

PHARMACY AND POISONS ORDINANCE

(CHAPTER 138)

APPLICATION FOR REGISTRATION OF PREMISES UNDER SECTION 13

We _____ of _____
(Name of business)

(Address of business)

wish to apply for the registration under section 13 of the Pharmacy and Poisons Ordinance of the premises as set out in paragraph 1 of this application to conduct the retail sale of poisons at such premises.

1. Address of premises _____
2. Name of business at the premises _____
3. Business Registration No. _____
4. Telephone No. of the premises _____
5. Name of registered pharmacist in whose presence or under whose supervision the retail sale of poisons is conducted under section 11(1) of the Ordinance _____

In support of this application, we submit a copy of the certificate of registration of the pharmacist named in paragraph 5.

Signature _____

Full name of signatory _____

Signed on behalf of _____

(Name of business)

Date _____

**LICENSING AND COMPLIANCE DIVISION
DRUG OFFICE
DEPARTMENT OF HEALTH**

Room 2001-2002, 20/F, Dah Sing Financial Centre,
248 Queen's Road East, Wan Chai, Hong Kong
Tel: 3107 3477 Fax: 3107 0221

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CHECKLIST

Application for Registration of Premises of an Authorized Seller of Poisons

Please submit this checklist with the following documents. If you answer “No” to any questions below, please provide a written explanation. **Documents submitted must be stamped with name and address of the applicant company.**

<u>Have you submitted</u>	<u>Yes</u>	<u>No</u>
(1) A completed application form?	<input type="checkbox"/>	<input type="checkbox"/>
(2) Copy of Business Registration Certificate?	<input type="checkbox"/>	<input type="checkbox"/>
(3) (a) For limited companies: (i) Copy of Certificate of Incorporation; and (ii) Copy of Directors' List (e.g. "Form NAR1" from Companies Registry or for, newly formed limited companies, photocopy of a full set of "Form NNC1" or "Form NNC1G")?	<input type="checkbox"/>	<input type="checkbox"/>
<u>OR</u> (b) For companies run by sole proprietorship: Copy of "Form 1(a)" from the Business Registration Office?		
<u>OR</u> (c) For companies run by partnership: Copy of "Form 1(c)" from the Business Registration Office?		
(4) A list including names, in English and Chinese, Hong Kong Identity Card numbers, posts and qualifications of the sole proprietor/ partners/ director(s), the pharmacist, and all the western medicine staff? For sole proprietor, partners, director(s), and person-in-charge (PIC), please also provide statement of relevant working experiences, and certificate of a recognized comprehensive course and recognized refresher course for the personnel of ASP ¹ , where applicable.	<input type="checkbox"/>	<input type="checkbox"/>
(5) Signed statement of appointment of all western medicine staff members by the owner (i.e. the sole-proprietor or partner) or the director, indicating their positions in the applicant's company?	<input type="checkbox"/>	<input type="checkbox"/>

- (6) Testimonials from previous employer(s) certifying the above relevant working experience as stated by the sole proprietor/ partners/ director(s), the pharmacist, and all the western medicine staff in the declarations? ☐ ☐
- (7) A signed declaration by each owner (i.e. sole proprietor or partner) or director, the pharmacist, PIC and each western medicine staff member², indicating whether: ☐ ☐
- (i) he/she has been an owner, a director or an employee of other trader(s) of western medicines (i.e. importer/exporter, retailer, wholesaler or manufacturer) in the past three years; and
 - (ii) he/she is being investigated/being prosecuted, or has any conviction, of drug-related offence(s) in the past three years?
- (8) A signed declaration by each owner (i.e. sole proprietor or partner) or director, and the PIC², indicating whether: ☐ ☐
- (i) he/she is being convicted of any criminal offence(s) in which he/she has been sentenced to imprisonment (whether suspended or not) in Hong Kong in the past five years;
 - (ii) he/she has been released from imprisonment in the past three years;
 - (iii) he/she is currently on non-custodial sentence, e.g. probation order or community service order; and
 - (iv) he/she is currently in bankruptcy or has any voluntary arrangement with an individual's creditor within the meaning of the Bankruptcy Ordinance (Cap. 6)?
- (9) A signed declaration by limited company³, indicating whether: ☐ ☐
- (i) it is being investigated/being prosecuted of drug-related offence(s);
 - (ii) it has any conviction of drug-related offence(s) in the past three years;
 - (iii) it has any conviction of other criminal offence(s) in the past five years; and
 - (iv) it has commenced to be wound up?
- (10) Copy of the Certificate of Registration and current Practising Certificate of the registered pharmacist? ☐ ☐
- (11) Floor plan of the Dispensary indicating the total area (e.g. dimension), and location(s) for the storage of pharmaceutical products, e.g. in the cockloft (if any), with declaration on if any controlled medicines will be stored other than in the dispensing room? ☐ ☐

- (12) Floor plan of the Dispensing Room indicating the total area (e.g. dimension), and the fixtures and fittings (e.g. water supply facility, fridge, cabinets for controlled medicines)? ☐ ☐
- (13) Letter of opening hours of the Authorized Seller of Poisons and the attendance hours of the registered pharmacist? ☐ ☐

¹ Only applicable if a comprehensive course organized for ASP personnel has been satisfactorily completed within the past three years, or a refresher course within the past year if the ASP and/or PIC has completed the comprehensive course more than three years ago. Both the comprehensive course and the refresher course have to be recognized by the Pharmacy and Poisons Board.

² Please use Form DCR E01A 0923: Declaration by Sole Proprietor/ Partner/ Director/ Pharmacist/ PIC/ Other Staff for the Application for Registration of Premises of an Authorized Seller of Poisons.

³ Please use Form DCR E02A 0923: Declaration by Limited Company for the Application for Registration of Premises of an Authorized Seller of Poisons.

**Guidance Notes on Application for Registration of Premises under Section 13 of
Pharmacy and Poisons Ordinance (Cap. 138)**

These Guidance Notes are to facilitate the application for registration of the premises to conduct retail sale of controlled medicines as an Authorized Seller of Poisons.

2. Application form can be downloaded from the website of Drug Office at <http://www.drugoffice.gov.hk>, or obtained in person at the Licensing and Compliance Division of Drug Office during the following office hours:

Licensing and Compliance Division, Drug Office, Department of Health, Room 2001-2002, 20/F, Dah Sing Financial Centre, 248 Queen's Road East, Wan Chai, Hong Kong.	<u>Monday to Friday</u> 9:00 a.m. to 1:00 p.m. 2:00 p.m. to 5:45 p.m. (up to 6:00 p.m. on Monday) (Closed on Saturdays, Sundays & Public Holidays)
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3. The completed application form, together with the required documents indicated in the attached checklist, should be submitted in person or by post, to the above address; by fax to 3107 0221; or by digitally signed email certified by Hong Kong Post Certification Authority to pharmgeneral@dh.gov.hk. For any enquiries, please call 3107 3477.

4. Upon receipt of the completed application, interview will be arranged with the person-in-charge (PIC) and the pharmacist to assess their knowledge and understanding of the relevant legislations and the “Code of Practice for Authorized Seller of Poisons” for operation of an Authorized Seller of Poisons. In addition, inspection will be conducted to assess whether the premises are suitable for conducting retail sale of controlled medicines. All applications will be submitted to the Pharmacy and Poisons Board for consideration.

5. In general, factors that would be taken into account when evaluating a new application as well as a renewal application include:

- Results of inspection;
- Previous drug-related and other criminal conviction(s), in particular those have significant impact to the public interest, registered against the applicant or the key personnel¹;
- Previous disciplinary action(s) against the applicant or the key personnel¹;

- Financial status of the sole proprietor, partners, directors or PIC ¹; and
- Qualification(s), competence, skills and experiences of the key personnel^{1,2}.

6. The prescribed fee for registration of premises of an authorized seller of poisons is HK\$1,000. For successful application, notification of payment will be sent to the applicant by mail. Upon payment, a Certificate of Registration of Premises under Section 13 will be issued with an expiry date of 1st January of the following year. The certificate may contain conditions relating to the registration of the premises as the Board thinks fit.

7. The performance pledge of the Department of Health is that application will be approved within two months, subject to clean criminal and disciplinary history, sound financial status of the applicant and the key personnel, satisfactory assessment during first interview, if applicable, and satisfactory inspection during the first inspection at the premises.

8. Any applicant aggrieved by a decision of the Board in respect of the application may, in the prescribed manner, appeal against such decision to the Pharmacy and Poisons Appeal Tribunal.

9. An Authorized Seller of Poisons may apply to the Board for the certificate to be renewed. The Board may change condition previously imposed by it in respect of renewal. The annual renewal fee for the registration of premises as an Authorized Seller of Poisons is HK\$1,310.

10. Applicants and their employees or agents must not offer an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201) to any Government officer or members of statutory organizations (including but not limited to the Pharmacy and Poisons Board and its Committees) in connection with their applications or while having dealings of any kind with Government departments or statutory organizations.

11. These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case. The Pharmacy and Poisons Ordinance and its subsidiary legislation can be downloaded from the website of the Department of Justice at <http://www.elegislation.gov.hk>, or be purchased by calling the Publications Sales Unit of the Information Services Department at 2537 1910 or by email to puborder@isd.gov.hk. The “Code of Practice for Authorized Seller of Poisons” can be downloaded from the website of the

Board at <http://www.ppbhk.org.hk>, or obtained in person at the Board during the following office hours:

Pharmacy and Poisons Board,
46/F, Revenue Tower,
5 Gloucester Road,
Wan Chai, Hong Kong.
Tel.: 2527 8432
Fax: 2865 5540

Monday to Friday
9:00 a.m. to 1:00 p.m.
2:00 p.m. to 5:45 p.m.
(up to 6:00 p.m. on Monday)
(Closed on Saturdays, Sundays
& Public Holidays)

¹Please refer to the 'Guiding Principles on Assessing Fitness and Properness of an Authorized Seller of Poisons and Appointed Person-in-Charge'.

