Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Overview

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Background

A nicotine replacement therapy (NRT) is a treatment that helps people quit smoking by delivering low doses of nicotine through means other than tobacco, such as through gums, patches, lozenges, or sprays. There is concern that some of these products may be appealing to, and may be accessed by, people who do not smoke, particularly young people (under 18 years of age). Nicotine is a toxic and addictive substance that can be harmful to health, particularly when consumed in excessive amounts. Further, young people may be particularly susceptible to its harmful effects, including addiction. Some products are available in a variety of flavours and may be labelled in appealing ways, such as with bright colours and graphics. Some products have also been advertised and promoted in ways that may appeal to young people through different types of media.

The objectives of the measures of the Supplementary Rules Respecting Nicotine Replacement Therapies Order (the Order) are to reduce the potential for nicotine exposure, dependence, and other health harms for this population.

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

Purpose

The purpose of this guide is to support industry stakeholders in complying with the new requirements and restrictions outlined in the Order. This guide is also intended to inform consumers of how these new rules may impact their access to certain NRTs.

The requirements in the Order are complementary to the provisions outlined in the *Natural Health Products Regulations* (the Regulations).

This guide is to be read in conjunction with other guidance for natural health products, including, but not limited to:

- *Natural Health Products Management of Applications Policy*
- *Pathway for licensing natural health products making modern health claims*
- *Labelling of natural health products*

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.

Scope

These requirements apply to NRTs regulated as natural health products, other than homeopathic medicines, under the Regulations that are administered in the oral cavity. These products include, but are not limited to, NRTs such as pouches, gums, sprays, and lozenges that contain or deliver 4 mg or less of nicotine per dosage unit or dose, as the case may be. The requirements do not apply to transdermal patches or nicotine-containing products regulated under the *Food and Drug Regulations* (i.e., prescription drugs). Further, these requirements do not apply to the sale or importation of NRTs for the purposes of a clinical trial regulated under the Regulations.

Learn more:

- *Supplementary Rules for Nicotine Replacement Therapies Order*
- Regulatory Impact Analysis Statement
- *Food and Drug Regulations*
- *Natural Health Products Regulations*

Definitions

The definitions in this section explain the regulatory terms in the Order that are used throughout this guide.

Brand element:
Includes a brand name, trademark, trade name, logo, distinguishing guise, graphic arrangement, design or slogan that is reasonably associated with, or that evokes, a product, a service or a brand of product or service. (subsection 1(1) of the Order)

List:
Means the document entitled *List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers*, as amended from time to time and published by the Government of Canada on its website. (subsection 1(1) of the Order)

Nicotine replacement therapy:
Means a natural health product, other than a homeopathic medicine, that

(a) Contains nicotine or its salts; and
(b) Is for administration in the oral cavity

(subsection 1(1) of the Order)

Pharmacist:
Has the same meaning as in subsection C.01.001(1) of the *Food and Drug Regulations*. (subsection 1(1) of the Order)

Regulations:
Means the *Natural Health Products Regulations*. (subsection 1(1) of the Order)

Young person:
Means an individual who is under 18 years of age. (subsection 1(1) of the Order)

Contact us

Contact us if you have any questions about the information in this guide.

Email: nnhpd-dpsnso@hc-sc.gc.ca

Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Prohibitions and Application Requirements

On this page

Overview

New prohibitions and application requirements have been introduced for NRTs to help reduce the appeal of these products to young people, including requirements relating to brand names, flavours, and the submission of mock-ups for labels and packages.

The *List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers* (the List) is a document incorporated by reference into the Order that sets out the dosage forms of NRTs that can be sold on a retail basis in self-selection areas.

At the time of the coming into force of the Order, the List does **not** include new and emerging dosage forms, for example, nicotine pouches and rapid disintegration nicotine tablets.

Brand names

Some brand names may be appealing to young people or may mislead consumers about the intended use of the product.

