

FORM 13
表格十三

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例
(Chapter 138)
(第一三十八章)

APPLICATION FOR REGISTRATION AS AN IMPORTER/
EXPORTER OF PHARMACEUTICAL PRODUCTS
註冊為藥劑製品進口商/出口商的申請

We wish to apply for registration as an importer and exporter of pharmaceutical products under the Pharmacy and Poisons Ordinance, Cap. 138.

我們欲根據《藥劑業及毒藥條例》(第 138 章)申請註冊為藥劑製品進口商及出口商。

Name of pharmaceutical product(s) registered by Applicant:
申請人所註冊的藥劑製品的名稱:

Name of manufacturer(s) represented by Applicant, if any:
申請人所代表的製造商(如有的話)的姓名或名稱:

Description of storage room/cubicle/receptacle *:
供貯存用的房間/小室/容器*:
(*Delete as appropriate)
(*刪去不適用者)

Name of Applicant:
申請人的姓名或名稱:

Business Address of Applicant:
申請人營業地址:

Tel. No.
電話號碼:

Name of person in charge:
掌管的人的姓名:

Date í í í í í í í í í í í í í í í í
日期

Signature í í í í í í í í í í í í í í í í
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CHECKLIST

**Application for Wholesale Poisons Licence/ Antibiotics Permit/
 Registration as an Importer and Exporter of Pharmaceutical Products/
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 and		
(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 NC1(G)")?		
OR		
(b) For companies run by sole proprietors :		
Copy of "Form 1(a)" from the Business Registration Office?		
OR		
(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 :		
(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.)		
OR	<input type="checkbox"/>	<input type="checkbox"/>
(b) Local distribution involved		
Copy of Certificate of Drug/Product Registration OR agency agreement document(s)/agency appointment letter from your supplier together with information showing ingredient(s) of the products?		
(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"/>
(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?	<input type="checkbox"/>	<input type="checkbox"/>
(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?	<input type="checkbox"/>	<input type="checkbox"/>
(14) For application for Registration as an Importer and Exporter of Pharmaceutical Products :		
A crossed cheque of HK\$720 made payable to "The Government of the Hong Kong Special Administrative Region" being the statutory application fee?	<input type="checkbox"/>	<input type="checkbox"/>

Pharmacy and Poisons Ordinance (Cap. 138)

Guidelines for Application for Registration as an Importer/Exporter of Pharmaceutical Products

1. A company wishing to import or export pharmaceutical products which do not contain poisons or dangerous drugs must first register as an importer/exporter of pharmaceutical products.

2. Application forms (Form 13) for registration as an importer/exporter of pharmaceutical products are available, free of charge, by downloading from the web site <http://www.psdh.gov.hk/eps/eng/html/forms.jsp> or in person from the following address. The completed application form together with the relevant documents indicated in the attached checklist and an application fee of HK\$720 should be submitted by post or in person to the following address during the following hours :

Department of Health,	<u>Monday to Friday</u>
Pharmaceutical Service,	9:00 a.m. to 1:00 p.m.
Inspection and Licensing Section,	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	

3. Payment must be made by crossed cheque and made payable to "The Government of the Hong Kong Special Administrative Region". The application fee is not refundable. A receipt for the application fee will be issued to the applicant.

4. General requirements for premises:

- Companies occupying commercial premises would normally be considered;
- Companies operating in secretarial or accountancy service holding companies would not be considered; and
- There must be adequate lockable storage room(s) for keeping pharmaceutical products. Detailed requirements on the storage facilities are set out in the attached "Requirements on storage of pharmaceutical products".

5. An inspection by a pharmacist inspector will be conducted at the company's premises. The application will be considered by an Executive Committee of the Pharmacy and Poisons Board. If approved, a Certificate of Registration as an Importer and Exporter will be issued and sent to the applicant by mail.

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

7. 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) The licence/certificate holder must ensure the storage facilities comply with the Laws of Hong Kong.
- (2) The 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 be proportionate to the scale of relevant business and should not be less than 100 square feet.
- (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 bulk and finished products, 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 bays should protect products from the weather. Reception areas 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 areas 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 store 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) The licence/certificate holder should report to Department of Health if any non-compliance of storage condition is detected.
- (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) The licence/certificate holder should report to Department of Health for any breakage of security, or any unexplainable stock discrepancy.
- (23) Should be ensured that all facilities for the storage of poisons are licensed or approved and have proper security control.

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(Chapter 138)
(第一三十八章)

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我們欲根據《藥劑業及毒藥條例》(第 138 章)申請註冊為藥劑製品進口商及出口商。

Name of pharmaceutical product(s) registered by Applicant:

普通西藥
(不含毒藥)

申請人所註冊的藥劑製品的名稱:

1

Name of manufacturer(s) represented by Applicant, if any:

申請人所代表的製造商(如有的話)的姓名或名稱:

2

Description of storage room/cubicle/receptacle *:

供貯存用的房間/小室/容器*:

(*Delete as appropriate)

(*刪去不適用者)

SPECIMEN

3

Name of Applicant:

申請人的姓名或名稱:

4

Business Address of Applicant:

申請人營業地址:

Tel. No.

電話號碼:

5

Name of person in charge:

掌管的人的姓名:

6

Date í í í í í í í í í í í í í í í í

日期

Signature í í í í í í í í í í í í í í í í

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How to Complete an Application Form for Registration as an Importer/ Exporter of Pharmaceutical Products (Form 13)

When you complete an application form (Form 13), please follow the guidelines below. The numbers given below against each of these guidelines correspond to the numbers in circles in the attached specimen application Form 13.

(1) Name of pharmaceutical product (s) registered by Applicant

Please give the names and active ingredients of any medicines to be imported, exported or distributed locally by your company.

(2) Name of manufacturer (s) represented by Applicant, if any;

Please indicate the name of overseas manufacturers, if any, and their country of origin.

(3) Description of storage room/cubicle/receptacle

Please indicate the storage facilities provided for keeping those imported medicines. Please note that only lockable storage room(s) would be accepted.

(4) Name of Applicant

Please insert the name of your company.

(5) Business Address of Applicant and Telephone Number

Please insert the full address and telephone number of your company.

(6) Name of person in charge

Please insert the name of the person in charge of medicines.

(7) Date and Signature

Please insert the date and sign the application form by an authorized person of the company.