

**Chinese Medicine Ordinance
(Cap.549)**

**Guide for Completion of Application Form for
Registration of Proprietary Chinese Medicines**

Chinese Medicine Council of Hong Kong

Guide for Completion of Application Form for Registration of Proprietary Chinese Medicines

The purpose of this “Guide for Completion of Application Form for the Registration of Proprietary Chinese Medicines” (hereafter called the Guide) is to provide guidance notes for those who wish to apply for registration of proprietary Chinese medicines (pCms).

This Guide is not a legal document, and is not inclusive of all the requirements for registration of pCms. For details of application procedures and requirements, please refer to “The Application Handbook for Registration of Proprietary Chinese Medicines” (hereafter called the Handbook).

For the legislation regarding the registration of pCms, the Chinese Medicine Ordinance and its subsidiary legislation including the Chinese Medicines Regulation, Chinese Medicine (Fees) Regulation and the Chinese Medicines Traders (Regulatory) Regulation shall prevail. Printed copies of these legislations can be purchased by calling the Publications Sales Unit of Information Services Department at 2537 1910 or downloaded from the internet (website: <https://www.elegislation.gov.hk>).

How to use this Guide

- ◆ Please read the contents of the Handbook as well as this Guide in details before completing the “Application Form for Registration of Proprietary Chinese Medicines” (hereafter called the Application Form).
- ◆ The section “Important notes” in this Guide lists those matters, which the applicant needs to pay attention to when completing the Application Form and submitting the application.
- ◆ The applicant should follow the guidance notes on pages 7 to 13 when completing the Application Form. In addition, there is an “Application Form for Registration of Proprietary Chinese Medicines (sample)” on pages 4 to 6. Applicants can refer to the sample as a reference when completing their own application(s).
- ◆ When submitting an application, the applicant should submit the required documents and the relevant checklist together with the Application Form. Submission of this Guide is not necessary.

Relevant checklist to be submitted

The Chinese Medicines Board has prepared 3 different checklists to assist applicants to submit the appropriate documents as required:

- Checklist (1): applicable for Group I registration;
- Checklist (2): applicable for Group II registration;
- Checklist (3): applicable for Group III registration;

Enquiries

For any further information regarding this Guide, please contact the Chinese Medicine Regulatory Office of the Department of Health.

Enquiry Hotline: 3904 9130

Important notes

1. Please fill in the Application Form with a black fountain pen or ballpen.
2. Please fill in the Application Form in Chinese (traditional or simplified form) or/and English in print form.
3. The applicant should complete all items on the Application Form and must provide true and correct information, as required.
4. If the applicant fails to provide the required information, or the application fails to meet the eligibility requirements, the application will not be considered.
5. If there is insufficient space on the Application Form, separate sheet(s) should be used and stated at the relevant part of the Application Form. The applicant should sign on each additional page, number the page(s), and attach the page(s) to the Application Form.
6. The applicant should keep a photocopy of the completed Application Form for reference.
7. The Application Form and checklists may be photocopied or downloaded from the homepage of the Chinese Medicine Council of Hong Kong (website: www.cmchk.org.hk) in case of insufficiency for use.

Requirements for application

8. All applications for registration of pCm are to be made by the local manufacturer, importer or local representative/agent of the non-local manufacturer (described as 'the applicant' in brief).

Submission of application

9. The applicant should submit the completed Application Form, the appropriate checklist, the application fee together with other required documents to the Chinese Medicine Regulatory Office of the Department of Health by hand, or by registered post.

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

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

Or by e-Form submission (applicable to holders of recognised organisational digital certificates only).

Website: <https://eform.cefs.gov.hk/form/dh0054/en/>

10. The Chinese Medicine Regulatory Office will issue a General Demand Note to the applicant, applicant can make payment according to the payment methods stated in the General Demand Note.