When applying for a product licence application for an NRT, you should ensure that the brand name of your product is not misleading, appealing to or associated with young people, or could be mistaken for a cannabis or food product.

Misleading
You must not sell an NRT with a brand name that could potentially lead a consumer or purchaser to believe that the product is intended for a use other than smoking cessation.

For example, ”NicoSport”, “NicBuzz” or “Head Rush” are not acceptable.

Appealing to, or associated with, young people
You must not sell an NRT with a brand name that could be appealing to, or associated with, young persons.

Health Canada will assess the appeal or the association of the brand name to ensure compliance with section 9 of the Order, and will consider the facts of each submission – including, but not limited to:

- **References to a person, character or animal:** Whether real or fictional, that are associated with young persons, such as cartoon characters, musicians, movie stars or social media influencers who are particularly popular among young people.
- **Popular trends in the preferences of young persons:** Trends among young people vary over time and can also vary based on the location where the young person resides.
- **References to activities or interests associated with young persons:** For example, movies associated with young people, toys, video games, music, sport or performers that are particularly popular among young people at a particular moment in time or geographic region.

This information is intended to assist regulated parties in meeting their obligations to support the objective of protecting young people from the potential appeal of NRTs.

Mistaken for a cannabis or food product
You must not sell an NRT with a brand name that could potentially lead a consumer or purchaser to believe that the product is a cannabis or food product.

For example, “Cannanic”, “NicoBud”, and “Choconic” are not acceptable.

For more information on products at the food-natural health product interface, refer to the *Classification of products at the food-natural health product interface: products in food formats* guidance document.

Flavours

Flavouring helps to disguise the taste of nicotine and supports the proper use of NRTs used orally for an extended period of time. However, some flavours can also be particularly appealing to young people.

If your NRT dosage form is **not** on the List, your NRT must only contain a flavour of mint, menthol, or a combination of mint and menthol. Variations of natural mint

flavours are allowed on the list of non-medicinal ingredients, for example, spearmint and peppermint. However, only "mint", "menthol" or a combination of "mint" and "menthol" may be listed on the principal display panel as the flavour name.

If your NRT dosage form is on the List, your NRT must not contain a dessert, confectionery, energy drink, or soft drink flavour. For example, the NRT flavour may not be "birthday cake", "cotton candy", or "cola".

Mock-ups

Mock-ups of labels and packages will allow Health Canada to proactively determine if your NRT is properly represented for use in smoking cessation and to ensure that all statements, including the required warning ("**WARNING:** Nicotine is highly addictive" and « **AVERTISSEMENT** : La nicotine crée une forte dépendence »), are displayed as set out in the Order and the Regulations.

Applications for new products

When applying for an NRT product licence, you must submit mock-ups of all product packages and labels - including any leaflets and package inserts, in addition to labelling and packaging information that appears on a website. This requirement also applies to those with a product licence application in queue (i.e., you have submitted an application before the coming into force of the Order and have not yet been issued a licence).

You must submit a mock-up of the label for every different flavour name. For example, if your NRT is available with the flavour names "orange", "lemon", and "mint", you must submit a mock-up for the label to be used in conjunction with each flavour.

You must also submit a mock-up of the label for every different brand name.

For products with labels and packages that are identical except for the net quantities, you are only required to submit one representative mock-up of each of the package and label – including any leaflets, package inserts and information on a website. For example, for a product available in packages with 10 pieces of gum and 25 pieces of gum, if the labels are identical except for the net quantity, you are only required to submit one representative mock-up of the label for review. However, you must attest that all other labels are identical, including text, format, size, layout, colour, etc., with all minor differences clearly stated.

