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Guidance on advertising nicotine replacement therapies



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

Également disponible en français sous le titre :
Lignes directrices sur la publicité pour les thérapies de remplacement de la nicotine

To obtain additional information, please contact:

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

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Foreword

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied to the approaches used to meet statutory or regulatory requirements. However, approaches other than those included in the guidelines in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to ensure that the applicable statutory or regulatory requirements are met.

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

This document should be read along with the relevant sections of other applicable guidance documents and policies. In case of a discrepancy between this guidance and the provisions of the Order, the regulations and documents incorporated by reference, the Order, regulations and the documents incorporated by reference take precedence.

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Overview

Purpose

This guidance document will help industry meet their advertising-related obligations under the *Supplementary Rules Respecting Nicotine Replacement Therapies Order* (the Order). This document also gives guidance to Health Canada staff on how relevant mandates and objectives should be met fairly, consistently and effectively. Advertising preclearance agencies may use this guidance to inform their internal practices and the services they provide to industry.

Background

Health Canada has authorized multiple nicotine replacement therapies (NRTs) with 4 mg of nicotine or less as natural health products (NHPs), which are regulated under the *Natural Health Products Regulations* (NHPR). These NRTs are authorized to help adults 18 years and over quit smoking cigarettes. NRTs provide low doses of nicotine through gums, patches, lozenges, pouches or sprays.

However, there is concern that these products may be appealing to, and accessed by, people who do not smoke, especially young people under the age of 18.

Nicotine is a highly toxic and addictive substance that can be harmful to health when consumed in large amounts. Young people may be particularly susceptible to its addictive properties.

To reduce the potential for nicotine exposure, dependence and other health harms for this population, the Order was published in the Canada Gazette, Part II, on August 28, 2024. To achieve these aims, the Order sets restrictions on the advertising of NRTs in addition to other measures such as those for labelling and packaging.

Learn more:

- [Supplementary Rules Respecting Nicotine Replacement Therapies Order](#)
- [Regulatory impact analysis statement](#)
- [Notice of intent to address risks of youth appeal and access to nicotine replacement therapies](#)

Advertising rules under the Order

The Order requires that standard statements and a warning be contained in all advertisements for NRTs. It also specifies how these statements and the warning must be communicated.

It prohibits people from advertising or promoting an NRT for a use other than smoking cessation, regardless of any additional indication authorized in the terms of market authorization for the product. It also prohibits advertisements and promotions that could reasonably appeal to young people.

The advertising requirements in the Order supplement the NHPR and section 9(1) of the *Food and Drugs Act* (act). The intent is to ensure that all advertisements only and explicitly convey the smoking cessation purpose and the intended audience, which is people over the age of 18.

Section 9(1) of the act states: “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.”

The Order imposes restrictions on the advertising of flavours based on the NRT dosage forms set out in the [List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers](#) (the List). This List is a document incorporated by reference into the Order.

Learn more:

- [Relevant advertising rules under the Order](#)
- [Guidelines on the interpretation of the Order](#)

Scope and application

This guidance applies to NRTs, which are defined in the Order as natural health products that contain nicotine or its salts and that are for administration in the oral cavity. Examples include nicotine pouches, gums, sprays and lozenges that contain or deliver 4 mg or less of nicotine per dosage unit or dose. Homeopathic medicines are not included in this definition.

This guidance does not apply to transdermal patches or to nicotine-containing products that are regulated under the *Food and Drug Regulations* (FDR) due to their dosage forms or nicotine content.

This guidance is specific to the advertising rules for NRTs set out in the Order. All advertising requirements that apply generally to NHPs still apply to NRTs subject to the Order.

Interpretation

Smoking cessation

Section 18 of the Order requires that advertisements and promotions can only communicate the smoking cessation use of the product. Advertisements should do so explicitly.

Advertisements should not use the following components and objectives:

- aspects or elements that could be interpreted as being potential additional uses other than smoking cessation
- incomplete, overpromising, exaggerated or erroneous claims of product efficacy
- downplaying potential risks associated with nicotine replacement therapies (NRTs)
- promises of immediate smoking cessation
- the association of NRT consumption with, or the evocation of, a positive or negative emotion about or image of:
 - personal, social, sexual, professional, educational, athletic or financial success
 - physical prowess, power or strength
- the portrayal of the NRT in activities that could convey the attainment of outcomes other than smoking cessation, such as competence, prestige and fulfillment

Digital marketing of products subject to the Order should not be associated with digital advertising of products not subject to the Order (for example, food, fashion), activities or events. For example, user-generated tagging that enables content to be cross-referenced by an unrelated topic or theme, such as through hashtags or hyperlinks, could convey the attainment of outcomes or a use other than smoking cessation.