11. For details on the prescribed fees related to the registration of pCm, please refer to Appendix I of this Handbook.
12. No refund will be made, irrespective of whether the application is approved or not.
13. If the applicant submits the application by registered post, the date of the post stamp will be taken as the submission date.

Issue of confirmation receipt

14. Upon receipt of the application for registration, the Chinese Medicine Regulatory Office of the Department of Health will carry out a preliminary screening on the documents submitted. If the documents submitted are complete, the applicant will, within a short period of time, receive a confirmation receipt confirming that the application is being processed. The confirmation receipt will include the reference number allocated to that application.

Application processing time

15. According to the trial arrangement for the “Tiered and Streamlined Assessment and Approval Mechanism for application for registration of proprietary Chinese Medicines” (Tiered and Streamlined Mechanism), applications for registration of pCm are classified into four tiers, namely “Urgent Public Health Demand”, “Innovative Drug”, “Designated Priority Product” and “Non-Designated Product”, with their respective target processing time as listed below:

pCm Tier	Target Processing Time¹
Urgent Public Health Demand ²	30 working days or less
Innovative Drug ²	120 working days or less
Designated Priority Product	150 working days or less
Non-Designated Product	Not Applicable

Note¹: Processing time includes assessment and administrative time by the Department of Health, excluding the time taken by the applicant to prepare documents and the approval time by the Chinese Medicines Committee. The "timer" and assessment pause when the Department of Health requests supplementary documents from the applicant, and resume upon receipt of compliant documents or upon expiry of the submission deadline.

Note²: If an applicant intends to seek registration under the “Urgent Public Health Demand” or “Innovative Drug” category for their pCm, they must submit a written application together with supporting documents proving that the product fulfills the categories’ requirements, for consideration by the Chinese Medicines Committee.

For details of the Tiered and Streamlined Mechanism, please visit the website of the Chinese Medicine Council of Hong Kong (website: www.cmchk.org.hk).

Application result

16. Having assessed and verified that the pCm under application meets the requirements for registration, upon payment of a prescribed issue fee, the Chinese Medicines Board will issue the “Certificate of Registration of a Proprietary Chinese Medicine” to the applicant, and the pCm becomes registered. The applicant can collect the certificate at the Chinese Medicine Regulatory Office of the Department of Health during office hours.

Application Form for Registration of Proprietary Chinese Medicines (Sample-Page 2)

When completing the Application Form, the applicant can refer to pages 7 to 13 of the relevant paragraphs in the "Guide for Completion of Application Form for Registration of Proprietary Chinese Medicines" according to the section numbers in the boxes in the left margin.

