



Health Canada Santé Canada

Healthy Environments and Consumer Safety Branch
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Guidance Document for Practitioners

To: Provincial Licensing Authorities of Physicians, Dentists and Veterinarians

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 can be found 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 practitioners regulatory requirements coming with the promulgation of these Regulations. Attached is a list of targeted substances to whose the Regulations will apply.

A practitioner may prescribe, administer, sell, provide, send, deliver or transport a targeted substance to an individual or for the benefit of an animal if:

- a) the individual or animal is a patient that the practitioner is treating in his/her professional capacity, and
- b) the targeted substance is required to treat the patient's condition.

Emergency Supply (for practitioners of medicine only)

An emergency supply of targeted substances may be stored by a practitioner of medicine at a remote location where emergency medical treatment is not readily available or in an emergency medical service vehicle, if an agent of the practitioner at that location or in the vehicle controls and administers the targeted substance on behalf of and under the direction of the practitioner.

In an emergency, the agent of the practitioner may administer to an individual a targeted substance from the emergency supply if:

- a) a direction to administer the targeted substance has been given by a practitioner of medicine by telephone or other means, or
- b) written directives with respect to the administration of the targeted substance have been given by the practitioner and the agent follows those directives.

The agent of the practitioner must keep the following records:

- a) the name, strength per unit and quantity of each targeted substance administered and the date on which it was administered;
- b) the name of the individual to whom the targeted substance was administered, and
- c) the name of the agent of the practitioner who administered the targeted substance.

The agent of the practitioner must also take any reasonable steps to protect any targeted substance from loss and theft and inform the practitioner without delay of any loss or theft of a targeted substance.

Records

A practitioner must keep records of the following information:

- a) the brand name of the targeted substance or, if the substance has no brand name, the specified name, the quantity and strength per unit of any targeted substance received from a licensed dealer, pharmacist or hospital and the date on which it was received;
- b) the name and address of the licensed dealer, pharmacist or hospital that sold or provided the targeted substance;
- c) if the transaction involves a quantity of targeted substance that exceeds five times the usual daily dose for the substance, the disposition of the substance and the date of the disposition;
- d) in the case of an emergency supply, the name of the administering agent, the location of the emergency supply, the name, quantity and strength per unit of each targeted substance, the date of all transactions related to that emergency supply and the name of the individual to whom the targeted substance was administered.

Storage

A practitioner must store a targeted substance in a place used for the purpose of conducting their professional practice and in an area in that place where only authorized employees have access.

Loss or theft

A practitioner must take any reasonable steps to ensure the security of a targeted substance in his/her possession and , not later than ten days after its discovery, report to the Minister any loss or theft of a targeted substance. Loss and Theft Report forms are available at the Office of Controlled Substances.

Destruction

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

- a) the practitioner 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;
- b) the method of destruction is in conformity with federal, provincial and municipal environmental legislation;
- c) the date of the destruction is recorded;
- d) the destruction is witnessed by a pharmacist or a practitioner;
- e) immediately after the destruction took place, the practitioner and the witness sign and print their names on a joint statement, indicating that they witnessed the destruction and that the targeted substance has been altered or denatured to such an extent that its consumption has been rendered improbable or impossible.

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

Request for renunciation

If a practitioner does not wish to receive or have possession of targeted substances, the practitioner may make a written request to the Minister to send to licensed dealers and pharmacies a notice stating that:

- a) recipients of the notice must not sell or provide any targeted substance to that practitioner, and
- b) pharmacists practising in the notified pharmacies must not fill a prescription or order for any targeted substance written by that practitioner.

Notice to cease providing targeted substances

The Minister must issue a notice stating that a targeted substance must not be sold or provided to the practitioner named in the notice and that prescriptions or orders for a targeted substance issued by that practitioner must not be filled when a circumstance to issue such a notice exists.

These circumstances are:

- a) the practitioner made a request to the Minister to issue the notice;
- b) the practitioner contravened a rule of conduct established by the licensing authority of the province in which the practitioner is practising and that licensing authority has requested the Minister in writing to issue the notice;
- c) the practitioner has been found guilty in a court of law of a designated drug offence or of an offence under the *Benzodiazepines and Other Targeted Substances Regulations*.

The notice will be sent to licensed dealers, pharmacies within the province in which the practitioner is registered and practising, the licensing authority of the province in which the practitioner named in the notice is registered or entitled to practise, any interested licensing authority in another province, and any pharmacies in an adjacent province in which a prescription or order from that practitioner may be filled.

The notice may also be issued if the Minister has reasonable grounds to believe that the practitioner named in the notice:

- a) has contravened a provision of the *Controlled Drugs and Substances Act* or the Regulations;
- b) has, on more than one occasion, self-administered a targeted substance under a self-directed prescription or order or, in the absence of a prescription or order, contrary to accepted medical, dental or veterinary practice;
- c) has, on more than one occasion, prescribed, provided or administered a targeted substance to a spouse, parent or child, contrary to accepted medical, dental or veterinary practice, or
- d) is unable to account for a quantity of targeted substance for which the practitioner was responsible.

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 that document or on the Regulations, do not hesitate to contact us at (613) 954-1541.

Carole Bouchard, B. Pharm. M.A.P.
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Office of Controlled Substances
Healthy Environments and Consumer Safety Branch

Attch.

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
 9. Meprobamate
 10. Methyprylon
 11. Pipradol