Guidelines for Consumer Advertising of Health Products

for Nonprescription Drugs, Natural Health Products, Vaccines and Medical Devices

Ad Standards™

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INTRODUCTION

Overview

The *Guidelines for Consumer Advertising of Health Products* (*Guidelines*) apply to consumer-directed advertising of nonprescription drugs, natural health products, medical devices and vaccines in all Canadian media. Canadian media include, but are not limited to: television; radio; mass print, e.g. newspapers, magazines; out-of-home, e.g. billboards, transit; point-of-purchase, e.g. in-store promotional materials; direct mail; digital, e.g. websites, e-mail, mobile, social media.

The *Guidelines* are designed to help creators of advertising communications:

- Understand the principles that govern health product advertising in Canada; and
- Develop messages that comply with the advertising provisions of Canadian federal legislation and are in accordance with Health Canada policies and guidance documents.

The *Guidelines* are also used by advertising preclearance agencies in the review of consumer-directed health product advertising. See *Regulatory Requirements for Advertising* on the Health Canada website.

The *Guidelines* do not have the force of law and should be used in conjunction with the *Food and Drugs Act* (FDA), the *Food and Drug Regulations* (FDR), the *Medical Devices Regulations* (MDR), the *Natural Health Products Regulations* (NHPR) and other applicable legislation, regulations and guidance documents.

Exclusions

The *Guidelines* **do not apply** to:

- Advertising of products for which there are specific consumer-directed advertising restrictions set out in the *Food and Drugs Act and Regulations* and the *Controlled Drugs and Substances Act*, e.g. controlled drugs, narcotics, prescription drugs, drugs listed in Section C.01.027(1).
- Advertising of medical devices used by a healthcare professional in procedures where the consumer does not purchase and take home the device, e.g. laser eye surgery equipment, laser hair removal equipment, liposuction devices.
- Advertising of food and cosmetic products.
- Advertising where only the brand name of an authorized health product is communicated, with no direct or implied therapeutic or non-therapeutic claims.
- Consumer-directed advertising of veterinary drugs.
- Consumer-directed Informational messages including, but not limited to:
  - Institutional messages
  - Patient information, e.g. support group information, information/instruction booklets
  - Help-seeking announcements
  - Clinical trial recruitment messages
  - Public health messages that do not promote an identifiable product, e.g. vaccination campaigns
- Healthcare professional-directed advertising of prescription drugs, nonprescription drugs, natural health products, vaccines, medical devices and veterinary drugs.

Acknowledgments

The publication of these *Guidelines* represents the culmination of a collaborative effort among Ad Standards, Health Canada, and other stakeholders. These *Guidelines* will be reviewed and updated regularly to reflect Canada's evolving regulatory framework and dynamic marketplace.

GUIDING PRINCIPLES

- All health products should be promoted in a responsible manner with consumer health and safety paramount.
- Advertising should clearly communicate the intended use of the product in a manner that is consistent with the Terms of Market Authorization (TMA).
- **For nonprescription drugs, natural health products and vaccines**, advertising must respect:

  Section 9(1) of the *Food and Drugs Act*
  "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."

- **For medical devices**, advertising must respect:

  Section 20(1) of the *Food and Drugs Act*
  "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."

1.0 Product Authorization

1.1 Terms of Market Authorization (TMA)

Therapeutic claims must be consistent with the TMA.

- A product's TMA sets out the claims authorized by Health Canada. These claims may be paraphrased, but must not directly or indirectly exceed the scope of the TMA.

HEALTH PRODUCT CATEGORY	TERMS OF MARKET AUTHORIZATION
Nonprescription Drugs	• Labelling Standard • Category IV Monograph • Product Monograph • Authorized Labelling
Natural Health Products (NHPs)	• Product Licence
Vaccines	• Product Monograph • Authorized Labelling
Medical Devices	**Class II**, e.g. contact lenses, tampons, power toothbrushes: • The indication(s) for use authorized by Health Canada **Class III**, e.g. dermal fillers, blood glucose meters: • Authorized Labelling **Class IV**, e.g. breast implants: • Authorized Labelling Note: Class I devices are not issued a Medical Device Licence and therefore, do not have a TMA. While this category is not subject to preclearance, it is the advertiser's responsibility to ensure that all advertising complies with Sections 3, 20 & 21 of the *Food and Drugs Act*.

Note: Products should not be advertised if the TMA has been withdrawn by Health Canada, or if products have been voluntarily withdrawn or discontinued by the manufacturer.

1.2 Indication/Recommended Use/ Intended Use/Purpose

The advertisement must clearly communicate the product indication/recommended use as per its TMA.

- At least one indication/recommended use must be included.
- For products with multiple medicinal ingredients authorized to relieve multiple symptoms of a condition, at least one symptom per medicinal ingredient must be presented in the advertisement. However, it is acceptable to give prominence to one symptom.
- For multi-vitamin/multi-mineral supplements it is sufficient to identify the indication/recommended use as "vitamin/mineral supplement".
- For medical devices, if the intended use is self-evident in the product name, inclusion of the intended use may not be required, e.g. ACME Hearing Aid, DENTA Powered Toothbrush. For other medical devices, succinct information clearly communicating the intended use in lieu of the full intended use as per the TMA is acceptable.

EXAMPLES	MEDICINAL INGREDIENT:	AUTHORIZED INDICATION/USE:	ACCEPTABLE CLAIM:
Analgesic/ Antipyretic	• acetaminophen	• Relieves pain and fever.	"Product X relieves pain"
Natural Health Product	• black cohosh • dong quai • holy thistle • crampbark	• Helps relieve symptoms associated with menopause.	"Struggling with menopause? Help relieve your symptoms with Product X"
Cough/Cold Preparation	• guaifenesin • dextromethorphan • chlorpheniramine	• Relieves chest congestion • Relieves dry cough • Relieves runny nose and sneezing	"Product X relieves cough, chest congestion and runny nose"
Allergy Medicine	• loratidine	• For the relief of allergy symptoms such as sneezing, runny nose, itchy watery eyes and allergic skin conditions such as hives.	"Relieves multiple allergy symptoms, including sneezing"
Vaccine		• Vaccine B is an inactivated influenza virus vaccine indicated for active immunization of persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and B contained in the vaccine.	"Help prevent influenza with Vaccine B"
Device		• Handheld laser device intended for use in the treatment of periorbital wrinkles.	"Discover ReVisage, an at home laser option for your crow's feet"

Advertising Multiple Products in One Message:

- The indication/recommended use should be clearly communicated for each advertised product. There should be no suggestion that therapeutic claims for one product apply to others if they do not.
- Where a beauty shot depicts a family of products indicated for a common purpose, e.g. all depicted products are indicated to treat a variety of cold symptoms, it is sufficient to include a general "symptom relief" statement, e.g. "For relief of your cold symptoms, there's a Brand X product for you."