28 30	商標文字 (如有) Trade mark text (if any) 中文 (Chinese): 安定牌 英文 (English): AN DING BRAND 此商標是否已根據《商標條例》註冊* <input type="checkbox"/>是 Yes <input checked="" type="checkbox"/>否 No Whether the trade mark has been registered under the Trade Marks Ordinance*: 如是, 請註明其商標註冊編號 If yes, please fill in the registration number of the trade mark: _____	
31 32	該中成藥的製造商名稱及地址 Name(s) & address(es) of manufacturer(s) of the pCm: 中文 (Chinese): 人民健康製藥廠、廣州市中央路25號 英文 (English): PEOPLE'S HEALTH PHARMACEUTICAL CO. LTD. No. 25, ZHONG YANG ROAD, GUANGZHOU, CHINA	
33 41	劑型形式 (請參照指引填寫) Dose form (please refer to the Guide): 丸劑	給藥途徑* Route of administration* <input checked="" type="checkbox"/> 內服 For internal use <input type="checkbox"/> 外用 For external use <input type="checkbox"/> 其他 (請註明) Other (please specify): _____
		包裝規格說明 每丸9克 Packing specification: 1) 每盒10丸 2) 每盒1丸
42 45	主治用途 Indications: 因血虛氣滯所引起的脇痛、 痛經和月經不調	功能 Functions: 疏肝理氣、養血行血 健脾和胃、清泄郁熱
46 52	有效成分的名稱及其份量* Name(s) and quantity(ies) of active ingredient(s) *: <input type="checkbox"/> 單味製劑 Single active ingredient preparation <input checked="" type="checkbox"/> 複方製劑 Multiple active ingredients preparation 1) 香附(醋製) 30.8% 2) 當歸 20.5% 3) 白朮 10.3% 4) 白芍 10.3% 5) 熟地黃 10.3% 6) 川芎 5.1% 7) 陳皮 5.1% 8) 黃芩 5.1% 9) 砂仁 2.5%	
53 54	功能分類 (請參照指引填寫) Categorization of functions (please refer to the Guide): 理氣劑	科別分類 (請參照指引填寫) Categorization of specialty (please refer to the Guide): 內科
55	該中成藥是否含有《中醫藥條例》附表1的中藥材* Whether the pCm contains Chinese herbal medicine(s) listed in Schedule 1 of the Chinese Medicine Ordinance*: 如是, 請註明其名稱 If yes, specify the name(s): _____	
56	該中成藥是否含有《保護瀕危動植物物種條例》的高度瀕危物種* Whether the pCm contains highly endangered species listed in the Protection of Endangered Species of Animals and Plants Ordinance *: 如是, 請註明其品種名稱 If yes, specify the species name(s): _____	

Application Form for Registration of Proprietary Chinese Medicines (Sample-Page 3)

When completing the Application Form, the applicant can refer to pages 7 to 13 of the relevant paragraphs in the "Guide for Completion of Application Form for Registration of Proprietary Chinese Medicines" according to the section numbers in the boxes in the left margin.

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聲明 Declaration	
1. 本人現聲明本中成藥已符合《保護瀕危動植物物種條例》的規定* I hereby declare that the proprietary Chinese medicine has met the requirements of the Protection of Endangered Species of Animals and Plants Ordinance. *	<input checked="" type="checkbox"/> 是 Yes <input type="checkbox"/> 否 No
2. 本人現聲明本中成藥並無摻雜西藥*。 I hereby declare that the proprietary Chinese medicine is not adulterated with western medicine. *	<input checked="" type="checkbox"/> 是 Yes <input type="checkbox"/> 否 No
3. 本人明白及同意以下事項*： I understand and agree the following statements*: (i) 本人謹此聲明，就本人所知及所信，此申請表所提供的資料皆屬真確事實的全部。 I hereby declare that all the foregoing information in this application form is full, complete and true to the best of my knowledge and belief. (ii) 本人授權香港中醫藥管理委員會中藥組，按其認為合適的方式核實此申請所提供的資料。 I authorize the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong to verify the foregoing information in any manner it deems fit. (iii) 本人明白根據《中醫藥條例》第 153(3)條的規定，任何人在向中藥組提出申請或在給予任何資料時，在要項上作出他知道是虛假或他不相信是真實的陳述或申述，即屬犯罪，最高可處第 6 級罰款及監禁 2 年。 I understand that according to Section 153(3) of the Chinese Medicine Ordinance, any person who, in making an application to the Chinese Medicines Board or in giving any information, makes a statement or representations which he knows to be false or does not believe to be true in a material particular, commits an offence and shall be liable to maximum penalty of a fine at level 6 and to imprisonment for 2 years. (iv) 本人明白所提交的個人資料，將會用作執行《中醫藥條例》的條款。 I understand that the personal data provided by me are for the purposes of facilitating the execution of the provisions of the Chinese Medicine Ordinance. (v) 本人明白所提交的個人資料，主要由香港中醫藥管理委員會內部使用，但亦可能因以上第(iv)段所列目的，向其他政府部門、中介機構或行政管理機構披露；除此以外，這些資料只會在本人同意，又或是《個人資料(私隱)條例》所容許下，才會向其他人士披露。 I understand that the personal data provided by me are mainly for use within the Chinese Medicine Council but they may also be disclosed to other Government bureaux/departments, agencies or authorities for the purposes mentioned in paragraph (iv), if required. Apart from this, the information provided herein will only be disclosed to parties where I have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance. (vi) 本人明白根據《個人資料(私隱)條例》第 18 條及 22 條以及其附表 1 第 6 原則所述，本人有權查閱及修正個人資料，但查閱資料時，可能要繳交費用。 I understand that I have the right of access and correction with respect to personal data as provided for in Section 18 and 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. (vii) 在中藥組審批中成藥註冊申請期間，本人的個人資料或其他申報資料如有任何更改，會盡快通知衛生署中醫藥規管辦公室。 If, during the assessment and approval of the application for the registration of the proprietary Chinese medicine, any amendment is necessary to the personal data or other information submitted, I shall report to the Chinese Medicine Regulatory Office of the Department of Health as soon as possible.	<input checked="" type="checkbox"/> 是 Yes <input type="checkbox"/> 否 No
..... 公司負責人簽署 Signature of person-in-charge of the company 聯絡電話 Contact telephone number
..... 公司負責人姓名(正楷) Name of person-in-charge(block letters) 公司蓋章 Company chop
..... 職位 Position held 日期 Date

