

DEPARTMENT OF HEALTH
DRUG OFFICE
TRADERS LICENSING AND COMPLIANCE DIVISION

382 Nam Cheong Street,
3/F, Public Health Laboratory Centre, Kowloon.
Tel. 2319 8467 Fax: 2147 0457

衛生署藥物辦公室
藥商牌照及監察部

九龍南昌街 382 號
公共衛生檢測中心 3 樓
電話 : 2319 8467 傳真 : 2147 0457

Application for Wholesale Poisons Licence
毒藥批發牌照申請書

FOR OFFICIAL USE ONLY

(不必填寫本欄)

Date: _____

Misc. Receipt No.: _____

Application Fee: _____

Checked By: _____

PART A 甲部

DETAILS OF APPLICANT 申請人資料

Name of Business (In English) _____
商號名稱 (中文) _____
Address of Business 商號地址 _____

Name of Business at the premises (if different from above) _____
設在該處所的商號名稱 (如與上述不同) _____
Address of premises (if different from above) _____
處所地址 (如與上述不同) _____

Business Registration Number 商業登記號碼 _____

Telephone No. of the premises 處所電話號碼 _____ Fax No. 傳真號碼 _____

Name of Person in charge of Business (In English) _____
掌管業務的負責人姓名 (英文) _____

Name of Person in charge of Business (In Chinese) _____
掌管業務的負責人姓名 (中文) _____

HK Identity Card No. _____
香港身份證號碼 _____

Post 職位 *Proprietor 東主/Partner 合夥人/Director 董事 /Others, please specify 其他, 請註明 _____

(*Delete whichever is inapplicable 請將不適用的刪去)

Applicant must nominate a person in charge of poisons 申請人必須指定一位掌管毒藥負責人

Name of Person in charge of Poisons (In English) _____
掌管毒藥負責人姓名 (中文) _____

H K Identity Card No. 香港身份證號碼 _____ Post 職位 _____

If applicable, applicant may also nominate a deputy to act during the temporary absence of this responsible person

如適用, 申請人亦可以指定一名代理, 在該負責人暫時缺勤時代司其職

Name of deputy Person in charge of Poisons (In English) _____
代理掌管毒藥負責人姓名 (中文) _____

H K Identity Card No. 香港身份證號碼 _____ Post 職位 _____

Scope of Business: 業務性質

Import/ Export 進口 / 出口 Local Distribution 本銷

Storage facilities at premises 處所內之貯存設備

locked storage room 鎖上的貯存室 (area 面積 _____ sq. m 平方米)
 additional warehouse (Please fill in Part B) 附加倉庫 (請填乙部)

PART B 乙部 (FOR ADDITIONAL WAREHOUSE ONLY) 附加倉庫適用)

Address of Additional Warehouse _____

附加倉庫的地址 _____

Area of Additional Warehouse 附加倉庫的面積 _____ sq. m. 平方米

Business Registration Number 商業登記號碼 _____

Name of Person in charge of Additional Warehouse
(In English) _____

掌管附加倉庫負責人姓名 (中文) _____

H K Identity Card No. 香港身份證號碼 _____ Post 職位 _____

PART C 丙部 DECLARATION OF APPLICANT 申請人聲明

We wish to apply for a Wholesale Poisons Licence under the Pharmacy and Poisons Ordinance.
We hereby declare that the information given in this application is true and correct.
我們欲根據《藥劑業及毒藥條例》申請毒藥批發牌照。我們現聲明此申請書內所填報的資料，均全屬確實無誤。

Signature 簽署 _____

Company Stamp

公司蓋印

Full name of Signatory

簽署人全名 _____

Signed on behalf of

代表簽署商號 _____

(Name of business 商號名稱)

Date 日期 _____

(DO 09/2011)

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CHECKLIST

**Application for Wholesale Poisons Licence/ Antibiotics Permit/
Wholesale Dealer's Licence to Supply Dangerous Drugs**

Please submit this checklist with the following documents. If you have answered "No" to any question, please provide a written explanation.

<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) Copy of Business Registration Certificate of additional storage / warehouse (if any)?	<input type="checkbox"/>	<input type="checkbox"/>
(4) (a) For limited companies :		
(i) Copy of Certificate of Incorporation <u>and</u>		
(ii) Copy of Directors' List (e.g. "Form AR1" from Companies Registry or for newly formed limited companies, photocopy of a full set of "Form NC1" or "Form NC1G")?		
<u>OR</u>		
(b) For companies run by sole proprietors : Copy of "Form 1(a)" from the Business Registration Office?	<input type="checkbox"/>	<input type="checkbox"/>
<u>OR</u>		
(c) For companies run by partners: Copy of "Form 1(c)" from the Business Registration Office?		
(5) A list including name(s) in English and Chinese, Hong Kong Identity Card number(s) and posts of sole proprietor/ partners/ directors and staff?	<input type="checkbox"/>	<input type="checkbox"/>
(6) A signed declaration of each owner (i.e. sole proprietor or partner) or director, and each key personnel (e.g. person-in-charge of western medicines) indicating whether 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, regardless whether the trader is still in business)? [If yes, please list out the relevant information, including the English name(s) of the trader(s) and the period involved]	<input type="checkbox"/>	<input type="checkbox"/>