Note: If no therapeutic claims are made (either visually and/or in audio), such a message is not subject to the requirements set out in Section 1.2, e.g. "Brought to you by XYZ Brand".

1.3 Product Classification

A health product must be accurately represented as to the product category under which it received its TMA.

- A Homeopathic Medicine (including Homeopathic Remedy or Homeopathic Preparation) or Traditional Medicine, e.g. Ayurvedic Medicine, should be identified as such in the advertisement.
- A health product should not be represented as a food or cosmetic.
- Claims about non-therapeutic* product features or non-therapeutic ingredients may be included in advertising, but such claims should not imply a therapeutic benefit or obscure the therapeutic indication.

EXAMPLES

Therapeutic Claims:

"Fights acne"
"Relieves allergy symptoms for up to 12 hours"
"Helps prevent infection"
"Relaxes muscles"
"Kills 99.9% of germs"

Non-therapeutic Claims:

"Moisturizes dry skin"
"Whitens teeth"
"90% of users say ABC Product is easy to use"
"You can see your readings in 5 seconds with XYZ Blood Glucose Meter"
"24-hour comfort (contact lenses)"
"#1 selling brand"

1.4 Product Representation

Each claim presented and the advertisement in its entirety must be consistent with the TMA.

- The advertised product or product line should be clearly identified. This can be done visually and/or in audio.
- Visuals should not be used to directly or indirectly suggest product benefits that exceed those found in the TMA.
- Graphics, schematics and statistics should be used in a manner consistent with the TMA.
- Quotations, journal articles, study results, etc., must be consistent with, and not expand the TMA.
- Superscripts and footnotes may be used to provide clarification or additional information. However, they should be legible and not be used to correct an otherwise misleading impression about the product.

* For additional information regarding non-therapeutic claims for nonprescription drugs, natural health products and cosmetics, please refer to the *Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims*

1.5 Directions for Use

When depicted or described, directions for use, dosing and product administration must be consistent with the TMA.

EXAMPLE

TRAVEL VACCINE

Authorized Indication/Use:

Part III – Consumer Information – Helps prevent Disease X. Protection against Disease X starts about 3 weeks after the 1st dose and lasts for about 3 years. Booster: If you had your last dose of the vaccine between 3 and 4 years before, a single dose will renew your protection. If more than 4 years has passed since your last dose, you should have the complete primary vaccination course (3 doses) again.

Acceptable Claim:

"Protection against Disease X lasts for about 3 years. For prolonged protection, a booster dose is required between 3-4 years after first injection."

Unacceptable Claim:

"Vaccine B - Just one shot and you're done!"

1.6 Children

An advertisement must not suggest that a child is capable of making a rational decision regarding the use of the advertised health product.

- Health product advertising must be overtly directed to adults.
- An advertisement must not depict or encourage unsupervised use of drugs by children, or suggest that a child can self-diagnose or self-medicate.
- Advertisements must not depict product storage in locations accessible to children. A child may approve of the taste of a medicine, but may not make recommendations concerning the use of the advertised product.

Note: With the exception of children's fluoride toothpastes, drug advertising directed to children in broadcast media is prohibited under the provisions of the *Broadcast Code for Advertising to Children* and the *Canadian Code of Advertising Standards*.

1.7 Duration of Use

When depicted or described, the duration of product use must be consistent with the TMA.

- A product intended for short term use should not be represented for long term or chronic use.

1.8 Storage

When depicted or described, product storage must be consistent with the TMA.

1.9 Co-Packaged Products

When a drug product is co-packaged with other drug products or non-drug products, e.g. cosmetics or devices, each product must be represented in a manner that is consistent with its product class.

- Claims should be consistent with those authorized for each product.
- There should be no suggestion that claims for one product apply to the others if they do not.

1.10 New/Improved

Terms that communicate a product is new, improved or reformulated, e.g. "new", "improved", "now available", "introducing", may be used for a period of one year from the date it is first available for retail sale.

- The product attribute that is new or improved should be clearly specified, e.g. "improved taste", "new format".

1.11 Sampling

Advertisements for drugs (including NHPs) must not include offers for samples to the general public.

- Section 14 of the *Food and Drugs Act* prohibits the distribution of drugs as samples to the general public.

Note: Medical devices are not subject to Section 14. However, as outlined in Section 24(2) of the Medical Devices Regulations, 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.

2.0 Product Performance

2.1 Exaggeration of Product Performance

When depicted or described, product performance must be consistent with the TMA.

- Hyperbolic terminology, e.g. “amazing”, “powerful”, “fantastic”, should not be used to exaggerate the therapeutic effect/benefit of a product or ingredient.
- All health products are authorized to be effective for the condition/symptoms they are designed to relieve/treat/prevent and therefore, can claim to be “effective”, “strong enough”, “tough enough” or have the power to relieve/treat/prevent the condition/symptoms in question. However, it is unacceptable to suggest that the product in and of itself is “strong” or “powerful”.
- An advertisement should not suggest that product use is essential. It is acceptable to communicate that one “needs or wants **relief**”. However, it is unacceptable to claim that a consumer “needs” a specific health product or ingredient.
- Depiction of product results, e.g. before and after images, should accurately reflect the results that can be obtained from product use.
- The degree of relief/benefit obtained from product use should not be exaggerated.

EXAMPLE

ACNE THERAPY

Authorized Indication/Use:

For the treatment/management of acne.

Acceptable Claim:

“Clear your face. Fight acne with the power of Product X. It worked for me!”

Unacceptable Claim:

“Fight acne with powerful Product X!”

EXAMPLE

VACCINE

Authorized Indication/Use:

Vaccine X is used to prevent meningococcal diseases such as meningitis, meningococcal pneumonia and septicemia caused by groups A, C, W-135 and Y of the bacteria *Neisseria meningitidis*. Vaccine X only protects against *N meningitidis* A, C, W-135 and Y serogroups and will not protect against disease caused by serogroup B or any other infectious agents.

