

# **【 Registration of proprietary Chinese medicines 】**

## **Application Handbook**

Chinese Medicine Council of Hong Kong

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## Introduction

1. Chinese medicine has been widely used in the community and plays a very important role in providing health care services in Hong Kong. The Chinese Medicine Ordinance (Cap. 549) was passed by the Legislative Council on 14 July 1999 as to promote the development of Chinese medicine and to strengthen the regulation on Chinese medicine. The regulatory system for Chinese medicine constituted under this Ordinance safeguards public health, and at the same time, legitimizes the position of Chinese medicine.
  
2. The Chinese Medicine Council of Hong Kong (hereunder the Council) is a statutory body established under the Chinese Medicine Ordinance. It is responsible for the formulation and implementation of the regulatory measures of Chinese medicine. The Chinese Medicines Board established under the Council is mainly responsible for regulatory measures for Chinese Medicines traders, Chinese herbal medicines and proprietary Chinese medicines (pCm). The committees established under the Chinese Medicines Board include:
  - (i) The Chinese Medicines Committee - mainly responsible on matters related to registration of pCms and for the regulation of Chinese herbal medicines;
  - (ii) The Chinese Medicines Traders Committee - mainly responsible on matters related to licensing of Chinese medicines traders;
  - (iii) The Regulatory Committee of Chinese Medicines Traders - mainly responsible for the supervision and regulation of the professional practice and conduct of Chinese medicines traders.The committees make recommendations on relevant regulatory measures to the Chinese Medicines Board, and carry out any other functions assigned to them under the Chinese Medicine Ordinance, or as delegated by the Chinese Medicines Board.
  
3. The Chinese Medicine Division of the Department of Health is responsible for providing administrative support and to implement the regulatory measures for, the Council, the Chinese Medicines Board and the committees.
  
4. According to the Chinese Medicine Ordinance, no person shall sell, import or possess any pCm in Hong Kong unless it is registered. Those who wish to register their pCms should submit their applications to the Chinese Medicines Board with all the required documents. After the assessment and approval by the Chinese Medicines Board, the pCm under application can then be registered.

5. The purpose of this Handbook is to provide guidance notes for those who wish to apply for registration of pCms. Please refer to this Handbook for the definition of pCm, classification category & registration group, and application procedures as well as other relevant issues in relation to pCm registration.
  
6. This Handbook is not a legal document, and is not exhaustive relating to the requirements for registration of pCms. In any case, the legislation should prevail. For the legislation regarding the registration of pCms, the applicant should refer to the Chinese Medicine Ordinance (Cap.549) and its subsidiary legislation including the Chinese Medicines Regulation, Chinese Medicine (Fees) Regulations and the Chinese Medicines Traders (Regulatory) Regulation. Other requirements as stipulated in relevant ordinances have been included in Chapter 6 of this Handbook. Printed copies of these legislations can be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910 or downloaded from the internet (website: <http://www.legislation.gov.hk>).

## **Chapter 1 Registration System of Proprietary Chinese Medicines**

### **(I) Proprietary Chinese medicines to be registered**

1. According to section 119 of the Chinese Medicine Ordinance (CMO), no person shall sell, import or possess any pCm unless the pCm is registered under section 121 of the Ordinance.
2. The transitional registration application period determined by the Chinese Medicine Board, in accordance with section 128(1), was ended on 30 June 2004. Applicants did not submit their applications, which were eligible for transitional registration (i.e. pCms that are being manufactured, sold or supplied for sale in Hong Kong on 1 March 1999) on or before 30 June 2004, were disqualified for transitional registration. As such applicants are subsequently required to register their pCms in accordance with section 121 of the CMO.
3. Based on the claims, ingredients and pharmacological effects, products containing Chinese herb can be classified into four main categories, namely proprietary Chinese medicine, western medicine, food and consumer goods (including personal hygiene products and cosmetics).

### **Definition of proprietary Chinese medicine**

4. According to the CMO, "proprietary Chinese medicine (pCm)" means any proprietary product -
  - (a) composed solely of the following as active ingredients:
    - (i) any Chinese herbal medicines; or
    - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
    - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
  - (b) formulated in a finished dose form; and
  - (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

The substances as described in (a)(i) and (a)(ii) above will be referred as "Chinese herb" in this Handbook.

5. Products containing both Chinese herb and western medicine are regarded as western medicine products, and are registered and regulated under the Pharmacy and Poisons Ordinance (Cap. 138).
6. Products that contain Chinese herb and meet all the following criteria can be regarded

as food (e.g. ShanZhaBing/Haw flakes), and are governed by the Public Health and Municipal Services Ordinance (Cap. 132):

- (a) Used in form or manner of normal foods (e.g. to be taken orally, and usually without recommended dose regimens);
- (b) The product does not contain any claim on curative or health care function; and
- (c) All the Chinese herbs used in the product are generally being considered as food.

7. Except products that contain western medicine and are regarded as western medicine products, products that contain ephedra are regarded as pCm.

8. Products that contain Chinese herbs and meet all the following criteria can be regarded as personal hygiene products or cosmetics, and are governed by the Consumer Goods Safety Ordinance (Cap. 456):

- (a) To be spread, sprayed or applied on the surface of the human body;
- (b) The product does not contain any claim on curative or health care function; and
- (c) Can only be used for cleansing, beautifying, maintaining the skin in good condition or altering the odours of the body.

### **Proprietary Chinese medicines exempted from registration**

9. According to the CMO and Chinese Medicines Regulation, the following pCms may be exempted from registration (the following interpretation is for reference only. In any case, the legislation should prevail);

- (a) a pCm of a reasonable quantity that is manufactured by a manufacturer, or imported by a wholesaler of pCm, for the purposes of providing samples and seeking registration (Reference: section 119(3), CMO );
- (b) a pCm that is required for the purposes of education or scientific research. The Chinese Medicines Board may exempt, with or without conditions or restrictions, a person or institution concerned with education or scientific research from the requirements for registration for the pCms in question (Reference: section 158(1), CMO );
- (c) a pCm that is imported by a wholesaler of pCms for the purpose of re-exporting by the same wholesale dealer (Reference: section 158(5)(a), CMO );
- (d) a pCm that is imported by a holder of a valid certificate for clinical trial and medicinal test and is to be used for the purposes of the clinical trial or medicinal test to which the certificate relates (Reference: section 158(5)(b), CMO );
- (e) a pCm that is compounded by or under the supervision of a registered Chinese medicine practitioner or a listed Chinese medicine practitioner at the premises where he practises if, and only if, such pCm is being used for the purpose of administering or supplying to a patient under his direct care (Reference: section 158(6)(a), CMO );
- (f) a pCm that is individually prepared or compounded for one patient-
  - (i) by a person nominated under section 114(2)(b)(i) or (ii) of CMO; or



- (ii) under the supervision of such person, at the premises in respect of which a retailer licence is in force and in accordance with a prescription given by a registered Chinese medicine practitioner or a listed Chinese medicine practitioner (Reference: section 158(6)(b), CMO );
- (g) (i) a pCm that is manufactured in the premises in respect of which a manufacturer licence is in force and by or under the supervision of a responsible person in accordance with a prescription given by a registered Chinese medicine practitioner, or a listed Chinese medicine practitioner; and
- (ii) a pCm that is, in the case where the medicine is for internal application or both internal and external application, to be administered or supplied to the patient to whom the prescription is given and who is under the direct care of the Chinese medicine practitioner; or in the case where the medicine is for external application only, and is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner (one patient for internal application, and several patients for external application); and
- (iii) The Chinese Medicines Board has received from the manufacturer, at least one working day before the day on which the manufacturing process of the medicine begins, a written notification including the particulars set out in section 37(2) of the Chinese Medicines Regulation and being accompanied by an undertaking referred to in section 37(3) of the Chinese Medicines Regulation (Reference: section 37(1), Chinese Medicines Regulation).

## **(II) Applicant for registration of pCms**

10. According to sections 120 of the CMO, an application for the registration of a pCm shall be made -
- (a) in the case of its being manufactured in Hong Kong, by the manufacturer;
  - (b) in the case of its being manufactured outside Hong Kong,
    - (i) by the importer; or
    - (ii) by the local representative or agent of the manufacturer.
- The applicant applying for registration of pCm as described in paragraphs (a), (b)(i) and (b)(ii) above will be referred to as the ‘applicant’ in this Handbook.

11. In addition, the applicant should hold a valid Manufacturer Licence in Proprietary Chinese Medicines or Wholesaler Licence in Proprietary Chinese Medicines. For details on the application of licences, please refer to the “Handbook of the Application for Chinese Medicines Trader Licences”.

12. For product that falls within the definition of pCm, the applicant should submit all the required documents according to the classification category and registration group of the pCm. For detailed information, please refer to chapter 2, chapter 3 and the flow chart on page 51 of this Handbook.

## **Chapter 2 Classification Category & Registration Group of pCms**

1. The requirements for registration of pCms are dependent on the classification category of the pCm under application, and the registration group selected by the applicant.
2. Applicants should submit all the required documents in respect to the classification category and registration group of the pCm to the Chinese Medicines Board for assessment and approval.

### **(I) Classification categories of pCms**

3. The classification categories of pCms include the “Established medicines category”, the “Non-established medicines category”, and the “New medicines category”. “Health-preserving medicines” and “Other medicines” are the two sub-categories under the “Non-established medicines category”. The “Other medicines category” includes “Single Chinese medicine granules” that fall within the definition of pCm.

### **Established medicines category**

4. Except for Chinese medicine injections, pCm that fulfills any of the following shall be regarded as “Established medicines”:
  - (a) its prescription is:
    - i. an ancient prescription (which has been documented in Chinese medicines bibliography in, or before, the Qing dynasty); or
    - ii. a modified ancient prescription (the prescription of which is based on an ancient prescription with reasonable and rational modifications) ; or
    - iii. a pharmacopoeia prescription (which has been documented in the Pharmacopoeia of the People’s Republic of China); or
    - iv. any other prescriptions originated from the National Drug Standards of the People’s Republic of China and accepted by the Chinese Medicines Board.The original dose form of the prescription should not be changed, otherwise the pCm will be regarded as “New medicines category” (except for those ancient prescriptions provided that their principal manufacturing method remains unchanged).
  - (b) it is made from single Chinese herb, its claimed indications and functions are the same as its crude drug (except Single Chinese medicine granules).
5. The Chinese Medicines Board will adopt the following principles in deciding whether to accept a prescription originated from the National Drug Standards of the People’s Republic of China as “Established medicines”:-
  - (a) Accept only the latest promulgated standard of the prescription. For example, if a prescription is both documented in the Drug Standard of the Ministry of Health and the Pharmacopoeia of the People’s Republic of China, the Chinese Medicines Board will only accept the one in current edition of the Pharmacopoeia.

