Pharmacy and Poisons Board

Guidance on Application for Licence for Manufacturer of Pharmaceutical Product (Secondary Packaging)

Introduction

Under the Pharmacy and Poisons Ordinance (Cap.138, Laws of Hong Kong), "manufacture" —

(a) means—

(i) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for clinical trial, sale or distribution; or

(ii) the repackaging of pharmaceutical products as finished products for clinical trial, sale or distribution; but

(b) does not include the individual dispensing on a prescription or otherwise of the product if the product—

(i) is not an advanced therapy product; or

(ii) is an advanced therapy product the dispensing of which does not involve substantial manipulation of cells or tissues.

"Manufacturer", in relation to a pharmaceutical product, means a person who manufactures the product.

2. "Pharmaceutical product" —

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product.

3. Secondary packaging is a manufacturing step involving the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pharmaceutical products which are already enclosed in the container in which they are to be sold or supplied.

4. A person is not regarded as manufacturing a pharmaceutical product only by affixing to the

container of the product a label:

(a) that does not state any of the following particulars—

(i) particulars regarding—

(A) designation and quantitative particulars of the ingredient(s),

(B) batch number,

(C) expiry date of the pharmaceutical product,

(D) for an advanced therapy product—

(i) the product code, and the unique donation identifier, assigned in accordance with the codes of practice issued by the the Pharmacy & Poisons Board ("the Board"); and

(ii) if the product is for autologous use only—

- the unique recipient identifier assigned in accordance with the codes of practice issued by the Board; and
- the English words "For autologous use only" or the Chinese characters "只供自體使用";

(ii) particulars regarding the dosage, route or frequency of administration of the product;

(iii) the name of the product; and

(b) that does not obscure, change or obliterate any of the following particulars labelled on the container—

(i) particulars mentioned in subparagraph (a) above;

(ii) name and address of the manufacturer.

5. According to regulation 29(1) of the Pharmacy and Poisons Regulations (Cap. 138A, Law of Hong Kong), no person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products.

Application for a Licence for Manufacturer (Secondary Packaging)

6. The criteria for granting a Licence for Manufacturer (Secondary Packaging) includes but not limited to the following:

(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 GMP Guide issued by the Board and the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products;

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

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

(e) proper labelling of pharmaceutical products manufactured;

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

(g) compliance with the GMP Guide;

(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.

For details of the requirements, please refer to regulations 30 to 35 of Cap. 138A and the GMP Guide.

7. The applicant should employ at least two key personnel (i.e. the authorized person stated in paragraph 6(b) who is also known as the "Quality Assurance Officer" ("QAO") and the "Person-in-charge of Secondary Packaging" ("PIC")). The requirements for QAO and PIC are specified in the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong" ("QET Guidance"). The QET Guidance is available at website of Drug Office of Department of Health (www.drugoffice.gov.hk).

8. Where unlabelled containers of pharmaceutical products are received for secondary packaging, the identity of each batch should be verified by testing representative samples of the batch by an appropriately accredited laboratory using specific chemical or instrumental techniques (irrespective of the availability of a certificate of analysis for the batch). Furthermore, each batch such unlabelled pharmaceutical products received should be packed in a single packaging run during the secondary packaging process in order to minimize the risk of mix-up of remaining unlabelled containers. Containers with batch number, expiry date and information traceable to the identity of the product and the manufacturer, printed in a conspicuous place and not covered during the packaging process, may be considered as labelled containers and the requirements provided under this paragraph may not apply.

9. For products that require special attention, such as advanced therapy products, products requiring cold chain management or unlabelled parenteral products, adequate and special precautionary measures must be in place before licensee is allowed to handle these products.

Application Procedure

10. The Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") is established under the Board to approve the applications for licence to manufacture pharmaceutical products in Hong Kong. The Drug Office of Department of Health is the executive arm of the Committee.

11. Application form for Licence for Manufacturer (Secondary Packaging) and the document checklist are attached at Appendices 1 and 2 respectively.

12. Applicant should submit the completed application form together with the relevant documents indicated in the document checklist to the Licensing and Compliance Division, Drug Office of the Department of Health by:

- email to gmp@dh.gov.hk; or
- fax to 3904 1225; or
- mail or in person to the below address:

Licensing and Compliance Division
Drug Office
Department of Health
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road,
Wan Chai, Hong Kong
Tel.: 2594 7647

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)

13. Provided that all the submitted documents are satisfactory after review, an inspection by pharmacist inspector(s) will be conducted at the company's premises. Other relevant documents such as packaging records, quality control documents, complaint records, recall procedures, distribution records, and other relevant standard operation procedures, should be made available during site inspection. For details of the requirements on documentation, you may make reference to the GMP Guide.

14. A licence may be granted by the Committee subject to any conditions imposed. It may be restricted to certain manufacturing operations or products in accordance with the competence of, and facilities available to, the manufacturer. The Committee may suspend or revoke the licence if the licensed manufacturer has contravened a condition of the licence, any provisions of Cap. 138 and Cap. 138A, the code of practice applicable to licensed manufacturers or the GMP Guide, or convicted of other drug-related offence. Alternatively, the Committee may issue a warning letter or vary a condition of the licence for the above circumstances.

15. A licence is valid for one year and is renewable annually. A prescribed licence fee of $2,680 is payable.

16. 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.

17. 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.

Application for a Licence to Manufacture Dangerous Drug

18. If the applicant is also involved in manufacturing of dangerous drugs, additional Licence to Manufacture Dangerous Drug granted by the Director of Health under the Dangerous Drugs Ordinance (Cap. 134, Laws of Hong Kong) is required.

19. The applicant must nominate a Person-in-charge of Dangerous Drugs. The Person-in-charge of Dangerous Drugs must be a registered pharmacist if a Dangerous Drug specified in Part I of the First Schedule to the Ordinance is handled.

20. Applicant should submit the completed application form (Appendix 4) together with the relevant documents indicated in the document checklist (Appendix 5) to the Licensing and Compliance Division, Drug Office of the Department of Health by means as stated in paragraph 12.

21. The application will be considered by the Director of Health. A licence may be granted subject to any conditions imposed. On granting of a licence, a fee of $1,540 is payable. The licence is valid until 1st January every year. An annual licence fee of $1,540 is payable upon renewal.

Notes

1. This guidance document is 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, Dangerous Drugs Ordinance and their subsidiary legislations can be found at the Hong Kong e-Legislation's website (www.elegislation.gov.hk).

3. The GMP Guide issued by the Board is available at the websites of the Board (www.ppbhk.org.hk) and the Drug Office (www.drugoffice.gov.hk).

Appendix 1

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road, Wan Chai, Hong Kong
Tel. 2594 7647 Fax: 3904 1225

衞生署藥物辦公室
牌照及監察科
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話 ：2594 7647 傳真 ：3904 1225

Application for Licence for Manufacturer of Pharmaceutical Product (Secondary Packaging)

FOR OFFICIAL USE ONLY

Date: _____ Application Fee: _____

Misc. Receipt No.: _____ Checked By: _____

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: _____

Licence(s) related to medicines held by the company and the responsible person of the licence(s) (Please choose):

☐ Wholesale Dealer Licence
Person-in-charge of the poisons or pharmaceutical products: _____

☐ Antibiotics Permit
Responsible person: _____

☐ Wholesale Dealer's Licence to supply Dangerous Drugs
Responsible person: _____

☐ Others: _____

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

Company E-mail: _____

PART B DETAILS OF KEY PERSONNEL

Applicant MUST nominate a Quality Assurance Officer (QAO) and a Person-in-charge of Secondary Packaging (PIC)

Name of QAO (in English): _____

Name of QAO (in Chinese): _____ HK Identity Card No.: _____

Position: _____ E-mail: _____

Telephone No.: _____ Mobile: _____

Name of PIC (in English): _____

Name of PIC (in Chinese): _____ HK Identity Card No.: _____

Position: _____ E-mail: _____

Telephone No.: _____ Mobile: _____

PART C DETAILS OF THE BUSINESS

Type(s) of secondary packaging operations going to conduct (can choose more than one):

- ☐ Affixing additional label(s) to or chop/print on the original container labelled by the primary manufacturer
- ☐ Affixing label(s) to unlabelled container(s)
- ☐ Addition or replacing of package box(es) and/or package insert(s)
- ☐ Repackaging of packaged dosage forms (such as blisters, sachets, etc) from larger pack size into smaller pack size
- ☐ Involving advanced therapy products
- ☐ Others (please specify: _____)

Scale of secondary packaging operations:

Number of packaging lines/stations: _____ Number of cold chain packaging lines/stations: _____

Number of pharmaceutical products going to be packed: _____

Premises:

Type of building: ☐ Industrial ☐ Commercial

Total area of the premises: _____ sq. m.

Total area for secondary packaging: _____ sq. m.

Please provide the floor plan of the premises indicating the dimensions and purposes of different areas (e.g. packaging area, quarantine area, incoming product storage area, printed packaging materials storage area, finished product storage area, etc). If there is any packaging equipment, please also indicate their position in the floor plan.

PART D DECLARATION OF APPLICANT

We wish to apply for a Licence for Manufacturer (Secondary Packaging) under the Pharmacy and Poisons Ordinance. We hereby declare that the information given in this application is true and correct.

Signature: _____

Full name of Signatory: _____

Signed on behalf of: _____

Date: _____

Company Stamp

Appendix 2

DEPARTMENT OF HEALTH
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衞生署藥物辦公室
牌照及監察科
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話 : 2594 7647 傳真 : 3904 1225

DOCUMENTS CHECKLIST

Application for Licence for Manufacturer of Pharmaceutical Product (Secondary Packaging)

Please submit this checklist with the following documents. Please provide a written explanation if any of the documents is not submitted.

☐ Completed application form (Appendix 1)

☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement

☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement of storage facilities at other premises (if any)

☐ **For limited companies:**

(a) Copy of Certificate of Incorporation and

(b) Copy of Directors' List (e.g. "Form AR1" from Companies Registry or for newly formed limited companies, photocopy of a full set of "Form NNC1" or "Form NNC1G")

OR

For companies run by sole proprietors:

Copy of "Form 1(a)" from the Business Registration Office

OR

For companies run by partners:

Copy of "Form 1(c)" from the Business Registration Office

☐ A list including name(s) in English and Chinese, Hong Kong Identity Card number(s) and posts of sole proprietor / partners / directors and staff involved in secondary packaging operations

☐ A signed declaration of each owner (i.e. sole proprietor or partner) or director, and each key personnel (Person-in-charge of Secondary Packaging, Quality Assurance Officer) indicating whether he or 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), position(s) held and the period involved]

☐ Completed form of "Information Sheet of Key Personnel (Secondary Packaging Manufacturers)" as in Appendix 3 for the Person-in-charge of Secondary Packaging and Quality Assurance Officer

☐ Supporting documents of the academic qualification of Person-in-charge of Secondary Packaging and Quality Assurance Officer

☐ Testimonial(s) of relevant working experience of Person-in-charge of Secondary Packaging and Quality Assurance Officer issued by the employer(s) (with information such as years of service, position(s) held and job descriptions)

☐ A table showing the name(s) of all the pharmaceutical product(s) planned to be involved in secondary packaging and a description of the corresponding secondary packaging operation(s) applied to each pharmaceutical product(s)

☐ Floor plan of the premises involved

Please indicate the dimensions and purposes of different areas (e.g. packaging area, quarantine area, incoming product storage area, printed packaging materials storage area, finished product storage area, etc).

If there is any packaging equipment, please also indicate their position in the floor plan.

☐ Specifications of the packaging area(s) and the associated storage area(s) (e.g. temperature, relative humidity, and method employed to provide filtered air to the packaging area, etc)

Appendix 3

DEPARTMENT OF HEALTH
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牌照及監察科
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話 ：2594 7647 傳真 ：3904 1225

Information Sheet of Key Personnel (Secondary Packaging Manufacturers)

Name of Manufacturer			
Position of Key Personnel*	☐ Quality Assurance Officer (QAO) ☐ Alternative QAO ☐ Person-in-charge of Secondary Packaging (PIC) ☐ Alternative PIC		
Name (in English)			
Name (in 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 (including GMP related Training)

Qualification awarded	Awarding institution	Year awarded

Working Experience

Name of employer	Position held	Period of employment

*Please tick if appropriate

For office use only			
Approved previously	Yes / No	File ref	/ 7A /
Previously approved as	PIC / QAO	Date of first approval	

Appendix 4

DEPARTMENT OF HEALTH
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衞生署藥物辦公室
牌照及監察科
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話 : 2594 7647 傳真 : 3904 1225

Application for Licence to Manufacture Dangerous Drug (Secondary Packaging)

FOR OFFICIAL USE ONLY

Date: _____ Application Fee: _____
Misc. Receipt No.: _____ Checked By: _____

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.: _____

Company E-mail: _____

Applicant MUST nominate a Person-in-charge of Dangerous Drugs
(If nominate more than one person, please provide information on a separate sheet)

Name of Person-in-charge of Dangerous Drugs (in English): _____

Name of Person-in-charge of Dangerous Drugs (in Chinese): _____ HK Identity Card No.: _____

If the Person-in-charge of Dangerous Drugs is a registered pharmacist, the number of Certificate of Registration: _____

Position: _____ E-mail: _____

Telephone No.: _____ Mobile: _____

PART B DECLARATION OF APPLICANT

We wish to apply for a Licence to Manufacture Dangerous Drug (Secondary Packaging) under the Dangerous Drugs Ordinance. We hereby declare that the information given in this application is true and correct.

Signature: _____

Full name of Signatory: _____

Signed on behalf of: _____

Date: _____

Company Stamp

Appendix 5

DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
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牌照及監察科
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話 : 2594 7647 傳真 : 3904 1225

DOCUMENTS CHECKLIST

Application for Licence to Manufacture Dangerous Drug (Secondary Packaging)

Please submit this checklist with the following documents. Please provide a written explanation if any of the documents is not submitted.

☐ Completed application form (Appendix 4)

☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement

☐ Copy of Business Registration Certificate, Branch Registration Certificate, or tenancy agreement of storage facilities at other premises (if any)

☐ **For limited companies:**

(a) Copy of Certificate of Incorporation and

(b) Copy of Directors' List (e.g. "Form AR1" from Companies Registry or for newly formed limited companies, photocopy of a full set of "Form NNC1" or "Form NNC1G")

OR

For companies run by sole proprietors:

Copy of "Form 1(a)" from the Business Registration Office

OR

For companies run by partners:

Copy of "Form 1(c)" from the Business Registration Office

☐ Copy of the Certificate of Registration and Practising Certificate of the registered pharmacist (if applicable)

☐ Floor plan of the premises involved

Please indicate the dimensions and purposes of different areas (e.g. packaging area, quarantine area, incoming product storage area, finished product storage area, etc).

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 3817, 38/F, Revenue Tower,
5 Gloucester Road,
Wan Chai, Hong Kong.
Tel: 2961 8028