Guidance on Application for Licence for Manufacturer of Pharmaceutical Products

Introduction

Under the Pharmacy and Poisons Ordinance (Cap. 138), "manufacture" means (a) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for sale or distribution; or (b) the repackaging of pharmaceutical products as finished products for sale or distribution. "Manufacturer" has a corresponding meaning. It shall not include the individual dispensing on a prescription or otherwise of any pharmaceutical products.

2. This set of guidance notes does not apply to manufacturers solely engaged in secondary packaging operations of pharmaceutical products. Please refer to the separate guidance on the application for Licence for Manufacturer (Secondary Packaging) which is available at the website of the Drug Office (http://www.drugoffice.gov.hk).

3. Part 7 of the Pharmacy and Poisons Regulations relates to the licensing of pharmaceutical manufacturers. A person must not manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises.

4. A licensed manufacturer selling his own products by way of wholesale dealing does not require a wholesale dealer licence, but he shall comply with the requirements under Part 6 of the Regulations in the same way as a wholesale dealer.

5. The licensing authority is the Pharmacy & Poisons (Manufacturers Licensing) Committee ("the Committee"), an Executive Committee established under the Pharmacy and Poisons Board ("the Board"). When determining to grant a licence to manufacture pharmaceutical products, the Committee shall consider the follow criteria, but not limited to :-

(a) pharmaceutical products are manufactured by or under the supervision of a registered pharmacist or a person approved by the Board;

(b) at least one authorized person is employed to be responsible for ensuring and certifying that each batch of the pharmaceutical products has been manufactured and checked in accordance with the Good Manufacturing Practice (GMP) Guide[1]; and the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products;

(c) proper labelling of pharmaceutical products manufactured;

(d) premises used in the manufacturing, testing and dispatch of pharmaceutical products being suitable for the purpose;

(e) adequate hygiene control of personnel and premises to avoid contamination of pharmaceutical products;

(f) retention of a control sample and all related records;

(g) compliance with the GMP Guide issued by the Board;

(h) results of pre-licensing inspection, which is conducted for all new applications to evaluate whether the premises under application are fit for the licence purposes;

(i) previous drug-related conviction(s), in particular those have significant impact to the public interest, of the applicant or his key personnel, if applicable; and

(j) previous disciplinary action(s) against the applicant or his key personnel, if applicable.

[1] Currently, the GMP Guide issued by the Board is the Guide to Good Manufacturing Practice for Medicinal Products (PE 009-11) published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S)

6. The Committee may revoke a licence to manufacture pharmaceutical products 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 manufacturer has contravened a condition of the licence or any of the regulations provided by the Pharmacy and Poisons Regulations, a code of practice applicable to the licensed manufacturer or the GMP Guide, or has been convicted of a drug-related offence.

Applications for licences to manufacture pharmaceutical products

A. Expression of Intent and Submission of Proposal

The Drug Office of the Department of Health is the executive arm of the Board and the Committee. Any company interested to apply for a licence to manufacture pharmaceutical products may express their intent in writing and submit a related project proposal for obtaining the approval, in principle, of the layout of the premises by the Committee. A letter of intent with the project proposal and supporting documents should be sent by post, by fax, by email or in person to 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. During the planning stage of setting up new premises and facilities, the company should take into consideration of the "Explanatory Notes for Pharmaceutical Manufacturers on Preparation of Site Master File" in the PIC/S website (http://www.picscheme.org).

3. A meeting with the company may be held. The company should present specific information about the quality management policies and activities of the site, the production and/or quality control of pharmaceutical manufacturing operations carried out therein, and any closely integrated operations at adjacent and nearby buildings.

B. Requirements for Key Personnel

At the stage of intent expression, the company may wish to provide personal particulars, qualification and working experience of the following key personnel for consideration:

(a) the authorized person responsible for product release;
(b) the head of production; and
(c) the head of quality control.

2. The requirements for the 3 key personnel are specified in the "Guidance on Qualification, Experience, and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong" which is available at the website of the Drug Office (http://www.drugoffice.gov.hk).

C. Application for a Licence for Manufacturer

Upon completion of commissioning and qualification of the site and implementation of quality management system according to the requirements in the GMP Guide, the company may wish to apply for a licence to manufacture pharmaceutical products.

2. The completed application form (Appendix 1), the relevant completed checklist of supporting documents, together with supporting documents indicated in the checklist, should be submitted by post, by fax, by email or in person to the Manufacturers Regulatory Unit at the above address.

3. An inspection by pharmacist inspectors will be conducted at the company's premises. The application will be considered by the Committee. If approved, a licence valid for one year will be granted subject to the payment of the prescribed licence fee (currently $2,680). The Committee may impose any conditions on the licence (for example: restricted to certain manufacturing operations or products in accordance with the competence of, and facilities available to, the manufacturer).

4. Any applicant aggrieved by a decision made by the Committee in respect of the applicant may, in the prescribed manner, appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

5. Any enquiries on matters related to licence application should be sent to the Manufacturers Regulatory Unit at the above address.

6. The performance pledge of the Department of Health is that applications will be approved within two months upon full compliance with the legal and licensing requirements.

D. Application for a Certificate for Manufacturer

For the purpose of certifying a manufacturer is licensed and is subject to regular inspections which have shown that it follows the requirements of GMP, the Committee may issue to a licensed manufacturer a certificate for manufacturer.

2. An application must be made in writing on the same application form for a Licence for Manufacturer (Appendix 1).

3. A prescribed licence fee of $2,020 is payable. The expiry date of the certificate is the same as that of the corresponding licence to manufacture pharmaceutical products.

Applications for licences to manufacture Dangerous Drugs

Manufacturers of Dangerous Drugs are required to hold an additional licence issued by the Director of Health under the Dangerous Drugs Ordinance, Cap. 134.

2. The completed application form (Appendix 2) should be submitted by post, by fax, by email or in person to the Manufacturers Regulatory Unit at the above address.

3. The applicant shall nominate in writing at least one registered pharmacist to be in charge of dangerous drugs at the time of application. A copy of the Certificate of Registration and Practising Certificate of the registered pharmacist should be submitted together with the application.

4. On granting of a licence, a fee of $1,540 is chargeable. The licence is valid until 1st January every year. An annual licence fee of $1,540 is payable upon renewal.

5. The performance pledge of the Department of Health is that applications will be approved within two months upon full compliance with the legal and licensing requirements.

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 Ordinance, the Dangerous Drugs Ordinance and their Regulations can be found at the Department of Justice's website http://www.elegislation.gov.hk.

Appendix 1

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING & 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 Licence for Manufacturer of Pharmaceutical Products
藥劑製品製造商牌照申請書

FOR OFFICIAL USE ONLY **(只供本署人員填寫)**

Date: _____

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: _____

Email address 電郵地址: _____

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) (in Chinese)
掌管業務的負責人姓名: (英文) (中文)

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)

PART B 乙部 DETAILS OF KEY PERSONNEL 關鍵人員資料

Name of Authorized Person (In English) (in Chinese)
獲授權人的姓名: (英文) (中文)

HK Identity Card No.
香港身份證號碼: _____

Telephone & Mobile No.
電話及手提電話號碼: _____

Registration No.
註冊號碼: _____

Name of Pharmacist(s) supervising production 監督生產的藥劑師姓名: (except advanced therapy products 先進療法產品除外)	(In English) (英文)	(in Chinese) (中文)
	HK Identity Card No. 香港身份證號碼:	
	Registration No. of Pharmacist 藥劑師註冊號碼:	
Name of Head of Production 生產部主管姓名:	(In English) (英文)	(in Chinese) (中文)
	HK Identity Card No. 香港身份證號碼:	
Name of Head of Quality Control 品質控制部主管:	(In English) (英文)	(in Chinese) (中文)
	HK Identity Card No. 香港身份證號碼:	

PART C 丙部 PARTICULARS OF BUSINESS AND PRODUCTS 業務及產品詳情

Scope of Business 業務範圍[#]:

- ☐ Manufacture of Active Ingredients 製造原料藥
- ☐ Manufacture of Finished Pharmaceutical Product 製造成品
- ☐ Manufacture of Intermediate or Bulk 製造中間產品或待包裝產品
- ☐ Primary Packaging 內包裝
- ☐ Secondary Packaging 外包裝
- ☐ Batch Release 批次放行
- ☐ Laboratory Testing 實驗室測試
  - ☐ Physical & Chemical 理化分析
  - ☐ Biological & Microbiological 生物及微生物
- ☐ Contract Manufacture 合約製造
- ☐ Contract Analysis 合約分析
- ☐ Local Distribution 本銷
- ☐ Import 進口
- ☐ Export 出口

Nature of Products 產品性質[#]:

- ☐ For human use 供人類使用
- ☐ For veterinary use 供禽畜使用
- ☐ Penicillins 青霉素
- ☐ Cephalosporins 頭孢菌素
- ☐ Cytotoxics 細胞毒素類
- ☐ Hormones 激素
- ☐ Vaccines 疫苗
- ☐ Sterile products (terminally sterilized) 無菌製劑 (最終滅菌)
- ☐ Sterile products (aseptically prepared) 無菌製劑 (以無菌操作配製)
- ☐ Biological products 生物製品
- ☐ Advanced therapy products 先進療法產品
  - ☐ Somatic cell therapy products 體細胞治療產品
  - ☐ Gene therapy products 基因治療產品
  - ☐ Tissue engineered products 組織工程產品
- ☐ Investigational products 試驗用藥品
- ☐ Others (please specify) 其他〔請註明〕_____

Dosage Forms of Products Manufactured 產品劑型#:

☐	Tablets 片劑	☐	Rectal preparations 直腸用製劑
☐	Capsules 膠囊劑	☐	Vaginal preparations 陰道用製劑
☐	Granules 顆粒劑	☐	Ear preparations 耳道用製劑
☐	Oral powders 口服散劑	☐	Nasal preparations 鼻腔用製劑
☐	Oral liquids 口服水劑	☐	Preparations for inhalations 吸入用製劑
☐	External liquids 外用水劑	☐	Eye drops 滴眼液
☐	External powders 外用粉劑	☐	Injections 注射劑
☐	Creams & ointments 膏劑	☐	Large volume parenterals 大容量注射劑
☐	Buccal & throat preparations 口腔及咽喉用製劑	☐	Others (please specify) 其他〔請註明〕_____