Acceptable Claim:

“Get Vaccine X to help prevent meningococcal diseases like meningitis, caused by *N meningitidis*”

Unacceptable Claim:

“Meningitis kills. Make sure you’re protected. Get immunized with Vaccine X”

2.2 Duration of Therapeutic Action

When depicted or described, the duration of therapeutic action must be consistent with the TMA.

- Claims for a specific duration of therapeutic action are acceptable only if included in the TMA.
- Dosing interval should not be equated to duration of therapeutic action.
- When the product benefit in the TMA is identified as “temporary”, this must be communicated in the ad.

EXAMPLE

HYDROCORTISONE 0.5% CREAM

Authorized Indication/Use:

Relieves itch. Dosing: Apply sparingly to affected area every 6 hours.

Acceptable Claim:

“Product X relieves itch”

Unacceptable Claim:

“Product X relieves itch for 6 hours”

- Unless specified in the TMA, duration of pharmacological action should not be equated to the duration of therapeutic action.

EXAMPLE

H2-ANTAGONIST

Authorized Indication/Use:
Relieves heartburn. Controls acid for up to 12 hours.

Acceptable Claim:
"Product X controls acid for up to 12 hours and relieves heartburn"

Unacceptable Claim:
"Product X relieves heartburn for up to 12 hours"

2.3 Onset of Therapeutic Action

When depicted or described, the onset of therapeutic action must be consistent with the TMA.

- Claims for therapeutic action within a specific time period are acceptable only if included in the TMA.
- The pharmacokinetics of a product, e.g. how quickly a product dissolves, absorption rate, should not be equated with time to onset of therapeutic action unless supported by the TMA.

EXAMPLE

ANALGESIC

Authorized Indication/Use:
Relieves headache in 45 minutes. Tablet dissolves in 10 minutes.

Acceptable Claim:
"Product X provides headache relief in 45 minutes"

Unacceptable Claim:
"Product X dissolves in 10 minutes for fast headache relief"

- When an advertisement makes a representation about the onset of action for a product that must be used for a specific period of time before results are seen, this information should be communicated accurately.

EXAMPLE

PRODUCT X GLUCOSAMINE

Authorized Indication/Use:
Helps to reduce joint pain. Use for minimum of 2 months to see beneficial effects.

Acceptable Claim:
"Product X Glucosamine reduces joint pain when used for at least 2 months"

Unacceptable Claim:
"Product X Glucosamine reduces joint pain quickly"

2.4 Mechanism of Action

When depicted or described, the mechanism of action that contributes to the therapeutic effect must be consistent with the TMA.

2.5 Natural Action / Naturally

A product's therapeutic action must not be described as "natural", "natural action", "acting naturally" since every health product modifies the body's physiological functions or structure.

EXAMPLE

PRODUCT X VALERIAN ROOT

Authorized Indication/Use:
Traditionally used in Herbal Medicine as a sleep aid.

Acceptable Claim:
"Product X. A natural health product traditionally used in herbal medicine as a sleep aid"

Unacceptable Claim:
"Product X Valerian Root sleep aid. Fall asleep the natural way"

2.6 Absence of Side Effect

Absence of side effect claims must be consistent with the TMA.

- Claims for the absence of a side effect are acceptable only under the following conditions:
  - The claim does not contradict the side effect profile in the TMA.
  - The weight of scientific evidence exists to support the statement.
  - The claim does not create an erroneous impression about the advertised product or comparable products.
  - The side effect is commonly associated with the comparable products of the same class.
  - No undue emphasis is placed on the statement.
  - The statement provides useful information to consumers.

Note: Absence of side effect claims involving comparisons with other products should meet the provisions outlined in Section 4.1 Therapeutic Comparisons (pg. 12).

2.7 Strength

Claims for degree of product efficacy based on the amount of medicinal ingredient may be made only if included in the TMA.

- Advertising should not suggest an "extra strength" product provides a greater benefit than a "regular strength" product in cases where both products are indicated for the same condition.

EXAMPLE

ANALGESIC

100mg tablet – Regular Strength
200mg tablet – Extra Strength
300mg tablet – Ultra Strength

Authorized Indication/Use (for all strengths):
Relieves back pain.

Acceptable Claim:
"For backache pain, use Product X. Available in three strengths"

Unacceptable Claim:
"Choose Regular Strength Product X to relieve your backache pain. And when you've REALLY overdone it, use Ultra Strength Product X"

- The use of terms such as "regular strength" and "extra strength" are acceptable to describe products within a product line that have varying amounts of medicinal ingredients. In most cases, the term "extra strength" can be used only if there is a regular strength reference product on the market containing the same medicinal ingredients.
- The term "maximum strength" is acceptable only where regulatory limits for the maximum allowable doses are defined, e.g. "Maximum strength X available without a prescription".

2.8 Guarantees

Therapeutic guarantees are not permitted in advertising.

- An advertisement should not directly or indirectly suggest that a product is effective for all individuals, or that it will be effective every single time it is used.
- Guarantees of overall product satisfaction or other non-therapeutic attributes, e.g. purity, quality or physical characteristics, are acceptable if true and supportable.

EXAMPLE

Acceptable Claim:
"Satisfaction guaranteed, or your money back"

Unacceptable Claim:
"Guaranteed relief, or your money back"

2.9 Health / Healthy / Healthful

Any representation about health, general health, health restoration, maintenance or promotion must be consistent with the TMA.

- Advertising should not:
  - Suggest a product is a substitute for good health practices or a healthy lifestyle.
  - Suggest health will suffer or full health cannot be achieved without the product.
  - Exaggerate the possible consequences of not treating a condition or disorder.
  - Expand a general health maintenance claim to suggest that a product provides specific health benefits.

EXAMPLES

FISH OIL

Authorized Indication/Use:
Source of omega-3 fatty acids for the maintenance of good health.

Acceptable Claim:
"Contains Omega-3s to help support good health"

Unacceptable Claim:
"Promotes heart health"

PROBIOTIC

Authorized Indication/Use:
Helps support intestinal/gastrointestinal health.

