

香港中醫藥管理委員會中藥組
Chinese Medicines Board of
The Chinese Medicine Council of Hong Kong

教育及科研人士或機構根據第 158(1)條之豁免申請
(有關中成藥註冊的豁免申請—供中成藥製造商使用)

Application for exemption in accordance with section 158(1) by a person or
institution concerned with education or scientific research
(For application of exemption in relation to proprietary Chinese medicine registration by
proprietary Chinese medicine manufacturer)

《中醫藥條例》

第 549 章

第 158(1)條

CHINESE MEDICINE ORDINANCE (Cap. 549)

Section 158(1)

申請編號：

Application Ref. No.:

教育及科研人士或機構根據第 158(1)條
(使其免受第 119 條的規限) 之豁免申請表

Form of the application in accordance with section 158(1)
(exemption from the application of section 119)

by a person or institution concerned with education or scientific research

申請者請填寫甲部、乙部、丙部及丁部。

Applicant please complete Part A, Part B, Part C and Part D.

甲部分 Part A	申請者資料 Particulars of applicant
中成藥製造商名稱：	(中文)
Name of proprietary Chinese medicine manufacturer:	(English)
通訊地址：	(中文)
Correspondence address:	(English)
中成藥製造商牌照的編號：	
Licence number of the proprietary Chinese medicine manufacturer:	
負責人姓名：	(中文)
Name of responsible person:	(English)
香港身份證號碼／護照號碼：	
HKID no. / Passport no.:	
職位：	
Position:	
聯絡電話：	
Contact telephone no.:	
傳真號碼：	
Fax no.:	
電郵地址：	
E-mail address:	

乙部分 Part B	臨床試驗申辦者及試驗機構資料 Particulars of sponsor and institution conducting clinical trial	
臨床試驗申辦者名稱：	_____	(中文)
Name of the sponsor for clinical trial:	_____	(English)
臨床試驗申辦者地址：	_____	(中文)
Address of the sponsor for clinical trial:	_____	(English)
_____	_____	
負責人姓名：	_____	(中文)
Name of responsible person:	_____	(English)
職位：	_____	
Position:	_____	
聯絡電話：	_____	
Contact telephone no.:	_____	
傳真號碼：	_____	
Fax no.:	_____	
電郵地址：	_____	
E-mail address:	_____	
進行臨床試驗的機構名稱：	_____	(中文)
Name of institution conducting clinical trial:	_____	(English)
進行臨床試驗的地址：	_____	(中文)
Address of the place where clinical trial is conducted:	_____	(English)
_____	_____	
負責人姓名：	_____	(中文)
Name of responsible person:	_____	(English)
職位：	_____	
Position:	_____	
聯絡電話：	_____	
Contact telephone no.:	_____	
傳真號碼：	_____	
Fax no.:	_____	
電郵地址：	_____	
E-mail address:	_____	

丙部分 Part C	詳情 Details
欲申請豁免的範圍及理由： Scope of exemption applied for and reason(s):	
範圍 Scope	理由 Reason(s)
中成藥註冊 <input type="checkbox"/> Registration of proprietary Chinese medicine	
其他 <input type="checkbox"/> Others	
臨床試驗的名稱： Title of the clinical trial: _____ _____	
臨床試驗的鑑別號（如適用）： Identifying no. of the clinical trial (if applicable): _____	
臨床試驗的內容： Content of the clinical trial: _____ _____ _____	
需要有關中成藥的名稱、劑型及其數量： Name, dose form and quantity of the proprietary Chinese medicine required: _____ _____	
需要有關中成藥的原因： The reason(s) of requiring the concerned proprietary Chinese medicine: _____ _____	
參與以上項目的人士的姓名及其職位名稱： The name and post of the person(s) involved in the above-mentioned project: _____ _____ _____	
請詳述參與以上項目人士所負責的工作範圍、性質： Please give details on the duties and responsibilities of the person(s) involved in the above-mentioned project: _____ _____	
完成臨床試驗所需的總時間： Total time required for completion of the clinical trial: 由 _____ 至 _____ From _____ to _____	

(請在適當方格內加上✓號) (Please tick ✓ as appropriate)

