



Healthy Environments and Consumer Safety Branch
Address Locator: #3618A
Ottawa, Ontario
K1A 1B9

July 25, 2000

00-101336-119

To All Licensed Dealers and Other Drug Manufacturers:

**Re: Information Bulletin for Controlled Substances Licensed Dealers
for the Regulations on Benzodiazepines and Other Targeted Substances**

The *Regulations on Benzodiazepines and Other Targeted Substances* have been published in Canada Gazette, Part II, on June 21, 2000. They will come into force **September 1, 2000**, except for the labelling and physical security requirements which will come into effect on September 1, 2001.

The following information is provided to lessen the impact and explain new regulatory requirements to current licensed dealers as well as to individuals or companies that will have to apply for a licence to be authorized to produce, make, assemble, import, export, sell, provide, send, deliver, transport or destroy benzodiazepines and other targeted substances.

The *Regulations on Benzodiazepines and Other Targeted Substances* are available on the Therapeutic Products Programme (TPP) Website at the following location under Gazette Part II:

English <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/schedule.html>

French <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmlfrn/schedule.html>

For your information, a list of drugs involved can be found in Appendix A.

A. Licence Issuance for Benzodiazepines and Other Targeted Substances

1. If You Currently Possess a Licence for Controlled Substances:

Please forward as soon as possible to the Licencing and Permits Division, Office of Controlled Substances, the following:

- Your current licence and licence appendix for amendment.
- A letter specifying the name(s) of the substance(s) you wish to add to your licence.
- When products or compounds containing a targeted substance will be made or assembled by or for another licensed dealer under a custom order, specify in the letter which activity will be carried on (making, assembling...) and to whose products this specific activity will apply.

2. If You Do not Possess a Licence for Controlled Substances:

Please contact the Licencing and Permits Division, Office of Controlled Substances, in order to obtain a New Licence application form.

Once completed, the form should be returned to the Manager, Licencing and Permits Division, Office of Controlled Substances. Allow sufficient time for processing before September 1st.

All licences expire on December 31st of each year.

If you have any questions or need application and guidance documentation, please contact us at the telephone number listed below.

The address for the Office of Controlled Substances is:

**Office of Controlled Substances
Address Locator #3502A
Ottawa, Ontario
K1A 1B9
Telephone Number: (613) 957-0345
Fax Number: (613) 941-4760**

B. Import - Export Permits

The *Regulations on Benzodiazepines and Other Targeted Substances* require import and export permits for all shipments of these substances into, or out of, Canada. However, no compliance action will be initiated against a company for any importation or exportation of benzodiazepines or other targeted substances, for legitimate medical or scientific use, if the shipment is in transit the day that the *Regulations on Benzodiazepines and Other Targeted Substances* come into effect.

Import-Export permits may only be granted to licensed dealers. Therefore, any company requiring such a permit must obtain a licence prior to making a request for a permit. Import and export permit application forms are available from the Licensing and Permits Division of the Office of Controlled Substances.

Please note that within 15 days after the importation or exportation has taken place, the licensed dealer must complete Part B of the document attached to the permit and return it to the Licensing and Permits Division, Office of Controlled Substances.

C. Transportation

The requirement for a chain of signature during transportation or delivery does not apply to the shipment of benzodiazepines and other targeted substances. However, reasonable measures must be put in place during transportation of these substances to prevent their loss or theft and diversion to illicit market.

D. Record Keeping

A licensed dealer must keep at the premises indicated on its licence such things as transaction and inventory control records, electronic data and other documents pertaining to all targeted substances transactions (including benzodiazepines). These must be kept in a manner that ensure *the licensed dealer is accountable for all transactions* for targeted substances and allows the independent audit of activities of the licensed dealer.

E. Loss or Theft

Any loss or theft of a benzodiazepine or any other targeted substance must be reported to the Office of Controlled Substances within ten days of its discovery. Loss and Theft Report forms are available from the Office of Controlled Substances.

F. Monthly Sales Reports

Licensed dealers are not required to report transactions of benzodiazepines and other targeted substances on their monthly sales reports.

G. Qualified Person in Charge

Just as for narcotics and controlled drugs licensed dealers, a Qualified Person in Charge who supervises the activities with respect to targeted substances and who is responsible for ensuring compliance with these Regulations on behalf of the licensed dealer must be physically on the premises to manage any transaction for a targeted substance that take place. To apply to become a Qualified Person in Charge, the individual shall have the academic background specified in the Regulations and relevant working experience.

A significant change in requirements for a QPIC and A/QPIC is the Criminal Record Check described next.

