

Pharmacy and Poisons Board of Hong Kong

Pharmacy and Poisons Ordinance (Cap. 138)

Guidelines for Application for Change of Particulars of Wholesale Dealer Licence (Cap. 138 Pharmacy and Poisons Ordinance)/ Antibiotics Permit (Cap. 137 Antibiotics Ordinance)/

Wholesale Dealer's Licence to Supply Dangerous Drugs (Cap. 134 Dangerous Drugs Ordinance)

Should any Wholesale Dealer Licence/ Antibiotic Permit/ Wholesale Dealer's Permit holder wish to apply change of any particular(s); they shall submit application by writing to the Pharmacy and Poisons (Wholesale Licences) Committee (hereafter as 'the Committee') and/or Drug Office Licensing and Compliance Division Wholesalers Regulatory Unit (hereafter as 'Wholesalers Regulatory Unit') well in advance. The applied change of particulars shall be valid upon the Wholesale Dealer Licence holder obtained approval from 'the Committee' and/or 'Wholesalers Regulatory Unit'.

The licence holder must maintain the business of wholesale and storage of Poisons/Pharmaceutical Products according to the approved terms and condition under the respective licence(s) or 'permit' until further applied changes approved by the 'the Committee' and/or 'Wholesalers Regulatory Unit'. Under "Cap. 138 Pharmacy and Poisons Ordinance", 'the Committee' may revoke a Wholesale Dealer Licence or suspend it for a period it thinks fit, issue a warning letter, or vary a condition of the licence, if, in the Committee's opinion, the licensed wholesale dealer has contravened a condition of the licence or any of the regulations provided by the "Pharmacy and Poisons Ordinance" or "Antibiotic Ordinance" or "Dangerous Drugs Ordinance" Regulations, a "Code of Practice for Holder of Wholesale Dealer Licence", and/or has been convicted of a drug-related offence.

I. Application requirements

1. The applicant must be the licence holder (the holder's proprietor/ partner(s)/ director(s), person in charge of poisons and pharmaceutical products (hereafter as 'PIC of PP/Poisons') or deputy person in charge of poisons and pharmaceutical products (hereafter as 'DPIC of PP/Poisons'). If it is necessary to appoint an authorized person to handle the application, please attach an authorization letter signed by the license holder (refer to Appendix 12);and
2. The new applied change of particulars shall comply with the licensing requirements.
3. General requirements for personnel:
 - The licence holder shall notify 'the Committee' in writing of any change in its proprietor, partner(s) or director(s) within one month from the date of change.
 - The licence holder shall obtain approval from 'the Committee' and/or 'Wholesalers Regulatory Unit' prior to any change of 'PIC of PP/Poisons', 'DPIC of PP/Poisons person and/or 'PIC of Dangerous Drugs' and 'the Committee' and/or 'Wholesalers Regulatory Unit' shall not approve the change unless it considers the person nominated fit and proper.
 - Applicant must nominate a person-in-charge of poisons and pharmaceutical products ("PIC"), whom will be subjected to approval by the Pharmacy and Poisons (Wholesale Licences) Committee ("the Committee"). The nominated person must be a fit and proper person and also possess adequate knowledge to carry on trade related to the pharmaceutical industry. The nomination of a nominated person who is already a PIC for another holder of Wholesale Dealer Licence would normally not be considered.
4. General requirements for premises:
 - Only companies occupying commercial premises or industrial buildings would 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;
 - Companies sharing premises with another holder of Wholesale Dealer Licence would require a written explanation¹; and
 - If there is no storage facility within the business premises, the company must maintain adequate lockable storage facilities at another premises, and provide a written explanation¹ on why storage facility cannot be provided within the business address of the premises.
5. There must be adequate lockable storage facilities with appropriate temperature and humidity for keeping antibiotics/ poisons/ dangerous drugs/ pharmaceutical products within the premises. If there is no storage facility within the premises, the company must maintain adequate lockable storage facilities at another premises, and provide a written explanation¹ on why storage facility cannot be provided within the business address of the premises, provide details of the store, routine maintenance and monitoring. Application with storage facilities outside the premises are subjected to consideration and approval by 'the Committee' on a case by case basis. If the application involved handling of Part I Dangerous Drugs, lockable receptacle designated for storage of Part I Dangerous Drugs must be made available. Detailed requirements on the storage facilities are set out in the "Code of Practice for Holder of Wholesale Dealer Licence".

