All newswires have a fee to post/distribute press releases, and PR agencies a fee to share news more broadly. It is a common practice for manufacturers to pay for the broadcast.

2.11 Press Releases and Press Conferences

2.11 Press Releases and Press Conferences

It is common practice for a pharmaceutical manufacturer to release various health product-related news, including new developments in research, at the time of a Notice of Compliance, the launch of a new drug or a new indication for use added in the TMA of a previously authorized product; reimbursement status; formulary coverage etc.

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

- the announcement is maintained 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, when maintained for more than one year from the initial date of publication, without being archived;
- statements regarding the degree of safety or efficacy and comparisons to other treatments are not factual and/or observed
- there is an attempt to influence the pick-up or placement of the announcement e.g., payment is made by the manufacturer to influence the visibility in the press and for subsequent publications or broadcasts; and
- there is undue reference to a health product as being a "breakthrough" product (defined as a health product that is proven to be therapeutically more beneficial compared to existing therapies based on clinically significant endpoints) and not in the context of a factual statement that the product has been granted a breakthrough therapy designation by the U.S. Food and Drug Administration

2.12 Risk Management Plans

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

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.

2.12 Risk Management Plans

1. The RMP is a confidential document not widely distributed to HCPs. It should not be included in this guidance document.

2. Which materials are intended for dissemination to HCPs, i.e. tools developed as outputs of the RMP rather than the RMP?

3. Dissemination of RMTs via the salesforce/KAMs should not be restricted.

4. We recommend expanding this to “the document has been required or requested by HC or otherwise filed with HC”.

2.12 Risk Management Plans

2.12 Risk Management Plans & Risk Minimization Measures

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 a health product, 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 product's life-cycle upon discussion and agreement between Health Canada and the sponsors/market authorization holders.

Risk minimization measures (RMMs) / Risk Minimization Tools (RMTs) or activities are interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient, should adverse reactions occur. The RMMs may include warnings on the label or minimization activities beyond routine, such as healthcare professionals' educational material. They are part of Health Canada required RMPs and are created solely with the aim of minimizing / managing / mitigating risks. A RMM may be considered promotional in the following circumstances:

- the document is not scientifically accurate and inconsistent with the Canadian Product Monograph;
- there are direct or implied product benefits not necessary for defining the risk (e.g. a risk associated with one use, strength etc.);
- it contains unauthorized safety or benefit claims and/or comparative claims;
- the document is disseminated to HCPs or patients prior to being accepted by Health Canada; and
- the document is distributed to HCPs by sales and/or marketing staff during their promotional activities, including being used as detailing aids during a sales call.

2.13 Reference Texts, Peer-reviewed Journal Articles

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.

2.13 Reference Texts, Peer-reviewed Journal Articles

1. Suggest “the material was not solely written by an employee or agent of the manufacturer”.

2. Does not address the issue of selective choice of articles, choosing only articles favourable to their products.

3. Only scientific materials without industry funding and no author had relationship with the company should be allowed.

4. Does not prevent selection of materials to support a message that is inconsistent with the full scientific literature.

2.13 Reference Texts, Peer-reviewed Journal Articles

2.13 Reference texts, Peer-reviewed Journal Articles

This section discusses the dissemination of reference texts (textbooks and 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. The distribution of these resources or information may be considered promotional in the following circumstances:

- the material provided is altered and is accompanied by additional verbal or written information designed by or on behalf of the manufacturer for the purpose of promoting a health product (e.g., detail aid, a summary or interpretation of the text); and
- the material provided was solely written or edited by an employee or agent of the manufacturer.

2.14 Responses to Inquiries

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.

2.14 Responses to Inquiries

1. Clarify that manufacturers can respond to “patient support” requests for unauthorized medications.

2. Remove “request for proposal” or clarify if it includes requests for “patient support”.

3. Suggest: “the inquiry has not been actively solicited by the manufacturer.

4. Suggest: “the response to the inquiry may not be communicated by sales and/or marketing personnel if not in line with the TMA”.

2.14 Responses to Inquiries

5. Restricting responses by non-sales/marketing staff would be especially problematic for smaller companies and start-ups.

2.14 Responses to Inquiries

2.14 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 in the following circumstances:

- the inquiry has been directly or indirectly solicited by the manufacturer of the health product; and
- the response to the inquiry regarding unauthorized products or indications is communicated by sales and/or marketing personnel.

Next Steps & Conclusion

Next Steps – Approximate Dates:

- Finalizing document: January 31, 2023
- Completing plain language version: February 28, 2023
- Posting plain language document: March 31, 2023

Conclusion

- Health Canada's goal is to protect the health and safety of Canadians and allow them to make informed decisions about their health, in the context of health product advertising

- In order to achieve that goal, Health Canada works collaboratively with:
  - Advertising Preclearance Agencies in the oversight of health product advertising
  - Industry toward continuous improvement of the Canadian health product advertising environment, while fulfilling its commitment for transparency

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