

Chinese Medicine Council of Hong Kong
Chinese Medicine Ordinance
Cap. 549

Guidance Notes on the Application for Certificate for Manufacturer
(Good manufacturing practice in respect of proprietary Chinese medicines)

According to Section 133 of the Chinese Medicine Ordinance, licensed proprietary Chinese medicines manufacturers may apply to the Chinese Medicines Board under the Chinese Medicine Council for a certificate for manufacturer to prove that they follow the requirements of good practices in manufacture and quality control of proprietary Chinese medicines (Good Manufacturing Practice (GMP)).

1. Application Requirements

- (i) The manufacturers must be licensed manufacturers in proprietary Chinese medicines. The application procedures of manufacturer licence in proprietary Chinese medicines can be referred to the “Handbook of the Application for Chinese Medicines Trader Licences”.
- (ii) The manufacturers must prove that they follow the requirements of good practices in manufacture and quality control of proprietary Chinese medicines. The requirements can be referred to the “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines”.
- (iii) The applicants must be the holders of the licence or the persons authorized by the companies.

2. Application Procedures

How to obtain application form

Application form (Form 1E) and the Documentation Checklist (Checklist 2E) can be obtained free of charge from:

Chinese Medicine Regulatory Office, Department of Health
16/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon.

Office Hours:	Monday to Friday	9:00am to 5:30pm
	Saturday, Sunday and public holidays	Close

Enquiry No.: 3908-7296

Application form (Form 1E) and the Documentation Checklist (Checklist 2E) can also be obtained free of charge by the following ways:

- (i) To download from the homepage of the Chinese Medicine Council of Hong Kong (Website: www.cmchk.org.hk)

Submission of information

Applicants are required to submit the following information:

- (i) The duly completed Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Form 1E); and
- (ii) Documentation Checklist-Application for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Checklist 2E) and all the documents or information listed in the checklist.

How to submit application and pay application fee

Applicants may submit the application by the following ways:

- (i) Mail to the Chinese Medicine Regulatory Office of the Department of Health by registered post (the date shown on the post stamp will be taken as the submission date);
- (ii) Lodge with the office of the Chinese Medicine Regulatory Office of the Department of Health in person during office hours; or
- (iii) Submit by e-form (Applicable to holders of recognized organizational digital certificates only).

(<https://eform.cefs.gov.hk/form/dh0053/en/>)

The application fee for certificate for manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) is HK\$29,300. Applicant can make payment according to the payment methods stated in the General Demand Note issued by the Chinese Medicine Regulatory Office.

The application fee will not be refunded whether the application is approved or not.

3. Issue of acknowledgement

After receiving an application, the Department of Health will check the submitted application form, information and application fee. If all the required information is submitted, the Department of Health will shortly issue an acknowledgement to the applicant to confirm that the application is being processed. If some information is found to be omitted, the Department of Health will send a letter to remind the applicant to submit the supplementary documents as soon as possible, so as to further process the application.

4. Application Results

Officers of the Department of Health will inspect the business premises of the applicant and submit a report to the Chinese Medicines Board for verification.

The Chinese Medicines Board will approve the application within 2 months upon full compliance with the legal and relevant Good Manufacturing Practice Guidelines requirements.

The applicant will be notified in writing if the application is approved. Certificate for manufacturer will be sent to the applicant by post. The applicant may choose to go to the Chinese Medicine Regulatory Office of the Department of Health to collect the certificate in person during office hours. If the applicant has provided an email address via designated means, an e-Certificate will also be issued by email. The applicant will be notified in writing if the application is rejected. The validity period will be shown on the certificate, and normally it shall not be more than 2 years.

(Note: If the applicant does not receive the certificate for manufacturer due to postal error, the applicant will not be re-issued another certificate for manufacturer from the Chinese Medicines Board. The applicant can apply to the Chinese Medicines Board for a certified true copy of the certificate for manufacturer.)

5. Change of submitted information of application

If the applicant would like to change the submitted information while the application is being processed, the applicant should inform the Department of Health in writing as soon as possible.

6. Personal Data

Personal data (privacy) policy

In protection of the privacy in relation to personal data, the Department of Health has developed its data protection policy modeled on the six data protection principles as set out in Schedule 1 of the Personal Data (Privacy) Ordinance. The Department of Health respects personal data privacy and is fully committed to implementing and complying with the data protection principles and all relevant provisions of the Ordinance.

Personal data collected for the purposes of the Chinese Medicine Ordinance (Cap 549)

The personal data provided by the applicants to the Chinese Medicines Board is used for the purposes of the Chinese Medicine Ordinance. It will be kept and used in future for handling matters relating to the registration of proprietary Chinese medicines, licensing of Chinese medicines traders and law enforcement. The provision of personal data is voluntary. If an applicant fails to provide sufficient data, the Chinese Medicines Board will be unable to process the application for certificate for manufacturer.

Transfer of personal data

The personal data provided by the applicants is mainly used within the Chinese Medicine Council of Hong Kong, but they may also be disclosed to other Government bureaux/departments, agencies or authorities for the purposes mentioned above. Besides, such data will only be disclosed to parties where the applicants have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to and correction of personal data

The applicants have the 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. Data access and correction requests and enquiries may be addressed to the relevant offices or clinics of the Department of Health by which the personal data is collected. Requests should be made by submission of a duly completed Data Access Request Form

<http://www.pcpd.org.hk/english/resources_centre/publications/forms/files/Dforme.pdf>.

The Department of Health will charge a reasonable fee for complying with any data access request.

Should there be any data access and correction requests and enquiries related to personal data collected for the purposes of the Chinese Medicine Ordinance, the applicants should write to **Senior Pharmacist (Chinese Medicines)** at the address: 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon.

7. Enquiries

Enquiries on the application for certificate for manufacturer or the content of this guidance notes can be made by telephone, fax or post to the Chinese Medicine Regulatory Office of the Department of Health:

Tel No.: 3908-7296

Fax No.: 3908-7297

Address: 16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon.