

From: [NNHPD Consultation / DPSNSO \(HC/SC\)](#)
To: [Gauthier, Matt](#)
Subject: Nicotine Replacement Therapy
Date: Friday, October 11, 2024 10:09:09 AM

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Dear Matt Gauthier,

Thank you for your correspondence.

In Canada, nicotine replacement therapy (NRT) products are classified as a drug under the *Food and Drugs Act* (FDA) as they are intended for use by adults aged 18 years and older for smoking cessation. Health Canada regulates NRTs under the FDA to ensure regulatory requirements for safety, efficacy and quality are met before authorizing them to be sold in the Canadian market.

All NRTs need market authorization from Health Canada and must carry an approved health claim for smoking cessation to be legally sold in Canada.

As part of its process, Health Canada reviews the evidence behind health claims to make sure that the product does what it claims to do, and the benefits outweigh the risks. Depending on the amount of nicotine contained or delivered by the product, an NRT would be considered a prescription drug or a natural health product.

Strong concerns have been raised regarding the access and potential appeal to youth of certain new and emerging NRTs, such as nicotine pouches, and the way they are marketed. Youth smoking rates are at an all-time low in Canada and advertising of NRTs should not be appealing to youth.

As indicated in the [Notice of Intent](#) published on March 20, 2024, Health Canada committed to taking action to address risks associated with the access and apparent youth appeal of certain NRTs, such as nicotine pouches.

In June 2024, Departmental officials consulted on the potential new requirements for the regulation of certain NRTs with a variety of partners and stakeholders, including representatives from provincial and territorial (PT) ministries of health, health advocacy groups, health professional associations, industry, pharmacists' associations, and consumers with lived/living experience with smoking and smoking cessation.

The engagement approach was consistent with the [Statutory Instruments Act](#) (<https://ow.ly/vX9R50ST8Hm>) and the [Cabinet Directive on Regulation](#) (<https://ow.ly/OBH250ST8KS>).

The Department received wide-ranging and constructive feedback during these engagement sessions which informed the development of the [Supplementary Rules](#)

Respecting Nicotine Replacement Therapies Order (the Order) as announced on August 22, 2024.

The Order came into force immediately upon publication in *Canada Gazette*, Part II, on August 28, 2024, subject to a six-month transition period in respect of packaging, labelling, and advertising requirements and a sell-through period in some circumstances.

The Order introduced new measures for NRTs to reduce the appeal of access to, and use of these products by youth, while maintaining access for adults who need them to quit smoking. More specifically, the new measures:

- Prohibit NRTs in new and emerging dosage forms (for example, nicotine pouches and rapid disintegration tablets) to be sold by anyone other than a pharmacist or an individual working under the supervision of a pharmacist. New and emerging dosage forms must not be accessible for self-selection, meaning they will be kept behind the pharmacy counter;
- Prohibit the sale of NRTs under brand names that may mislead purchasers or consumers about their intended use, be appealing to, or be associated with, young people, or be mistaken for a cannabis or food product;
- Prohibit the manufacturing or sale of NRTs in certain flavours as set out in the Order. For example, the use of any flavour other than mint and menthol is prohibited for NRTs in new and emerging dosage forms (for example, pouches and rapid disintegration tablets);
- Prohibit labels and packages from being appealing to youth;
- Require mock-ups of labels and packages to be submitted for all new NRT product licence and amendment applications, including those arising from a change to an NRT's brand name or non-medicinal ingredient affecting its flavour;
- Require a front-of-package nicotine addiction warning on NRT labels, as well as a clear indication of the intended users (in other words, people who smoke intending to quit smoking) on the outermost label; and
- Prohibit advertising or promotion that could be appealing to youth under the age of 18 or convey a use other than smoking cessation and require a health warning statement on all advertisements.

Health Canada also continues to work on identifying and seizing unauthorized nicotine products in retail locations across Canada and disrupting the supply of these

products into the country by working closely with the Canada Border Services Agency.

Sincerely,

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