- (b) Consider the current use of the prescription. For example the Chinese Medicines Board will not accept the Drug Registration Standards that have been withdrawn due to safety concerns.
  - (c) The product specification of the pCm must fulfill the requirements imposed by the Chinese Medicines Board.
6. If the prescription of a registered pCm (including transitional registration) is required to be amended in accordance with the country/district for sale, such pCm is required to be registered again. Moreover, if the manufacturer can provide the following evidence, the pCm can be regarded as “Established medicines”:
- (a) the amendment is according to the requirement or regulation of the country/district for sale;
  - (b) the amendment is made to the prescription of a pCm that is qualified for transitional registration, transitionally registered or registered; and
  - (c) the amendment does not affect the pharmacodynamic and pharmacological effects of the product. For example, the principal and assistant drug(s) shall not be changed.

### **Non-established medicines category**

7. Except for Chinese medicine injections, any pCms, which are used for the purpose of regulating the functional states of the human body, shall be regarded as “Health-preserving medicines” in the “Non-established medicines category”. However, the prescription of the “Health-preserving medicines” should not contain any newly discovered Chinese herb, new medicinal part(s) of Chinese herb, active group extracted from Chinese herb or set of active groups extracted from compound prescription. Otherwise, the pCm will be required for registration under the “New medicines category”.
8. “Single Chinese medicine granules” are those granules that fall within the definition of pCm, and are made from single Chinese herbs, and their claimed indications and functions are the same as those of their crude drugs.

### **New medicines category**

9. PCms that meet any of the following descriptions shall be regarded as “New medicines”:
- (a) its prescription comprises any one (or several) of the following:
    - (i) a newly discovered Chinese herb <sup>(1)</sup> ;
    - (ii) a new medicinal part of a Chinese herb <sup>(2)</sup> ;
    - (iii) an active group extracted from Chinese herb <sup>(3)</sup> ;
    - (iv) a set of active groups extracted from a compound prescription;
  - (b) Chinese medicine injection <sup>(4)</sup> ;

- (c) preparation of a new Chinese medicine prescription <sup>(5)</sup> ;
- (d) pCm with altered route of administration <sup>(6)</sup> ;
- (e) pCm with new indication <sup>(7)</sup> ;
- (f) pCm with altered dose form <sup>(8)</sup> .

*Notes :*

- <sup>(1)</sup> *A newly discovered Chinese herb refers to species that is not documented in any Chinese medicines bibliography or the Pharmacopoeia of the People's Republic of China.*
- <sup>(2)</sup> *A new medicinal part of a Chinese herb refers to the part of Chinese herb that is not documented in any Chinese medicines bibliography or the Pharmacopoeia of the People's Republic of China.*
- <sup>(3)</sup> *An active group refers to a non-isolated chemical constituent extracted from Chinese herb, e.g. flavones.*
- <sup>(4)</sup> *Chinese medicine injection refers to a Chinese medicine prescription in the form of injection. It can be a non-isolated chemical constituent, single herb prescription or compound prescription preparation.*
- <sup>(5)</sup> *New Chinese medicine prescription preparation refers to preparation that is not formulated based on an ancient prescription, a pharmacopoeia prescription, a modified ancient prescription, and any other prescriptions originated from the National Drug Standards of the People's Republic of China as approved by the Chinese Medicines Board.*
- <sup>(6)</sup> *An example of altered route of administration: from oral administration to application to mucous membrane.*
- <sup>(7)</sup> *New indication refers to indication that is additional to the already documented indications of the registered pCm, the ancient prescription or the pharmacopoeia prescription.*
- <sup>(8)</sup> *Altered dose form refers to those, which are different from the dose form of the registered pCm, the ancient prescription (except those without changing the principle manufacturing process), the pharmacopoeia prescription, or any other prescriptions originated from the National Drug Standards of the People's Republic of China.*

## **(II) Registration groups of pCms**

10. The registration groups of pCm are Group I, Group II and Group III. Different registration groups have different registration requirements, and hence require different documents.
11. For pCms under the “Established medicines category” and “Non-established medicines category”, applicants may choose to apply for registration in any of the three groups. However, for pCms in the “New medicines category”, as their compositions, routes of administration, indications or dose forms are different from traditional use, hence

scientific evidence is essential to ensure their safety and efficacy and they must be registered according to Group III registration requirements.

## Registration requirements for each group

12. The registration groups applicable for each group of pCm are summarised as follows:-

**Table 1: Registration groups applicable for various categories of pCm**

Group	I	II	III
Established medicines category	✓	✓	✓
Non-established medicines category	✓	✓	✓
New medicines category	--	--	✓

13. For pCms in the “Established medicines category” and “Non-established medicines category” to be registered under Group I, applicant is required to submit basic documents in respect of safety, efficacy & quality of the medicine for the application. For “Health-preserving medicines” in the “Non-established medicines category”, long-term toxicity test report is required to verify the safety of the health-preserving medicines which are intended for long-term use.
14. For pCms in the “Established medicines category” and “Non-established medicines category” to be registered in Group II, applicant is required to submit further documents supporting their safety & quality, such as real-time stability test report, in addition to the basic documents in respect of safety, efficacy & quality of the medicine.
15. For pCms under the “Established medicines category”, “Non-established medicines category” and “New medicines category” to be registered in Group III, applicant is required to submit comprehensive documents in respect of safety, efficacy & quality of the medicine, such as principal pharmacodynamic studies report, clinical trial protocol and summary report, etc.

## Chapter 3 Application Procedures for Registration of pCms

### (I) Registration of pCms

1. For product that falls within the definition of pCm, application for registration of pCm should be made in accordance with section 121 of the CMO.
2. All pCms with indication of containing Aristolochia Linn herbs are prohibited from sale or importation by the Chinese Medicine Board. Moreover, it will not be approved for registration. In addition, pCm to be submitted for registration shall not contain aristolochia acid. For details on banned Aristolochia Linn herbs, please refer to appendix II on page 49 of this Handbook.

### (II) Documents required for registration of pCms

3. In addition to this Handbook, the Chinese Medicines Board has also compiled the “Guide for Completion of Application Form for Registration of Proprietary Chinese Medicines” (hereunder the “Guide”) and the “Checklist (1), (2) & (3)” in order to assist the applicant to complete the “Application Form for Registration of pCms” (hereafter the “Application Form”) and submit the documents required respectively.
4. “Checklist (1)” is applicable for Group I registration. “Checklist (2)” for Group II registration, and “Checklist (3)” for Group III registration. Applicants are required to submit the appropriate and duly completed checklist together with the documents required.
5. For technical requirements for various tests on safety, quality and efficacy of pCm, please refer to the relevant technical guidelines compiled by the Chinese Medicines Board.

### How to obtain Application Form and other relevant information

6. An applicant may obtain this Handbook, the Application Form, the Guide and “Checklist (1), (2) & (3)” in any of the following ways:

**(a) Visit the Chinese Medicines Section of the Department of Health during office hours**

Address: 2/F, Public Health Laboratory Center, 382 Nam Cheong Street,  
Shek Kip Mei, Kowloon

Office Hours: Monday to Friday: 9:00 am to 5:30 pm

Close on Saturday, Sunday & public holidays

**(b) Through facsimile request of the interactive information hotline (except this Handbook)**



period of time, receive a confirmation receipt confirming that the application is being processed. The confirmation receipt will include the file reference number allocated to that application.

#### **(V) Approval for registration**

12. Having assessed and verified that the pCm under application meets the requirements for registration, upon payment of a prescribed issue fee, the Chinese Medicine Board will issue the “Certificate of registration of pCm” to the applicant who holds a valid Manufacturer Licence in pCm or Wholesaler Licence in pCm, and the pCm becomes registered. In this certificate, the registration number of the pCm and conditions that the Chinese Medicines Board thinks fit will be specified.
13. The registration number of the pCm will be in a format of [HKC-XXXXXX], in which [HKC] indicates that the pCm is registered in Hong Kong, [XXXXXX] is the serial number of application. The registration group under which such pCm is approved for registration will be shown on the “Certificate of Registration of pCm”.
14. If the manufacturer concerned has been issued with a “Certificate for manufacturer (Good Manufacturing Practice in respect of proprietary Chinese medicines)” by the Chinese Medicines Board and the manufacturing process of such pCm meets the required standards, “GMP” can be added after the registration number on the pCm packaging label. For detail requirements for “Good Manufacturing Practice”, please refer to the “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines” compiled by the Chinese Medicines Board.

#### **(VI) Registered particulars**

15. According to section 15 of the Chinese Medicines Regulation, for the purposes of section 121(1)(b), the following particulars are required to be registered for a pCm-
  - (a) its Chinese and English name;
  - (b) its dose form;
  - (c) the name and quantity of each of its active ingredient;
  - (d) the name and quantity of each of its excipient (if any);
  - (e) its specification;
  - (f) its indication (if any);
  - (g) its dosage and method of usage;
  - (h) each of its labels to be attached or printed on its package;
  - (i) the package insert to be supplied for its sales inside Hong Kong;
  - (j) each of the package inserts to be supplied for its sales outside Hong Kong (if any);
  - (k) the name and address of each of its manufacturer; and
  - (l) its function or pharmacological action.



