Guidance on Application for Free Sale Certificate of Pharmaceutical Product and Certificate of Pharmaceutical Product

Introduction

Under Regulation 29 of the Pharmacy and Poisons Regulations (Cap. 138A), for the purpose of exporting pharmaceutical products manufactured by a licensed manufacturer, the Pharmacy & Poisons (Manufacturers Licensing) Committee ("the Committee") may, subject to any conditions it may impose, issue to the manufacturer a free sale certificate of pharmaceutical product, or a certificate of pharmaceutical product in the specified forms.

Application procedure

The Drug Office of the Department of Health is the executive arm of the Committee. The completed application form (Appendix) should be submitted by the manufacturer of the pharmaceutical product by post, by fax, by email or in person to the Manufacturers Regulatory Unit of the Drug Office at the following address:

Manufacturers Regulatory Unit
Licensing and Compliance Division
Drug Office
Department of Health
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong.
Tel.: 2961 8162 Fax: 3904 1225
Email: gmp@dh.gov.hk

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. For application of free sale certificate of pharmaceutical product, a fee of $180 is payable. The performance pledge of the Department of Health is that applications will be processed within 7 working days upon receipt of all the required documents.

3. For application of certificate of pharmaceutical product, a fee of $140 is payable. The performance pledge of the Department of Health is that applications will be processed within 12 working days upon receipt of all the required documents.

Notes

1. 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.

2. Contents of the Pharmacy and Poisons Regulations can be found at the Hong Kong e-Legislation website (www.elegislation.gov.hk).

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East, Wan Chai, Hong Kong
Tel. 2961 8162 Fax: 3904 1225

衞生署藥物辦公室
牌照及監察科
香港灣仔皇后大道東 213 號
胡忠大廈 25 樓 2550 室
電話 : 2961 8162 傳真 : 3904 1225

Application for Free Sale Certificate of Pharmaceutical Product / Certificate of Pharmaceutical Product
藥劑製品自由銷售證明書 / 藥劑製品證明書 申請書

PART A 甲部 DETAILS OF APPLICANT 申請人資料

The application should be submitted by the manufacturer of the pharmaceutical product.
申請必須由該藥劑製品的製造商提交。

Name of Manufacturer (in English):
製造商名稱 (英文) _____

Name of Manufacturer (in Chinese):
製造商名稱 (中文) _____

Address of Manufacturer:
製造商地址 _____

Telephone No.:
電話號碼 _____ Fax No.:
傳真號碼 _____

Business E-mail:
商號電郵地址 _____

Is the applicant the holder of the certificate of registration of the pharmaceutical product?
申請人是否該藥劑製品的註冊證書持有人？

☐ Yes 是

☐ No 否 (Please submit an authorization letter from the certificate holder 請提交該證書持有人的授權書)

PART B 乙部 APPLICANTION DETAILS 申請內容

Type of Application:
申請類別

☐ Free Sale Certificate of Pharmaceutical Product
藥劑製品自由銷售證明書

☐ Certificate of Pharmaceutical Product
藥劑製品證明書

	Product 製品	Product 製品	Product 製品
Name of Pharmaceutical Product: 藥劑製品名稱			
Product Registration Number: 製品註冊編號			
Number of Certificate(s) Required: 申請證明書數量			

If apply for certificates of more than 3 products, please provide information on a separate sheet.
如申請多於三種製品的證明書，請在單獨的附加頁上提供資料。

PART C 丙部 DECLARATION OF APPLICANT 申請人聲明

We wish to apply for a ☐ Free Sale Certificate of Pharmaceutical Product / ☐ Certificate of Pharmaceutical Product under the Pharmacy and Poisons Regulation. We hereby declare that the information given in this application is true and correct.

我們欲根據《藥劑業及毒藥規例》申請 ☐ 藥劑製品自由銷售證明書 / ☐ 藥劑製品證明書。我們現聲明此申請書內所填報的資料，均全屬確實無誤。

Signature:
申請人簽署 _____

Full name of Signatory:
簽署人全名 _____

Position of the Signatory:
簽署人職位 _____

Signed on behalf of:
代表簽署商號 _____

Date:
日期 _____

Company Stamp 公司蓋印

Please mark with a "✓" in the box whichever is applicable

請在方格內以"✓"號註明適用的選項

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 2550, 25/F, Wu Chung House,
213 Queen's Road East,
Wan Chai, Hong Kong.
Tel: 2961 8028