



National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

Benzodiazepines Regulations: Guidance Document for Pharmacists

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August 29, 2000
00-102830-878

Guidance Document for Pharmacists

Subject : Benzodiazepines and Other Targeted Substances Regulations

The *Benzodiazepines and Other Targeted Substances Regulations* have been published in Canada Gazette, Part II, on June 21, 2000. They will come into force on **September 1, 2000**. These regulations are available on the Therapeutic Products Programme website at the following location <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/schedule.html>.

The following information is provided to explain to pharmacists regulatory requirements that will come with the promulgation of these regulations. For pharmacists practicing in hospitals, please refer to the guidance document prepared for these establishments. Attached is a list of targeted substances to whose the regulations will apply.

Record keeping for the receipt of targeted substances

A pharmacist receiving a targeted substance from a licensed dealer, another pharmacist or a hospital must keep a record of the following information:

- the brand name of the targeted substance received,
- the quantity and strength per unit of the targeted substance received, the number of units per package and the number of packages,
- the name and address of the licensed dealer, pharmacist or hospital that supplied it, and
- the date on which it was received.

Prescription required

The new regulations do not introduce any change to current practice with regard to prescription requirement. A targeted substance can only be sold or provided to an individual or for the benefit of an animal upon receipt of a prescription issued by a practitioner either in writing or verbally.

If the prescription is transmitted verbally, the following information must be recorded by the pharmacist before filling it :

- the name and address of the individual or animal for whose benefit the prescription is issued,
- the date that the verbal prescription was provided,
- the specified name or brand name of the targeted substance, as specified in the prescription,
- the quantity and, if applicable, the strength per unit of the targeted substance,



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- the name of the recording pharmacist and the name of the practitioner who issued the prescription, the directions for use, as specified by the practitioner,
- if applicable, the number of refills authorized and, if specified, the interval between refills.

The pharmacist must also keep a hard copy or create a written record of the verbal prescription.

Refills

A prescription for a targeted substance can be refilled if the practitioner specified on the prescription the number of refills. Conditions applicable to refills are described in the Regulations.

Records

When a pharmacist fills or refills a prescription for a targeted substance, the following information must be recorded :

- the date the prescription was filled or refilled,
- the quantity of the targeted substance provided,
- the pharmacist's name or initials,
- the number assigned to the prescription.

For refills, copies of the original prescription are not required as long as the above mentioned information is recorded.

Prescriptions for targeted substances do not have to be filed in the special prescription files used for narcotics and controlled substances.

Authorized transfers

A pharmacist can transfer a prescription for a targeted substance to another pharmacist, except if that prescription has already been transferred.

Before selling or providing a targeted substance under a prescription that has been transferred, a pharmacist must :

- in the case of a verbal transfer, record the required information as per verbal prescription issuance,
- in the case of a written transfer, obtain from the transferring pharmacist a copy of either the written prescription issued by the practitioner or the record of the verbal prescription ,
- the name and address of the transferring pharmacist,
- the number of authorized refills remaining and, if specified, the intervals between refills
- the date of the last refill.

The transferring pharmacist must record the date of the transfer, the name of the pharmacist to whom the prescription is transferred, the name and address of the pharmacy where the prescription is being transferred and, if applicable, the number of refills that are being transferred.

Activities without a prescription

A pharmacist may sell, provide, send, deliver, transport a targeted substance without a prescription to one of the following persons upon receipt of an order from that person specifying the name and quantity of the targeted substance:



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- the licensed dealer who sold or provided the targeted substance or one who is licensed to destroy targeted substances other than those produced, made, assembled, sold or provided by him
- a practitioner
- a pharmacist
- a hospital
- the Minister
- a person to whom an exemption with respect to the targeted substance has been granted under Section 56 of the Controlled Drugs and Substances Act.

For transactions with a licensed dealer, the Minister or an individual to whom an exemption has been granted, the order must be written.

Transactions with another pharmacist are authorized only if the targeted substance is required by that other pharmacist because of a delay or shortfall in an order for the targeted substance placed with a licensed dealer.

Details pertaining to information that must be recorded upon receipt of a verbal order are described in the Regulations.