¹ The written explanation must be supported by relevant and sufficient reasons to the satisfaction of the Pharmacy and Poisons (Wholesale Licence) Committee. Each case will be considered on a case-by-case basis and at the discretion of the Committee.

II. Application procedures

How to obtain application forms

1. Application Form for Change of Particulars for Wholesale Dealer Licence/ Antibiotics Permit/ Wholesale Dealer's Licence to Supply Dangerous Drugs (hereafter as 'COP Application Form') can be obtained free of charge from:

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

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)*

2. 'COP Application Form' can also be download from the Drug Office official website:

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html

Submission of documents or information

Applicants are required to submit the following information:

1. A fully completed 'COP Application form'; and
2. Supporting documents in relation to the change of particulars. It is unnecessary to submit repeated supporting document(s) for different particular(s) of change; and
3. If the application only involves license cancellation, certified copy and/or license refund, the applicant only needs to complete the relevant appendix.
4. Applicant(s) may be required to submit original(s) with his/her signature and company chop for their supporting document(s).

How to submit application

Applicants may submit the application forms, the relevant information and documents via the following ways:

- (i) Mail to Licensing and Compliance Division, Drug Office, Department of Health by post or registered mail (the date shown on the post stamp will be taken as the submission date); or
- (ii) Lodge to the Licensing and Compliance Division, Drug Office, Department of Health in person during office hours.

III. Application results

If the change application involved revise the terms and conditions on licence(s) and/or permit(s), the applicant will receive a demand note for payment of update of license. Upon the receipt of the prescribed fee, the applicant will be informed to present the original licence in person or by a representative on his/her behalf, to the 'Wholesalers Regulatory Unit' to complete necessary procedures; If the change application do not involved revise the terms and conditions on licence(s) and/or permit(s), the applicant will receive a written notification by 'Wholesalers Regulatory Unit' on behalf of 'the Committee' if the application is approved. If the application is rejected or required further revise that the applicant will still be notified by email or via phone call.

IV. Prescribed fee and methods of payment

The fee for change of particulars application per licence is HK\$155. The Licensing and Compliance Division, Drug Office of the Department of Health will issue a General Demand Note to the applicant. The applicant could make payment according to the payment methods stated in the General Demand Note.

V. Enquiries

Further enquiries regarding the change of particulars as specified in the licence(s) and/or permit(s) or on the content of these guidelines can be made by calling the enquiry hotline, email or post to the 'Wholesalers Regulatory Unit':

Enquiry Hotline: 3107 2194

Enquiry Email: enquirywru@dh.gov.hk

Address: Room 2001-2002, 20/F., Dah Sing Financial Centre 248 Queen's Road East, Wan Chai, Hong Kong

VI. Notes

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 organisations (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 organisations.

Appendix 8

(For reference purpose)

Cancellation of Wholesale Dealer Licence Form

Name of Business: _____

Application for Cancellation for Licence (Licence number format: 1/2A/1234):

- | | |
|--|-----------------------|
| <input type="checkbox"/> Wholesale Dealer Licence (WDL); | Licence no: _____/2A/ |
| <input type="checkbox"/> Antibiotics Permit (AP); | Licence no: _____/1A/ |
| <input type="checkbox"/> Wholesale Dealer's Licence to Supply Dangerous Drugs (Part I); | Licence no: _____/6A/ |
| <input type="checkbox"/> Wholesale Dealer's Licence to Supply Dangerous Drugs (Part II); | Licence no: _____/5A/ |

Date of Withdrawal: _____

I, ***Mr/ Mrs/ Miss/ Ms** _____ (_____),

Full Name: (in English – *Surname first, then Other Names*) (in Chinese)(if any)

***HKID / Passport** No.: _____, the undersigned **company's director** hereby declare that once the above withdrawal of licence is approved, the company **shall not involve in the dealing of business relating to any licence restricted products** (e.g. pharmaceutical products / poisons / antibiotics permit / dangerous drugs). If the company consider to resume relevant business, a new application of licence is required.

Contact Person (if different to the undersigned person):

Name: _____ Tel: _____

Signature of Director : _____

Name of Director : _____

Name of Business : _____

Contact No. : _____

Email Address : _____

Company Chop : _____

Date : _____

[Fill in Details as stated on Hong Kong Identity Card / Passport]

*** Delete as appropriate**

Statement of Purposes

Purpose of Collection

1. 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.
Telephone Number: 3107 2194