Appealing to young people

Section 19 of the Order requires that a person must not advertise or otherwise promote an NRT if there are reasonable grounds to believe that the advertisement or promotion may appeal to young people.

Aspects and elements of advertising that may appeal to young people must not be used. These include using:

- models and actors who could mislead consumers about the acceptable age of the intended users of the NRT
- brand identification, including logos, trademarks and names used on, and licensed for, clothing, toys, games and game equipment, and for other items intended for use primarily by young people
- aspirations such as independence, liberation, attractiveness, adventurousness, sophistication, athleticism, social acceptability, sexual attractiveness, popularity and being “cool”

Advertising should not evoke emotions or images of a way of life that may appeal to young people. Examples of such emotions or images are glamour, recreation, excitement, vitality, risk and daring.

Advertising should not use characters, spokespersons or animals (real or fictional), themes or a way of life, settings, graphic design elements and visual, audio or other effects that could reasonably appeal to young people. These include using:

- themes that are linked to identity and self-discovery, being “cool”, romantic relationships, rebellion, adventure and exploration, fantasy and the supernatural, science fiction, fitting in, studying, rites of passage such as prom and first dates, peer-to-peer relationships and trends popular among teens
- settings such as school, parties, dances, concerts and music festivals, sporting events and amusement parks
- graphic design elements and visual effects such as memes, short text, unique fonts or font styles, bright or multi-coloured designs and popular expressions or vocabulary
- audio effects such as jingles, melodies and memes

Advertising should not use social media influencers whose primary audience may mislead consumers about the acceptable age of the intended users of the NRT.

Regardless of its format (for example, print, radio, television, digital media), advertising should not be used if most of the targeted audience could mislead consumers about the acceptable age of the intended users of the NRT. For example:

- Digital marketing communications that are intended to be forwarded by users (“forwardable content”) should include instructions to not forward these materials to young people.
- Advertisements should not be placed in television shows, movies, social media posts (for example, Instagram, Tik Tok), comics and other sources of entertainment for which the audience is made up of mainly young people.

Refer to the [glossary for definitions](#).

Flavours

Sections 20 to 23 of the Order set restrictions on how NRT flavours are to be conveyed to consumers and purchasers.

Section 20 of the Order:

A person must not advertise a nicotine replacement therapy, including by means of its label or package, in a manner that could cause a purchaser or consumer to believe that it contains:

- (a) if the nicotine replacement therapy is in a dosage form set out in the List, the flavour of a confectionery, dessert, soft drink or energy drink or
- (b) if the nicotine replacement therapy is in a dosage form not set out in the List, a flavour other than mint, menthol or a combination of mint and menthol

Flavour name — descriptive or qualifying words

Section 21 of the Order:

A person must not advertise a nicotine replacement therapy, including by means of its label or package, by displaying a flavour name that is preceded or followed by any descriptive or qualifying words.

For example, NRT advertisements must not contain descriptive flavour names such as the words “chill”, “cool” or “splash” before or after the flavour name.

Flavour name — reasonably conveyed

Section 22 of the Order:

A person must not advertise a nicotine replacement therapy that is in a dosage form set out in the List, including by means of its label or package, by displaying a flavour name that does not reasonably convey its flavour.

For example, advertisements for NRTs in a dosage form set out in the List must appropriately convey the actual flavour of the product. Generic and nondescriptive flavour names are not allowed (for example, “original”, “spicy”). It is also not acceptable to use a colour in the flavour name (for example, “blue”).

Flavour name — mint or menthol

Section 23 of the Order:

A person must not advertise a nicotine replacement therapy that is in a dosage form not set out in the List, including by means of its label or package, by displaying a flavour name that is other than “mint”, “menthol” or a combination of “mint” and “menthol”.

For example, if the only flavour listed among the non-medicinal ingredients is peppermint, the flavour name that must appear on the package or label should be “mint” and not “peppermint”.

Statements, warning, and audio, visual and audio-visual advertising

Sections 26 to 28 of the Order set restrictions on how the following statements and warning for NRTs are to be conveyed to consumers and purchasers.

The guidelines to support compliance with these restrictions depend on the advertising medium.

Section 24 of the Order:

Any advertisement for a nicotine replacement therapy must contain:

- (a) In the case of an advertisement in English, the statement:
 - (i) “This product is intended for smoking cessation only. Do not use if you are under 18 years of age” or
 - (ii) “Only to be used by adults who are trying to quit smoking”
- (b) in the case of an advertisement in French, the statement:
 - (i) “Ce produit est uniquement destiné à vous aider à cesser de fumer. Ne pas utiliser si vous avez moins de 18 ans” or
 - (ii) “À utiliser uniquement par des adultes qui désirent cesser de fumer”
- (c) In the case of an advertisement in both official languages, the statements set out in:
 - (i) subparagraphs (a)(i) and (b)(i) or
 - (ii) subparagraphs (a)(ii) and (b)(ii) and
- (d) in any other case, the statement set out in subparagraph (a)(i) or (ii) or (b)(i) or (ii)

Section 25 of the Order:

Any advertisement for a nicotine replacement therapy must contain:

- (a) in the case of an advertisement in English, the warning “WARNING: This product contains nicotine. Nicotine is highly addictive”
- (b) in the case of an advertisement in French, the warning “AVERTISSEMENT : Ce produit contient de la nicotine. La nicotine crée une forte dépendance”
- (c) in the case of an advertisement in both official languages, the warnings set out in paragraphs (a) and (b) and
- (d) in any other case, the warning set out in paragraph (a) or (b)

Audio advertising

Under section 26 of the Order, statements and warnings required under sections 24 and 25 that are contained in an audio advertisement for a nicotine replacement therapy must be communicated:

- (a) in their entirety at the same speed, volume and tone as the main message, without any word being emphasized more than any other and
- (b) without any music or background sound

The information required for audio advertising should be conveyed at the end of the audio advertising and must not be combined with any other audio information.

Visual advertising, including static and video advertising

Under section 27 of the Order, statements and warnings required under sections 24 and 25 that are contained in a visual advertisement for a nicotine replacement therapy must be:

- (a) clearly and prominently displayed and
- (b) readily discernible to a purchaser or consumer

The following guidelines are specific to visual advertising, which includes static and video advertising.

Surface area:

- From the edge that is in the horizontal plane, that forms the upper limit of the advertisement and that extends from the left edge to the right edge of the advertisement

The statements and warning should comprise at least 20% of the surface area of the advertisement and be visible at first sight to purchasers and consumers. For video advertisements, the required warning and statements should occupy at least 20% of the surface area of the advertisement for the duration of the advertisement.

Text of warning and statements:

The required warning and statements should be displayed in such a manner that:

- (a) the text is presented in a consolidated manner, without any intervening words or images
- (b) the text is capitalized in the manner set out in the Order and
- (c) if the required warning and statements are displayed on more than 1 line of text, the letters in each word appear on the same line of text and a word should not be split into 2 lines of text

Each character in the text of the required warning and statements should have the same font and type size. The required warning and statements should be displayed in a standard sans serif font type that is not compressed, expanded or decorative.

Rectangular border:

The warning and statements required for visual advertising should be enclosed within a rectangular border. They should be displayed on the advertisement in such a manner that the border demarcates the required statements and warning from any other statement displayed on the advertisement.

The required warning and statements should be centred in the rectangular border, oriented parallel to the upper limit of the visual advertisement. They should not occupy less than 60% and not more than 70% of the rectangular border.

Background:

The area in which the required warning and statements are displayed should have a black or white background that contrasts with the colour of the text used.

Official languages — placement:

If the warning and statements are conveyed in both official languages, each language version should be displayed immediately beside, below or above the other version.

Audio-visual advertising

Section 28 of the Order specifies that sections 26 and 27 apply to an advertisement for an NRT that consists of both audio and visual components. In the case of audio-visual advertising by video, the audio component of the required statements and warning should be conveyed at the end of the advertisement and must not be combined with any other audio information.

The ability of online platforms, including social media, to comply with the Order and this guidance, particularly with provisions pertaining to audio and visual requirements, should be assessed before using them for advertising purposes.

Brand recognition advertisements

All forms of advertising should be upfront and transparent about:

- the smoking cessation use of the product
- the intended target population of people over the age of 18 and
- nicotine's addictive properties

Advertising and promotion activities that only promote the recognition of the brand name and related brand elements are to be avoided.

Section 18 of the Order states that a person must not advertise or otherwise promote an NRT for a use that is other than smoking cessation. Compliance with section 18 should not be accomplished solely by using the required statements specified in section 24.

Additional measures should be taken to adequately convey the intended use of smoking cessation and the intended target population (people over the age of 18). Measures can include using specific scenarios that depict the real-world use of the NRT, as well as images and elements that indicate the smoking cessation purpose and target population.

