Health Canada Santé Canada

Protected B (when completed)
Office of Controlled Substances
July 2018

Application for a Controlled Drugs and Substances Dealer's Licence

(disponible en français)

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act and the Narcotic Control Regulations. This information will be used to process your Application for a Controlled Drugs and Substances Dealer's Licence. This information may be used to provide reports to management. This information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described online at Info Source: Sources of Federal Government and Employee Information Health Canada. In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Canada

1. Name and Physical Address of the Applicant

Applicant Name					
Street Address					
City		Province		Postal Code	
Contact Name					
Telephone Number		Email Address			

2. Corporate Documentation

If the applicant is a corporation, both of the following must be attached to the application form.

Documentation Required	Check if attached
Proof of corporate name (e.g., a photocopy of a certificate of incorporation or patent letter)	☐
Any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.	☐

Note: The above documents are not required for an applicant who is the holder of a position that includes responsibility for narcotics, targeted substances, controlled drugs or restricted drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

3. Mailing Address (if different from applicant address)

Street Address					
City		Province		Postal Code	

4. Billing Address (if different than mailing address provided above)

Street Address					
City		Province		Postal Code	

5. Licensing Fee and Substance Identification

Licensing Fee

Q1. Are any of the substances subject to this application included in the Schedule(s) to Part G of the Food and Drug Regulations or to the Narcotic Control Regulations? (Check Yes or No)

Yes ◯ If yes, an application fee is applicable. To assess the applicable fee, go to Q2.
No ◯ If no, no application fee is applicable.

Q2. Are all the Controlled Drugs and the Narcotics intended for veterinary use only? (Check Yes or No)

Yes ◯ If yes, a $1,750 fee will be payable upon renewal of your licence.
No ◯ If no, a $5,184 * fee will be payable upon renewal of your licence.

* The Dealer's Licence fee is to be increased annually by 2%, rounded upwards to the nearest dollar, beginning April 1, 2012.

Note: If you are a new company applying for a Dealer's Licence, your fee is deferred until the end of your first full calendar year of activities under the licence or within 90 days after the day on which that first calendar year ends. More information concerning licensing fees associated with this application can be found on Health Canada's Drug Establishment Licensing Fees website.

Identification of Drug Type

The table below will help you determine the Drug Type that you need to identify in other tables of this document. The Drug Type is related to the regulatory schedule under which the substance is listed.

Substances to be listed on the Dealer's Licence	Drug Type	Identify Substances to be listed on the Dealer's Licence
Substances included in the Schedule(s) to the Benzodiazepines and Other Targeted Substances Regulations	T	Yes ◯ or No ◯
Substances included in the Schedule(s) to PART G of the Food and Drug Regulations	G	Yes ◯ or No ◯
Substances included in the Schedule(s) to PART J of the, Food and Drug Regulations	J	Yes ◯ or No ◯
Substances included in the Schedule(s) to the Narcotic Control Regulations	N	Yes ◯ or No ◯
Products approved and labeled "For Veterinary use only"	V	Yes ◯ or No ◯

6. Proposed Physical Security

All Licensed Dealers are required to have a secure environ for the storage of controlled drugs and substances. A description of each of the 11 security levels and the requirements for each one are found in the Directive on Physical Security Requirements for Controlled Substances (Security Directive). The security levels are determined by the geographical location and total value of controlled drugs and substances to be stored on the premises at any given time. Following a complete assessment of your application, if it is determined that your security proposal may meet the requirements of the Security Directive, an inspection of your facilities will be conducted to confirm the information provided.

Geographical region	◯ Region I ◯ Region II ◯ Region III
Type of secure environ	◯ Vault ◯ Safe ◯ Cage ◯ Other:
Maximum illicit value of all controlled substances to be stored at any given time	$
Proposed security level	
Description of proposed security measures	☐ Security template attached ☐ Floor plan attached ☐ Security proposal attached

Note: If a completed template and floor plan are not included, your application will be returned to you without being reviewed.