**Table 2: Documents required for registration of pCm**

✓ Required      × Not required

<b>General documents</b>	<b>Group I</b>	<b>Group II</b>	<b>Group III</b>
1. Completed Application Form & appropriate checklist	✓	✓	✓
2. Application fee	✓	✓	✓
3. Personal information of the person-in-charge of the company	✓	✓	✓
4. Documentary proofs of manufacture or sales history of the product	✓	✓	✓
5. Copy of manufacturing authorization issued by the country of origin (if applicable)	✓	✓	✓
6. Copy of free sale documentation issued by the country of origin (if applicable)	✓	✓	✓
7. Product sample and prototype sales pack	✓	✓	✓
8. Label & package insert that have complied with the laws	✓	✓	✓
9. Master formula	✓	✓	✓
<b>Product safety documents</b>			
1. Heavy metals and toxic elements test report	✓	✓	✓
2. Pesticide residues test report	✓	✓	✓
3. Microbial limit test report	✓	✓	✓
4. Acute toxicity test report	✓	✓	✓
5. Long-term toxicity test report	✓ <sup>(1)</sup>	✓	✓
6. Local toxicity test report	✓ <sup>(2)</sup>	✓ <sup>(2)</sup>	✓ <sup>(2)</sup>
7. Mutagenicity test report	×	✓ <sup>(3)</sup>	✓ <sup>(4)</sup>
8. Carcinogenicity test report	×	✓ <sup>(5)</sup>	✓ <sup>(6)</sup>
9. Reproductive and development toxicity test report	×	✓ <sup>(7)</sup>	✓ <sup>(8)</sup>
10. Summary report on product safety documents	✓	✓	✓
<b>Product efficacy documents</b>			
1. Interpretation and principle of formulating a prescription	✓ <sup>(9)</sup>	✓ <sup>(9)</sup>	✓ <sup>(9)</sup>
2. Reference materials on product efficacy	✓	✓	✓
3. Principal pharmacodynamic studies report	×	×	✓
4. General pharmacological studies report	×	×	✓ <sup>(10)</sup>
5. Clinical trial protocol and summary report	×	×	✓
6. Summary report on product efficacy documents	✓	✓	✓
<b>Product quality documents</b>			
1. Manufacturing method	✓	✓	✓
2. Physicochemical properties of crude drugs	✓	✓	✓
3. Product specification, method and certificate of analysis	✓ <sup>(11)</sup>	✓ <sup>(11)</sup>	✓ <sup>(11)</sup>
4. Accelerated stability test report or general stability test report	✓ <sup>(12), (13), (14)</sup>	×	×
5. Real-time stability test report	× <sup>(14), (15)</sup>	✓ <sup>(14)</sup>	✓ <sup>(14)</sup>

**Notes:**

- (1) *This document is only required for “health-preserving medicines” in the “non-established medicines category”.*
- (2) *This document is only required for those pCms to be applied on skin or mucous membranes.*
- (3) *This document is only required for those pCms which contain ingredient(s) with cytotoxic or known carcinogenic/mutagenic effects.*
- (4) *This document is only required for those pCms which contain newly discovered Chinese herb(s), ingredient(s) with cytotoxic or known carcinogenic/mutagenic effects.*
- (5) *This document is only required for those pCms which contain ingredient(s) with known carcinogenic/mutagenic effects or have been found positive in mutagenicity test.*
- (6) *This document is only required for those pCms which contain newly discovered Chinese herb(s) or ingredient(s) with known carcinogenic/mutagenic effects, or have been found positive in mutagenicity test.*
- (7) *This document is only required for those pCms which relate to pregnancy, have proven to have toxic effect on the reproductive system in other toxicity tests, or have been found positive in mutagenicity test.*
- (8) *This document is only required for those pCms which contain newly discovered Chinese herb(s), relate to pregnancy, have proven to have toxic effect on reproductive system in other toxicity tests or have been found positive in mutagenicity test.*
- (9) *If the product is a single Chinese medicine granule, submission of this document may be exempted.*
- (10) *For pCms under the new medicines category with altered routes of administration, altered dose form or new indications, submission of this document may be exempted.*
- (11) *For a pCm that has been sold or manufactured in Hong Kong before the commencement of pCm registration system (i.e. before 19 December 2003), the applicant can submit the chemical assay, test method and analytical report that are required in product specification upon the renewal of such registration. For a pCm that is sold or manufactured in Hong Kong after the commencement of pCm registration system (i.e. on/after 19 December 2003), the applicant must submit a complete set of reports upon application.*
- (12) *For a pCm that is sold or manufactured in Hong Kong after the deadline of application for transitional registration(i.e. after 30 June 2004), an accelerated stability test report should be submitted and the shelf life of the pCm shall not be longer than 2 years.*  
*For a pCm that has been sold or manufactured in Hong Kong before the deadline of application for transitional registration(on/before 30 June 2004), if the sales history is over two years, only a general stability test report is required; if the sales history is less than 2 years, an accelerated stability test report will also be required.*
- (13) *If a real-time stability test report is to be submitted, there is no need to submit accelerated stability test report and general stability test report.*
- (14) *For a pCm that has been sold or manufactured in Hong Kong before the commencement of pCm registration system (i.e. before 19 December 2003), the applicant can submit to the Chinese Medicine Board the general stability test report of at least one batch of the pCm, and a documentary proof showing that test on the remaining batch(es) has/have been commenced. Test report of the remaining batch(es) should be submitted upon the renewal of such registration. Whereas for the accelerated*

*stability test report or real-time stability test report(3 batches), the applicant can submit it upon the renewal of such registration.*

*For a pCm that has been sold or manufactured in Hong Kong after the commencement of pCm registration system (i.e. on/after 19 December 2004) and before the deadline of application for transitional registration (i.e. on/before 30 June 2004), applicant should submit to the Chinese Medicines Board the accelerated stability test report(3 batches), inspection plan of retained samples, results of initial tests conducted on at least one batch of pCm when release from the manufacturer (0 year), and a documentary proof showing that test on the remaining batch(es) has/have been commenced upon application. Thereafter, the applicant should conduct tests according to the plan, and submit the test report of at least one batch of pCm after completion of test. Test report of the remaining batch(es) should be submitted upon the renewal of such application.*

- <sup>(15)</sup> *For a pCm that is sold or manufactured in Hong Kong after the deadline of application for transitional registration(after 30 June 2004), a real-time stability test report( 3 batches) should be submitted if the pCm has a shelf life of longer than 2 years.*

## **Chapter 4 Assessment and Approval for Registration of pCms**

### **(I) Assessment and approval of application**

1. All applications for registration of pCms will be assessed and approved by the Chinese Medicines Board, or the Chinese Medicines Committees as delegated by the Chinese Medicines Board. Applicants will be notified in writing of the result.
2. In the course of an application assessment, the Chinese Medicines Board may, if it considers necessary, require the applicant to provide additional documents or information for the registration of pCms.

### **(II) Factors relevant to determination of application for registration**

3. According to section 122(1) of the CMO, in determining an application for registration of a pCm, the Chinese Medicines Board shall in particular take into consideration the safety, quality & efficacy of the pCm.
4. According to section 122(4) of the CMO, in determining an application relating to a pCm which is to be imported, the Chinese Medicines Board -
  - (a) shall also take into consideration in particular the methods, standards and conditions of manufacture of the medicine; and
  - (b) may, if it thinks fit, require the production by the applicant of any one or a combination of the following –
    - (i) an undertaking, given by the manufacturer of the pCm, to permit the premises where it is or is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Chinese Medicines Board;
    - (ii) an undertaking, given by the manufacturer of the pCm, to comply with any conditions as imposed by the Chinese Medicines Board;
    - (iii) a declaration, given by or on behalf of the manufacturer of the pCm that, in relation to the manufacture of the pCm any requirements imposed by or under the law of the place in which it is or is to be manufactured have been or will be complied with.

## **Chapter 5 Requirements for Individual Documents**

### **(I) Documents required for registration of pCms**

1. Documents to be submitted for registration of pCms can be categorised into 4 groups, namely general documents; product safety documents; product efficacy documents, and product quality documents.
2. Requirements for these documents are described briefly in this chapter. For detailed technical requirements of various tests, please refer to the relevant technical guidelines compiled by the Chinese Medicines Board.
3. In addition to the requirements as specified for registration in Group I, Group II & Group III, the Chinese Medicines Board may, if it considers necessary, require applicants to provide additional documents or information relating to the registration of such pCms.
4. Documents issued in the Mainland should be certified by the issuing government department. Certified copies verified by notary agency in the Mainland, law firms in Hong Kong and embassy are also accepted. For documents issued in other countries, other than certification by law firms in Hong Kong or embassy, only certified copies issued by the issuing institution will be accepted.

### **(II) General documents**

#### **Application form**

5. Applicants should provide accurate information and complete the Application Form properly. For explanatory notes, please refer to the Guide compiled by the Chinese Medicines Board.

#### **Personal information of the person-in-charge of the company**

6. The applicant should provide detailed information about the person-in-charge of the company, including the name (in Chinese and English), Hong Kong identity card number, contact telephone number and postal address. Any change of personal particulars of the person-in-charge should be reported to the Chinese Medicines Board as soon as possible.

#### **Documentary proofs of manufacture or sales history of the pCm**

7. Documentary proofs of manufacture or sales history can be retail or wholesales sales invoice, import & export licences, manufacturing records and related raw materials purchase invoices, newspapers or magazines advertisements of the pCm under application. If necessary, the Chinese Medicines Board may ask for the relevant

original documents for verification.

### **Copy of manufacturing authorization issued by the country of origin**

8. If the pCm is not manufactured in Hong Kong, the applicant is required to submit certified true copy of the production permit or the manufacturer's licence of the pCm's manufacturer issued by the drug regulatory authority of the country of origin.

### **Copy of free sale documentation issued by the country of origin**

9. If the pCm is not manufactured in Hong Kong, the applicant shall submit certified true copy of the free sale certificate, or certificate of registration of the pCm issued by the drug regulatory authority of the country of origin.
10. If the pCm is manufactured in China but not for sale there, the applicant can submit the "permit of contract manufacturing for exporting purposes" issued by the provincial drug regulatory agency instead of the free sale certificate, but the manufacturer in China must be commissioned by the applicant and hold a valid manufacturer licence in China.
11. For applicant who is unable to obtain free sale certificate because his/her pCm is regarded as health product or food in Mainland or any other countries, he/she should submit document issued by the relevant authority to prove his/her product is manufactured legally.

### **Product samples and prototype sales pack**

12. The applicant should submit samples of the pCm and prototype sales pack. The samples and prototype submitted shall be identical to the actual sales pack.
13. The quantity of samples submitted shall be sufficient for conducting necessary laboratory tests. The absolute amount varies among products.

### **Package inserts**

14. According to section 144 of the CMO, no person shall-
  - (a) sell; or
  - (b) have in his possession for the purpose of selling, any pCm without a package insert which complies with the prescribed requirements.
15. According to section 28 of the Chinese Medicines Regulation, no person shall sell in Hong Kong or have in his possession for the purpose of selling in Hong Kong any pCm without a package insert which -
  - (a) includes the particulars set out in paragraph 16 below; and

- (b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.
16. A package insert of a pCm to be sold in Hong Kong shall include, at least in Chinese, the following particulars in respect of the medicine -
- (a) the name of the medicine;
  - (b) if -
    - (i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredients and its quantity; or
    - (ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients and their respective quantities;
  - (c) either 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;
  - (d) its dosage and method of usage;
  - (e) its functions or pharmacological action;
  - (f) its indications (if any);
  - (g) its contra-indications (if any);
  - (h) its side-effects (if any);
  - (i) its toxic effects (if any);
  - (j) the precautions to be taken regarding its use (if any);
  - (k) its storage instructions; and
  - (l) its packing specification.
17. For all pCms that contain ephedra, instruction likes “This product is not suitable for long term use or this product should be used in accordance with doctor’s instruction”, or similar wording should be given in the package insert.
18. No other package insert or information (e.g. promotional leaflets) shall be enclosed in product package without the prior approval of the Chinese Medicines Board.