此欄供有關部門填寫 For Office Use Only	
日期 Date:	繳交申請費用 Paid application fee:

請將不適用刪去 # Delete as appropriate *請於適當的□空格內填上✓號 *Please tick in appropriate box
 【註：以上資料乃申請人提供作中成藥註冊參考之用，其真確性尚有待證實】【Note: The information is provided by the applicant for reference purposes in connection with an application for registration of a proprietary Chinese medicine. The authenticity of these information is subject to verification.】

Guidance notes for completing the Application Form

Name of company

17. Please write the Chinese and English names of the company exactly as they appear on the business registration certificate held by the applicant. The information provided by the applicant will form an integral part of the “Name of the registered pCm”.

Address of company

18. Please write the Chinese or English address of the company exactly as it appears on the business registration certificate held by the applicant.

Business registration number/Manufacturer or Wholesaler Licence in pCm number

19. Please write the business registration number of the company exactly as it appears on the business registration certificate held by the applicant.

20. In the case of the pCm being manufactured in Hong Kong, the applicant should hold a valid Manufacturer Licence in pCm and please fill in the Manufacturer Licence number.

21. In the case of the pCm being manufactured outside Hong Kong, the applicant should hold a valid Wholesaler Licence in pCm and please fill in the Wholesaler Licence number.

Classification category & registration group of pCm

22. Please tick () in the appropriate boxes to indicate which classification category and registration group chosen to apply for.

23. The classification categories of pCm are divided into “Established medicines category”, “Non-established medicines category”, and “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”.

- i. With the exception of Chinese medicine injections, the “Established medicines” includes those pCms that are formulated according to ancient prescriptions, modified ancient prescriptions, prescriptions documented in the Pharmacopoeia of the People’s Republic of China, or any other prescriptions originated from the National Drug Standards of the People’s Republic of China, and accepted by the Chinese Medicines Board, or any products that are made from single Chinese herb and their claimed indications and functions are the same as those of their crude drugs;
- ii. With the exception of Chinese medicine injections, the “Health-preserving medicines” in the “Non-established medicines” are products used for the purpose of regulating the functional states of the human body. ‘Single Chinese medicine granules’ are those granules that fall within the definition of pCm and are made from single Chinese herbs.
- iii. The “New medicines” includes those products developed through modern Chinese

medicine researches, and Chinese medicine injections.

24. The registration groups of pCm are Group I, Group II and Group III. 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”, they must be registered according to Group III registration requirements.