丙部分 (續) Part C (Cont'd)	詳情 Details
本人已附上以下文件副本作審批申請之用： I attach the following copies of documents for approval of the application:	
(i) 中成藥製造商牌照及製造商證明書副本 Copy of the Manufacturer Licence in proprietary Chinese medicines, and the Certificate for Manufacturer	<input type="checkbox"/>
(ii) 中成藥製造商授權負責人提出申請的文件 Document issued by the applicant authorizing the responsible person to make an application	<input type="checkbox"/>
(iii) 中成藥製造商負責人的身份證明文件 Document to prove the identity of the responsible person	<input type="checkbox"/>
(iv) 科學研究 (臨床試驗) 計劃書 Proposed plan of the scientific research (clinical trial)	<input type="checkbox"/>
(v) 中成藥製造商就臨床試驗獲委託製造中成藥的合約副本 Copy of the contract covering the manufacture of proprietary Chinese medicine for clinical trial	<input type="checkbox"/>
(vi) 該中成藥的完整處方及製造方法 Master formula and manufacturing method of the proprietary Chinese medicine	<input type="checkbox"/>
(vii) 如屬為境外臨床試驗機構提供試驗用藥，須提供由當地藥物監管機構發出的證明，以確認該臨床試驗機構已獲批准使用相關中成藥在當地進行相關臨床試驗。 For application related to the supply of investigation product for clinical trials conducted outside Hong Kong, documentary proof issued by regulatory authority certifying that the related clinical trial and the use of the proprietary Chinese medicine have been approved.	<input type="checkbox"/>
中藥組如認為有需要，可要求申請者提交任何其他文件或資料。 The Chinese Medicines Board may, if necessary, request the applicant to submit any other documents or information. 中藥組如認為有需要，可要求申請者提交任何文件或資料的正本以供核對。 The Chinese Medicines Board may, if necessary, request the applicant to submit original copy of any of the above documents or information for verification.	

(請在適當方格內加上✓號) (Please tick ✓ as appropriate)

丁部分 Part D	聲明（人士或機構必須填寫） Declaration (To be completed by person or institution)
<p>1. 本人謹此聲明，就本人所知及所信，此申請表的甲、乙及丙部分所提供的資料皆屬真確事實的全部。 I hereby declare that all the foregoing information in Parts A, B and C of this application is FULL, COMPLETE and TRUE to the best of my knowledge and belief.</p> <p>2. 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，核實此申請表所提供的資料。 I authorize the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong to verify the foregoing information in any manner as it deems fit.</p> <p>3. 本人明白所提交予香港中醫藥管理委員會中藥組的個人資料及其他相關資料，將會用作執行《中醫藥條例》的條款。 I understand that my personal data or other relevant information given to the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong are for the purposes of facilitating the implementation of the relevant provisions of the Chinese Medicine Ordinance.</p> <p>4. 本人明白所提交的個人資料，主要供香港中醫藥管理委員會內部使用，但亦可能因以上第3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；除此之外，其他個人資料只會在本人同意、又或者在《個人資料（私隱）條例》所容許下，向其他人士披露。 I understand that my personal data are mainly for use within the Chinese Medicine Council of Hong Kong but they may also be disclosed to other Government bureaux / departments, agencies or organizations for the purposes mentioned in paragraph 3 above. Apart from this, my personal particulars and information 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.</p>	
<p>中成藥製造商負責人簽署： Signature of the responsible person of the manufacturer: _____ (代表中成藥製造商簽署 Signing for and on behalf of the manufacturer)</p> <p>中成藥製造商負責人的姓名（正楷）： Name of responsible person of the manufacturer: _____</p> <p>中成藥製造商名稱： Name of manufacturer: _____</p> <p>中成藥製造商的蓋章： Stamp of the proprietary Chinese medicine manufacturer: _____</p> <p>日期： Date: _____</p>	

一般事項：

General Remarks:

1. 請用黑色墨水筆或原子筆填寫申請表。
Please use black inked pen or ball pen to fill in the application form.
2. 申請人須填妥申請表各有關項目（包括中英文地址），並提供正確資料。
Applicant shall complete every relevant items of the application form (including Chinese and English addresses), and provide correct information.
3. 除註明外，請以中文正楷或英文填寫申請表格。
Unless otherwise specified, please use Chinese or English block letters to fill in the application form.
4. 申請人如未能提供所需的所有資料，或所填寫的資料未能清楚顯示申請人符合最基本的申請規定，或申請人未能在申請之後註明的一段時間內補交所需的資料，中藥組可拒絕進一步處理或拒絕其申請。
In the event that an applicant cannot provide all necessary information, or that the information provided does not clearly indicate the applicant has complied with all basic application requirements, or that the applicant fails to provide all necessary information within a specified period of time after application, the Chinese Medicines Board may decline to process the application further or reject the application.
5. 申請人應保留一份填妥的申請表副本，以備參考。
Applicant should retain a photocopy of the application for reference.
6. 申請人提交申請表後，如欲更改或查詢個人資料，請與衛生署中藥事務組聯絡（電話號碼：3904 9130）。
If an applicant wishes to amend or inquire personal information after submission of the application form, please contact the Chinese Medicines Section of Department of Health (telephone no.3904 9130).
7. 如申請表空位不敷填寫，請另頁填寫，並在申請表有關部分註明。申請人須在該附頁上寫明其姓名及簽署，然後將附頁釘附在申請表內。
If there is insufficient space in the application form, please use a separate sheet and indicate accordingly in the relevant part of the application form. The applicant shall write his / her name and sign on the sheet and attach it to the application form.