Acceptable Claim:
"Helps support gut health"

Unacceptable Claim:
"For healthy digestion"

2.10 Prevention / Risk Reduction

Prevention and risk reduction claims for a product or ingredient must be consistent with the TMA.
Section 3(1) of the *Food and Drugs Act* prohibits the advertising of drugs and medical devices 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 of the FDR. However, sections A.01.067 and A.01.068 of the FDR and sections 103.2 and 103.3 of the NHPR exempt **nonprescription drugs and NHPs** from the general prohibition on labelling and advertising of **preventative** claims for Schedule A diseases.

- Risk reduction or prevention claims should not:
  - exaggerate the degree of risk reduction that will result from product use; or
  - imply the risks of developing a disease will be eliminated through product use.

Additional guidance regarding **medical devices**:

- Condoms may be advertised to the general public for the purpose of preventing the transmission of sexually transmitted diseases if the advertisement and label of the condom claim only that a condom reduces the risk of transmitting sexually transmitted diseases. [Section 24(1) of the *Medical Devices Regulations*]
- Contraceptive devices, except intrauterine devices (IUDs), may be advertised to the general public for use in the prevention of conception as long as they are not distributed as samples either door-to-door or through the mail. [Section 3(3) of the *Food and Drugs Act* and Section 24(2) of the *Medical Devices Regulations*].

EXAMPLE

CALCIUM SUPPLEMENT

Authorized Indication/Use:
Adequate calcium as part of a healthy diet may help prevent bone loss/osteoporosis.

Acceptable Claims:
"Product X calcium supplement may reduce the risk of developing osteoporosis" / "Product X calcium supplement may assist in the prevention of osteoporosis"

Unacceptable Claim:
"Product X calcium supplement prevents osteoporosis"

EXAMPLE

TRAVEL VACCINE

Authorized Indication/Use:
Helps prevent infection X (food and waterborne). However, as with all vaccines, 100% protection is not guaranteed. The risk of infection can be further reduced by taking hygienic precautions with all food, drink and drinking-water consumer when travelling and by voiding direct contact with polluted recreational waters.

Acceptable Claims:
"Going on vacation? Watch what you eat and drink and get vaccinated with Vaccine X to help prevent infection"

Unacceptable Claim:
"Going on vacation? Get vaccinated with Vaccine X so you can indulge without a care!"

3.0 Composition: Ingredients / Content

3.1 Absence of Ingredient

Absence of ingredient claims must not create an erroneous impression about the advertised product or competitive products.

Absence of ingredients statements are acceptable under the following conditions:

For **Medicinal Ingredients**:

- The absent ingredient would likely be found in a product of that type.
- There is no misleading representation as to the safety and merit of the absent ingredient.
- When a Canadian regulatory agency has prohibited the use of a substance, it is acceptable to claim that the product has been reformulated to remove the ingredient or that the product does not contain that ingredient. Under most circumstances reformulation claims should be used for no longer than one year.

For **Sweetening Agents**:

- A product can be described as "sugar free" if it contains none of the chemical classes of sugar, including sugar alcohols.
- Statements claiming the absence of a particular artificial sweetener, e.g. aspartame, should identify the actual sweetener(s) used, if any.
- A "sucrose free" claim is acceptable for a product containing no sucrose, whether or not it contains sugar alcohols. However, if sugar alcohols are present, each one must be identified.

For **Allergens**:

- A product should not be described as "allergen free". However, a product formulated to be free of all Health Canada's priority allergens* may be described as "priority allergen free". When a product that is free of one or multiple priority allergens, it is acceptable to claim "priority allergen x free" or "priority allergen x and y free".
- Products containing any amount of intentionally added gluten should not be described as "gluten free". If gluten is present as a contaminant, the product should not be described as "gluten free" if the gluten quantity exceeds the tolerable threshold of 20 ppm.

For **Salt and Sodium**:

- A product without sodium chloride can be described as "salt free".
- A product without sodium can be described as "sodium free".
- A product that provides 25 mg or less sodium per day can be described as "low sodium" or "suitable for sodium restricted diets".

For Other **Non-medicinal Ingredients**:

- There is no direct or indirect suggestion that the absent ingredient is medicinal.
- There is no misleading representation as to the safety and merit of the absent non-medicinal ingredient.
- When a Canadian regulatory agency prohibits the use of a substance, e.g. colour, flavour, it is acceptable to claim the product has been reformulated to remove the ingredient, or the product does not contain that ingredient. Under most circumstances such claims should be used for no longer than one year.

3.2 Natural

An ingredient or product can be described as "natural" or "natural source(d)" if it meets specific criteria set out in Health Canada's definitions (pg. 20) for "natural/natural source(d)" ingredients.

- A synthetically derived ingredient should not be represented as "natural" or "natural source(d)".
- Claims that a product is "natural" or "natural source(d)" are permissible only if the claim is true for all ingredients (**both** medicinal and non-medicinal).
- Claims that one or several ingredients in a multi-ingredient product are "natural" or "natural source(d)" are permissible, as long as it is clear to which ingredient(s) the claim applies.

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* Health Canada's priority allergens include eggs, milk, mustard, peanuts, seafood (fish, crustaceans and shellfish), sesame, soy, sulphites, tree nuts and wheat.

EXAMPLES

ECHINACEA CAPSULE

Medicinal Ingredient Quantity:
500mg

Source Material:
Aerial part(s), Root(s)

Acceptable Claim:
"Natural echinacea" or "Naturally sourced Echinacea"

ECHINACEA TINCTURE

Medicinal Ingredient Quantity:
500mg

Extract:
1:1 / DHE: 500 mg

Source Material:
Aerial part(s), Root(s)

Acceptable Claim:
"Naturally sourced echinacea"

Unacceptable Claim:
"Natural echinacea"

3.3 Organic

An ingredient or product can be described as "organic" if it is certified according to recognized organic standards.

- Advertisers should possess evidence of certification, i.e. a copy of the Organic Certificate, issued by a recognized certification body.
- Products that are certified organic, i.e. where the organic content is greater than or equal to 95%, may be advertised as "organic". The trademark of the recognized certification body may be included in advertising.

Note: The *Organic Products Regulations, 2009* set out the standard to which agricultural products must be certified, but do not apply to health products. Organic claims may be made for health products, provided the product is certified organic or contains a significant proportion of certified organic ingredients. Licence holders should consult provincial legislation regarding proper use of the term "organic" and its derivatives, as requirements may vary between provinces.

3.4 Potency

When depicted or described, representations of product potency must be consistent with the TMA.