## **Labels**

19. According to section 143 of the CMO, no person shall -
- (a) sell; or
  - (b) have in his possession for the purpose of selling, any pCm unless the package of the pCm is labelled in the prescribed manner.
20. According to section 26 of the Chinese Medicines Regulation, a person who sells in Hong Kong or has in his possession for the purpose of selling in Hong Kong a pCm shall ensure that a label on a package of the medicine -
- (a) includes the particulars set out in paragraphs 21 and 22 below, as the case may be;

and

- (b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.
21. Except as otherwise provided in paragraphs 22 below, a label on a package of a pCm to be sold in Hong Kong, whether being the outermost package (not including the package boxes for transportation purpose) to be sold or distributed to an ultimate user of the medicine or otherwise, shall include the following particulars, at least in Chinese --
- (a) the name of the medicine;
  - (b) (i) (if the medicine is composed of less than 3 kinds of active ingredients) the name of each kind of active ingredients; or  
(ii) (if the medicine is composed of 3 or more kinds of active ingredients) the names of more than half of the total number of kinds of active ingredients;
  - (c) the name of the country or territory in which the medicine is produced;
  - (d) the registration number of the medicine as specified in its certificate of registration;
  - (e) if the package –
    - (i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or
    - (ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;
  - (f) its packing specification ;
  - (g) its dosage and method of usage;
  - (h) its expiry date; and
  - (i) its batch number.
22. A label on a package of a pCm to be sold in Hong Kong, not being the outermost package to be sold or distributed to an ultimate user of the medicine, which -
- (a) is in the form of a strip pack, blister pack or similar article, shall include (at least in Chinese) the name of the medicine, 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 the expiry date, packing specification and batch number of the medicine;
  - (b) is in the form of an ampoule, vial or similar receptacle, with not more than 10 ml capacity or equivalent, shall include, at least in Chinese, the name of the medicine; or
  - (c) contains a single dose in the form of a pill, shall include, at least in Chinese, the name of the medicine.
23. According to section 27 of the Chinese Medicines Regulation, a person who exports or has in his possession for the purpose of exporting a pCm manufactured in Hong Kong



shall ensure that a label on the outermost package of the medicine likely to be sold or distributed to an ultimate user of the medicine (not including the package boxes for transportation purpose)-

- (a) includes the following particulars -
  - (i) the name of the medicine;
  - (ii) the name of the holder of the certificate of registration of the medicine as specified in the certificate; and
  - (iii) the registration number of the medicine as specified in its certificate of registration; and
- (b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

- 24. All packages of pCms must be properly labelled. If the pCm is sold in more than one package, each of the packages must be properly labelled. No other information shall be printed on the labels of the product label text without the prior approval of the Chinese Medicines Board.
- 25. For all pCms that contain ephedra, instruction likes “This product is not suitable for long term use or this product should be used in accordance with doctor’s instruction”, or similar wording should be given in the label.
- 26. These requirements for package inserts and labels of pCms are legal requirements. This Handbook is for reference purpose only. In any case, the CMO and Chinese Medicines Regulation should prevail.

### **Master formula**

- 27. The applicant should submit the master formula provided by the manufacturer of the pCm under application. This should include the names and quantities of all the Chinese herbs and excipients used.
- 28. Chinese herbal medicines should be named according to the names specified in Schedule 1 and Schedule 2 of the CMO. For Chinese herbs that are not listed in Schedule 1 and Schedule 2, the applicant may refer to the Pharmacopoeia of the People’s Republic of China, ‘Zhonghua Bencao’, ‘Zhongyao Dacidin’ or ‘Chinese Materia Medica’ for the official names.

### **(III) Product safety documents**

- *The requirements for product safety documents vary according to the pCm’s classification category and the registration group being applied.*
- *For the detailed technical requirements of the following tests, please refer to the “Technical guidelines - product safety documents”.*

## Heavy metals and toxic element test report

29. Heavy metal or toxic element contained in pCms may be a result of environmental pollution in the raw herbs; from contamination in the preparatory process; or simply due to the Chinese herb(s) which originally contained heavy metal(s) or toxic element(s) as ingredient(s) is/are formulated in the preparation.
30. The applicant should submit reports on test methods and result for heavy metals and toxic element on the finished product. The permitted level of heavy metals or toxic element is calculated by the total maximum intake per day or per dose. If the pCm does not contain any minerals which originally contained heavy metal(s) or toxic element(s) as ingredients, the content levels of the heavy metals and toxic element must not exceed the maximum permitted levels, as set out by the Chinese Medicines Board (see Table 4 below).

**Table 3: Permitted levels of heavy metals and toxic element**

<b>Heavy metals or toxic element</b>	<b>Maximum Permitted Level (total intake)</b>
Arsenic	1,500 microgram/day
Cadmium	3,500 microgram/dose
Lead	179 microgram/day
Mercury	36 microgram/day

31. For preparations that have formulated Chinese herb(s) which originally contained heavy metal(s) or toxic element(s) as ingredient(s) in their prescriptions, the following requirements should be referred:
- (a) Established medicines category:
- The quantity of the Chinese herb which originally contained heavy metal(s) or toxic element(s) used must strictly adhere to the amount specified in the Pharmacopoeia of the People's Republic of China, etc.
  - The applicant must also ensure that the product meets the requirements for processing and production, in the course of manufacturing. For instance, the processing of Cinnabaris should be in accordance with Chinese medicines bibliography, and should be accepted by the Chinese Medicines Board.
- (b) (i) Health-preserving medicines in the non-established medicines category:
- As products in this category may be used long term, Chinese herb which originally contained heavy metal(s) or toxic element(s) should not, generally be formulated in these products.
- (ii) Single Chinese medicine granules in the non-established medicines category:

- It is recommended that no Chinese herb which originally contained heavy metal(s) or toxic element(s) should be formulated in these products.
- (c) New medicines category:
  - Comprehensive test reports under the new medicines category are required to support the product's efficacy and safety.

### Pesticide residues test report

32. Pesticide residues in pCms refer to the pesticide, its degraded substances and impurities, etc. that remain in the crude drugs. The content level of pesticide residues is measured by the concentration of the pesticide residues in the product.
33. The pesticide residues test shall be performed in accordance with the following requirements:
- (a) The applicant may choose either the finished product or individual crude drug to test for the 9 types of organochlorine pesticides(see table 4). If necessary (for instance, when the manufacturing methods of the pCm cause condensation of the remaining pesticides in the finished products), the Chinese Medicines Board may require the test to be conducted on the finished product.
  - (b) The applicant is required to submit reports on the test methods and results, and the test results must not exceed the maximum permitted level as specified in Table 4 below.

**Table 4: Maximum permitted levels of pesticide residues in the finished products or individual crude drugs of pCms**

English name of pesticide	Chinese name of pesticide	Test parameters	Maximum permitted level (mg/kg)
1) Aldrin & Dieldrin	艾氏劑 及狄氏劑	Sum of Aldrin and Dieldrin	0.05
2) Chlordane	氯丹	Sum of <i>cis</i> -chlordane, <i>trans</i> -chlordane, and oxychlordane	0.05
3) DDT	滴滴涕	Sum of <i>p,p'</i> -DDT, <i>o,p</i> -DDT, <i>p,p'</i> -DDE and <i>p,p'</i> -TDE	1.0
4) Endrin	異狄氏劑	Endrin	0.05
5) Heptachlor	七氯	Sum of Heptachlor and Heptachlor epoxide	0.05
6) Hexachlorobenzene	六氯苯	Hexachlorobenzene	0.1
7) Hexachlorocyclohexane	六六六	Sum of its isomers, except for the Lindane	0.3
8) Lindane	林丹	Lindane	0.6

9) Quintozene	五氣硝基苯	Sum of Quintozene, Pentachloroaniline and Methyl pentachloropheny sulphide	1.0
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### Microbial limit test report

34. The microbial limit test report submitted by the applicant needs to be able to prove that the microbial limit of the pCm meets the criteria set out by the Chinese Medicines Board.
35. The microbial limit test shall be performed in accordance with the following requirements:
- (a) The criteria of microbial limit for pCms cover three aspects, namely ‘total aerobic count’, ‘moulds and yeast count’ and ‘the presence of specified bacteria’. The subject product shall be assessed in respect to its dose form and will be considered pass only when it meets all the three criteria set. For the microbial limit of various dose forms of pCms, please refer to Table 5 below.
  - (b) If the ‘total aerobic count’ and ‘moulds and yeast count’ exceed the criterion set for that particular dose form in the first test, samples shall be taken randomly from the same batch to repeat the test two more times and the average value of the 3 tests will be taken to determine whether the product being examined meets the specified criterion for that particular test.
  - (c) For eye preparations, if the ‘moulds and yeast count’ exceeds the criterion set in the first test, samples need to be taken randomly from the same batch to repeat the test twice more. The product being examined passes the requirements only when no evidence of moulds and yeast growth has been found in the last 2 tests.
  - (d) If the specified bacterium for any dose form is detected in the first test, this result shall be final and no re-test is allowed, the test product shall be considered not meeting the requirement.
  - (e) Other requirements :
    - (i) For oral preparations containing animal-origins raw ingredients, *Salmonella* must not be detected. For oral preparations containing animal horn, royal jelly, bee honey and Colla Corii Asini, test for *Salmonella* is exempted.
    - (ii) For preparations containing crude drug powder used for haemostasis or on wounds, ulcers or deep tissue, *Clostridium tetani* must not be detected.
    - (iii) Moulds and yeast count: the liquid / semi-solid preparations containing no sugar, royal jelly or bee honey, and the solid preparations should be examined for moulds; liquid or semi-solid preparations containing sugar, royal jelly or bee honey should be examined both for moulds and yeast.
    - (iv) Vaginal preparations: In every 1g or 1ml of the preparation, the aerobic count should not exceed 100, the moulds and yeast count should not exceed 10, and *Staphylococcus aureus* and *Pseudomonas aeruginosa* should not be detected.

For those dose forms containing crude drug powder, *Clostridium tetani* should not be detected.

(v) Preparations found with mildew and growing acarid will be considered not meeting the requirements.

(vi) Injections should be tested for sterility.