PART D 丁部 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 E 戊部 APPLICATION FOR CERTIFICATE FOR MANUFACTURER 申請製造商證明書

We also wish to apply for a Certificate for Manufacturer#
我們欲同時申請製造商證明書#:

☐ Yes 是
☐ No 否

PART F 己部 DECLARATION OF APPLICANT 申請人聲明

We wish to apply for a Licence for Manufacturer 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》申請製造商牌照。我們現聲明此申請書內所填報的資料，均全屬確實無誤。

Signature
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

請在適當方格內加上 "✓" 號 Please insert a "✓" in the appropriate box

Appendix 1A

Licensing and Compliance Division
Drug Office, Department of Health
Information Sheet of Key Personnel of Pharmaceutical Manufacturers

Name of Manufacturer			
Position of key personnel*	☐ Authorized Person ☐ Head of Production ☐ Head of Quality Control	☐ Alternative Authorized Person ☐ Alternative Head of Production ☐ Alternative Head of Quality Control	
Name	**(English)**	**(Chinese)**	
HK Identity Card No.		**Gender***	☐ Male ☐ Female
Telephone No.		**Mobile No.**	
Is the key personnel a registered pharmacist*?	☐ Yes (Reg. No.: _____) ☐ No		
Is the key personnel a registered authorized person*?	☐ Yes (Reg. No.: _____) ☐ No		
Date of appointment to the present position			

Academic and professional qualifications

Qualification awarded	Awarding institution	Year awarded

Working experience

Name of employer	Position held	Period of employment

*Please tick if appropriate

For office use only			
Recognized previously	Yes / No	File ref:	
Previously recognized for	AP / HP / HQC	Date first recognized	

Appendix 1B

CHECKLIST

Application for Licence for Manufacturer of Pharmaceutical Products

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

Have you submitted	**Yes**	**No**
(1) Completed application form?	☐	☐
(2) Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement?	☐	☐
(3) Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement of additional storage / warehouse (if any)?	☐	☐
(4) (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")? 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 key personnel (i.e authorized person, head of production and quality control)?	☐	☐
(6) Completed form of "Information Sheet of Key Personnel of Pharmaceutical Manufacturers"? (Appendix 1A)	☐	☐
(7) Supporting documents for qualifications (including relevant academic/professional qualifications) of key personnel?	☐	☐
(8) Testimonial(s) of relevant working experience of key personnel issued by the employer(s) (with information such as years of service, position held and job descriptions)?	☐	☐

(9)	A signed declaration of each owner (i.e. sole proprietor or partner) or director, and key personnel 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]	☐	☐
(10)	Site Master File of the manufacturer (Please refer to "Explanatory Notes for Pharmaceutical Manufacturers on Preparation of Site Master File" in the PIC/S website)?	☐	☐
(11)	Floor plans showing name, number, dimensions and floor area of each room and allotted area, personnel flow, material flow, layout and to-scale dimensions of equipment/instruments (if applicable)?	☐	☐
(12)	Summary of changes from the proposal approved in principle (if applicable) by the Pharmacy & Poisons (Manufacturers Licensing) Committee, showing the level of change (e.g. critical, major, minor) and rationale for changes?	☐	☐
(13)	Commissioning and qualification documentation of the premises and related utilities?	☐	☐
(14)	Equipment qualification approach and timeline?	☐	☐

Appendix 2

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 Licence to Manufacture Preparations of Dangerous Drugs

PART A DETAILS OF APPLICANT

Name of Business (in English): _____

Name of Business (in Chinese): _____

Address of Business: _____

Name of Business at the Premises (if different from above): _____

Address of Premises (if different from above): _____

Business Registration Number: _____

Telephone No. of the Premises: _____ Fax No.: _____

Business E-mail: _____

PART B PHARMACIST IN CHARGE OF DANGEROUS DRUGS

Applicant MUST nominate a registered pharmacist to be in charge of dangerous drugs.
(If more than one pharmacist is nominated, please provide information on a separate sheet)

Name of pharmacist in charge of dangerous drugs (in English): _____

Name of pharmacist in charge of dangerous drugs (in Chinese): _____ HK Identity Card No.: _____

Pharmacist Registration Number: _____

Position _____ E-mail: _____

Telephone No.: _____ Mobile: _____

Please submit a copy of the Certificate of Registration and Practising Certificate of the registered pharmacist(s).

PART C DECLARATION OF APPLICANT

We wish to apply for a Licence to Manufacture Preparations of Dangerous Drugs under the Dangerous Drugs Ordinance. We hereby declare that the information given in this application is true and correct.

Signature: _____

Full Name of Signatory: _____

Position of the Signatory: _____

Signed on behalf of: _____

Date: _____

Company Stamp

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