For **nonprescription drugs**:

- Potency: the quantity of medicinal ingredient needed to produce an effect. It is used to determine the required dose of the drug.
- Advertising should not suggest a product is "potent" or has a "potent" formulation or imply that the product is powerful, strong or more effective based on the amount of medicinal ingredient.

For **natural health products**:

- Quantity: the amount of medicinal ingredient(s) per dosage unit.
- Potency: the amount of the standardized component per dosage unit, which helps characterize the quantity of and/or describe the activity of the medicinal ingredient.
- Advertising should not suggest that a product is "potent" or has a "potent" formulation or imply the product is powerful, strong or more effective based on the amount of medicinal ingredient.

For **homeopathic medicines**:

- Homeopathic Potency: the strength or quantity of a homeopathic medicine. Also called homeopathic attenuation, the potency refers to the number of times the original substance has been diluted and succussed according to a method described in one of the accepted homeopathic pharmacopeia. Homeopathic potency is written as a number associated with one of the following letters of combinations of letters: X,D,C,CH,K,CK,M, MK, LM or Q. Examples: Arnica montana 6X, Chamomilla 30 CH.

4.0 Comparisons

4.1 Therapeutic Comparisons

Therapeutic comparisons must be consistent with the TMA and must not create an erroneous impression about the advertised product or competitive products.

- A **therapeutic comparative claim** is a statement that compares an identified therapeutic attribute of one health product or ingredient to that of another health product or ingredient in terms of comparability or superiority.

Consistent with the provisions of Sections 9(1) and 20(1) of the Food and Drugs Act, health product advertisers are required to observe the following principles in making claims that compare the therapeutic aspects of health products:

- The compared health products have an authorized common indication for use, and the comparison is related to that use; or, in addition to the common indication for use, a second authorized indication is claimed as an added benefit of the advertised health product.
- The comparison is drawn between health products under the same conditions of use, e.g. in a similar population.
- The claim does not conflict with the TMA of the compared products.
- The claim is of clinical relevance in humans, i.e. relevant to treatment selection, and, where this is not readily apparent, its clinical relevance can be justified by the sponsor.
- The evidence generated to substantiate the claim is conclusive and based on:
  - consideration of all relevant data, and
  - scientifically accurate, unbiased, reproducible data obtained from studies conducted and analyzed to current scientific standards using established research methodologies and validated end points, and
  - appropriate interpretation of the data.
- The claim and its presentation should:
  - identify the compared entities, and
  - the indicated use related to the claim where this is not readily apparent, and
  - not obscure the therapeutic use of the advertised product/ingredient, and
  - not attack the compared health product(s)/ ingredient(s) in an unreasonable manner, and
  - be expressed in terms, language and graphics that can be understood by the intended audience.

For nonprescription drugs and NHPs:

- Please refer to Health Canada's *Therapeutic Comparative Advertising: Directive and Guidance Document* for the data requirements to support comparative therapeutic claims in consumer-directed advertising and labelling.

Note: Comparisons between nonprescription drugs/ NHPs and prescription drugs are not permitted as per Section E – Part I of the Health Canada guidance document cited above.

EXAMPLES

Nonprescription Drug & Natural Health Product

"Clinically proven to relieve headaches 32 minutes faster than Analgesic Y"

Vaccine:

"Our adjuvant formula provides better protection than traditional vaccines"

Medical Device:

"Healthier gums in 2 weeks vs. Regular Manual Toothbrush B"

4.2 Non-therapeutic Comparisons

Non-therapeutic comparisons must not create an erroneous impression about the advertised product or competitive products.

- A **non-therapeutic comparative claim** is a statement that compares an identified non-therapeutic attribute of a health product with that of another health product, or with that of other product categories for human use, e.g. "moisturizes better", "best-selling", "#1 recommended".
- The comparison must be a fair and factual comparison of similar properties and features between products.
- Advertisers should possess valid, reliable, up-to-date data to support the comparative claim.

For nonprescription drugs and NHPs:

- Non-therapeutic comparative claims should meet the criteria set out in Health Canada's guidance document *Principles for Claims Relating to Comparison of Non-Therapeutic Aspects of Non-prescription Drug Products*.

Note: For information related to the standards for research to support comparative non-therapeutic advertising claims please refer to Ad Standards' *Guidelines for the Use of Comparative Advertising and Guidelines for the Use of Research and Survey Data to Support Comparative Advertising Claims*.

EXAMPLES

"4 out of 5 children prefer the taste of Cough Syrup K"

"Provides 6x the hydration of any eczema cream"

"Whitens teeth better than the leading anti-cavity toothpaste"

"Nine out of 10 patients choose Lancet System X because it is easier to use"

"The highest water content of any soft contact lens for superior comfort"

"Number one best selling dermal filler in Canada"

4.3 Unique

Claims for "unique" must be specific and accurate.

- A claim for a "unique" therapeutic property or benefit can be made only in cases where the product is unique or exclusive, e.g. its effect, action, formulation. The therapeutic product attribute that is "unique" should be clearly communicated.
- The term "unique" can be used to describe a product's formulation if the product is the only one on the market that contains the particular medicinal ingredient. However, a "unique" ingredient claim cannot be expanded to suggest the product offers a unique therapeutic effect.
- "Unique" claims are unacceptable if based solely on a difference in the level of active ingredient.
- In the context of a therapeutic claim, the terms "unique" and "special" should be reserved for those health products that provide a singular benefit or offer a distinct therapeutic advantage to the consumer in terms of effect, onset, duration, or other therapeutic benefit.
- In the context of a non-therapeutic claim, the term "unique" may be used to describe non-therapeutic product features, e.g. unique fragrance, texture, but such claims should not be presented in a manner that suggests or implies a therapeutic benefit.

5.0 Representations of Opinion and Authorization

5.1 Testimonials / Endorsements / Seals / User Generated Content

Testimonials, quotations, endorsements or seals of recognized organizations are acceptable in advertising, provided the claims made for the product are consistent with the TMA.

- A testimonial should represent the honest opinions or current beliefs of the individual making the statement(s).
- In the case of a claim that a product has been endorsed by or bears a seal of a recognized organization, the advertiser should possess (and provide upon request) documentation that the product has attained this recognition.
- It is the advertiser's responsibility to ensure that all user generated content on its website(s) is consistent with the TMA.

Note: For additional guidance on testimonials and endorsements, refer to the *Competition Act* and the *Canadian Code of Advertising Standards*. Refer to medical and health care professional codes of ethics/ conduct for specific prohibitions regarding product endorsement.

5.2 Government / Health Canada Approval

An advertisement must not make any direct or indirect reference to the Act or Regulations, as per Section C.01.007 of the *Food and Drug Regulations*, and Section 92 of the *Natural Health Products Regulations*.

- Any representation that states or implies endorsement, approval or recommendation by Health Canada or any other Canadian government agency is prohibited.
- A claim that "Product X is authorized for sale by Health Canada" is acceptable, as is the inclusion of the DIN, DIN-HM, NPN or Licence Number (for medical devices), providing the product has been issued a DIN, DIN-HM, NPN or Medical Device Licence.
- Class I medical devices cannot be represented as "reviewed" or "approved" by Health Canada.

Note: For additional information related to the use of the Canadian flag or other Canadian symbols please refer to the *Trade-marks Act*. For guidance on "Product of Canada" and "Made in Canada" claims, please refer to the Competition Bureau website.

6.0 Safety / Risk / Side Effects

6.1 Safe / Side Effect Free

An advertisement must not create an erroneous impression regarding product safety.

- Since all health products, including those derived from nature, carry some degree of risk, it is unacceptable to suggest that a product is "safe", "side effect free" or has "no known side effects".
- It is unacceptable to suggest that a product that is "natural" or "naturally sourced" is safer than a synthetic, man-made pharmaceutical.

6.2 Risk / Safety Information Communication

An advertisement must present accurate, truthful, objective and balanced information on the benefits and risks of a health product.

- In order to make informed decisions about their health, consumers should be provided with fair and balanced information about the benefits and the risks associated with the use of the advertised product.
- Advertisements that emphasize only positive features of a health product, while ignoring or minimizing significant safety concerns or side effects are unacceptable.
- The overall content and context of an advertisement will be considered to assess fair balance.
- The risk statement must be clearly communicated visually and/or in audio.

The following information is intended to help advertisers comply with this requirement in the various health product categories. The examples cited are not exhaustive.

Nonprescription Drugs and Natural Health Products

RISK COMMUNICATION: NONPRESCRIPTION DRUGS AND NATURAL HEALTH PRODUCTS		
PRODUCT	**REQUIREMENT IN ADVERTISING**	**EXAMPLE**
NOTE: Products without specific directions for use, label instructions or with no known risks, e.g. SPF lip balms, toothpastes, are exempt from the requirements set out below.		
Where label provides directions for use	• Advise consumers to read the label and follow directions of use.	**Multivitamin** Always read and follow the label.
Where product use may not be appropriate for certain individuals or some risks have been identified	• Advise consumers to read the label and follow directions of use. • Explain that the product may not be suitable for everyone.	**Analgesic** This product may not be right for you. Always read and follow the label.
Where a safety advisory has been issued and label information has not yet been updated	• Make consumers aware of the new risk information through an additional source of information, e.g. supplemental advertisement, reference to Health Canada's website, until the label of the advertised product is revised to reflect the new information. • Direct consumers to contact a healthcare professional for up-to-date information.	**Cold medicine** This product may not be right for you. Always read and follow the label. Talk to your healthcare professional and visit coldmedicine.com for new product safety information.

(continued on page 16)

Nonprescription Drugs and Natural Health Products *(continued)*

TECHNICAL REQUIREMENTS

Video Supers:

Duration: On screen for a minimum of 3.5 seconds.

Contrast: The type should either be a light colour over a predominantly dark background or a dark colour over a predominantly light background. Opacity should be set at 100% and the kerning set at 0. A drop shadow could also be used to aid legibility.

Font: A sans serif font should be used for maximum legibility.

Audio:
The statement should be communicated in a clear, understandable manner. The volume should be no lower than that of the main message.

Print, Out-of-Home, Online, etc.:
Type size, font, contrast and copy placement should be sufficiently prominent for an average consumer to read and comprehend.

Vaccines

In order for consumers to be provided with fair and balanced information about the benefits and the risks associated with the use of vaccines, the inclusion of a combination of the following elements (not an exhaustive list) should always be considered:

- Information about the indications, benefits, most common and serious side effects, allergic reactions, important precautions and warnings, contraindications in certain populations, etc.
- Information related to the protection offered by the vaccine, such as duration of protection, need for booster doses, time to onset, clear identification of types of disease-causing microorganisms the vaccine offers protection against and any limitations of strains.
- Indication of the preventative role of vaccines as opposed to treatment.
- An explanation that everyone may not be fully protected by the vaccine.
- Where applicable, information about the need and importance of continuing specific testing, screening or monitoring by a healthcare professional.
- Inclusion of a reference to Health Canada's authorized consumer information, where complete and objective information about the risks and benefits of the product can be found.
- Inclusion of a reference on broadcast ads or shorter media to another source of additional complete, objective and balanced information about the risks and benefits of the product, e.g. print ad, website, toll-free number.
- Inclusion of a generic statement advising consumers to consult and discuss the advantages and disadvantages of the product with their healthcare professional to make sure that it is suitable for them.

For additional information regarding the guiding principles for risk communication in vaccine advertisements, please refer to Health Canada's Interim Guidance *Fair Balance in Direct-to-Consumer Advertising of Vaccines*

Vaccines *(continued)*

RISK COMMUNICATION: VACCINES	
PRODUCT	**EXAMPLE**
Flu Vaccine	Vaccine X helps prevent Influenza caused by strain A of the virus. It may not protect everyone who gets vaccinated. Side effects and allergic reactions can occur. Ask your healthcare professional if Vaccine X is right for you. URL
HPV Vaccine	Vaccine X helps protect girls/women against cervical cancer caused by HPV (type #). It does not protect against all HPV strains and may not protect everyone who is vaccinated. Regular Pap tests should continue after vaccination. Side effects and allergic reactions can occur. Visit URL for more information.
Travel Vaccine	Vaccine X helps prevent infection caused by Bacteria Y. Must be taken at least 6 weeks before travel. 100% protection is not guaranteed. Precautions to avoid contaminated food or water should still be taken. Side effects and allergic reactions can occur. Talk to your doctor to see if Vaccine X is right for you. For complete product information visit URL

TECHNICAL REQUIREMENTS

Video Supers:

Duration: The statement should remain on screen for as long as required to ensure that it can be easily read in its entirety.