For those dose forms not listed in the Table below, they will be considered by the Chinese Medicines Board on individual basis.

**Table 5 Microbial limits for various dose forms of pCms (Unit: per g or per ml)**

Preparation	Item 1	Item 2	Item 3 (Specified bacteria)		
	Total aerobic count	Moulds and yeast count	<u><i>Escherichia. Coli.</i></u>	<u><i>Staphylococcus aureus</i></u>	<u><i>Pseudomonas aeruginosa</i></u>
Pill					
Without crude drug powder	1000	100	--		
With crude drug powder	30000	100	--		
Powder	30000	100	--		
Used for oral and external	30000	100	--	--	--
Granule, tablet, capsule					
Without crude drug powder	1000	100	--		
With crude drug powder	10000	100	--		
Troch	10000	100	--		
Used for oral and external	10000	100	--	--	--
Concentrated decoction	100	100	--		
Glue	1000	100	--		
Syrup · mixture	100	100	--		
Dripping pill	1000	100	--		
Medicinal wine	500	100	--		
For external use	500	100	--	--	--
Tincture	100	100	--		
For external use	100	100	--	--	--
Liquid extract and extract	100	100	--		
Ointment	1000	100	--	--	--
Used for burns, ulcers or wounds	100	10	--	--	--
Medicinal distillate	100	100	--		
Medicinal tea					
Without sugar	10000	100	--		
With sugar	1000	100	--		
Liniment	100	100	--		
Suppository	10000	100	--	--	--
Used for ulcers, hemorrhages	100	10	--	--	--
Nasal drops, aerosol, spray	100	10	--	--	--
Eye drops	100	--	--	--	--

*Note: ‘ -- ‘ stands for not detecting in per g or per ml.*

### **Acute toxicity test report**

36. The objective of acute toxicity test is to provide a preliminary evaluation on the safety of the drug. Through this test, the acute toxicity reaction of the test medicine to the tested animals can be determined. The acute toxicity of test medicine is usually expressed in Median Lethal Dose (LD<sub>50</sub>) or Maximum Tolerable Dose (MTD).
37. The test report shall include the test methods, results and conclusions, etc.

### **Long-term toxicity test report**

38. The objective of long-term toxicity test is to observe the toxic reaction of the tested animals after continuous administration of the test medicine, including their first symptoms & signs and seriousness of intoxication, the development and recovery of tissue damage and organ dysfunctions after the administration is ceased, so as to provide reference for determining a safe clinical dose level.
39. The test report shall include the test methods, results and conclusions, etc.
40. Long term use of ephredra can cause unreversible damage to human body, and in general, ephredra is not recommended for long term use. If a pCm claims that it can be used for long term, the applicant must submit acute toxicity test report and long-term toxicity test report to show its safeness.

### **Local toxicity test report**

41. Local applications include those apply to skin and mucosa (e.g. ophthalmic applications, nasal drops, inhalants, buccal cavity applications, ear drops, rectal or vaginal applications, etc.) The objective of the local toxicity test is to determine any irritation and allergic reactions caused by the pCm.
42. The test report shall include the test methods, results and conclusions, etc.

### **Mutagenicity test report**

43. The objective of the mutagenicity test is to examine whether the test medicine has any possible carcinogenicity or reproductive toxicity. The basic principle of the mutagenicity test is to expose specific strains of bacteria to the test medicine, and to observe whether mutation happens.
44. The test report shall include the test methods, results and conclusions, etc.

### **Carcinogenicity test report**

45. The objective of carcinogenicity test is to determine the potential carcinogenicity or

tumorigenicity of the test medicine and its metabolites. Carcinogenicity tests are generally divided into two stages: the preliminary study and the full-scale study.

46. The test report shall include the test methods, results and conclusions, etc.

### **Reproductive and development toxicity test report**

47. The objective of the reproductive and development toxicity test is to examine whether the test medicine has toxic effects on animal's reproductivity and whether it has teratogenic effect on their offspring. A reproductive and development toxicity test is usually conducted in three stages in accordance with the three periods from before conception to ab lactation.

48. The test report shall include the test methods, results and conclusions, etc.

### **Summary report on product safety documents**

49. The objective of the summary report on product safety documents is to give an overall conclusion and a reasonable assessment on the safety of the pCm. The applicant should draw the conclusion based on the product safety documents that he/she submits.

### **(IV) Product efficacy documents**

- *The requirements for product efficacy documents vary according to the pCm's classification category and the proposed registration group being applied.*
- *For the detailed technical requirements of the following tests, please refer to the "Technical guidelines - product efficacy documents".*

### **Interpretation and principle of formulating a prescription**

50. The applicant should submit a document relating to the interpretation and principle of formulating the prescription written by professionals. The contents should include an analysis based on the theory of Chinese medicine, (e.g. the different roles of 'the principal, assistant, adjuvant and guiding drugs' in the prescription), the description on the properties and flavours, channel tropism, functions, indications, compatibility and other related information of each drug in the prescription, and the clinical application of this prescription shall be analyzed. The Chinese Medicines Board may, if necessary, require the applicant to provide proof of the professional background of the person who writes this document.
51. The general requirements on the interpretation and principle of formulating a prescription are:
- (a) **Source** : The provenance of the prescription should be clearly stated. If necessary, the Chinese Medicines Board may require the applicant to produce copies of relevant bibliography for verification. Further elaboration and interpretation may

be required if the prescription is an empirical prescription, a modified ancient prescription or a newly developed prescription.

- (b) **Ingredients** : Including name, quantity and processing method of all ingredients of the prescription.
- (c) **Usage and Dosage** : Usage and dosage of the preparation shall be specified.
- (d) **Functions and indications** : The therapeutic functions and indications of a prescription should be interrelated. Generally speaking, the indications should refer mainly to syndromes in Chinese medicine theory and be expressed in academic terminology of Chinese medicine.
- (e) **Interpretation**: An analysis and description on functions, indications of the prescription, interaction and compatibility of each ingredient should be given. Interpretation of a prescription can start with the Chinese medicine syndromes – elaboration on etiology, pathogenesis, characteristics of the syndrome, and syndrome differentiation and establishment of therapeutic principles. Then, interaction and compatibility analysis on the basis of the ‘principal, assistant, adjuvant and guiding ingredients’ in the prescription. In the description, the properties, flavours, functions, status and actions of each ingredient in the prescription should be well explained.
- (f) **Precautions (if any)** : This section should contain cautions when using the prescription, for instance: contraindications or patients for whom this prescription is not suitable.

### **Reference materials on product efficacy**

52. The applicant should provide relevant reference materials on product efficacy according to the category of pCm under application. The requirements for reference materials on product efficacy are specified below:

- (a) Established medicines category
  - For pCm that is formulated in according to an ancient prescription, a modified ancient prescription or pharmacopoeia prescription, or any other prescription from National Drug Standards of the People’s Republic of China, the applicant shall submit copies of relevant materials from Chinese medicines bibliography, Pharmacopoeia or any other National Drug Standards of the People’s Republic of China
- (b) Health-preserving medicines in the non-established medicines category
  - The claimed therapeutic functions shall be supported by research studies, or the function of which have been described in health care literatures compiled by Chinese medicines professionals.
- (c) Single Chinese medicine granules in the Non-established medicines category
  - Copies of relevant materials from Chinese medicines bibliography or Pharmacopoeia shall be submitted.
- (d) New medicines category



- Reports on product efficacy evaluation and clinical trials, etc. are necessary.

### **Principal pharmacodynamic studies report**

53. The objective of principal pharmacodynamic study of pCms is, through application of modern scientific methods e.g. to develop animal models for selected syndromes or diseases, to preliminarily verify the therapeutic effects and to determine the potency, extent of effects and properties of the pCm.
54. The report shall include the test methods, results and conclusions, etc.

### **General pharmacological studies Report**

55. The objective of general pharmacological studies is to observe and identify other pharmacological effects in addition to the principal therapeutic actions of pCms on animals. In these studies, the pharmacological effects on the animals' nervous system, cardiovascular system and respiratory system are the major areas for observation.
56. The report shall include the test methods, results and conclusions, etc.

### **Clinical trial protocol and summary report**

57. Clinical trial refers to trial with humans as test participants. Under controlled conditions, the safety and efficacy of the product are examined and assessed in a scientific manner. It is divided into Phase I, II, III and IV. Phase I study is a preliminary evaluation on the clinical pharmacological effect and safety profile of the test medicine in humans. Phase II study mainly aims to assess the test medicine's efficacy and safety, thereby to determine the clinical administration dosage. Phase III study involves multi-center studies and is essential to further evaluate the efficacy and safety of the test medicine. Phase IV study is the post-marketing surveillance of the medicine.
58. When applying for registration, the applicant shall submit the clinical trial protocol of all phases, an approval letter from the Ethics Committee, and the summary report of Phases I, II & III of the clinical trial. Within 2 years after the registration of the pCm, the applicant shall submit to the Chinese Medicines Board the Phase IV summary report.

### **Summary report on product efficacy documents**

59. The purpose of the summary report on product efficacy documents is to give an overall conclusion and a reasonable assessment of product efficacy. The applicant should draw the conclusion based on the product efficacy documents (e.g. the interpretation and principle of formulating a prescription, reference materials for product efficacy, and the clinical trial protocol and summary report) that he/she submits.

## **(V) Product quality documents**

- *The requirements for product quality documents vary according to the pCm's classification categories and the registration group being applied.*
- *For the detailed technical requirements for the following tests, please refer to the "Technical guidelines - product quality documents".*

### **Manufacturing method**

60. The applicant should submit the manufacturing method of the pCm provided by the manufacturer which should include concise manufacturing procedures based on each processing step, preparation and processing method for each raw herb, as well as the names and quantities of all excipients used. For any procedure that can affect the quality of the finished product, a related controlling method shall be specified e.g. number of hours and times required to boil the Chinese herbs. For pharmacopoeia prescription, the manufacturing method can be adopted from the Pharmacopoeia of the People's Republic of China.
61. For a pCm which contains Herba Asari, the manufacturer is recommended to use the root of the species as specified in the CMO. The manufacturing step should also be aware, the herb should be prepared by water-extraction, and extraction by organic solvent like ethanol should be avoided. It is not recommended to blend the herb directly for oral use.