7. Preferred Language of Communication

	Written	**Verbal**
English	☐	☐
French	☐	☐

8. Proposed Personnel in Charge

8.a Proposed Individual in Charge of the Premises

Surname (last name)		Given Name(s)	
Title			
Telephone Number		Email Address	
Date of Birth	(YYYY/MM/DD)		

8.b Proposed Qualified Person in Charge (QPIC)

Proposed Qualified Person in Charge:			
Surname (last name)		Given Name(s)	
Telephone Number		Email Address	
Date of Birth	(YYYY/MM/DD)		

University, Degree and Year of Graduation	
Supporting documentation	☐ Copy of degree included, if applicable* ☐ Copy of course transcript included, if applicable* ☐ Copy of Canadian equivalency included, if applicable* ☐ Copy of Curriculum Vitae included
Professional licence number* and Province issuing licence (if applicable)	
Schedule – Work Hours and Days (e.g. 8am – 4pm, Mon – Fri)	
Title at the premises	
Name & Title of Supervisor at the premises	

*The proposed QPIC must be a pharmacist or a practitioner of medicine, dentistry or veterinary medicine registered with a provincial professional licensing authority, or have a degree in an applicable science. In the latter case, a copy of the degree and course transcript for that degree must be submitted. If the degree was obtained outside of Canada, you must also include proof that the degree is recognized by a Canadian university or a Canadian professional association**.**

Complete this table for each alternate work location of the proposed QPIC.

Check here if additional pages are included: ☐

Name of other work location(s)	
Licence Number of other work location(s)	
Title at other work location(s)	
Hours of work at other locations(s)*	
Name & title of supervisor at other work location(s)	

* The hours for the QPIC must not overlap between working locations.

8.c Proposed Alternate Qualified Person in Charge (A/QPIC)

Complete this table for each proposed A/QPIC.

Proposed Alternate Qualified Person in Charge:			
Surname (last name)		Given Name(s)	
Telephone Number		Email Address	
Date of Birth	(YYYY/MM/DD)		
University, Degree and Year of Graduation			
Supporting documentation	☐ Copy of degree included, if applicable* ☐ Copy of course transcript included, if applicable* ☐ Copy of Canadian equivalency included, if applicable* ☐ Copy of Curriculum Vitae included		
Professional licence number* and Province issuing licence (if applicable)			
Schedule – Work Hours and Days			
Title at the premises			
Name & Title of Supervisor at the premises			

*The proposed A/QPIC must be a pharmacist or a practitioner of medicine, dentistry or veterinary medicine registered with a provincial professional licensing authority, or have a degree in an applicable science. In the latter case, a copy of the degree and course transcript for that degree must be submitted. If the degree was obtained outside of Canada, you must also include proof that the degree is recognized by a Canadian university or a Canadian professional association.

Complete this table for each alternate work location of each proposed A/QPIC.

Check here if additional pages are included: ☐

Name of other work location(s)	
Licence Number of other work location(s)	
Title at other work location(s)	
Hours of work at other locations(s)*	
Name & title of supervisor at other work location(s)	

* The hours for the A/QPIC must not overlap between working locations.

8.d Proposed Individuals Authorized to Place Orders

Check here if additional pages are included: ☐

Proposed Individual(s) Authorized to Place Orders:			
Surname (last name)		Given Name(s)	
Surname (last name)		Given Name(s)	
Surname (last name)		Given Name(s)	
Surname (last name)		Given Name(s)	

Notes:

1. The individual authorized to place an order for controlled substances on behalf of the applicant must be working at the premises at which the dealer's licence would apply. This individual would be entitled to sign an order for the purchase of controlled substances on behalf of the applicant.

2. A Qualified Person in Charge (QPIC) or an Alternate Qualified Person in Charge (A/QPIC) may be designated as the individual authorized to place an order for controlled substances on behalf of the applicant. The QPIC or A/QPIC may be added to the list of Individual(s) Authorized to Place Orders, but is not automatically entitled to place orders.

3. Proposed Individuals Authorized to Place Orders do not need to submit documentation on educational background, a declaration regarding an absence of a conviction of a designated drug offence or a designated criminal offence, or a criminal record check, provided that the proposed Individual Authorized to Place Orders on behalf of the applicant would not have responsibility for supervising activities with respect to controlled substances at any time.

9. Activities and Substances to Be Specified on the Licence

Check all the activities that you intend to conduct at the proposed site of the licence and complete the relevant sections as per the "Completed Section(s)" column.

Licensable Activities	Complete Section(s)	
(a) Possession	9.a	☐
(b) Production (includes manufacturing) of:		
(i)Pharmaceutical product(s)[1]	9.bi	☐
(ii)Base substance material(s)[1]	9.bii	☐
(c) Packaging (includes assembling) of: [1]		
Pharmaceutical product(s)[1]	9.c	☐
(d) Sale (includes distribution and sale)	9.a	☐
(e) Sending, transportation and/or delivery	9.a	☐
Other Activities		
(f) Laboratory analysis		☐
(g) Research and development[1,3]		☐
(h) Conducting clinical studies[1,3]		☐
(i) Distribution under Special Access Program (SAP) only		☐
(j) Import / Export		☐
(k) Other activity (to specify)[4]		☐

Notes:

1. The substances and products involved with those activities must be specified in the following tables.
2. It is the responsibility of the Licensed Dealer to obtain the additional paperwork or authorization required for research and development and for clinical studies (e.g. exemptions, authentications, etc.).
3. For "other activity", please attach a complete description in a separate document.

