WORLD TRADE ORGANIZATION

G/TBT/N/CAN/775

10 April 2026

(26-2789)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English, French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** CANADA **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Health Canada
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], Other:**
4.	**Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Pharmaceutics (ICS 11.120) and Medical equipment (ICS 11.040)
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Notice of intent to make a Ministerial Exemption Order to permit continued supply of naloxone kits on the Canadian market; (3 page(s), in English), (3 page(s), in French) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://gazette.gc.ca/rp-pr/p1/2025/2025-03-01/html/notice-avis-eng.html
6.	**Description of content:** Notice was given by the Department of Health (Health Canada) on March 1, 2025, in the *Canada Gazette, Part I, Volume 159, Number 9*, of its intent to make a Ministerial Exemption Order (the Order) to permit the continued supply of naloxone kits on the Canadian market. The Notice described proposed exemptions from certain packaging, labelling and licensing requirements under the *Food and Drug Regulations* (FDR), the *Medical Devices Regulations* (MDR) and the *Natural Health Products Regulations* (NHPR). These exemptions would apply only if conditions are met to help ensure the safety, quality, efficacy and traceability of naloxone kits.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The objective of the proposed Order is to help ensure the continued supply of naloxone kits in Canada, in support of the response to the ongoing opioid overdose crisis. Naloxone kits are assembled from several different health products (naloxone, medical devices and antiseptic wipes), and each of these products is normally subject to its own regulatory requirements. The Order would include exemptions from the application of certain provisions in the FDR, MDR and NHPR, as some stakeholders may not be able to meet all current regulatory requirements. The exemptions would only apply if certain conditions are met. This approach would replace the *Interim policy on the packaging, labelling and sale of naloxone kits* with a predictable and transparent regulatory instrument to avoid disrupting the supply of naloxone kits in Canada. *Link to Interim Policy:* https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/activities/interim-policy-packaging-labelling-sale-naloxone-kits.html

8.	**Relevant documents:** Not applicable
9.	**Proposed date of adoption:** Anticipated for July 2026, upon publication in the Canada Gazette, Part II. The proposed Order will not go through pre-publication in the Canada Gazette, Part I; therefore, this notification provides the only opportunity to comment before finalization. **Proposed date of entry into force:** The proposed Order would come into force 12 months after its publication in the Canada Gazette, Part II.
10.	**Provision of comments** **Final date for comments:** 7 June 2026 **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** Canada's Notification Authority and Enquiry Point Technical Barriers and Regulations Division Global Affairs Canada 111 Sussex Drive Ottawa, Ontario, K1A 0G2 Canada Email: enquirypoint@international.gc.ca