²Interview of the sole proprietor, partners, director(s) and/or PIC may be required for assessment.

Statement of Purposes

Purpose of Collection

This personal data are provided by licence applicants for the purposes of application for licences under the Pharmacy and Poisons Ordinance, the Antibiotics Ordinance and the Dangerous Drugs Ordinance. The personal data provided will be used by DH for the following purposes:

- (a) Proof of eligibility for a licence
- (b) Assessment of whether the applicant is a fit and proper person to be granted a licence

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to prove your eligibility for a licence, or to assess whether you are a fit and proper person to be granted a licence.

Classes of Transferees

3. The personal data you provide are mainly for use within DH and the Pharmacy and Poisons Board. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to:

Senior Pharmacist
Licensing and Compliance Division
Drug Office
Department of Health
Room 2001-2002, 20/F,
Dah Sing Financial Centre,
248 Queen's Road East,
Wan Chai, Hong Kong
Tel: 3107 3477

**Declaration by Sole Proprietor/ Partner/ Director/ Pharmacist/ PIC/ Other staff
for the Application for Registration of Premises of an Authorized Seller of Poisons**

I, _____ (HK ID No.: _____)
(Name)

am the *sole proprietor/ partner/ director/ pharmacist/ person-in-charge/ other staff of

(Name of business)

at _____
(Address of business)

I would like to provide the following information in relation to the application for registration of premises of an Authorized Seller of Poisons.

(* Please delete where applicable.)

1. I have been an owner, a director, or an employee of other trader(s) of western medicines, i.e. importer/exporter, retailer, wholesaler or manufacturer, in the past three years:

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

([#] If yes, please provide relevant details regardless of whether the engagement is part-time in nature or whether the business was closed or not in the table below.)

Company Name and Address	Position Held	Period	
		From (Month/Year)	To (Month/Year)

(Please use separate sheet if needed.)

2. I am currently being investigated, or being prosecuted, of drug-related offence(s):

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

([#] If yes, please provide relevant details in the table below.)

Date of Offence	Offence and Description	Involved Company Name and Address

(Please use separate sheet if needed.)

3. I have conviction of drug-related offence(s) in the past three years:

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

([#] If yes, please provide relevant details in the table below.)

Date of Conviction	Offence and Description	Involved Company Name and Address

(Please use separate sheet if needed.)

4. For sole proprietor, partner, director, or person-in-charge, please fill in sections 4a-c below:

a. I have been convicted of criminal offence(s) in the past five years in which I have been sentenced to imprisonment (whether suspended or not) in Hong Kong:

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

b. I was released from imprisonment in the past three years:

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

c. I am currently on non-custodial sentence, e.g. probation order or community service order:

(Please “✓” in the appropriate box below.)

☐ **No** ☐ **Yes[#]**

([#] If yes, please provide relevant details in the table below.)

Date of Conviction	Offence and Description

(Please use separate sheet if needed.)

5. For sole proprietor, partner, director, or person-in-charge, please fill in the section below:

I am currently in bankruptcy or has voluntary arrangement with an individual's creditor within the meaning of the Bankruptcy Ordinance (Cap. 6):

(Please “✓” in the appropriate box below.)

☐ No ☐ Yes[#]

(# If yes, please provide relevant details in the table below.)

Details

(Please use separate sheet if needed.)

I declare that the information given in this declaration is true, correct and complete.
I understand that making false declaration will be liable to criminal prosecution.

Signature: _____

Name in Block Letters: _____

Date: _____

**Declaration by Limited Company for the
Application for Registration of Premises of an Authorized Seller of Poisons**

I, _____ (HKID No.: _____)
(Name)

(Position: _____) on behalf of _____
(Name of Limited Company)

(Business Registration Certificate No.: _____) would like to declare in
relation to the application for registration of premises of an Authorized Seller of Poisons
that: _____
(Name of Limited Company)

- (1) ***is / is not** being investigated or being prosecuted of drug-related offence(s);
(2) ***has / does not have** any conviction of drug-related offence(s) in the past three years;
(3) ***has / does not have** any conviction of other criminal offence(s) in the past five
years; and
(4) ***has / has not** commenced to be wound up.

(*Please delete where applicable.)

Please provide relevant details below where applicable:

(1-3)	Date of Conviction	Offence and Description
(4)	Date	Description

(Please use separate sheet if needed.)

I declare that the information given in this declaration is true, correct and complete.
I understand that making false declaration will be liable to criminal prosecution.

Authorized Signature: _____

Name in Block Letters: _____

On behalf of: _____
(Name of limited company)

Company Chop: _____

Date: _____