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

Introduction

Under the Pharmacy and Poisons Ordinance (Cap.138, Laws of Hong Kong), “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, but does not include the individual dispensing on a prescription or otherwise of any pharmaceutical products.
“Manufacturer” has a corresponding meaning.

2. “Pharmaceutical product” means any substance or combination of substances—
(a) presented as having properties for treating or preventing disease in human beings or animals; or
(b) that may be used in, or administered to, human beings or animals, either with a view to
   (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
   (ii) making a medical diagnosis.

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) designation and quantitative particulars of ingredients, batch number or expiry date;
      (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 labeled on the container:
      (i) particulars mentioned in subparagraph (a);
      (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 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 Pharmacy & Poisons Board (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\(^1\) 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 (http://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 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 (DH DO) 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, DH DO by:

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

**Address:**

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

**Office Hours:**

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 Licence to Manufacture Preparations of Dangerous Drugs**

18. If the applicant is also involved in manufacturing of dangerous drugs, additional Licence to Manufacture Preparations of Dangerous Drugs 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, DH DO 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. 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, Dangerous Drugs Ordinance and their subsidiary legislations can be found at the Department of Justice’s website http://www.elegislation.gov.hk.
Application for Licence for Manufacturer
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

☐ 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: __________

Total area for secondary packaging: __________

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
**DOCUMENTS CHECKLIST**

**Application for Licence for Manufacturer 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.

- □ A completed application form (Appendix 1)
- □ Copy of Business Registration Certificate
- □ Copy of Business Registration Certificate 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 NAR1” 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/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]

- □ Completed information sheet as in Appendix 3 for the person in charge of secondary packaging and quality assurance officer

- □ Certifications of the academic qualification and experience of person in charge of secondary packaging and quality assurance officer

- □ 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)
## Information Sheet of Key Personnel
### (Secondary Packaging Manufacturers)

<table>
<thead>
<tr>
<th>Name of Manufacturer</th>
<th>Position of Key Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ Quality Assurance Officer (QAO)</td>
</tr>
<tr>
<td></td>
<td>☐ Alternative QAO</td>
</tr>
<tr>
<td></td>
<td>☐ Person in Charge of Secondary Packaging (PIC)</td>
</tr>
<tr>
<td></td>
<td>☐ Alternative PIC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name (in English)</th>
<th>Name (in Chinese)</th>
</tr>
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<table>
<thead>
<tr>
<th>HK Identity Card No.</th>
<th>Sex</th>
<th>☐ Male ☐ Female</th>
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<table>
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<tr>
<th>Telephone No.</th>
<th>Mobile No.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is the key personnel a registered pharmacist?</th>
<th>☐ Yes (Reg. No.:_______) ☐ No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is the key personnel a registered authorized person?</th>
<th>☐ Yes (Reg. No.:_______) ☐ No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of appointment to the present position</th>
</tr>
</thead>
</table>

### Academic and professional qualifications (including GMP related training)

<table>
<thead>
<tr>
<th>Qualification awarded</th>
<th>Awarding institution</th>
<th>Year awarded</th>
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</table>

### Working experience

<table>
<thead>
<tr>
<th>Name of employer</th>
<th>Position held</th>
<th>Period of employment</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

### For office use only

<table>
<thead>
<tr>
<th>Approved previously</th>
<th>Yes / No</th>
<th>File ref:</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Previously approved as</th>
<th>PIC / QAO</th>
<th>Date of first approval</th>
</tr>
</thead>
</table>
Application for Licence to Manufacture Preparations of Dangerous Drugs (Secondary Packaging)

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 Preparations of Dangerous Drugs (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
DOCUMENTS CHECKLIST

Application for Licence to Manufacture Preparations of Dangerous Drugs
(Secondary Packaging)

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

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☐ Copy of Business Registration Certificate 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 NNCl” or “Form NNClG”)

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