Health Canada will only issue a product licence for an NRT if the requirement to submit mock-ups has been met, in addition to the requirements set out in section 7 of the Regulation

Applications for licensed products

You are only required to submit mock-ups of all product packages and labels, including any leaflets, package inserts, and information that appears on a website, for NRTs with existing authorizations (i.e., NRTs that have been issued NPNs) if you would like to make a change to your NRT product licence that will impact the brand name, a change to a non-medicinal ingredient that affects the flavour of the NRT, or any change outlined in paragraphs 11(1)(a) to (h) of the Regulations. The mock-ups would be submitted as part of an amendment application. In any other case, changes made to the label to comply with sections 14 to 16 of the Order do not require the submission of mock-ups.

If the packaging and labels for your product are identical except for the net quantities, you are required to submit only one representative mock-up for each of the package and label including any leaflets, package inserts and information on a website. For more information, refer to the section on Applications for new products.

Health Canada will only approve an amendment to a product licence for an NRT if the requirement to submit mock-ups has been met, in addition to the requirements set out in section 11 of the Regulations.

Content of mock-ups

Mock-ups must contain all information required as per the Regulations (Sections 93 and 94) and the Order.

Inner and outer labels

Mock-ups of the inner and outer label (as applicable) should be representative of the package and label. They must be bilingual, full colour and actual size. They must contain:

- The proposed text
- Placeholders for lot number, expiry date, and NPN XXXXXXXX including the descriptor (e.g., EXP) and the format to be used (e.g., YYYY/MM/DD)
- The label dimensions
- Any illustrations or graphic design elements

All sides of the package must be visible in the mock-ups.

You must ensure that the type size and font style of the text of all required statements and warnings are met as described in the Order.

For more information on designing packages and labels as per the Regulations, refer to the *Labelling of natural health products guidance document*.

How the mock-ups will be reviewed

In addition to assessing that labels comply with existing regulatory requirements, the review of the design elements will focus on, but not be limited to, the following key elements of an inner and outer package or label mock-up:

- Type size
- Font style
- Colour
- Placement (including proximity, overlap, and panel location)
- Graphic design elements and packaging (to ensure there are no elements appealing to young people)

For more information on existing regulatory requirements, refer to the *Labelling of natural health products guidance document*.

Design elements will be evaluated to determine whether they support or impede the reader's ability to read and understand the label. Health Canada will communicate any concerns to applicants via Information Request Notices.

Finalized versions of the inner and outer labels in both official languages must be provided before the product licence can be issued.

Change to a brand name or non-medicinal ingredient

If you would like to make a change to the brand name or add an additional brand name to your NRT, it must be submitted as an amendment to the product licence. Product licence amendments will also be required if you would like to add or substitute a non-medicinal ingredient in your NRT that affects its flavour. When submitting an application for any of these changes, Health Canada recommends that you submit the Amendment and Notification Form (ANF) with a cover letter indicating that you are making an amendment for an NRT. While the form does not yet categorize these changes as amendments, the changes to your NRT will require an assessment and therefore be processed as amendments. Health Canada will send a letter of acknowledgement and an epost message confirming that it was changed to an amendment in accordance with the Order.

You may not sell any lot or batch of the NRT affected by the change until after you submit the ANF and the licence has been amended accordingly.

As mentioned in the Mock-ups section above, you must submit mock-ups of packages and labels as part of your application to amend your NRT product licence.

Health Canada will only amend a product licence for an NRT if the requirement to submit mock-ups has been met, in addition to the requirements set out in section 11 of the Regulations.

Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Place of Sale

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Overview

Certain new and emerging NRT dosage forms on the Canadian market have caused concerns related to inappropriate access and use by young people. To help address issues related to inappropriate access to these products, new place of sale restrictions have been introduced to prohibit direct public access to NRTs with a limited history of appropriate use in Canada.

The *List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers* (the List) is a document incorporated by reference into the Order that sets out the NRT dosage forms that can be sold on a retail basis in self-selection areas.

Retail Sale

General Retail

Only NRTs in the approved dosage forms on the List are allowed to be sold at retail. This means that only these specific NRTs can be placed in self-selection areas across various retail settings, where a purchaser or consumer can directly access the product. For example, NRTs in dosage forms on the List can be sold in retail locations such as convenience stores, pharmacies, or gas stations, as well as through online retailers. Refer to the List for more information on these NRT dosage forms.