Product name

25. The applicant should ensure that the product name is in line with the “Naming principles of pCm” as stipulated by the Chinese Medicines Board. For details of the requirements, please refer to the relevant paragraphs in the Handbook.
26. The applicant should provide the Chinese and English names of the product. The English name of the product can be given in English, Hanyu Pinyin, or Cantonese Pinyin, etc.
27. In the case of a product name registered under the Trade Marks Ordinance (Cap. 559), the applicant should tick (☑) in the “Yes” box, and fill in the registration number of the trademark. The applicant should be the owner of the registered trademark, or a permitted user authorized by the trademark owner of the pCm under application.

Trade mark text (if any)

28. “Trade mark” can be any type of commercial sign or mark in the form of text and/or graphic, used to promote and distinguish the product. The applicant should display the trade mark on product packages, to help the general public to distinguish among products.
29. The applicant should provide the Chinese and English trade mark text, including the text part in a combined text & graphics trade mark of the pCm under application. The information supplied will form an integral part of the “name of the registered pCm”.
30. If the text trade mark/text & graphics trade mark of the product has been registered under the Trade Marks Ordinance (Cap. 559), the applicant should tick (☑) in the “Yes” box, and provide the registration number of the trade mark. The applicant should be the owner of the registered trade mark, or a permitted user authorized by the trade mark owner of the pCm under application.

Name(s) & address(es) of manufacturer(s) of the pCm

31. The applicant should write the name and full address of the manufacturer of the pCm in both Chinese and English.
32. The “manufacture” in relation to a pCm means “preparation”, “production”, “packing” or “re-packing” of the pCm for sale or distribution. Therefore, additional pages may be attached when there is more than one manufacturer involved.

Dose form

33. In the case of a pCm presented in different dose forms, a separate application will be required for each dose form. Similarly, in the case of a dose form presented with different concentrations or content levels, a separate application will be required for each.

34. Please refer to the following listed dose forms when completing the Application Form.

- | | | | | |
|--------------------------|----------------------------|--------------------------|----------------------------|------------------------------|
| 1) Pill | 11) Medicinal wine | 21) Glue | 31) Suspension | 41) Sugar-coated tablet |
| 2) Dan | 12) Cone-shaped drug | 22) Medicinal pastry | 32) Eye ointment | 42) Syrup |
| 3) Tablet | 13) Medicated roll | 23) Troch | 33) Ointment | 43) Granule |
| 4) Mixture | 14) Powder | 24) Medicinal distillate | 34) Microcapsules | 44) Cataplasm (Babu Plaster) |
| 5) Fermented preparation | 15) Medicinal stick | 25) Medicinal thread | 35) Concentrated decoction | 45) Liquid extract |
| 6) Moxa-preparation | 16) Liniment | 26) Lozenge | 36) Dripping pill | 46) Adhesive plaster |
| 7) Emulsion | 17) Plaster | 27) Oral liquid | 37) Eye drops | 47) Other (Please specify) |
| 8) Tincture | 18) Hot medicated compress | 28) Injection | 38) Nasal drops | |
| 9) Suppository | 19) Paste | 29) Aerosol | 39) Spray | |
| 10) Medicinal tea | 20) Medicinal membrane | 30) Extract | 40) Capsule | |

Route of administration

35. The applicant should select the appropriate route of administration and tick () in the corresponding box. If the route of administration is neither for internal nor for external use, please ticks the “Other” box and specify the route of administration.

Packing specification

36. The applicant should present the specifications of the product in respect of the weight, quantity or contents (in the decimal system) of each preparation unit, e.g. 0.6 g per tablet, 10 ml per bottle. The “preparation unit” shall be the basic usage unit, and be the same as the administration dose unit. For example, if the administration of a pCm is “1 bottle each time, 3 times per day”, then the preparation unit is “bottle”; if the administration of a product is “3 times per day, 6 g each time”, then the preparation unit is “g”.

