

# 《中醫藥條例》

(第 549 章)

## Chinese Medicine Ordinance

(Chapter 549)

### 更改註冊中成藥的註冊詳情申請書

《中醫藥條例》第 124 條

Application Form for Variation of Registered Particulars of Registered Proprietary Chinese Medicines

Section 124, Chinese Medicine Ordinance

檔案編號：  
Ref. No.

本公司 \_\_\_\_\_ 地址為  
My company, \_\_\_\_\_ (公司名稱 / Name of company) is located at

\_\_\_\_\_  
(公司地址 / Address of company)

所持有的中成藥製造商牌照 / 中成藥批發商牌照<sup>#</sup>，其編號為：  
Our company's Manufacturer Licence number / Wholesaler Licence number in pCm<sup>#</sup> is:

現提供以下資料作申請更改下述註冊中成藥的註冊詳情之用  
The following information is provided for application for variation of registered particulars of the below registered proprietary Chinese medicines (pCm)

中成藥名稱(中文) 【 \_\_\_\_\_ 】  
商標文字 \_\_\_\_\_ 產品名稱 \_\_\_\_\_

Name of pCm (English) 【 \_\_\_\_\_ 】  
Trademark Text \_\_\_\_\_ Product name \_\_\_\_\_

其列載於「中成藥註冊證明書」的中成藥註冊編號：

Its registration number of pCm listed in the Certificate of registration of pCm:

HKC- \_\_\_\_\_

要求申請更改的項目\* (可要求更改多於一項，並請附上有關更改項目的資料及文件)

Item(s) which apply for variation\* (Supporting documents in related to the application should be submitted upon application, can select more than ONE item)

賦形劑的名稱及份量

Name and quantity of its excipient

規格說明

Specification

主治用途

Indication

用量及使用方法

Dosage and method of usage

標籤即指《中藥規例》第 26 條須包括的詳情，並包括但不限於:-  
Labels i.e. the particulars as listed under section 26 of the 《Chinese Medicines Regulation》 include but not limited to:-

說明書(包括在香港境內及境外銷售而供應的)

Package inserts (including those to be supplied for its sales inside and outside Hong Kong)

產品的商標文字 Trademark text of the pCm

證明書持有人 Certificate's Holder

製造商的姓名或名稱及地址

Name and address of its manufacturer(s)

功能或藥理作用

Function or pharmacological action

其他 Others: (請註明 Please specify) \_\_\_\_\_

就上述要求更改的項目，本公司希望於接到審批確認後 即時 / 30 天後 / 60 天後<sup>#</sup> 生效。

Our company wishes the variation of the above item(s) takes effect *immediately* / 30 days / 60 days<sup>#</sup> upon receipt of confirmation of approval.

**申請人聲明**  
**Declaration**

1. 本人 / 公司明白根據《中醫藥條例》第 153 條第 3 款的規定，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。本人現聲明盡本人所知及所信，申請書所提供的資料均屬真確事實的全部。  
I / Our company 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. 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.
2. 本人 / 公司明白如本人 / 公司未有就所申請更改的註冊詳情提供全部所需文件，或擬作出的更改違反中藥組制訂的相關指引或指導原則的要求，衛生署中醫藥規管辦公室職員會向本人 / 公司發出補交文件通知書，如本人 / 公司於該補交文件通知書指定日期內，仍未能把指定的文件送交中藥組，則該申請將當作放棄申請論。  
I / Our company understand that if I / we have not submitted all the required documents for the application for variation of registered particulars, or if the proposed variation(s) is(are) against the requirements of the relevant guidelines stipulated by the Chinese Medicines Board, the Chinese Medicine Regulatory Office of the Department of Health will issue a reminder to me / us. If I / our company cannot submit the required documents to the Chinese Medicines Board within the specified period stated in the reminder, the application will be deemed withdrawal.
3. 本人 / 公司明白遞交此申請書並不表示申請已獲批准，一切更改的生效日期以中藥組 / 中藥管理小組發出的通知文件上所顯示的生效日期為準。  
I / Our company understand that submission of this application does not mean approval has been given. The effective date of the variation is shown on the notice issued by the Chinese Medicines Board / Chinese Medicines Committee.
4. 本人 / 公司承諾在有關的更改開始生效前，於合理可能的範圍內，收回或安排收回已供應的該中成藥。  
I / Our company promise to recall or cause to recall, to the extent reasonably possible, the pCm already supplied before the relevant variation takes effect.

.....  
公司負責人<sup>+</sup>簽署  
Signature of the person-in-charge of the company<sup>+</sup>

.....  
聯絡電話  
Contact telephone number

.....  
公司負責人姓名<sup>+</sup> (正楷)  
Name<sup>+</sup> of person-in-charge (block letters)

.....  
公司蓋章  
Company chop

.....  
職位  
Position

.....  
日期  
Date

<sup>+</sup> 請將不適用者刪去。 Please delete as appropriate.

\* 請在適當的  空格內加上  號。 Please tick  in the appropriate box.

<sup>+</sup> 此簽署及姓名須與該中成藥註冊申請書的簽署相符。 This signature and name must be same as the one on the Application form for registration of pCm.

【註：以上資料乃申請人提供作申請更改註冊中成藥的註冊詳情參考之用，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 Variation of registered particulars of registered pCm. The authenticity of this information is subject to verification.】

**此欄供有關部門填寫 For Office Use Only**

日期 Date : ..... 繳交申請費 Paid application fee : .....

此頁只適用於更改註冊證明書持有人的申請，並須由新註冊證明書持有人填寫  
**This page is only applicable for application for change of certificate's holder and  
to be filled by the new certificate's holder**

新註冊證明書持有人的資料 Details of the New certificate's holder:

公司名稱 Name of company

公司地址 Address of company

商業登記證號碼 Business registration number of the company

中成藥製造商牌照/中成藥批發商牌照<sup>#</sup> 編號  
Manufacturer Licence/Wholesaler Licence<sup>#</sup> number in pCm

**新註冊證明書持有人聲明  
New Certificate's Holder Declaration**

1. 本人現聲明在新註冊證明書的發出日期以後，將承擔上述中成藥一切的法律責任。  
I hereby declare that I will take all legal responsibilities of the pCm starting from the date of the new Certificate issued.
2. 本人現聲明上述中成藥的處方、製造工藝及劑型形式在取得新註冊證明書後，會維持不變。  
I hereby declare that the master formula, the manufacturing method and dose form of the captioned pCm will remain unchanged since the new Certificate is granted.
3. 本人明白根據《中醫藥條例》第 153 條第 3 款的規定，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。本人現聲明盡本人所知及所信，申請書所提供的資料均屬真確事實的全部。  
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. 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.

公司負責人<sup>◆</sup>簽署  
Signature of the person-in-charge of the company<sup>◆</sup>

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

日期  
Date

<sup>#</sup> 請將不適用者刪去 Please delete as appropriate.

<sup>◆</sup> 公司負責人需為申請公司的東主、合夥人或董事。 Person-in-charge of the company should be the owner, partner or director.

【註：以上資料乃申請人提供作申請更改註冊中成藥的註冊詳情參考之用，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 Variation of registered particulars of registered pCm. The authenticity of this information is subject to verification.】