### **Physicochemical properties of crude drugs**

62. If the pCm contains i) a newly-discovered Chinese herb; ii) a new medicinal part of Chinese herb; iii) an active group extracted from Chinese herb; or iv) a set of active groups extracted from compound prescription; then the applicant shall submit relevant bibliography or scientific research reports detailing the physicochemical properties of the crude drug(s) of the pCm. Physicochemical properties of crude drugs generally refer to 4 aspects: 'description', 'identification', 'inspection' and 'assay', as well as to other relevant information.
63. If the crude drug(s) of the pCm do(es) not fall into any of the four categories mentioned above, generally speaking, the applicant is only required to submit a copy of the bibliography on the physicochemical properties of each crude drug from references and specify the sources of the relating documents, for example, copy of the monograph recorded in the Pharmacopoeia of People's Republic of China containing description, identification, inspection and assay of the herb, without conducting the relevant scientific researches.

### **Product specification, method and certificate of analysis**

64. The applicant should submit the product specification issued by the manufacturer of the pCm. The product specification of pCms should include at least these 4 aspects:

‘description’, ‘identification’, ‘assay’ and ‘inspection’.

65. In addition, the applicant should submit the method of analysis and the certificate of analysis for each test of the product specification. The method of analysis should include the test condition and selection criteria. The certificate of analysis should be in conformity with the requirements specified in the product specification of pCms. For general tests for various dose forms of pCms, please refer to Table 6 below.
66. For pCm which is not eligible for transitional registration but was sold and manufactured in Hong Kong before the commencement of the pCm registration system (i.e. before 19 December 2003), the applicant can submit the chemical assay, test method and the report required in product specification upon the renewal of such registration. Nevertheless, applicant must submit the standard, test method and the report of other testing items of the product specification upon application. For pCm that is sold or manufactured after the commencement of the pCm registration system (i.e. on and after 19 December 2003), the applicant must submit a complete set of reports upon application.

### **Table 6: General tests for various dose forms of pCms**

The general tests for various dose forms of pCms are listed below. The applicant should decide other tests that are required according to the product quality (e.g. heavy metals and toxic element test, pesticide residues test, etc.). For dose forms not listed below, it is the applicant to decide on the test items and provide the basis for his/her selection for approval by the Chinese Medicines Board.

<b>Dose form</b>	<b>General tests</b>
1. Pill	Determination of water, weight variation, packing variation, disintegration test, microbial limit test
2. Powder	Uniformity, determination of water, packing variation, degree of fineness of powder, microbial limit test
3. Granule	Size of granules, determination of water, determination of dispersibility, hardness, packing variation, weight variation, microbial limit test
4. Tablet	Weight variation, disintegration test, hardness (friability), dissolution rate, microbial limit test
5. Troch	Weight variation, disintegration test, pH value, microbial limit test
6. Concentrated decoction	Relative density, insoluble materials, filling, pH value, microbial limit test
7. Glue	Filling, determination of water, total ash, microbial limit test
8. Syrup	Filling, relative density, pH value, microbial limit test
9. Cataplasm (babu plaster)	Adhesion test, test for excipient property, assay
10. Mixture	Filling, relative density, pH value, clarity of solution, microbial limit test
11. Dripping pill	Weight variation, disintegration test, determination of water, microbial limit test
12. Capsule	Determination of water, packing variation, disintegration test, microbial limit test

13. Medicinal wine	Total solids, determination of methanol, filling, microbial limit test
14. Tincture	Determination of methanol, filling, microbial limit test
15. Liquid extract	pH value, total solids, determination of ethanol, microbial limit test, filling
16. Extract	Microbial limit test, filling
17. Plaster	Weight variation, softening test, skin irritation test
18. Adhesive plaster	Assay, heatproof test, cold-proof test, tension
19. Ointment	Filling, skin irritation test, microbial limit test
20. Medicinal distillate	pH value, microbial limit test
21. Medicinal tea	Determination of water, weight variation, determination of dispersibility, hardness, microbial limit test
22. Injection	Packing variation, clarity of injection, sterility, particulate matter, pH value, pyrogen, hemolysis, irritation test
23. Suppository	Weight variation, disintegration test, pH value, microbial limit test.
24. Nasal drops	Filling, microbial limit test
25. Eye drops	Clarity of solution, particle size of suspension, filling, microbial limit test, pH value, osmotic pressure, viscosity
26. Aerosol and spray	Delivery rate, total amount of sprays, total number of deliveries per container, emitted quantity in each delivery, content of active ingredient in each delivery, particle size, spray test, filling, microbial limit test
27. Liniment	Filling, microbial limit test

### **Accelerated stability test report**

68. Accelerated stability test refers to the regular assessment on changes in product quality to establish the stability and shelf life of the product when it is kept in a specified temperature and humidity storage conditions. Depending on different property of various pCms, the shelf life deduced from this test shall not be longer than 2 years.
69. The report on this test should include relevant information on the shelf life of the pCm as proposed by the manufacturer, the test method, tests for such dose form, summary report on stability tests, etc. For suggested tests for various dose forms, please refer to Table 8 below. Accelerated stability test report may be exempted if a real-time stability test report has been submitted.

### **Real-time stability test report**

70. Real-time stability test refers to the regular assessment on changes in product quality to determine the stability and shelf life of the product when it in its sales packaging kept in ambient conditions. The applicant should conduct different tests according to different dose forms.
71. The report on this test should include relevant information on the shelf life of the pCm as proposed by the manufacturer, the test method, tests for such dose form, summary report on stability tests, etc. For suggested tests for various common dose forms, please refer to Table 7 below.

**Table 7: Stability tests-suggested tests for various common dose forms**

<b>Dose Form</b>	<b>Tests</b>
1. Injection	Description, identification, clarity of injection, pH value, sterility, pyrogen, hemolysis, irritation test, assay
2. Mixture	Description, identification, clarity of solution, relative density, pH value, assay, microbial limit test
3. Syrup	Description, identification, relative density, pH value, assay, microbial limit test
4. Medicinal wine	Description, identification, determination of ethanol, total solids, assay, microbial limit test
5. Pill	Description, identification, disintegration test, determination of water, assay, microbial limit test
6. Powder	Description, identification, uniformity, determination of water, degree of fineness of powder, assay, microbial limit test
7. Concentrated decoction	Description (crystallization, forming layers), identification, relative density, dissolution test, pH value, assay, microbial limit test
8. Capsule, dripping pill	Description, identification, determination of water, disintegration test, assay, microbial limit test
9. Tablet	Description, identification, hardness, disintegration test, assay, microbial limit test
10. Liquid Extract	Description, identification, pH value, determination of ethanol, total solids, assay, microbial limit test
11. Extract	Description, identification, assay, microbial limit test
12. Emulsion	Description, identification, assay, microbial limit test
13. Granule	Description, identification, determination of water, size of granules, assay, microbial limit test
14. Suspension	Description, identification, assay, microbial limit test
15. Ointment	Description, identification, assay, microbial limit test, skin irritation test
16. Plaster	Description, identification, softening point, assay, skin irritation test
17. Adhesive plaster	Description, identification, tension, assay, skin irritation test, cold-proof test, heatproof test
18. Glue	Description, determination of water, identification, assay, microbial limit test
19. Suppository, troch	Description, identification, disintegration test, pH value, assay, microbial limit test
20. Aerosol	Description, identification, spraying efficacy, odour, irritation test, assay, microbial limit test
21. Medicinal membrane	Description, dissolution test, irritation test, pH value, assay, microbial limit test
22. Other dose forms	Test items to be selected depending on the specific features of the dose form of the pCm

### **General stability test report**

72. For all pCms of Established medicines and Non-established medicines categories that are manufactured or sold in Hong Kong before 30 June 2004, their applicants may conduct stability assessment on the retained samples according to the local sales history and the claimed shelf life of the pCm. The proposed shelf life of the pCm should not be longer than 4 years.

73. Stability assessment on retained samples means regular assessment on the pCm to

provide a basis for determining the shelf life when it is in its sales packaging kept under room temperature or proposed storage conditions. The applicant should conduct the assessments according to the proposed shelf life and the specified assessment schedule.

74. The report on this test should include relevant information on the shelf life of the pCm as proposed by the manufacturer, the test method, tests for such dose form, summary report on stability tests, etc. For suggested tests for the various common dose forms, please refer to Table 7 on page 37. For specified schedule of assessment and tests on retained samples, please refer to the “technical guidelines - product quality documents”.
75. In consideration of the financial burden on traders, the Chinese Medicines Board has given a longer time for traders to submit the general stability test reports of all the 3 batches of product. For details of the requirements and arrangement, please refer to note 14 on page 18 of this Handbook, or refer to “Technical guideline- product quality documents”.
76. The applicant must submit test reports to the Chinese Medicines Board for approval within the prescribed timeframe. If the quality of any product fails to meet the required standard before the expiry of the observation period, the Chinese Medicines Board may require the manufacturer to revise the claimed shelf life and the assessment schedule accordingly.

#### **(VI) Requirements for test laboratories**

77. Laboratories conducting the product safety tests, product quality tests, principal pharmacodynamic tests and general pharmacological tests for pCms must have met the requirements set by the International Standardization Organization (i.e. ISO/IEC 17025), Good Laboratory Practice (GLP), or any other laboratories which are accepted by the Chinese Medicines Board. Other municipal Institutes for Drug Control in China that are recognized both by the State Food & Drug Administration (SFDA) and the Chinese Medicines Board will also be accepted.
78. If the laboratory has been granted ISO/IEC 17025 accreditation of the three basic tests, namely:
  1. Heavy metals and toxic element test;
  2. Pesticide residues test; and
  3. Microbial limit test,the Chinese Medicines Board will also accept crude drugs test report, certificates of analysis and stability test reports issued by this laboratory.

79. For the laboratory which carries out stability test, the stability test of at least the first batch of product should be conducted in the test laboratory that has met the requirements as specified in paragraph 78 above. The stability tests for the remaining batch(es) can be conducted by the manufacturer of the product or the test laboratory that have met the requirements as specified in paragraph 78 above, and that manufacturer should have met the requirements of Good Manufacturing Practice in respect of the manufacturing and quality control of pCm (GMP). Nevertheless, the Chinese Medicine Board emphasizes there are differences between the accreditation requirements for GMP and ISO/IEC 17025 or GLP. Therefore she does not recognize that the accreditation of GMP is equivalent to ISO/IEC 17025 or GLP. The current arrangement is only made in consideration of the burden on traders and infrastructure at present.
80. Centres conducting the clinical trials for pCms must have met the requirements of “Good Clinical Practice for proprietary Chinese medicines” or other equivalent standards. Other clinical trial centers in China that are recognised both by the SFDA and the Chinese Medicines Board will also be accepted.