Transparency

The following is not specific to the Order and is general guidance.

All digital marketing should clearly and visibly show that all promotional posts featuring the product are sponsored by the product brand or manufacturer. This enhances transparency and the ability to monitor compliance.

Social media influencers should also be transparent about any advertising arrangements they have with the product brand or manufacturer. They should:

- ensure that disclosures are highly visible
 - consumers should not need to search them out
- ensure that disclosures are inseparable from the content so that they are linked when shared
- disclose material connections in each post
- use clear and contextually appropriate words and images
- avoid ambiguous references and abbreviations
 - for example, "thank you company X", "ambassador", "partner"

Glossary

Acronyms

FDA: *Food and Drugs Act*

NHPs: natural health products

NHPR: *Natural Health Products Regulations*

NRTs: nicotine replacement therapies

Order: *Supplementary Rules Respecting Nicotine Replacement Therapies Order*

TMA: terms of market authorization

Definitions

The following definitions are for the purposes of this guidance.

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

Advertising preclearance agencies: Independent entities that review and preclear advertising material before the material is used in the marketplace. Their objective is to help interested parties comply with the advertising provisions of the *Food and Drugs Act* and its regulations. This includes any applicable Health Canada guidance documents. These agencies also help ensure compliance with the Canadian Radio-television and Telecommunications Commission and industry codes. Some agencies also offer mechanisms to resolve complaints on advertising for authorized health products.

The board of directors or advisory bodies of these agencies may include stakeholders from academia, consumer groups, the media, advertising agencies, the pharmaceutical industry and health care practitioner associations. Health Canada acts as an ex-officio observer and advisor to some of these boards and advisory bodies, without relinquishing any part of its authority under the act and its associated regulations.

Audio advertising: An audio advertisement, such as a radio advertisement.

Audio-visual advertising: An advertisement consisting of audio and visual components (static or dynamic), such as a television or dynamic social media post advertisement.

Brand name: A name in English or French, including the name of a manufacturer, corporation, partnership and individual:

- that is used to distinguish the natural health product and
- under which a natural health product is sold or advertised

Brand recognition: The ability of consumers to recognize a brand without prompting and to recognize a brand based on a company's name, logo, colours, advertisements and any other associated elements.

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

Digital marketing: The use of digital technology includes web and multimedia processes for developing, distributing and promoting products and services. Digital technologies also include internet media such as websites, social media and email, and other digital media such as wireless or mobile and media, for delivering digital television (both cable and satellite).

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

- diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals
- restoring, correcting or modifying organic functions in human beings or animals or
- disinfecting premises where food is manufactured, prepared or kept

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

- diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state or its symptoms in humans
- restoring or correcting organic functions in humans or
- modifying organic functions in humans to maintain or promote health

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

Nicotine replacement therapy (NRT): A natural health product, other than a homeopathic medicine, that:

- contains nicotine or its salts and
- is for administration in the oral cavity

Product licence: A permit granted to the manufacturer of a natural health product that demonstrates the product has been assessed by Health Canada and found to be safe, effective and of high quality under its recommended conditions of use. All natural health products sold in Canada require a product licence before they can be marketed.

Real-world use: How an individual interacts with the nicotine replacement therapy in scenarios and settings that only and explicitly convey the use of the nicotine replacement therapy for the purpose of smoking cessation.

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

Visual (static) advertising: An advertisement consisting solely of static visual components, such as a billboard or a static social media post.

Youth appeal: Advertising targeting young persons to solicit positive or negative emotions about the product, or the settings or scenarios associated with the product.

Young person: A person under 18 years of age.

References

Advertising guidance for health products

- [Guidance on distinction between advertising and other activities for health products](#)
- [Guidelines for consumer advertising of health products](#)
 - The information on this web page was provided by external sources. The Government of Canada is not responsible for the accuracy, reliability or currency of this information. Content provided by external sources is not subject to official languages, privacy and accessibility requirements.
 - You should consult the source directly if you wish to rely on this information.
- [Guidance document - Health Canada and advertising preclearance agencies' roles related to health product advertising](#)
- [Therapeutic comparative advertising: Directive and guidance document](#)
- [Policy: Principles for claims relating to comparison of non-therapeutic aspects of non-prescription drug products](#)

Guidance for nicotine replacement therapies

- [Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order](#)

Contact us

Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1912C
Ottawa ON K1A 0K9
[Email: drug-device-marketing@hc-sc.gc.ca](mailto:drug-device-marketing@hc-sc.gc.ca)