Contrast: The type should either be a light colour over a predominantly dark background or a dark colour over a predominantly light background. Opacity should be set at 100% and the kerning set at 0. A drop shadow could also be used to aid legibility.

Font: A sans serif font should be used for maximum legibility.

Audio:

The statement should be communicated in a clear, understandable manner. The volume should be no lower than that of the main message.

Print, Out-of-Home, Online etc.:

Type size, font, contrast and copy placement should be sufficiently prominent for an average consumer to read and comprehend.

Medical Devices

RISK COMMUNICATION: MEDICAL DEVICES		
PRODUCT	**REQUIREMENT IN ADVERTISING**	**EXAMPLE**
Where label provides directions for use	• Advise consumers to read the label and follow directions for use.	**Powered Toothbrushes, Blood Glucose Meters** Always read and follow the label.
Where product use may not be appropriate for certain individuals or some risks have been identified	• Advise consumers to read the label and follow directions for use. • Explain that the product may not be suitable for everyone.	**Tampons, Wart Removers (with freezing technology), Antibacterial Bandages/Gels** This product may not be right for you. Always read and follow the label.
Where product use may not be appropriate for certain individuals or some risks have been identified and use, installation, adjustment, etc., must be done through a healthcare professional	• Advise that the product may not be suitable for everyone. • Advise consumers that product suitability should be discussed with a healthcare professional.	**Dermal Filler, Contact Lenses, Hearing Aids** This product may not be right for you. Talk to your healthcare professional.
Where a safety advisory has been issued and label information has not yet been updated	• Make consumers aware of the new risk information through an additional source of information, e.g. supplemental advertisement, reference to Health Canada's website, until the label of the advertised product is revised to reflect the new information. • Invite consumers to contact a healthcare professional for up-to-date information.	**Light Therapy** This product may not be right for you. Always read and follow the label. Talk to your healthcare professional and visit lighttherapy.ca for new product safety information.

TECHNICAL REQUIREMENTS

Video Supers:

Duration: The statement should remain on screen for as long as required to ensure that it can be easily read in its entirety.

Contrast: The type should either be a light colour over a predominantly dark background or a dark colour over a predominantly light background. Opacity should be set at 100% and the kerning set at 0. A drop shadow could also be used to aid legibility.

Font: A sans serif font should be used for maximum legibility.

Audio:

The statement should be communicated in a clear, understandable manner. The volume should be no lower than that of the main message.

Print, Out-of-Home, Online, etc.:

Type size, font, contrast and copy placement should be sufficiently prominent for an average consumer to read and comprehend.

DEFINITIONS

Some of the following terms may be interpreted differently in non-advertising contexts; however, for the purpose of this guidance document, they are defined as follows:

Advertisement: Any representation by any means whatever for the purpose of promoting directly or indirectly the sale or use of any food, drug, cosmetic or device.

Biologic Drug: A drug listed in Schedule D to the *Food and Drugs Act*. Schedule D lists individual products (such as "insulin"), product classes (such as "immunizing agents"), references to particular sources (such as "drugs, other than antibiotics, prepared from microorganisms"), and methodology (such as "drugs obtained by recombinant DNA procedures"). Biologic drugs are derived through the metabolic activity of living organisms and tend to be significantly more variable and structurally complex than chemically synthesized drugs.

Brand Name: means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual, under which the health product is sold or advertised; and that is used to distinguish the health product.

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 that is designed to promote the sale of a health product by highlighting a specific product attribute, such as "long lasting" (a therapeutic claim) or "tastes great" (a non-therapeutic claim).

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

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

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

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

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

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

For the purpose of this guidance document, drugs include prescription and nonprescription drugs, biologics (such as vaccines), natural health products, and radiopharmaceuticals.

Food: Includes any article manufactured, sold, or represented for use as food or drink for human beings, chewing gum and any ingredient that may be mixed with food for any purpose whatever.

Health Product: Includes prescription and nonprescription drugs, biologics (such as vaccines), natural health products, medical devices, and radiopharmaceuticals.

Indication for Use (Nonprescription drugs, NHPs, Vaccines): A statement that describes the limitations for use of a health product, 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. The indication for use is part of the Terms of Market Authorization (TMA), as identified in the Product Monograph (PM) accompanying the Notice of Compliance (NOC) or in the document that assigns a Drug Identification Number (DIN), a Natural Product Number (NPN) or a Drug Identification Number for Homeopathic Medicine (DIN-HM) and any related authorized labelling material.

Indication for Use (Medical Devices): A general description of the disease(s) or condition(s) the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. The indications include all the labelled uses of the device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population. The indications for use are generally labelled as such, but may also be inferred from other parts of the labelling, including the Directions for Use, Precautions, Warnings and bibliography sections.

Label: Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. Advertisers may consult the guidance document Labelling of Pharmaceutical Drugs for Human Use, Labelling Guidance Document (for NHPs), Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices - Appendices for the Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons and Labelling of In Vitro Diagnostic Devices as complementary sources of information to be used in conjunction with these *Guidelines*.

Market Authorization Holder: The Market Authorization Holder (MAH) is also referred to as Sponsor or Manufacturer. The MAH is the legal entity that holds the Notice of Compliance, the Drug Identification Number (DIN), the Natural Product Number (NPN), the Homeopathic Medicine Number (DIN-HM), the medical device licence number, or that is authorized to sell a drug or device for the purposes of a clinical trial in Canada.

Natural Ingredient: An ingredient that is obtained from a natural source material, is in a form found in nature, and has undergone only the most minimal processing, e.g. drying, grinding, powdering, chopping, encapsulating. Example: encapsulated powdered garlic.

Natural Health Product: A substance set out in Schedule 1 of the *Natural Health Products Regulations* or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. However, a natural health product does not include a substance set out in Schedule 2 of the *Natural Health Products Regulations*, 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 Source(d) Ingredient: An ingredient that is obtained via extraction, isolation and/or processing of plant, algal, fungal, bacterial, or animal material or minerals. Processing can include such steps as boiling and steaming. The ingredient must have the same chemical identity as that in the source material. Ingredients are considered synthetic, not natural source, if they undergo any chemical modification – for example, to become a derivative or salt form. Examples: Vitamin E (d-alpha-tocopherol) isolated from soybean is natural source. The derivative, d-alpha-tocopheryl acetate, produced via chemical modification

of vitamin E from soybean, is not natural source, nor is the totally synthetic dl-alpha-tocopheryl acetate.