## Chapter 6 Other Requirements

### (I) Other legal requirements

1. In addition to the requirements as stipulated in the CMO, the applicant should also comply with the provisions of other relevant ordinances when applying for registration of a pCm. The relevant legal requirements are:
  - (a) Undesirable Medical Advertisements Ordinance (Cap.231): relevant sections on regulating the names, claims and labels of medicinal products;
  - (b) Trade Marks Ordinance (Cap. 559): relevant sections on regulating the use of registered trade marks;
  - (c) Trade Descriptions Ordinance (Cap. 362): relevant sections on prohibition of false description, false signs and/or fraudulent statements of products;
  - (d) Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586): relevant sections on restrictions on the import, export and possession of endangered species of plants & animals;
  - (e) Pharmacy and Poisons Ordinance (Cap.138): relevant sections on supervising and regulating the registration and sale of pharmaceutical products (include products which containing both Chinese herbs and western medicines).
  - (f) Public Health and Municipal Services Ordinance (Cap.132): relevant sections on regulating whether a product is suitable for human consumption;
  - (g) Import and Export (General) Ordinance (Cap. 60): relevant sections on regulating and controlling the import and export of pCms and Chinese herbal medicines into and out of Hong Kong.

Printed versions of this legislation can be purchased by calling the Publications Sales section of Information Services Department at 2537 1910 or downloaded from the internet (Website: <http://www.legislation.gov.hk> ).

### (II) Declaration

2. The applicant must declare in the Application Form that:
  - (a) The pCm under application meets the requirements of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586); and
  - (b) The pCm is not adulterated with western medicine; and
  - (c) All the information provided in the Application Form is true and correct.

### (III) Naming of pCms

3. The Chinese Medicines Board has compiled principles for naming pCms. When applying for registration of pCms, the applicant must ensure that the name of the pCm is in line with the principles, or the Chinese Medicines Board may require the applicant to change the name of the product.
4. No matter whether the prescriptions of the product are the same or not, different products



should have different product names for registration.

5. Some manufacturers produce various products with different prescriptions but the same product name for overseas market. In order to protect traders' right and reserve the speciality of the name of registered pCm, applicants should suffix number(s) or word(s) to the product name making it forms a part of the product name to identify among products with different prescriptions.
6. In processing the application for registration of pCms, the Chinese Medicines Board will append the "text trade mark" (if any) used by the applicant and the "name of company" of the applicant to the "product name" to form the "name of the registered pCm", which will be in a format as shown below:  

**【Text trade mark (if any) + product name + name of company】**
7. However, the applicants are not required to display the "name of the registered pCm" in order as shown on the outer or inner package of the pCm.
8. Once the pCm has been registered, the "product name" will become one of the registered particulars of the registered pCm. Any change to the product name will require a new application for the registration of such pCm.

### **Naming principles of pCms**

9. The name of pCms must not contravene the Undesirable Medical Advertisements Ordinance (Cap. 231).
10. The "product name" shall include the dose form of the product. If the dose form is not included in the "product name", it can be displayed independently on the outer package.
11. The "product name" should not be named using both Chinese medicine & Western medicine theory, and should not be misleading or exaggerated in any way.
12. For compound prescription preparations that are not of pharmacopoeia prescription or ancient prescription, if the product's proposed name is by combining the name of a single Chinese herb with the dose form, the word "*Fufong*", "Compound" or any other wordings with the same meaning must be prefixed to the name of the Chinese herb to avoid any possible confusion with a single herb preparation. In addition, the single herb by which the product is named must be the principal medicine, or the medicine with principal pharmacodynamic functions.

### **Protection of trade mark**

13. The registration of pCm under the CMO does not infer that the “name of the registered pCm” enjoys trade mark protection under the Trade Marks Ordinance. Therefore, the applicant may consider registering the trade mark, or name of product, under the Trade Marks Ordinance to protect his/her own rights and to prevent the trade mark or name of such product from being used by others.
  
14. The owner of the trade mark and/or the product name that have/has been registered under the Trade Marks Ordinance will have priority in the use of such trade mark/product name, when applying for registration of the pCm.

## **Chapter 7 Other Applications Relating to Registration of pCms**

1. The following summarizes other stipulations in the CMO relating to registration of pCms. The applicant may refer to the CMO, and other relevant documents compiled by the Chinese Medicines Board for further details.

### **(I) Duration and renewal of registration**

2. For pCms registered under section 121 of the CMO, the certificate of registration is valid for 5 years. The holder of a certificate of registration will receive a notice for renewal before the expiry of the certificate, and may apply to the Chinese Medicines Board for the renewal of registration. Upon receipt of the application for renewal, the Chinese Medicines Board will assess the application and determine whether to approve or refuse such application.
3. If an applicant decides not to renew the registration of a pCm, he/she must notify the Department of Health in writing as soon as possible, and shall notify the wholesalers/retailers concerned to recall the pCm from the market before the expiry of the valid registration period.

### **(II) Variation of registered particulars of registered pCms**

4. According to section 124 of the CMO, the holder of a certificate of registration may, on payment of a prescribed fee, apply in writing to the Chinese Medicines Board for approval to vary the registration particulars of the pCm to which the certificate relates. If the Chinese Medicines Board is satisfied that the proposed variation will not adversely affect the safety, quality and efficacy of the relevant pCm, it may approve the variation as proposed in the application.
5. However, the product name, the dose form and the name and quantity of any active ingredient shall not be varied. Any variation in any of these three particulars will require a new application for registration of the pCm.

### **(III) Certified copy of certificate of registration**

6. According to section 127 of the CMO, the Chinese Medicines Board may, upon application and payment of a prescribed fee by the holder of a certificate of registration, issue a certified copy of that certificate of registration to the certificate holder.

### **(IV) Certificate for clinical trials and medicinal tests**

7. According to section 129 of the CMO, for the purpose of facilitating the conduct of a clinical trial or medicinal test of any pCm in Hong Kong, the Chinese Medicines Board may, upon application and payment of a prescribed fee, issue a certificate for clinical trial and medicinal test.

### **(V) Certificate of sale of pCms**

8. According to section 130 of the CMO, for the purpose of exporting a pCm which has been registered in Hong Kong, a licenced manufacturer may apply to the Chinese Medicines Board for issue of a certificate certifying that the pCm is allowed to be sold in Hong Kong. The Chinese Medicines Board may issue the certificate upon payment of prescribed fee.

## **Chapter 8 Personal Data**

### **(I) The purpose of collecting personal data**

1. The personal data provided by applicants to the Chinese Medicines Board are used for the purpose of implementing the provisions of the CMO.
2. The provision of personal data is on a voluntary basis. However, if an applicant fails to provide sufficient personal data, the Chinese Medicines Board shall be unable to process the application for registration of the pCm.

### **(II) Transfer of personal data**

3. The personal data provided by applicants are mainly for use within the Department of Health and the Council. However, for the purpose of implementing the provisions of the CMO, such data may also be disclosed to other Government bureaux/departments, agencies or authorities.
4. Apart from these, such personal data will only be disclosed where the applicants, their representatives (e.g. attorney) have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

### **(III) Access to and correction of personal data**

5. Applicants have the right of access and correction with respect to personal data as provided for under sections 18 & 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. A fee may be imposed for complying with a data access request. Should there be any amendment to the personal data or other information submitted, he/she should notify the Chinese Medicines Section of the Department of Health in writing, by post or by fax, as soon as possible.

Address: 2/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Shek Kip Mei, Kowloon

Fax Number: 2319 2664

## **Chapter 9 Important Notes and Enquiries**

### **(I) Violation of the relevant provisions of the CMO**

1. According to section 155 of the CMO, any person who found guilty of an offence under this Ordinance, including selling, import or having in his possession any unregistered pCms, shall be liable to a fine at level 6 and to imprisonment for 2 years.

### **(II) Provision of information**

2. According to section 153(1) & (2) of the CMO, for the purposes of determining an application for a certificate or renewal of the same under this Ordinance, the Chinese Medicines Board may serve on the applicant a notice requiring him to furnish to it such information relating to the application and within such time as may be specified in the notice. Where the applicant fails to furnish the information, the Chinese Medicines Board may decline to process the application further or reject the application.

### **(III) Consequences of providing false information**

3. According to section 153(3) of the CMO, no person who, in making an application to the Chinese Medicines Board or in giving any information which he is required to give under this Ordinance, shall make a statement or representations which he knows to be false or does not believe to be true in a material particular. Any person who violates the aforesaid provisions commits an offence and shall be liable to a fine at level 6 and to imprisonment for 2 years.
4. It is a criminal offence for an applicant to provide false or fraudulent information when applying to the Chinese Medicines Board for registration of pCms, and the case will be referred to relevant authorities for further investigation. Upon conviction, the Chinese Medicines Board may cancel the application for registration or revoke the certificate of registration of the pCm. All fees paid will not be refunded.

### **(IV) Review of decisions and right of appeal**

5. According to section 140 of the CMO, any person aggrieved by the decision of the Chinese Medicines Committee regarding registration of pCm may request the Chinese Medicines Board to review the decision. A request for review shall state in writing the reasons relied upon and shall be made to the Chinese Medicines Board within 14 days after the receipt of the notification of decision. Upon receipt of the written request for review, the Chinese Medicines Board shall review the decision and shall serve a notice of its decision together with the reasons for its decision on the person concerned. In reviewing a decision, the Chinese Medicines Board may invite the person concerned to give representations in writing or in person.

6. According to section 141 of the CMO, a person aggrieved by the decision of the Chinese Medicines Board regarding registration of pCm may appeal to the Court of First Instance within 1 month from the date of service of the notice. The Court of First Instance may affirm, reverse or vary the decision appealed against. The decision of the Court of First Instance shall be final.

#### **(V) Disclosure of confidential information obtained officially**

7. According to section 154(1) of the CMO, no public officer or member of the Council, Boards or Committees shall, except in the circumstances set out below, disclose or give to another person any information that concerns a trade, business or manufacturing secret which has come to his knowledge or into his possession in the course of the discharge of his functions under this Ordinance, other than:
  - (a) to discharge his functions under this Ordinance; or
  - (b) under an order of the court as prescribed in section 154(3) of the CMO; or
  - (c) with the consent in writing of all persons who appear to him, after reasonable inquiry, to be interested in the confidentiality of the information.

#### **(VI) Penalty for bribing officers**

8. According to the Prevention of Bribery Ordinance (Cap. 201), it is a criminal offence for any person who offers any advantage (such as money or gifts) to a public servant as an inducement to, or reward for, or otherwise on account of avoiding proper assessment on the application. Upon conviction, he/she may be liable to a fine of HK \$ 500,000 and to imprisonment for 7 years.

#### **(VII) Fees not repayable**

9. According to section 160 of the CMO, no refund shall be made to any person, or institution, of any prescribed fee, or any part of any prescribed fee paid under this Ordinance.

#### **(VIII) Enquiries**

10. Should the applicant need any further information regarding the registration of pCms, or in relation to this Handbook, please contact the Chinese Medicines Section of the Department of Health by telephone, fax or post:

Enquiry hotline : 2574 9999

Fax Number : 2319 2664

Address : 2/F, Public Health Laboratory Center, 382 Nam Cheong Street,  
Shek Kip Mei, Kowloon.

## Appendix I      Fees for registration of pCms

According to the Chinese Medicine (Fees) Regulation, the prescribed fees related to the registration of pCms are listed below:

Item	Fee (HK \$ )
Application for the registration of a pCm (with single active ingredient/herb)	500
Application for the registration of a pCm (with multiple active ingredients/herbs)	1,000
Issue of a certificate of registration of a pCm (with single active ingredient/herb)	500
Issue of a certificate of registration of a pCm (with multiple active ingredients/herbs)	1,000
Application for a certificate for clinical trial & medicinal test	2,440
Issue of a certificate for clinical trial and medicinal test	79
Renewal of the registration and issue of a certificate of registration of a pCm	1,170
Application for variation of registered particulars of a registered pCm	1,790
Change of the address of the holder of the certificate of registration of a pCm	155
Issue of a certificate of sale of a pCm	270
Issue of a certified copy of a certificate of registration	130

Note: The fees listed above are for reference only. Applicants should refer to the Chinese Medicine (Fees) Regulation for the latest fees charged.



## Appendix II

## Banned Aristolochia Linn.

Herb Name (Chinese)	Plant name (Chinese)	Medicinal part	Latin Name
大葉青木香	川南馬兜鈴	Rhizome	<i>Aristolochia austroszechuanica</i> Chien et C. Y. Cheng
滇南馬兜鈴	滇南馬兜鈴	Root	<i>Aristolochia austroyunnanensis</i> S. M. Hwang
南木香	青香藤	Root, rhizome, stem	<i>Aristolochia calcicola</i> C. Y. Wu
管南香	管蘭香	Rhizome	<i>Aristolochia cathcartii</i> Hook. f.
三筒管	長葉馬兜鈴	Rhizome	<i>Aristolochia championii</i> Merr. et Chun [ <i>A. longifolia</i> Champ. ex Benth.]
苞葉馬兜鈴	苞葉包兜鈴	Root	<i>Aristolochia chlamydophylla</i> C. Y. Wu ex S. M. Hwang
朱砂蓮	四川朱砂蓮	Rhizome	<i>Aristolochia cinnabarina</i> C. Y. Cheng et J. L. Wu
馬兜鈴	北馬兜鈴	Fruit	<i>Aristolochia contorta</i> Bunge
	馬兜鈴	Fruit	<i>Aristolochia debilis</i> Sieb. et Zucc.
天仙藤	北馬兜鈴	Aerial part (stem and leaf)	<i>Aristolochia contorta</i> Bunge
	馬兜鈴	Stem and leaf	<i>Aristolochia debilis</i> Sieb. et Zucc.
青木香	北馬兜鈴	Root	<i>Aristolochia contorta</i> Bunge
	馬兜鈴	Root	<i>Aristolochia debilis</i> Sieb. et Zucc.
葫蘆葉馬兜鈴	葫蘆葉馬兜鈴	Root	<i>Aristolochia cucurbitoides</i> C. F. Liang
廣防己	廣防己	Root	<i>Aristolochia fangchi</i> Y. C. Wu ex L. D. Chow et S. M. Hwang [ <i>Aristolochia westlandii</i> auct. non Hemsl.]
通城虎	通城虎	Whole plant or the root	<i>Aristolochia fordiana</i> Hemsl.
海南馬兜鈴	海南馬兜鈴	Leaf, root	<i>Aristolochia hainanensis</i> Merr.
漢中防己	異葉馬兜鈴	Root	<i>Aristolochia heterophylla</i> Hemsl. [ <i>A. kaempferi</i> Willd. f. <i>heterophylla</i> (Hemsl.) S. M. Hwang]
藤香	窄葉馬兜鈴	Rhizome and root	<i>Aristolochia heterophylla</i> Hemsl. var. <i>linearifolia</i> S. M. Hwang
南粵馬兜鈴	南粵馬兜鈴	Rhizome	<i>Aristolochia howii</i> Merr. Et Chun
凹脉馬兜鈴	凹脉馬兜鈴	Whole plant	<i>Aristolochia impresinervis</i> C. F. Liang
淮通	大葉馬兜鈴	Root, stem, fruit	<i>Aristolochia kaempferi</i> Willd. [ <i>A. mollis</i> Dunn; <i>A. shimadai</i> Hayata]
背蛇生	川西馬兜鈴	Root, stem	<i>Aristolochia kaempferi</i> Willd. f. <i>thibetica</i> (Franch.) S. M. Hwang [ <i>A. feddei</i> Levl.]
管南香	廣西馬兜鈴	Rhizome	<i>Aristolochia kwangsiensis</i> Chun et How ex C. F. Liang
關木通	木通馬兜鈴	Stem	<i>Aristolochia manshuriensis</i> Kom. [ <i>Hocquartia manshuriensis</i> (Kom.) Nakai]
尋骨風	尋骨風	Whole plant or the root	<i>Aristolochia mollissima</i> Hance
淮通	寶興馬兜鈴	Root, stem	<i>Aristolochia moupinensis</i> Franch.
革葉馬兜鈴	革葉馬兜鈴	Rhizome	<i>Aristolochia scytophylla</i> S. M. Hwang et D. Y. Chen
假大薯	耳葉馬兜鈴	Root	<i>Aristolochia tagala</i> Champ.
蝴蝶暗消	粉質花馬兜鈴	Root	<i>Aristolochia transecta</i> (Chatt.) C. Y. Wu [ <i>Isotrema transecta</i> Chatt.]
白朱砂蓮	廣西朱砂蓮	Rhizome	<i>Aristolochia tuberosa</i> C. F. Liang et S. M. Hwang [ <i>Aristolochia kaempferi</i> auct. non Willd.]
逼血雷	管花馬兜鈴	Root, fruit	<i>Aristolochia tubiflora</i> Dunn [ <i>Aristolochia gentilis</i> auct. non Franch.]
白金果攬	變色馬兜鈴	Rhizome	<i>Aristolochia versicolor</i> S. M. Hwang [ <i>A. westlandii</i> auct. non Hemsl.]
小南木香	雲南馬兜鈴	Root, stem	<i>Aristolochia yunnanensis</i> Franch. [ <i>Aristolochia westlandii</i> auct. non Hemsl. ; <i>Aristolochia kaempferi</i> auct. non Willd.]

Note: The list above will be updated when necessary, please refer to the homepage of the Chinese Medicine Council of Hong

Kong for the most updated list. (Website: [www.cmchk.org.hk](http://www.cmchk.org.hk))

## Appendix III Asarum Linn.

Herb name (Chinese)	Plant name (Chinese)	Medicinal part	Latin name
土細辛	短尾細辛	Whole plant or the rhizome	Asarum caudigerellum C. Y. Cheng et C. S. Yang
	尾花細辛	Whole plant or the root	Asarum caudigerum Hance [A. leptophyllum Hayata]
	花葉尾花細辛	Whole plant	Asarum caudigerum Hance var. cardiophyllum (Franch.) C. Y. Cheng et C. S. Yang
	雙葉細辛	Whole plant	Asarum caulescens Maxim.
	川北細辛	Whole plant and the root	Asarum chinense Franch. [A. fargesii Franch.]
	皺花細辛	Whole plant	Asarum crispulatum C.Y. Cheng et C.S. Yang
	川滇細辛	Whole plant	Asarum delavayi Franch.
	福建細辛	Whole plant	Asarum fukiense C. Y. Cheng et C. S. Yang
	地花細辛	Root	Asarum geophilum Hemsl.
	單葉細辛	Whole plant	Asarum himalaicum Hook. f. et Thoms. ex Klotzsch.
	小葉馬蹄香	Whole plant	Asarum ichangense C. Y. Cheng et C. S. Yang
	大花細辛	Whole plant and the root	Asarum macranthum Hook. f.
	五嶺細辛	Root	Asarum wulingense C. F. Liang
	南川細辛	Whole plant	Asarum nanchuanense C.S. Yang et J.L. Wu
	紫背細辛	Whole plant	Asarum porphyronotum C.Y. Cheng et C.S. Yang
深綠細辛	Whole plant	Asarum porphyronotum C.Y. Cheng et C.S. Yang var. atrovirens C.Y. Cheng et C.S. Yang	
大細辛	大葉馬蹄香	Root	Asarum maximum Hemsl.
	祁陽細辛	Whole plant	Asarum magnificum Tsiang ex C. Y. Cheng et C. S. Yang
雜細辛	銅錢細辛	Whole plant	Asarum debile Franch.
杜衡	杜衡	Whole plant	Asarum forbesii Maxim.
細辛	北細辛	Whole plant	Asarum heterotropoides Fr. Schmidt var. mandshuricum (Maxim.) Kitag.
	細辛(華細辛)	Whole plant with root	Asarum sieboldii Miq.
	漢城細辛	Whole plant	Asarum sieboldii Miq. f. seoulense(Nakai) C.Y. Cheng et C.S. Yang [Asiasarum heterotropoides Fr. Schmidt var. seoulense (Nakai) Maekawa]
金耳環	金耳環	Whole plant	Asarum insigne Diels [A. longipedunculatum O. C. Schmidt.; A. gracilipes C. S. Yang et C. F. Liang]
	長莖金耳環	Whole plant	Asarum longerhizomatosum C. F. Liang et C. S. Yang
土金耳環	紅金耳環	Whole plant	Asarum petelotii O. C. Schmidt
	慈菇葉細辛	Whole plant	Asarum sagittarioides C. F. Liang [A. thunbergii auct. non A. Br.]
烏金草	長毛細辛	Whole plant and root	Asarum pulchellum Hemsl.
花臉細辛	青城細辛	Whole plant	Asarum splendens (Maekawa) C. Y. Cheng et C. S. Yang [Asarum chingchengense C. Y. Cheng et C. S. Yang; Asarum maximum auct. non Hemsl.; Asarum blumei auct. non Duch.]
台東細辛	大屯細辛	Root, rhizome	Asarum taitonense Hayata

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## Appendix IV Flow Chart for Application for Registration of proprietary Chinese medicine (pCm)

