香港中醫藥管理委員會
CHINESE MEDICINE COUNCIL OF HONG KONG

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10 February, 2017

To: Holders of Wholesaler Licence in proprietary Chinese medicines

Dear Sirs,

Licensing requirement for traders conducting external packing of proprietary Chinese medicines (pCm)

In accordance with the implementation measures endorsed by the Chinese Medicines Board ("CMB") of the Chinese Medicine Council of Hong Kong ("CMCHK") in January 2017, with effect from 1 March 2017, any person who conducts external packing[Note] of pCm shall apply for the "Manufacturer Licence in Proprietary Chinese Medicines (External Packing)".

CMB has stipulated a grace period of two and a half years (i.e. from 1 March 2017 to 31 August 2019). Upon the expiry of the grace period, except holding the relevant licence, any person (including a licensed wholesaler of pCm) shall not conduct external packing; otherwise, it will be considered as illegal manufacturing of pCm and enforcement action will be undertaken by the Department of Health.

From 1 March 2017, applicants may submit applications for "Manufacturer Licence in Proprietary Chinese Medicines (External Packing)" to the Chinese Medicine Division of Department of Health. For further information, please refer to the attached "Guidance Notes on Application for Manufacturer Licence in Proprietary Chinese Medicines (External Packing)" or the website of the CMCHK (http://www.cmchk.org.hk/pcm/eng/#main_down01.htm).

For enquiries, please contact the staff of the Department of Health at telephone number 2319 5119.

Yours faithfully,

(LO Nok-man)
for Secretary of
the Chinese Medicine Council of Hong Kong

[Note] External packing (also known as secondary packaging) is a manufacturing process involving the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pCm which are already enclosed in the container in which they are to be sold or supplied.

Guidance Notes on Application for Manufacturer Licence in Proprietary Chinese Medicines (External Packing)

Introduction

Pursuant to Section 131 of the Chinese Medicine Ordinance (CMO), no person shall manufacture any proprietary Chinese medicine (pCm) without a manufacturer licence. "Manufacture" (製造) in relation to a pCm, means the "preparation", "production", "packing" or "re-packing" of the pCm for sale or distribution, and "manufacturer" (製造商) shall be construed accordingly.

2. External packing (also known as "secondary packaging") is a manufacturing process involving the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pCm which are already enclosed in the container in which they are to be sold or supplied.

3. The following is not regarded as manufacturing a pCm only by affixing to the container of the pCm a label -

(i) that does not state any of the following particulars of that pCm:
   (1) the name of the medicine;
   (2) the names of the active ingredients;
   (3) its dosage and method of usage;
   (4) its packing specification;
   (5) its expiry date;
   (6) its batch number;
   (7) the name of the country or territory in which the medicine is produced; or
   (8) the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine; and

(ii) that does not obscure, change or obliterate any of the particulars set out in paragraph 3(i).

Licensing Requirements

4. Pursuant to section 132 of the CMO, any person may apply to the

Chinese Medicines Board (CMB) for a manufacturer licence in pCm, provided that the application complies with the licensing requirements on the premises, sanitary condition, fittings and equipment used in manufacturing, storage facilities, nominations of the responsible persons for the supervision of the manufacturing process with adequate knowledge and working experience; and upon payment of a prescribed fee, the manufacturer licence shall be issued. The applicant shall specify the location of the premises to which the application relates and shall nominate a responsible person and not more than 2 deputies for the supervision of the manufacturing process, one of whom shall act in the absence of the responsible person. Each responsible person and his deputy shall comply with the minimum requirements regarding knowledge and working experience as specified in the Chinese Medicines Regulation, details please refer to the ***Appendix 1***.

5. When applying for the **Manufacturer licence in proprietary Chinese medicines (External Packing)**, experience in external packing of pCm gained by the responsible person and his deputy is regarded as the practical experience in manufacturing pCm as stated in ***Appendix 1***.