Nonprescription Drug: A drug not included on the Prescription Drug List of the *Food and Drug Regulations*, and available to consumers without a prescription. This includes drugs that:

- are sold to the general public without the intervention of a health care professional (e.g. acetylsalicylic acid);
- are sold to the general public with the intervention of a health care professional, usually a pharmacist (e.g. nitroglycerin, insulin, injectable epinephrine for anti-allergic purposes);
- are sold directly to health care professionals and intended for professional use (e.g. contrast media, anaesthetics).

Non-therapeutic: Attributes of a health product that relate to its physical, sensory or market characteristics.

Organic: An internationally recognized standard denoting a material certified to have been produced in accordance with the production, processing, packaging, storage and distribution provisions of the organic product standards.

Pharmaceutical: For the purposes of this guidance document, pharmaceuticals include manufactured drugs in dosage form, excluding natural health products and biologics.

Prevention: Describes interventions that reduce the incidence of disease generally by modifying one or a number of risk factors. Unlike risk reduction claims, prevention claims imply that the risk of the disease is removed rather than reduced. In most cases, prevention claims should include qualifiers such as "helps", "aids" or "assists" in the prevention of a disease or condition.

Procedure: Act or conduct of diagnosis, treatment, or operation.

Product Line/Family or Product Line Extension: Two or more related health products sharing a brand name, part of a brand name, or common identifier as part of the brand or product name sold by the same manufacturer.

Risk Reduction: Describes the relationship between using a product or ingredient and reducing the risk of developing a specific disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in the development of the chronic disease or abnormal physiological state.

Terms of Market Authorization:

HEALTH PRODUCT CATEGORY	TERMS OF MARKET AUTHORIZATION
Nonprescription Drugs	• Labelling Standard • Category IV Monograph • Product Monograph • Authorized Labelling
Natural Health Products (NHPs)	• Product Licence
Vaccines	• Product Monograph • Authorized Labelling
Medical Devices	**Class II**, e.g. contact lenses, tampons, power toothbrushes: • The indication(s) for use authorized by Health Canada **Class III**, e.g. dermal fillers, blood glucose meters: • Authorized Labelling **Class IV**, e.g. breast implants: • Authorized Labelling Note: Class I devices are not issued a Medical Device Licence and therefore, do not have a TMA. While this category is not subject to preclearance, it is the advertiser's responsibility to ensure that all advertising complies with Sections 3, 20 & 21 of the *Food and Drugs Act*.

Traditional Medicine: A medicine based on the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. This definition is one modified from the World Health Organization Traditional Medicine Program, recognizing traditional medicines at their core as ancient medical practice that existed in human societies before the application of modern science to health and that have evolved to reflect different philosophical backgrounds and cultural origins.

Unique: of which there is only one; unequalled; having no like, equal or parallel.

Vaccine: Vaccines are biologic drugs containing killed bacteria or viruses, components of these micro-organisms or non-infectious variants of disease-producing organisms. Vaccines are introduced into the body in order to induce an immune response that will protect the person from infection caused by the disease-producing organism. The parts of the micro-organism responsible for inducing the body's immune response are called antigens.

APPENDIX A: List of Acronyms

DIN-HM: Drug Identification Number-Homeopathic Medicine
DIN: Drug Identification Number
FDA: *Food and Drugs Act*
FDR: *Food and Drug Regulations*
HPFB: Health Products and Food Branch
MAH: Market Authorization Holder
MDR: *Medical Devices Regulations*
MHPD: Marketed Health Products Directorate
NHP: Natural Health Product
NHPR: *Natural Health Products Regulations*
NOC: Notice of Compliance
NPN: Natural Product Number
PL: Product Licence
PLA: Product Licence Application
PM: Product Monograph
TMA: Terms of Market Authorization

APPENDIX B: Legislative and Regulatory Framework

Sections of the *Food and Drugs Act*:

Section 2:

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

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*, and sections 103.2 and 103.3 of the *Natural Health Products Regulations*, which exempt NHPs and nonprescription drugs from the *Food and Drugs Act* section 3 general prohibition on labelling and advertising of preventative claims for Schedule A diseases. Therefore, authorized claims for the prevention of Schedule A diseases may appear on the labels of NHPs and nonprescription drugs. Claims on product labels are to match the authorized wording. Claims used in advertising may deviate in their wording as long as the claims are consistent with the product's TMA and do not directly or indirectly exceed the scope of the TMA.

(2) No person shall sell any food, drug, cosmetic or device
   (a) that is represented by label, or
   (b) that the person advertises 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.

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

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 14:

(1) No person shall distribute or cause to be distributed any drug as a sample.

Exception:

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

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.

Section 21:

Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless the article complies with the prescribed standard.

Sections of the *Food and Drug Regulations*:

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.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 or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;

(b) the Minister has issued, pursuant to section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;

(c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006;

Sections of the *Natural Health Products Regulations*:

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*.

Sections of the *Medical Devices Regulations*:

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.

(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.

APPENDIX C: Health Canada Guidance Documents, Policies and Fact Sheets

The following guidance documents and policies are available on the Health Canada website:

Advertising Preclearance Agencies and Health Canada's Roles Related to Health Products Advertising Review and Complaint Adjudication

The Distinction Between Advertising and Other Activities

Evidence for Homeopathic Medicines

Fact Sheet – Regulating Advertising of Health Products

Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices - Appendices for the Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons

Guidance Document: Labelling of In Vitro Diagnostic Devices

Guidance Document: Labelling of Pharmaceutical Drugs for Human Use

Guidance Document: Schedule A and Section 3 to the Food and Drugs Act

Health Products and Food Branch Inspectorate Compliance and Enforcement Policy (POL-0001)

Interim Guidance on Fair Balance in Direct-to-Consumer Advertising of Vaccines

Labelling Guidance Document (for NHPs)

Notice: Section 2.21 (Risk Information) of the Consumer Advertising Guidelines for Marketed Health Products

Post Licensing Guidance Document: Natural Health Products Directorate

Post-Notice of Compliance (NOC) Changes

Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products

Therapeutic Comparative Advertising: Directive and Guidance Document

About Ad Standards

Ad Standards is the national, independent, not-for-profit advertising self-regulatory body. We are committed to fostering community confidence in advertising and to ensuring the integrity and viability of advertising in Canada through responsible industry self-regulation.

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