37. The applicant should detail the package size of **all** sales packs. For example, a tablet to be sold in three types of sales packs, which are respectively paper box package with 100 tablets/box, bottle with 100 tablets/bottle, and bottle with 500 tablets/bottle. All these three types of sales packs should be specified in the Application Form.

38. If smaller containers are used within a sales pack, the package size of both the external package and the internal package should be detailed. In the example given above, if the package of “100 tablets/box” contains 10 small bottles in each box, the applicant should state the package size of both the “box” and the “bottle”, i.e. 10 bottles/box, and 10 tablets/bottle.

39. In the example given above, if the package of “10 tablets/bottle” is to be used separately for

individual sale, then this package should be treated as a distinct sales pack, and should be stated separately in the Application Form. Any package that is not specified on the Application Form should not be used for sale.

40. It is the responsibility of the applicant to ensure that each sales pack of the pCm carries label and package insert, which comply fully with the labeling and package insert requirements under the relevant legislation.
41. Below are some examples on how to complete the packing specification:-

Example 1: A syrup is to be sold in two different types of package size, being of 50 ml/bottle and 100 ml/bottle. Therefore, this pCm should have two different sales packs. (preparation unit in “ml”)

Correct format:

Packing specification 1) 50 ml/bottle 2) 100 ml/bottle
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Example 2: A pill is to be sold in paper box packages, in each of which there are 10 small bottles containing the pills. As the small bottles are not for individual sale, this pCm has only one sales pack. (preparation unit in “bottle”)

Correct format:

Packing specification 1) 3 g/bottle 10 bottle/box

Example 3: A tablet has two different packages, being of 100 tablets/box and 100 tablets/bottle. In each of the paper box, there are 10 small bottles containing the tablets (i.e. 10 tablets/bottle), and each of the small bottles can be sold separately with individual labels and package inserts. Therefore, this pCm has three different sales packs. (preparation unit in “tablet”)

Correct format:

Packing specification 0.5 g/tablet 1) 100 tablets/bottle 2) 10 (small) bottles/box, 10 tablets/bottle 3) 10 tablets/bottle

Indications / Functions

42. For pCms in the health-preserving medicines category, the applicant only needs to describe their functions, and leave out any indications.
43. Generally speaking, the applicant should refer to the indications & functions of the pCm by Chinese medicines syndromes, and be expressed in academic terminology of Chinese medicine.
44. Descriptions for indications and functions should be inter-related. Indications should be described directly and precisely, while the functions should be described accurately, comprehensively and with emphasis on the principal therapeutic effects. Exaggerated descriptions, such as “holy medicine” or “a cure for any diseases” etc. is prohibited.

45. Description of functions should be given in relation to the “categorization of functions” of the medicine.

Name(s) and quantity(ies) of active ingredient(s):

46. Please tick (☑) in the appropriate box to indicate whether the pCm under application is a single active ingredient preparation or a multiple active ingredients preparation. Single active ingredient preparations are those pCms containing only one type of active ingredient or Chinese herb. Multiple active ingredients preparations are those pCms containing more than one type of active ingredients or Chinese herbs. Thus, the applicant will pay the application fees according to the formula of the pCm under application.
47. The applicant should provide the required information according to the master formula provided by the manufacturer.
48. The applicant should provide the names & quantities of all active ingredients or Chinese herbs contained in the pCm under application. The list order of the active ingredients or Chinese herbs can be arranged according to their quantities used, or according to the order of “principal, assistant, adjuvant and guiding ingredients” in the principle of formulating a prescription. If the active ingredient(s) in the preparation is/are the functional part(s) or group(s) extracted from Chinese herb(s), the applicant should also list the name(s) of the Chinese herb(s).
49. 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 or Schedule 2, the applicant shall refer to the Pharmacopoeia of People’s Republic of China, “Zhonghua Bencao”, “Zhongyao Dacidin” or the “Chinese Materia Medica” for the official names.
50. The applicant should specify the processing requirement of each raw Chinese herb. If the processing requirement is not specified, it will be deemed to be an unprocessed raw Chinese herb.
51. When specifying the quantity of each active ingredient/Chinese herb, the quantity, or percentage of the quantity, in each preparation unit should be used (in the decimal system) for presentation. If the active ingredient(s) is/are extracted from Chinese herb(s) to form the functional part or groups in the preparation, the quantity of such ingredient(s) should also be specified.
52. Below are some examples on how to list the name(s) and quantity(ies) of active ingredient(s):-

a)