Application procedures

6. Applicants can obtain application forms and "Handbook of the Application for Chinese Medicines Trader Licences" from

I. Chinese Medicine Division, Department of Health
II. Any District Offices under Home Affairs Department (Enquiry no.: 2835-2500)

Applicants can also download the application forms from the homepage of the Chinese Medicine Council of Hong Kong (www.cmchk.org.hk), or by fax through our automatic enquiry hotline system (Enquiry no.: 2574-9999).

7. Applicants are required to provide duly completed Application Form for Manufacturer Licence in Proprietary Chinese Medicines (Form 1D); and Documentation Checklist-Application for Manufacturer Licence in Proprietary Chinese Medicines (Checklist 2D) and all the documents listed therein in person or by registered mail to the Chinese Medicine Division of the Department of Health. The required documents are listed as below:

I. Copy of Business Registration Certificate

II. For limited company only:

(i) Copy of Certificate of Incorporation; **and**

(ii) Copy of Directors' List, such as Form NAR1 of the Companies Registry or Form NNC1 (in case of a newly established limited company); or

For sole proprietorship only: Copy of Form 1(a) of Business Registration Office; or

For partnership only: Copy of Form 1(c) of Business Registration Office;

III. Name list of sole proprietor/ partners/ director(s) and key personnel (including full names in both Chinese and English, Hong Kong Identity Card Numbers/ Passport Numbers and posts. In the case of a director being a corporation, please state the name and Company Number of the corporation);

IV. Brief floor plan of business premises;

V. List of equipment involving in external packing of proprietary Chinese medicines;

VI. Evidence of academic qualifications/ or documentary proofs of relevant working experience of the person and his deputies responsible for the supervision of the external packing of proprietary Chinese medicines.

8. The Chinese Medicine Division will issue an acknowledgement letter within 30 days upon receipt of an application form. The letter of acknowledgement will contain an application number for the applicant. Any applicant who does not receive an acknowledgement letter after the said 30 days should contact the Chinese Medicine Division of the Department of Health.

9. After receiving an application, the Department of Health will send officer to inspect the applicant's business premises and prepare a report for assessment by the Chinese Medicines Board. If the application is approved by the Chinese Medicines Board, the applicant is required to pay the prescribed fees. When the relevant fees are received, the Department of

Health will send the licence to the applicant by post. If the application is refused, the applicant will be notified in writing thereof, and he may request for review or appeal against that decision. The duration of the licence will be shown on the licence, lasting for not more than two years normally.

Important notes

10. 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.

11. Copies of the Chinese Medicines Ordinance and its subsidiary legislation may be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910 or by email at puborder@isd.gov.hk. Contents of the relevant legislation may also be found at the Department of Justice's website http://www.legislation.gov.hk.

Appendix 1

According to Schedule 1 of Chinese Medicines Regulation (Cap.549F)

Minimum Requirements regarding Knowledge and Experience of a person and his deputy Responsible for the Supervision of the Manufacture of proprietary Chinese medicines

	Professional Qualifications	**Academic background／Qualifications**	**Working experience**
(a)	—	(i) holding a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or (ii) having a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i)	Having 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong
(b)	—	(i) holding a diploma in Chinese medicines awarded by a university in Hong Kong; (ii) holding a diploma in Chinese medicines awarded by the Vocational Training Council; or (iii) having a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii)	Having 1 year's practical experience in manufacturing proprietary Chinese medicines in Hong Kong
(c)	A registered or listed Chinese medicine practitioner	—	Having 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong
(d)	A pharmacist registered under the Pharmacy and Poisons Ordinance (Cap 138)	(i) holding a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or (ii) having a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i)	Having 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong

(e)	—	(i) holding a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120 hour course; (ii) holding a certificate in Chinese medicines awarded by the Vocational Training Council on completion of a 120 hour course; or (iii) having a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii)	Having 3 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong
(f)	—	—	Having 5 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong