



FAQs on Supplementary Rules Respecting Nicotine Replacement Therapies Order: SOR/2024-169

1. What is the Supplementary Rules Respecting Nicotine Replacement Therapies Order (SOR/2024-169)?

On August 15, 2024, the Supplementary Rules Respecting Nicotine Replacement Therapies Order: SOR/2024-169 was released by the government of Canada. The SOR/2024-169 is a regulation that establishes supplementary rules for the distribution and use of nicotine replacement therapies (NRTs) in Canada. This Order restricts public access to new and emerging forms of NRTs by placing them behind the counter, due to their limited history of appropriate use in Canada.

2. What type of NRT products are available in Canada?

Nicotine replacement therapies are first-line treatments for smoking cessation, acting as a substitute for the nicotine in cigarettes. In Canada, NRTs are available in various forms, including transdermal patches, inhalers, sprays, gums, lozenges, pouches and rapid disintegration tablets.

3. How were NRT products available for consumers previously?

NRTs are classified as natural health products. Prior to this legislative change, they were unscheduled for dosage forms administered orally for buccal absorption via a non-active device, provided they delivered 4 mg or less of nicotine per dose. As a result, these products could be purchased over the counter without professional supervision in pharmacies and other retail locations.

4. What dosage forms of nicotine replacement therapies are restricted under this order?

Health Canada has established a list of NRT dosage forms that can be sold on a retail basis in self-selection areas (See question 7 below). The Order restricts the sale of any nicotine products that are NOT on the approved list (currently, oral nicotine pouches and rapid disintegration tablets) from self-selection areas in pharmacies and other retail outlets. These products will now be available only behind the counter in pharmacies, requiring an intervention by a pharmacist or an individual working under the supervision of pharmacist, before purchase. All other NRTs, including patches, inhalers, sprays, gums and lozenges, will remain available for purchase in self-selection areas of pharmacies and other retail locations.

5. How do these rules affect the way pharmacists dispense NRTs?

Like other behind-the-counter medications, pharmacists are responsible for assessing the patient's needs, providing education on proper use, ensuring the safe and effective use of nicotine pouches and rapid disintegration nicotine tablets, checking for contraindications and offering follow-up as needed.

6. Do pharmacists need to verify age restrictions when selling restricted nicotine products under this order?

Under the SOR/2024-169, pharmacists are not explicitly required to verify age restrictions when selling NRTs. While NRTs are intended for use by adults aged 18 and older for smoking cessation, the Order does not impose a strict legal obligation for age verification. Instead, it recommends placing NRT products behind the counter in pharmacies to ensure they are used appropriately, which implies that pharmacists should still exercise discretion and caution when selling these products.

7. Does this rule apply to online sale of these products?

Yes, the rule applies to both brick-and-mortar pharmacies and those selling products online. If a person wishes to purchase these products online, they will still require pharmacist intervention.

8. Where can pharmacists find additional resources on SOR/2024-169 and NRTs?

- Canada Gazette: <https://www.gazette.gc.ca/rp-pr/p2/2024/2024-08-28/html/sor-dors169-eng.html>
- The List: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/lists-incorporated-by-reference.html>