NRTs in dosage forms **not** on the List may not be sold on a retail basis, with certain exceptions. For more information on where these NRTs may be sold, see the section below on Pharmacies.

Pharmacies
If you are a pharmacist or person working under the supervision of a pharmacist, you may sell an NRT in a dosage form that is **not** on the List provided it is placed in a location where it is not accessible to the public for self-selection (e.g., behind the counter).

Such NRTs may also be sold from a remote dispensing location, where:

- the pharmacist or a person working under the supervision of the pharmacist is physically present in either the remote dispensing location or in the pharmacy that operates the remote dispensing location; or
- a pharmacy sells them online—but only where the pharmacist or a person working under the supervision of the pharmacist intervenes in that sale. For example, such an NRT could be added to an online shopping cart/basket but could not be purchased without a secondary verification step performed by a pharmacist.

Further, you may only sell NRTs in dosage forms that are **not** on the List if they have a flavour that is mint, menthol, or a combination of mint and menthol.

Labelling – Retail Sale and Sale to Manufacturer or Distributor
Only NRTs that are packaged and labelled in accordance with the Order are permitted to be sold, unless the sale is to a manufacturer or distributor.

You may continue to sell certain marketed NRTs even if they do not comply with the packaging and labelling requirements set out in the Order. For more information on which products can continue to be sold, refer to the Implementation section.

Distributors and Wholesalers

You may not sell an NRT in a dosage form that is **not** on the List to anyone, other than a pharmacist, for further sale in a retail setting by that other person.

For example, NRTs in dosage forms **not** on the List must not be sold to persons for further sale in a convenience store.

Consumers

You will continue to have direct access to NRTs in dosage forms on the List in all current retail settings, including online.

If you plan to use an NRT that is in a new or emerging dosage form **not** on the List, such as a nicotine pouch or rapid disintegration nicotine tablet, you can visit a pharmacy and consult a pharmacist or person working under their supervision to purchase these products. These products may also be available online at pharmacy websites, with pharmacist intervention.

Do not buy or use unlicensed nicotine products. These products have not been assessed by Health Canada for safety, efficacy and quality and should not be used. They may, for example, contain ingredients not listed on the product label, which increases the risk of serious adverse or allergic reactions, or interactions with other medications and foods.

To be legally sold in Canada, NRTs, like all natural health products (NHPs), need to be licensed by Health Canada. NRTs licensed as NHPs must have an 8-digit NPN on the label. For more information on licensed NHP NRTs, refer to the Licensed Natural Health Product Database.

Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Labelling

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Overview

Product packages and labels can influence product perception and increase its appeal. Rules have been introduced that will help to clarify that NRT packages and labels appropriately represent the product and do not appeal to young people.

It remains the responsibility of those engaging in labelling activities related to NRTs to understand and comply with all the requirements of the Order and the Regulations and any other federal and provincial or territorial legislation that may apply.

Statement of intended subpopulation

You must have a statement indicating the intended subpopulation of the product (adults 18 years of age and older) clearly shown on the outer label of your product. The statement must be displayed in both official languages. If there is no outer label, the statement must be shown on the inner label.

Section 16 of the Order requires that the statement of the intended subpopulation be clearly and prominently displayed. It also requires that the statement be readily discernible to a purchaser or consumer when they buy the product and when they use it. This means that the purchaser or consumer must be able to read the warning without it being obstructed or having to manipulate the package or label.

Warnings

You must have the following warnings on the principal display panel of the inner label of your product: "**WARNING**: Nicotine is highly addictive." and « **AVERTISSEMENT** : La nicotine crée une forte dépendence. » If there is an outer label, these statements must also appear on the principal display panel of the outer label.

Section 16 of the Order requires that the warning be clearly and prominently displayed. It also requires that the warning be readily discernible to a purchaser or consumer when they buy the product and when they use it. This means that the purchaser or consumer must be able to read the warning without it being obstructed or having to manipulate the package or label.

The following elements are also required for the warning:

- The words "**WARNING**" and « **AVERTISSEMENT**» are bolded and capitalized
- The characters are of a single colour of type that is a visual equivalent of 100% solid black type (e.g., 100% screen black, dark blue, dark brown, and dark purple are acceptable) on a white background or a uniform neutral background with maximum 5% tint of colour
- The characters are of a standard sans serif font that is not decorative
- The characters are of a type size of at least 6 points

Bilingual warning

You may have a bilingual warning instead of separate English and French warnings.

The bilingual warning may be combined with the two warnings separated by a slash: "**WARNING**: Nicotine is highly addictive." / « **AVERTISSEMENT** : La nicotine crée une forte dépendence. »

Appealing to young persons

You may not sell an NRT if there are reasonable grounds to believe that the statements or graphic design elements, including brand elements, on the package or label could be appealing to young people.

What could be appealing to young people?

When conducting an assessment of an NRT's appeal to young people in terms of packages and labels for the purpose of ensuring compliance with section 10 of the Order, the facts of each case will be considered, including, but not limited to:

- **References to a person, character or animal:** whether real or fictional, that is associated with young persons, such as cartoon characters, musicians, movie stars or social media influencers particularly popular among young people;
- **Other shapes and references:** packages or labels in the shape of or evoking (including through a related brand element) popular toys or games related to young persons, sporting equipment or candies, etc., e.g., an NRT package or label in the shape of a video game controller;
- **Colours, font style and presentation**: brightly-coloured packages or labels if the colour theme, font style or overall presentation evokes something associated

with young people, e.g., an NRT package or label whose appearance evokes a cartoon associated with young people; the use of brand colours, lettering or design for an NRT that are similar to those used for other products appealing to young people;
- **Sensory attributes or functions:** certain flavours, scents or functions associated with products appealing to young people, e.g., an NRT that evokes a soft drink or energy drink; a multi-part NRT product or packaging design that may be assembled into a toy or game; graphics that may suggest a sensation, including words or images that depict "blast" or "chill";
- **Popular trends in the preferences of young persons:** trends among young people, which vary over time and can also vary based on the location where the young person resides;
- **Any references**, including through NRT-related brand elements, to movies associated with young persons, toys, video games, music, sport or performers that are particularly popular among young persons at a particular moment in time or in certain geographic regions, e.g., a brand element that evokes a dance from a video game or trend associated with young people.

Note: Some of these factors could also be relevant for the purpose of complying with other aspects of the Order, such as section 19, related to advertising and promotion in a manner that associates an NRT or any of its brand elements with young persons. The information enclosed is intended to assist regulated parties in meeting their obligations with a view to protect young people from the potential appeal of NRTs.

Flavour names

Your NRT package or label must display a flavour name that:
- Is not misleading regarding the required flavour
- Does not contain any descriptive or qualifying words
- Reasonably conveys the flavour

Not misleading

If your NRT is in a dosage form on the List, the flavour name displayed on the package or label of your product, including as part of the brand name (as applicable), must not lead a purchaser or consumer to believe that the flavour is a confection, dessert, soft drink or energy drink.

If your NRT is in a dosage form **not** on the List, the flavour name displayed on the package or label of your product, including as part of the brand name (as applicable), must not lead a purchaser or consumer to believe that the flavour is anything other than mint, menthol, or a combination of mint and menthol. The flavour name must be "mint", "menthol" or a combination or "mint" and "menthol", regardless of the non-medicinal ingredient(s) that impact(s) flavour. For example, if the only flavour listed among your non-medicinal ingredients is peppermint, the flavour name that must appear on your package or label is "mint", not "peppermint".

