NOTIFICATION

Addendum

The following communication, dated 29 August 2024, is being circulated at the request of the delegation of Canada.

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**Title:** Supplementary Rules Respecting Nicotine Replacement Therapies Order

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 28 August 2024 |
| [X] | Notified measure published - date: 28 August 2024 |
| [X] | Notified measure enters into force - date: 28 August 2024 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://canadagazette.gc.ca/rp-pr/p2/2024/2024-08-28/html/sor-dors169-eng.html> (English)  <https://canadagazette.gc.ca/rp-pr/p2/2024/2024-08-28/html/sor-dors169-fra.html> (French) |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [X] | Interpretive guidance issued and text available from1:  Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order  Available by request at: [nnhpd.consultation-dpsnso@hc-sc.gc.ca](mailto:nnhpd.consultation-dpsnso@hc-sc.gc.ca) |
| [ ] | Other: |

**Description:** The Supplementary Rules Respecting Nicotine Replacement Therapies Order (this Order) applies to nicotine replacement therapies (NRTs)s for administration in the oral cavity that are regulated under the *Natural Health Products Regulations* for use in smoking cessation by adults who smoke. This Order introduces new measures that:

* Incorporate by reference the List of Nicotine Replacement Therapy Dosage Forms that may be Accessible for Self-selection by Purchasers or Consumers (the List);
* Prohibit direct public access to dosage forms of NRTs that have a limited history of appropriate use, which are not on the List, by requiring that they be sold by a pharmacist or someone under their supervision and are otherwise inaccessible for self-selection;
* Require warnings about the addictive nature of nicotine and statements conveying the intended subpopulation (i.e., individuals 18 years of age or older) on product labels and in advertisements;
* Restrict advertising and promotion that could be appealing to young people or if they convey a use other than the product's intended use (i.e., smoking cessation);
* Restrict packaging and labelling that could be appealing to young people; and
* Prohibit persons from manufacturing or selling NRTs that are in certain flavours as outlined in the Order.

The Order comes into force immediately upon publication. At this time, NRTs must not be manufactured or sold unless they are compliant with the flavour restrictions set out in the Order and NRTs in dosage forms not on the List must not be sold on a retail basis except by a pharmacist or an individual working under the supervision of a pharmacist.

The Order provides a six-month transition period to come into compliance with requirements of the Order that relate to packaging and labelling, and advertising and promotion. In addition, the Order provides for the sale of an NRT that is not labelled or packaged in accordance with the Order if it was labelled prior to the coming into force of the Order, or, if the NRT was imported, it was imported and labelled in accordance with the *Natural Health Products Regulations* prior to the coming into force of the Order.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)