9.a List Of Controlled Substances And Their Associated Activities

Please list all substances to be included on your licence and activities to be conducted with each one. Applicants must verify that the proposed substances appear in the schedules of the Controlled Drugs and Substances Act (CDSA). For substances that are not listed, applicants must provide confirmation from the Status Confirmation of Substances Section of Health Canada (hc.status-demandedestatut.sc@canada.ca) indicating that the substance to be added to the licence is controlled under the CDSA.

Failure to include this confirmation with your application may result in it being returned to you as incomplete.

Check here if additional pages are included: ☐

(a) Possession
(bi) Production of pharmaceutical product(s)
(bii) Production of base substance material(s)
(c) Packaging of pharmaceutical product(s)
(d) Sale
(e) Sending, transportation and/or delivery
(f) Laboratory analysis
(g) Research and development
(h) Conducting clinical studies
(i) Distribution authorized under SAP only
(j) Import / Export
(k) Other activity

Substance [1]	Activities [2]	Substance [1]	Activities [2]

Notes:
1. Substance: Generic name as it appears in the Controlled Drugs and Substances Act (CDSA).
2. Activities: Indicate the activities and intended uses for each substance by using the letters (a to k) listed above.

9.b Production Activities

9.b.i Production of Pharmaceutical Products

List all products manufactured by or for the applicant. In cases where the product is manufactured by or for another party, that party must be identified in the "other" column.

The following documents are required for each manufactured product:

- A copy of the Notice of Compliance (NOC), if applicable;
- A copy of the Drug Identification Number (DIN), if applicable; and
- A sample label for each package size of the new product to be marketed.

Product	Substance[1]	Strength / Unit	DIN[2]	For/ By[3]	Other[4]
e.g: MY-Lorazepam	Lorazepam	20mg/tab	01231111	For ◉ By ○	Self (applicant to manufacture its own product)
e.g: MY-Nabilone	Nabilone	1 mg/tab	01111123	For ○ By ◉	Drugmakers Inc. (applicant to have other company manufacture product)
				For ○ By ○	
				For ○ By ○	
				For ○ By ○	
				For ○ By ○	

Notes:

1. Substance: Name as it appears in the Controlled Drugs and Substances Act (CDSA).
2. DIN: Drugs authorized for sale in Canada are issued an eight-digit Drug Identification Number (DIN).
3. For/By: Indicate whether the product is manufactured by the applicant for itself or for another company, or by another company.
4. Other: Name of party who is manufacturing the product for the applicant, or for whom applicant is manufacturing the product.

9.b.ii Production of Base Substance Material(s)

Check here if additional pages are included: ☐

This table is to be completed only if you intend to produce controlled substances as raw materials. For each substance, indicate the anticipated quantity to be produced per calendar year.

Substance[1]	Quantity (kg)	Calendar Year

Note:

1. Substance: Generic name as it appears in the Controlled Drugs and Substances Act (CDSA).

9.c Packaging of Pharmaceutical Products

List all products packaged by or for the applicant. In cases where the product is packaged by or for another party, that party must be identified in the "other" column.

The following documents are required for each manufactured product:

- A copy of the Notice of Compliance (NOC), if applicable;
- A copy of the Drug Identification Number (DIN), if applicable; and
- A sample label for each package size of the new product to be marketed.

Product	Substance[1]	Strength / Unit	Package Size	DIN[2]	For/ By[3]	Other[4]
e.g: MY-morphine	Morphine HCl	10 mg/tab	100, 500	12121111	For ○ By ◉	UR Pharm Ltd. (applicant has UR Pharm Ltd. packaging their product)
e.g: MY-Lorazepam	Lorazepam	20 mg/tab	50, 100	01231111	For ◉ By ○	Self (applicant packaging its own product)
					For ○ By ○	
					For ○ By ○	
					For ○ By ○	
					For ○ By ○	

Notes:

1. Substance: Name as it appears in the Controlled Drugs and Substances Act (CDSA).
2. DIN: Drugs authorized for sale in Canada are issued an eight-digit Drug Identification Number (DIN).
3. For/By: Indicate whether the product is packaged by the applicant for itself or for another company, or by another company.
4. Other: Name of party who is packaging the product for the applicant, or for whom applicant is packaging the product.