Descriptive or qualifying words

The flavour name displayed on the package or label of your product must not contain any descriptive or qualifying words.

For example, including the words “chill”, “cool” or “blast” before or after the flavour name is prohibited.

Reasonably conveyed

If your NRT is in a dosage form on the List, the flavour name displayed on the package or label of your product must appropriately convey the actual flavour of the product; nondescript flavour names are not permitted.

For example, “original”, “spicy”, or a colour, such as “blue”, are not acceptable flavour names.

Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Advertising

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Overview

Advertising and promotional activities can help bring awareness to adults considering their smoking cessation options; however, they can also influence a young person's desire to access and use certain NRTs.

This section provides an overview of the advertising restrictions outlined in the Order. Additional guidance will be developed to provide further clarification of advertising restrictions and will be made as available as soon as possible.

Smoking cessation

You must not advertise or promote an NRT for a use other than smoking cessation.

Appealing to young persons

You must not advertise or promote an NRT if there are reasonable grounds to believe that the advertisement or promotion could be appealing to young people.

For more information on what could be appealing to young people, refer to the Labelling section.

Flavour names

Your NRT advertisement must display a flavour name that:

- Is not misleading regarding the required flavour
- Does not contain any descriptive or qualifying words
- Reasonably conveys the flavour

For more information on the flavour name restrictions, refer to the Labelling section.

Statements

Any advertisement for an NRT must contain a statement indicating the product's smoking cessation objective.

English advertisements

If your advertisement is in English, it must contain at least one of the following statements:

"This product is intended for smoking cessation only. Do not use if you are under 18 years of age."

OR

"Only to be used by adults who are trying to quit smoking."

French advertisements

If your advertisement is in French, it must contain at least one of the following statements:

« Ce produit est uniquement destiné à vous aider à cesser de fumer. Ne pas utiliser si vous avez moins de 18 ans. »

OR

« À utiliser uniquement par des adultes qui désirent cesser de fumer. »

Bilingual advertisements

If your advertisement is in both official languages, it must contain:

"This product is intended for smoking cessation only. Do not use if you are under 18 years of age."
AND
« Ce produit est uniquement destiné à vous aider à cesser de fumer. Ne pas utiliser si vous avez moins de 18 ans. »

OR

"Only to be used by adults who are trying to quit smoking."
AND
« À utiliser uniquement par des adultes qui désirent cesser de fumer. »

Advertisements in a language other than English or French

If your advertisement is in a language other than English or French, or does not contain any text, it must contain one of the following statements:

"This product is intended for smoking cessation only. Do not use if you are under 18 years of age."

OR

"Only to be used by adults who are trying to quit smoking."

OR

« Ce produit est uniquement destiné à vous aider à cesser de fumer. Ne pas utiliser si vous avez moins de 18 ans. »

OR

« À utiliser uniquement par des adultes qui désirent cesser de fumer. »

Warnings

Any advertisement for an NRT must contain a warning regarding nicotine.

English advertisements

If your advertisement is in English, it must contain the warning "**WARNING:** This product contains nicotine. Nicotine is highly addictive."

French advertisements

If your advertisement is in French, it must contain the warning "**AVERTISSEMENT :** Ce produit contient de la nicotine. La nicotine crée une forte dépendance."

Bilingual advertisements

If the advertisement is in both official languages, each warning included above in the English and French advertisement sections, respectively, is required.

Advertisements in a language other than English or French

If your advertisement is in a language other than English or French, or does not contain any text, it must contain one of the following statements:

"**WARNING:** This product contains nicotine. Nicotine is highly addictive."

OR

"**AVERTISSEMENT :** Ce produit contient de la nicotine. La nicotine crée une forte dépendance."

Audio advertising

Your audio advertisement for an NRT must communicate the Statements and Warnings mentioned in the above sections in their entirety, at the same speed, volume and tone as the main message, without emphasizing any word more than any other.

