

**【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: <https://www.elegislation.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).

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: <https://www.elegislation.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.

Appendix II Banned Aristolochia Linn.

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 transsecta</i> (Chatt.) C. Y. Wu [<i>Isotrema transsecta</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.]
白金果欖	變色馬兜鈴	Rhizome	<i>Aristolochia versicolor</i> S. M. Hwang [A. <i>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)

Appendix III Asarum Linn.

土細辛	短尾細辛	Whole plant or the rhizome	<i>Asarum caudigerellum</i> C. Y. Cheng et C. S. Yang
	尾花細辛	Whole plant or the root	<i>Asarum caudigerum</i> Hance [<i>A. leptophyllum</i> Hayata]
	花葉尾花細辛	Whole plant	<i>Asarum caudigerum</i> Hance var. <i>cardiophyllum</i> (Franch.) C. Y. Cheng et C. S. Yang
	雙葉細辛	Whole plant	<i>Asarum caulescens</i> Maxim.
	川北細辛	Whole plant and the root	<i>Asarum chinense</i> Franch. [<i>A. fargesii</i> Franch.]
	皺花細辛	Whole plant	<i>Asarum crispulatum</i> C.Y. Cheng et C.S. Yang
	川滇細辛	Whole plant	<i>Asarum delavayi</i> Franch.
	福建細辛	Whole plant	<i>Asarum fukienense</i> C. Y. Cheng et C. S. Yang
	地花細辛	Root	<i>Asarum geophilum</i> Hemsl.
	單葉細辛	Whole plant	<i>Asarum himalaicum</i> Hook. f. et Thoms. ex Klotzsch.
	小葉馬蹄香	Whole plant	<i>Asarum ichangense</i> C. Y. Cheng et C. S. Yang
	大花細辛	Whole plant and the root	<i>Asarum macranthum</i> Hook. f.
	五嶺細辛	Root	<i>Asarum wulingense</i> C. F. Liang
	南川細辛	Whole plant	<i>Asarum nanchuanense</i> C.S. Yang et J.L. Wu
	紫背細辛	Whole plant	<i>Asarum porphyronotum</i> C.Y. Cheng et C.S. Yang
深綠細辛	Whole plant	<i>Asarum porphyronotum</i> C.Y. Cheng et C.S. Yang var. <i>atrovirens</i> C.Y. Cheng et C.S. Yang	
大細辛	大葉馬蹄香	Root	<i>Asarum maximum</i> Hemsl.
	祁陽細辛	Whole plant	<i>Asarum magnificum</i> Tsiang ex C. Y. Cheng et C. S. Yang
雜細辛	銅錢細辛	Whole plant	<i>Asarum debile</i> Franch.
杜衡	杜衡	Whole plant	<i>Asarum forbesii</i> Maxim.
細辛	北細辛	Whole plant	<i>Asarum heterotropoides</i> Fr. Schmidt var. <i>mandshuricum</i> (Maxim.) Kitag.
	細辛(華細辛)	Whole plant with root	<i>Asarum sieboldii</i> Miq.
	漢城細辛	Whole plant	<i>Asarum sieboldii</i> Miq. f. <i>seoulense</i> (Nakai) C.Y. Cheng et C.S. Yang [<i>Asiasarum heterotropoides</i> Fr. Schmidt var. <i>seoulense</i> (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

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)

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