Storage

A pharmacist may only store a targeted substance in a place that is used for the purpose of conducting their business or professional practice and in an area in that place where only authorized employees have access. The pharmacist must take any reasonable steps to ensure the security of the targeted substances and to prevent their loss or theft.

Loss or Theft Report

A pharmacist must report to the Minister any loss or theft of a targeted substance within 10 days of its discovery. Loss and Theft Report forms are available at the Office of Controlled Substances

Change of Location

A pharmacist who closes the premises in which a targeted substance is stored must inform the Minister of the date of the closure, the location to which the targeted substance was moved and the quantity of the targeted substance that has moved. The pharmacist has 10 days after the closure to provide to the Minister with the required information.

Destruction

A pharmacist may destroy a targeted substance if the following conditions are met :

- the pharmacist records, before the destruction, information with respect of the destruction including the name, strength per unit and quantity of the targeted substance to be destroyed,
- the method of destruction is in conformity with federal, provincial and municipal environmental legislation
- the date of the destruction is recorded
- the destruction is witnessed by a pharmacist or a practitioner
- immediately after the destruction took place, the pharmacist and the witness sign and print their names on a joint statement, indicating that they witnessed the destruction and the



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targeted substance destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

There will be no authorization or approval document issued by the Office of Controlled Substances with respect to this activity.

Notification

As for narcotics and controlled drugs, the Minister will issue a notice to licensed dealers and other pharmacists to inform them that they must not sell or provide targeted substance to the pharmacist named in the notice whenever the circumstances for issuing such a notice exist.

Those circumstances are :

- upon request from the pharmacist
- upon request from the licensing authority of a province in which the pharmacist is practising and that pharmacist has contravened a rule of conduct established by that licensing authority
- the pharmacist has been found guilty in a court of law of a designated drug offence or an offence under these Regulations

Other circumstances under which the Minister may issue a notice are :

- the pharmacist has contravened a provision of the Controlled Drugs and Substances Act or the regulations,
- the pharmacist has, on more than one occasion, self-administered a targeted substance under a self-directed order, or, when there is no such order, contrary to accepted pharmaceutical practice,
- the pharmacist has, on more than one occasion, provided a targeted substance to a spouse, parent or child, contrary to accepted pharmaceutical practice
- the pharmacist is unable to account for any quantity of targeted substance for which he/she was responsible under these Regulations.

This notice will be issued to :

- all licensed dealers
- all pharmacies within the province in which the pharmacist is registered and practising
- the licensing authority of the province in which the pharmacist named in the notice is registered or entitled to practise
- any interested licensing authority in another province
- any pharmacies in an adjacent province in which an order from the pharmacist named in the notice may be filled.

Since this document is only intended to summarize the main points of the content of the new *Benzodiazepines and Other Targeted Substances Regulations*, please refer to the regulations in their entirety.

Should you have any question on this document or on the Regulations, please do not hesitate to contact us at (613) 954-1541.



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List of Benzodiazepines and other targeted substances :

1. Benzodiazepines, their salts and derivatives, including

- (1) Alprazolam
- (2) Bromazepam
- (3) Brotizolam
- (4) Camazepam
- (5) Chlordiazepoxide
- (6) Clobazam
- (7) Clonazepam
- (8) Clorazepate
- (9) Cloxazolam
- (10) Delorazepam
- (11) Diazepam
- (12) Estazolam
- (13) Ethyl Loflazepate
- (14) Fludiazepam
- (15) Flurazepam
- (16) Halazepam
- (17) Haloxazolam
- (18) Ketazolam
- (19) Loprazolam
- (20) Lorazepam
- (21) Lormetazepam
- (22) Medazepam
- (23) Midazolam
- (24) Nimetazepam
- (25) Nitrazepam
- (26) Nordazepam
- (27) Oxazepam
- (28) Oxazolam
- (29) Pinazepam
- (30) Prazepam
- (31) Quazepam
- (32) Temazepam
- (33) Tetrazepam
- (34) Triazolam
- (35) Flunitrazepam

2. Clotiazepam
3. Ethchlorvynol
4. Ethinamate
5. Fencamfamin
6. Fenproporex
7. Mazindol
8. Mefenorex



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- 9. Meprobamate
- 10. Methyprylon
- 11. Pipradol