

《中醫藥條例》

(第 549 章)

Chinese Medicine Ordinance

(Chapter 549)

檔案編號：
Ref. No.

中成藥註冊申請書

《中醫藥條例》第 121 條

Application Form for Registration of Proprietary Chinese Medicines

Section 121, Chinese Medicine Ordinance

申請人在填寫申請書時，可根據各項目左邊方格內的數字，參考「填寫中成藥註冊申請書須知」內的有關段落。

When completing this application form, the applicant may refer to the relevant paragraphs of the "Guide for Completion of Application Form for Registration of Proprietary Chinese Medicines", according to the section numbers shown in the boxes in the left margin.

| | |
|---------------|---------------------------------------------------------------|
| 16 17 | 公司名稱 Name of Company 中文 (Chinese): 英文 (English): |
| | 公司地址 Address of Company |

現提供以下資料作申請中成藥註冊之用

The following information is provided for registration of proprietary Chinese medicine (pCm):

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| 18 20 | 本公司的商業登記號碼 Our company's business registration number is: _____。 並持有中成藥製造商牌照 / 中成藥批發商牌照 [#] ，其編號為 And the Manufacturer Licence / Wholesaler Licence [#] in proprietary Chinese medicines number is: _____。 |
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| 21 23 | 該中成藥的註冊類別* Classification category *: <input type="checkbox"/> 固有藥 Established Medicines <input type="checkbox"/> 非固有藥 Non-established Medicines <input type="checkbox"/> 保健品 Health-preserving Medicines <input type="checkbox"/> 單味中成藥顆粒 Single Chinese Medicine Granules <input type="checkbox"/> 新藥(必須作第 III 組別註冊) New Medicines (Group III registration only) |
| | 擬申請的註冊組別* Proposed registration group*: <input type="checkbox"/> 第 I 組別 Group I <input type="checkbox"/> 第 II 組別 Group II <input type="checkbox"/> 第 III 組別 Group III |

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| 24 26 | 產品名稱 Product name 中文 (Chinese) : 英文 (English) : 此產品名稱是否已根據《商標條例》註冊* Whether the product has been registered under the Trade Marks Ordinance*: <input type="checkbox"/> 是 Yes <input type="checkbox"/> 否 No 如是，請註明其商標註冊編號 If yes, please fill in the registration number of the trade mark: _____ |
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| 27 29 | 商標文字 (如有) Trade mark text (if any) 中文 (Chinese) : 英文 (English) : 此商標是否已根據《商標條例》註冊* <input type="checkbox"/>是 Yes <input 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: _____ | |
| 30 31 | 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) : 英文 (English) : | |
| 32 40 | 劑型形式 (請參照指引填寫) Dose form (please refer to the Guide): | 給藥途徑* Route of administration* <input 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): _____ |
| 41 44 | 主治用途 Indications: | 包裝規格說明 Packing specification: 功能 Functions: |
| 45 51 | 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 type="checkbox"/> 複方製劑 Multiple active ingredients preparation | |
| 52 53 | 功能分類 (請參照指引填寫) Categorization of functions (please refer to the Guide): | 科別分類 (請參照指引填寫) Categorization of specialty (please refer to the Guide): |
| 54 | 該中成藥是否含有《中醫藥條例》附表 1 的中藥材* <input type="checkbox"/>是 Yes <input type="checkbox"/>否 No 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): _____ | |
| 55 | 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* <input type="checkbox"/>是 Yes <input type="checkbox"/>否 No 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): _____ | |

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. * 是 Yes 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. * 是 Yes 否 No
3. 本人明白及同意以下事項*：
I understand and agree the following statements*:
是 Yes 否 No
- (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藥事務組。
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 Medicines Section of the Department of Health as soon as possible.

.....
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.】