<u>Have you submitted</u>	<u>Yes</u>	<u>No</u>
(7) Statement(s) of relevant experience of all staff members involved in western medicines ?	<input type="checkbox"/>	<input type="checkbox"/>
(8) Certifications of the above relevant experience, e.g. testimonials from previous employer(s)?	<input type="checkbox"/>	<input type="checkbox"/>
(9) Scope of Business :		
<p>(a) Import / export only Copy of document(s) showing offer for sale and purchase of antibiotics/poisons/dangerous drugs/pharmaceutical products (e.g. price quotations or proforma invoice from your supplier and buyer together with information showing ingredient(s) of the products.)</p> <p style="text-align: center;"><u>OR</u></p> <p>(b) Local distribution involved</p> <p>(i) For the applicant who is a product certificate holder of pharmaceutical product, copy of Certificate of Drug/Product Registration <u>OR</u></p> <p>(ii) For the applicant who is <u>not</u> a product certificate holder of pharmaceutical product, copy of Certificate of Drug/Product Registration <u>AND</u> exclusive agency agreement document(s)/ exclusive agency appointment letter from the product certificate holder <u>OR</u></p> <p>(iii) For the applicant dealing in non-pharmaceutical products, exclusive agency agreement document(s)/exclusive agency appointment letter from your supplier together with information showing ingredient(s) of the products?</p>	<input type="checkbox"/>	<input type="checkbox"/>
(10) Floor plan of the premises mentioned in the application form?	<input type="checkbox"/>	<input type="checkbox"/>
(11) Floor plan of the additional storage / warehouse (if any)?	<input type="checkbox"/>	<input type="checkbox"/>
<p>(12) For application for Wholesale Dealer's Licence to Supply Dangerous Drugs : Photocopy of the Certificate of Registration and Practising Certificate of the registered pharmacist supervising the transactions of dangerous drugs?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>(13) For application for Antibiotics Permit : A crossed cheque of HK\$450 made payable to “The Government of the Hong Kong Special Administrative Region” being the statutory application fee?</p>	<input type="checkbox"/>	<input type="checkbox"/>

Pharmacy and Poisons Ordinance (Cap. 138)

Guidelines for Application for Wholesale Poisons Licence

1. A company wishing to deal in any poison must first obtain a Wholesale Poisons Licence. "Poison" means a substance (or a preparation containing the substance) specified in the Poisons List made under the Pharmacy and Poisons Ordinance.

2. If the poison the company wishes to deal in is a psychotropic drug, then a registered pharmacist must be employed to handle all transactions of the psychotropic drug. A list of psychotropic drugs is attached.

3. Application forms for Wholesale Poisons Licence are available, free of charge, by downloading from the web site <http://www.drugoffice.gov.hk/eps/eng/html/forms.jsp> or in person during the following hours from :

Department of Health,	<u>Monday to Friday</u>
Drug Office,	9:00 a.m. to 1:00 p.m.
Traders Licensing and Compliance Division,	2:00 p.m. to 5:45 p.m.
382 Nam Cheong Street,	(up to 6:00 p.m. on Monday)
3/F., Public Health Laboratory Centre,	<i>(Closed on Saturdays,</i>
Kowloon.	<i>Sundays & Public Holidays)</i>
Tel. 2319 8467 Fax: 2147 0457	

4. The completed application form together with the relevant documents indicated in the attached checklist should be submitted by post, by fax (2147 0457), by digitally signed email certified by Hongkong Post Certification Authority (pharmgeneral@dh.gov.hk) or in person to the above address.

In case electronic documents are being used for the application, please refer to web site : <http://www.drugoffice.gov.hk> and call 2319 8577 or 2319 8486 for details.

5. General requirements for premises:

- Only companies occupying commercial premises would normally be considered.
- Companies occupying ground floor or retail premises would normally not be considered.
- Companies operating in secretarial or accountancy service holding companies would not be considered.
- There must be adequate lockable storage facilities, with appropriate temperature and humidity, for keeping poisons. A probe for detecting temperature & relative humidity should be installed.

6. An inspection by a pharmacist inspector will be conducted at the company's premises. Application for Wholesale Poisons Licence will be considered by an Executive Committee of the Pharmacy and Poisons Board. If approved, a Wholesale Poisons Licence will be issued. The licence may contain such conditions as the Executive Committee may think necessary or expedient to impose. The licence may also be revoked at any time.

