

THE CONTROLLED SUBSTANCES BULLETIN

PRODUCED BY THE OFFICE
OF CONTROLLED SUBSTANCES

This bulletin provides pharmacy regulatory authorities with information and reminders relating to the upcoming scheduling amendment of tramadol and its impact on pharmacist activities.

Amendment to the Controlled Drugs and Substances Act and the Narcotic Control Regulations

The Office of Controlled Substances (OCS) would like to remind Pharmacy Regulatory Authorities (PRA) that as of **March 31, 2022**, tramadol will be removed from the Prescription Drug List (PDL) and listed in Schedule I of the *Controlled Drugs and Substances Act* (CDSA). Tramadol will also be listed as item 19 in the Schedule of the *Narcotic Control Regulations* (NCR) and therefore subject to all the regulatory requirements set out in the CDSA and NCR. Controlling tramadol will strengthen Health Canada's oversight of legitimate activities with this substance, and facilitate detection and prevention of diversion.

Record Keeping Requirements

Starting March 31, 2022, pharmacists will be responsible for maintaining, in an auditable manner, all the records required by the NCR regarding their activities with tramadol for a minimum of two years. This includes, but is not limited to the following records:

- Purchase records
- Records of receipt
- Sale/Provision records
- Emergency transfer records
- Records of returns to licensed dealers
- Destruction records

Furthermore, pharmacists must include all tramadol prescriptions dispensed on or after March 31, 2022 in their special narcotic prescription file. This includes part-fills of tramadol that may be dispensed after March 31, 2022 pursuant to a prescription received or partially filled prior to the scheduling change.

Pharmacists must perform inventory counts and reconciliations on a regular basis (at minimum, every six months, after a pharmacy move, and after a change in pharmacy manager or owner) to ensure all controlled substances (including tramadol) are accounted for. If discrepancies are discovered, they must be investigated. Unexplained losses must be reported to the Office of Controlled Substances as a loss or theft within ten days of discovery.

Destruction

Pharmacists are reminded that starting March 31, 2022, post-consumer returns or unserviceable stock containing tramadol must be destroyed according to the instructions provided in the following guidance documents:

- [Guidance Document: Handling and destruction of post-consumer returns containing controlled substances](#)
- [Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances](#)

Any questions relating to the destruction of post-consumer returns or unserviceable stock can be directed to compliance-conformite@hc-sc.gc.ca.

Notice of Prohibition of Sale

Effective March 31, 2022, pharmacists must not sell or provide tramadol to a pharmacist or a practitioner that is named in a notice of restriction on which narcotics are listed, except when dispensed to them as a patient. Furthermore, a pharmacist cannot dispense a prescription for tramadol signed by a practitioner who is named in a notice of restriction for narcotics.

Additionally, pharmacists named in a notice of restriction on which narcotics are listed will not be able to purchase tramadol from licensed dealers or from other pharmacists for emergency purposes.

General Obligations of a Pharmacist

Loss or Theft Reporting

Pharmacists are reminded that starting March 31, 2022, any loss or theft of tramadol or tramadol containing products must be reported to the Minister within **10 days of discovery**.

For more information regarding the submission of loss or theft reports, please refer to the guidance document:

- [Reporting Loss or Theft of Controlled Substances or Precursors \(CS-GD-005\)](#).

Questions regarding losses or theft may be sent to ocs.reporting-rapporteur.bsc@hc-sc.gc.ca.

Security

Pharmacists shall take all reasonable steps that are necessary to protect tramadol on their premises or under their control against loss or theft.

Advertising and Labelling

Pharmacists must not advertise tramadol to the public, and must not publish a written advertisement about tramadol unless that advertisement displays the symbol “N” in a clear and conspicuous colour and size in the upper left quarter of the label and on the first page of said advertisement.

Lastly, Health Canada is allowing all units of tramadol, which were released and distributed prior to March 31, 2022, to be depleted off the market. To ensure patients receive consistent information regarding the risks and safe use of opioids during the transition period, pharmacists are reminded to affix the warning sticker and provide the patient information handout, as currently required under the *Food and Drug Regulations*.

For additional information regarding the amendment to the NCR, please visit the Canada Gazette, Part II, Volume 155, Number 7.