



12 February 2026

(26-0976)

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): Prescription status of medicinal ingredients for human use (ICS: 11.120; HS 3004.90)
5. Details of notified document(s) (title, number of pages and languages, means of access): Notice of consultation: Removing zuranolone from the Prescription Drug List (PDL) (1 page, English and French, webpage) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notices-changes/removing-zuranolone.html
6. Description of content: This Notice of Consultation provides an opportunity to comment on the proposal to remove "zuranolone or its salts" from both the Human and Veterinary parts of the Prescription Drug List (PDL).
7. Objective and rationale, including the nature of urgent problems where applicable: For the protection of human health or safety. Recently, Health Canada published in Canada Gazette Part I its intent to (1) add zuranolone to Schedule IV to the CDSA, and (2) regulate zuranolone as a targeted substance to permit its legitimate use. Medicinal ingredients are removed from the PDL when they are scheduled under the Controlled Drugs and Substances Act (CDSA) scheme because the controls under the CDSA framework provide sufficient oversight for any therapeutic use.
8. Relevant documents: Health Canada website: https://www.canada.ca/en/health-canada/programs/consultation-removing-zuranolone-prescription-drug-list.html , posted : 11 February 2026 (available in English and French)
9. Proposed date of adoption: to be determined Proposed date of entry into force: to be determined
10. Provision of comments

Final date for comments: 18 April 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
Global Affairs Canada
Technical Barriers and Regulations Division
111 Sussex Drive
Ottawa, ON K1A 0G2
Canada
Email: enquiry@international.gc.ca