7. Payment of prescribed fee HK\$625 will be required when the Wholesale Poisons Licence is ready for collection. Notification of payment will be sent by mail.

8. The performance pledge of the Department of Health is that applications will be approved within two months.

9. 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. Copies of the Pharmacy and Poisons Ordinance and its subsidiary legislation may be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910 or by email at puborder@isd.gov.hk. Contents of the relevant legislation may also be found at the Department of Justice's website <http://www.legislation.gov.hk>.

Requirements on storage of pharmaceutical products

The storage condition of wholesalers and importers/exporters of pharmaceutical products must be in compliance with the following requirements:

- (1) Storage facilities must comply with the Laws of Hong Kong.
- (2) Storage facilities of pharmaceutical products must be room or rooms designated for storage of pharmaceutical products, which shall be locked with an adequate lock. The storage area of the storerooms should not be less than 100 square feet or should be proportionate to the scale of relevant business.
- (3) Precautions must be taken to prevent unauthorized persons from entering storeroom.
- (4) Storeroom should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely products in quarantine, and released, rejected, returned or recalled products.
- (5) Storeroom should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature and humidity limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.
- (6) Storeroom should be clean, and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storeroom. There should also be written programme for pest control. The pest-control agents used should be safe, and there should be no risk of contamination of pharmaceutical products. There should be appropriate procedures for the clean up of any spillage to ensure complete removal of any risk of contamination.
- (7) Receiving and dispatch area should protect products from the weather. Receiving area should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.
- (8) Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security.
- (9) Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled, or returned products. The products and area concerned should be appropriately identified.
- (10) Radioactive materials, dangerous drugs, psychotropic substances, and cytotoxic drugs should be stored in dedicated areas that are subject to appropriate additional safety and security measures.
- (11) Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
- (12) A system should be in place to ensure that pharmaceutical products due to expiry first are sold and/or distributed first. Exceptions may be permitted as appropriate, provided

that adequate controls are in place to prevent the distribution of expired products.

- (13) Rejected pharmaceutical products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is taken on their fate.
- (14) Broken or damaged items should be stored separately from usable stock and disposed properly.
- (15) Storeroom should be provided with adequate lighting to enable all operations to be carried out accurately and safely.
- (16) Storage conditions for pharmaceutical products should be in compliance with the instructions on the label, which are based on the results of stability testing.
- (17) Recorded temperature and humidity monitoring data should be available for review. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year. Temperature and humidity mapping should show uniformity of the temperature and humidity across the storage facility. It is recommended that temperature and humidity monitors be located in areas that are most likely to show fluctuations.
- (18) Equipment used for monitoring of storage conditions should be calibrated and maintained at defined intervals. Relevant records should be kept and available for inspection by Department of Health.
- (19) Any non-compliance of storage condition detected should be reported to Department of Health.
- (20) Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.
- (21) All significant stock discrepancies should be investigated to check that there have been no advertent mix-ups, incorrect issue and/or misappropriation of pharmaceutical products.
- (22) Any breakage of security, or any unexplainable stock discrepancy should be reported to Department of Health.
- (23) All facilities for the storage of poisons should be licensed or approved and have proper security control.

**List of poisons which are psychotropic substances
and which must be handled by registered pharmacists
Effective: 1 January 2004**

屬於精神藥物之毒藥列表，必須由
藥劑師負責處理所有交易
(由2004年1月1日生效)

1. Allobarbital	阿洛巴比妥	14. Meprobamate	甲丙氨酯
2. Amineptine	阿米庚酸	15. Methylphenobarbital	甲苯比妥
3. Amobarbital	異戊巴比妥	16. Methyprylon	甲乙呱酮
4. Buprenorphine	丁丙諾啡	17. Pemoline	匹莫林
5. Butalbital	布他比妥	18. Pentazocine	噴他佐辛
6. Butobarbital	丁巴比妥	19. Pentobarbital	戊巴比妥
7. Cyclobarbital	環己巴比妥	20. Phenobarbital	苯巴比妥
8. Ethchlorvynol	乙氯維諾(乙氯 戊烯炔醇)	21. Pipradrol	呱苯甲醇
9. Ethinamate	炔己蟻胺	22. Pyrovalerone	吡咯戊酮
10. Fencamfamin	芬坎法明	23. Secbutabarbital	仲丁比妥
11. Glutethimide	格魯米特	24. Vinylbital	乙烯比妥
12. Lefetamine	勒非他明	25. Zolpidem	唑吡坦
13. Mazindol	馬吩哞哞	26. any salt or preparation of any of the above	任何上述物質之鹽類或製劑

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
Traders Licensing and Compliance Division
Drug Office
Department of Health
3/F., Public Health Laboratory Centre
382, Nam Cheong Street, Kowloon.

Tel: 2319 8467