The Statements and Warnings must also be communicated without any music or background sound.

This is also required for advertisements with both audio and visual components.

Visual advertising

Your visual advertisement for an NRT must display the Statements and Warnings mentioned in the sections above clearly and prominently. They must also be readily visible to a purchaser or consumer.

This is also required for advertisements with both audio and visual components.

Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order: Implementation

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Overview

The Order came into force on the day on which it was published (August 28, 2024). Health Canada has provided a transition period of six months (February 28, 2025) for your NRT to comply with certain requirements, as well as a 'sell-through' transitional rule in certain circumstances.

The impact of this Order on a given product depends on the status of the product licence and whether the product is in a dosage form on the List.

New requirements for new and pending NRT applications

If you wish to submit a product licence application for an NRT or have an NRT product licence application in queue with us, you must submit mock-ups of your packages and labels before a licence may be issued. You must also ensure that your NRT is compliant with all other requirements in the Order that come into force immediately, including new requirements relating to the brand name and flavour(s).

Refer to the Mock-ups subsection under the Prohibitions and Application Requirements section for more information.

Sell through period for licensed NRTs

NRT dosage forms on the List

If the dosage form of your NRT is on the List and it was labelled or imported and labelled in accordance with the Regulations before August 28, 2024, existing stock can continue to be sold after the transition period, even if it does not comply with the packaging and labelling requirements of the Order.

NRT dosage forms not on the List

If the dosage form of your NRT is **not** on the List, it was labelled or imported and labelled in accordance with the Regulations before August 28, 2024, and is flavoured with mint, menthol, or a combination of mint and menthol, existing stock can continue to be sold by a pharmacist or individual working under the supervision of a pharmacist after the transition period, even if it does not comply with the packaging and labelling requirements of the Order.

Transition period for marketed NRTs

There is a transition period of six months for marketed NRTs to comply with certain packaging and labelling requirements and advertising requirements.

These include the requirements relating to:

- The front-of-pack warnings
- The intended subpopulation label statement
- The flavour names
- Appeal to young persons
- The advertising statements
- The advertising warnings

Your NRT can continue to be sold even if it is not packaged or labelled in accordance with these requirements up to and including February 28, 2025. Your NRT must be in compliance with all rules in the Order, including all packaging, labelling and advertising requirements, thereafter, unless the sell-through provisions apply.

Compliance and enforcement measures

Health Canada will conduct compliance and enforcement activities through a risk-based approach, in alignment with existing departmental policies such as the *Compliance and enforcement policy for health products (POL-0001)* in order to protect the health and safety of individuals in Canada.

Surveillance

As per section 24 of the Regulations, all market authorization holders are required to report to Health Canada any serious adverse reactions associated with their product, within 15 days after the day on which they become aware of the reaction. In addition, all market authorization holders are required to annually prepare and

maintain a summary report that contains a concise and critical analysis of all adverse reactions associated with their product. Furthermore, the Minister may request licence holders to submit to Health Canada the Annual summary reports as per subsection 24 (3) of the Regulations.

A risk-based approach will be taken for surveillance of NRTs. For each authorized NRT product with a dosage form that is **not** on the List, it is expected that the licence holder will submit to Health Canada an Annual Summary Report after the first 12 months of marketing as per subsection 24 (2) of the Regulations. After review, Health Canada will determine if there is a need to submit reports on an annual basis. For authorized NRT products with a dosage form that is on the List, it is expected that the licence holder will only submit an Annual Summary Report to Health Canada upon request of the Minister.

Further guidance on preparing an Annual Summary Report is available in the Health Canada document, *Preparing and Submitting Summary Reports for Marketed Drugs and Natural Health Products - Guidance Document for Industry,*

Updating the List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers

Additional guidance will be developed to describe the type of evidence and information needed to amend the List.

In addition, the process of amending the List will also follow *Health Canada's Incorporation by Reference Policy*.

This guidance will be made available as soon as possible.