Name(s) & quantity(ies) of active ingredient(s):	
Each tablet contains:	
1) Rhizoma Corydalis (Processed with vinegar)	445 mg
2) Radix Angelicae Dahuricae	223 mg

b)

Name(s) & quantity(ies) of active ingredient(s):		
1) Rhizoma Corydalis (Processed with vinegar)		66.6%
2) Radix Angelicae Dahuricae		33.4%

c)

Name(s) & quantity(ies) of active ingredient(s):	
Each bag contains:	
1) Notoginsenosides 50mg, extracted from Radix Notoginseng	

Categorization of functions

53. By referring to the following list, the applicant can indicate the functional category of the pCm under application.

- | | | | |
|------------------------------|--------------------------|-------------------------------------|---|
| 1) Tranquilizers & sedatives | 7) Health-preserving | 13) Blood-regulating | 19) Laxatives/purgatives |
| 2) Neutralizing | 8) Summer heat clearing | 14) Promoting the circulation of Qi | 20) Antitussives & anti-asthmatics |
| 3) Inducing astringency | 9) Phlegm eliminating | 15) Resuscitation | 21) Exterior & interior syndromes relieving |
| 4) Wind calming | 10) Dampness eliminating | 16) Interior warming | 22) Digestives & evacuants |
| 5) Ulcer-healing | 11) Anthelmintics | 17) Tonics | 23) Other (please specify) |
| 6) Dryness syndrome treating | 12) Heat-clearing | 18) Exterior syndrome relieving | |

Categorization of specialty

54. By referring to the list below, the applicant can indicate the specialty of the pCm.

- | | | |
|-----------------|----------------|---------------------------|
| 1) Medicine | 4) Gynecology | 7) Ophthalmology |
| 2) Surgery | 5) Paediatrics | 8) Otorhinolaryngology |
| 3) Orthopaedics | 6) Dermatology | 9) Other (please specify) |

Products containing Chinese herbal medicines listed in Schedule 1 of the Chinese Medicine Ordinance

55. If the pCm contains any Chinese herbal medicines listed in Schedule 1 of the CMO, the applicant should tick () in the “Yes” box, and specify the names of all the Chinese herbal medicines.

Products containing highly endangered species listed in the Protection of Endangered Species of Animals and Plants Ordinance

56. If the pCm contains highly endangered species listed in the Protection of Endangered Species of Animals and Plants Ordinance, the applicant should tick () in the “Yes” box, and specify the names of all the highly endangered species used and specify the part(s) used.

Declaration

57. The applicant is required to declare in respect of the following:-

- (a) That the pCm under application meets the requirements of the Protection of Endangered Species of Animals and Plants Ordinance;
- (b) That the pCm is not adulterated with western medicine; and
- (c) That all the information provided in the Application Form is true and correct.

58. The applicant should provide the application date, the name, title and contact telephone number of the person in charge of the company, and affix the company chop. The person in charge of the company should sign the Application Form.

59. It is a criminal offence for an applicant to provide false or fraudulent information. Upon

conviction, he/she shall be liable to a fine at level 6 and to imprisonment for 2 years. In addition, 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.

60. During the assessment of the registration of pCm by the Chinese Medicines Board, any amendments to personal data of the applicant or other information submitted shall be reported to the Chinese Medicine Regulatory Office of the Department of Health in writing, by post or by fax, as soon as possible.

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