H. Criminal Record Check (New Requirement)

The *Regulations on Benzodiazepines and Other Targeted Substances* introduce new requirements for some individuals to show the absence of criminal records related to a designated drug offence. While these requirements apply only to these Regulations, it is intended that similar requirements will be applied for applications under the *Narcotic Control Regulations, Controlled and Restricted Drugs Regulations*. In the meantime, because targeted substances represent a lesser risk than narcotics, controlled drugs and restricted drugs, licensed dealers should take appropriate measures to deal with situations where an individual may be found to have a criminal record with respect to a designated drug offence under the new Regulations requirements and has similar responsibilities for narcotics, controlled and restricted drugs.

These requirements with regard to the criminal record are described in paragraphs 19 (2)(c), 20(3)(a)(b)(c) of the *Regulations on Benzodiazepines and Other Targeted Substances*. They read as follows:

Section 19(2)(c): “The qualified person in charge and, if applicable, the alternate qualified person in charge must not have, in the previous 10 years of their adult life, a criminal record in respect of

- (i) in Canada, a designated drug offence, or
- (ii) in a country other than Canada, an offence that, if committed in Canada, would have constituted a designated drug offence.”

Section 20(3)(a)(b)(c): “An application for a dealer’s licence must be accompanied by:

- (a) a signed declaration from the individual in charge of the premises, a signed declaration from the qualified person in charge and, if applicable, the alternate qualified person in charge, stating that the individuals have not, as an adult, been convicted of
 - (i) in Canada, a designated drug offence, and
 - (ii) in a country other than Canada, an offence that, if committed in Canada, would have constituted a designated drug offence;
- (b) a document issued by a Canadian police force with respect to each of the following individuals, setting out the individual’s criminal record, as an adult, in respect of a designated drug offence, or indicating that the individual has no such record:
 - (a) the individual in charge of the premises as set out in the request,
 - (ii) the qualified person in charge, and
 - (iii) if applicable, the alternate qualified person in charge;

- (c) if the individual in charge of the premises, the qualified person in charge or, if applicable, the alternate qualified person in charge has ordinarily resided in a country other than Canada in the preceding 10 years, a document issued by a police force of that country setting out the individual's criminal record, as an adult, in respect of a designated drug offence, or indicating that the individual has no such record.:

As stated in **Section 22(i)**, "the Minister must refuse to issue, renew or amend a dealer's licence if the individual in charge of the premises, the qualified person in charge or, if applicable, the alternate qualified person in charge has, in the previous 10 years of their adult life, a criminal record in respect of:

- (i) in Canada, a designated drug offence, or
- (ii) in a country other than Canada, an offence that, if committed in Canada, would have constituted a designated drug offence."

I. Postponed Requirements

1. Physical Security (Storage of Controlled Drugs)

The physical security requirements described in the Directive on Physical Security Requirements for Controlled Substances will only come into force on September 1, 2001, but licenced dealers are encouraged to follow them now. As a minimum, licensed dealers are expected to put in place interim measures to prevent loss or theft of those substances.

On September 1, 2001, benzodiazepines and other targeted substances will have to be stored as follows:

- Raw material - vault or safe,
- Finished products (in their final packaging) - cage,
- Flunitrazepam (raw material, finished product or preparation) - vault or safe.

Physical Security Levels:

Licensed dealers handling targeted substances might have to upgrade the physical security of their premises to meet the requirements of the Directive on Physical Security Requirements for Controlled Substances. The illicit value of targeted substances has been established as follows:

- Flunitrazepam: \$ 100,000.00 / kg
- Diazepam: \$ 50,000.00 / kg
- Other benzodiazepines: \$ 25,000.00 / kg
- Other targeted substances: \$ 1,000.00 / kg

Please take note that clozapine and olanzapine are excluded from the application of these Regulations and will remain, at this point in time, Schedule F drugs.

You may wish to consult the Directives on Physical Security Requirements for Controlled Substances dated December 1999 on the Therapeutic Products Programme Website at the address following:

English www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/cds.html

French www.hc-sc.gc.ca/hpb-dgps/therapeut/htmlfrn/cds.html

2. Labelling

Labelling requirements will come into force September 1, 2001. This delay in the implementation of this measure will allow the depletion of existing label supplies and enable manufacturers to introduce the new symbol in an appropriate and timely manner. Please consult the new Regulations for the new symbol to use.

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

Should you have any questions concerning this matter please do not hesitate to contact the Licensing and Permits Division at (613) 957-0345.

Yours sincerely,

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

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