10. Record Keeping

You are required to attach a detailed description of the method you are planning to use to ensure proper record keeping of the controlled substances transactions under the requested licence, as it is required by sections 15 of the Narcotic Control Regulations (NCR), G.02.014 of Part G of the Food and Drug Regulations (FDR), J.01.023 of Part J of the Food and Drug Regulations (FDR) and 35 of the Benzodiazepine and Other Targeted Substances Regulations (BOTSR).

A detailed description of the proposed record keeping method is attached ☐

In order to facilitate the review, a copy of the Standard Operation Procedure for the record keeping method and samples of the proposed record keeping templates may also be submitted.

11. Declarations For Designated Personnel

For each required individual, you must submit the following:

- Signed Declaration below, and
- A copy of a criminal record check certificate issued in the last 12 months.

Applicants are required to submit criminal record check (CRC) certificates along with their applications for a new licence. The Office of Controlled Substances (OCS) will consider a criminal record check certificate to be valid for twelve (12) months from the date of issuance. The CRC must be issued by the RCMP or a local police service must not be sent to our office directly from the RCMP or local police service. For more information on how to obtain a criminal record check, please consult the RCMP criminal check website. If an individual resided in another country in any of the previous 10 years, the application must also include a recent CRC issued by a police force in that country stating that the person has not been convicted, as an adult, in the previous 10 years, of an offence that, if committed in Canada, would have constituted a designated drug offence.

Failure to include the criminal record check certificate(s) may result in your application being returned to you.

I hereby certify that I have not in the last ten (10) years, as an adult, been convicted of a designated drug offence neither in Canada, nor in any country other than Canada, of an offence that would have constituted a designated drug offence if committed in Canada.

Proposed Individual in Charge of the Premises	
Full Name	
Signature:	Date: (YYYY/MM/DD)
Have you resided outside of Canada in the past 10 years? ◯ Yes ◯ No	
If yes, is the foreign CRC included? ◯ Yes ◯ No	Canadian CRC included

Proposed Qualified Person in Charge	
Full Name	
Signature:	Date: (YYYY/MM/DD)
Have you resided outside of Canada in the past 10 years? ◯ Yes ◯ No	
If yes, is the foreign CRC included? ◯ Yes ◯ No	Canadian CRC included

Proposed Alternate Qualified Person in Charge*	
Full Name	
Signature:	Date: (YYYY/MM/DD)
Have you resided outside of Canada in the past 10 years? ◯ Yes ◯ No	
If yes, is the foreign CRC included? ◯ Yes ◯ No	Canadian CRC included

*Additional pages may be attached if proposing more than one Alternate Qualified Person in Charge.

12. Application Statements For The Licence

For the licence requested, the following statements must be signed by the Individual in Charge of the Premises.

I hereby certify that I wish to apply for a dealer's licence to conduct activities described herein with the controlled substances listed in this application.

I hereby certify that the security measures at the premises to which the dealer's licence will apply are to the best of my knowledge accurate, complete and compliant with the minimum requirements described in the Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licenced Dealers for the Storage of Controlled Substances).

I hereby certify that the above corresponds to the proposed personnel with the corresponding responsibilities related to the licence requested.

I hereby certify that the proposed Qualified Person in Charge (QPIC) and, if applicable, the Alternate Qualified Person in Charge (A/QPIC) have the necessary knowledge of the Controlled Drugs and Substances Act (CDSA) and its Regulations to properly carry out their duties.

I hereby certify that the proposed method for the record keeping of the controlled drugs transactions is submitted to the best of my knowledge, to be used in order to be in compliance with the Controlled Drugs and Substances Act (CDSA) and its associated Regulations.

I hereby certify that all information and supporting documents provided with this application, are to the best of my knowledge correct, complete and in accordance with the relevant sections of the CDSA (Controlled Drugs and Substances Act) and its associated regulations.

I hereby certify that I have authority to bind the applicant.

Individual in Charge of the Premises:			
Surname (last name)		Given Name(s)	
Signature		Date	(YYYY/MM/DD)

Note: Any proposed changes to the physical security for the storage of controlled drugs and substances must be submitted to the Office of Controlled Substances (OCS) for approval and inspection before they can be implemented and reflected on the Controlled Drugs and Substances licence.

13. Submission

Submit this completed application form and all required documents by mail to the address below. Should you wish to have your new licence sent by courier, you must provide the waybill(s) with your application.

Controlled Drugs Section
Authorizations Division
Office of Controlled Substances
Health Canada
AL 0300B
161 Goldenrod Drwy
Ottawa ON K1A 0K9