申請編號:

Application Ref. No.:

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

教育或科研人士或機構根據第 158(1)條之豁免申請 有關中成藥批發商牌照及製造商牌照的豁免申請 Application for exemption in accordance with section 158(1) by a person or institution concerned with education or scientific research in relation to manufacturer licence and wholesaler licence in proprietary Chinese medicines

> 《中醫藥條例》 第 549章 第 158(1)條 Chinese Medicine Ordinance (Cap. 549) Section 158(1)

> > 表格 E1B Form E1B

教育或科研人士或機構根據第 158(1)條 (使其免受第131或134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 sections 131 or 134) 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.

申請者資料

| Part A | Particulars of applicant | | |
|-----------------------------------|----------------------------|--------------|--|
| 申請機構名稱 | 召稱: (中文) | | |
| Name of institution: | | (English) | |
| | | | |
| 通訊地址: (中 | | (中文) | |
| Correspondence | e address: | (English) | |
| | | | |
| 申請機構負責 | | (中文) | |
| Name of respon | nsible person of the | (English) | |
| institution: | | | |
| 香港身份證號 | 碼/護照號碼: | | |
| HKID no. / Pas | sport no.: | | |
| 職位 Position: | | | 電郵地址 E-mail address: |
| | | | |
| 聯絡電話 Con | tact telephone no.: | | 傳真號碼 Fax no.: |
| | | | |
| | | | |
| 乙部分 | 進行教育或科研工作機 | 構資料 | |
| Part B | Particulars of institution | carrying out | the educational project or scientific research |
| 進行教育或科 | 研工作的機構名稱: | (中文) | |
| Name of institu | tion carrying out the | (English) | |
| - | ject or scientific | | |
| research: | | | |
| 進行教育或科 | 研工作的地址: | (中文) | |
| Address where | the educational project | (English) | |
| or scientific res | earch is carried out: | | |
| | 作項目負責人姓名: | (中文) | |
| | | (English) | |
| educational project or scientific | | | |
| research: | | | |
| 職位 Position: | | | 電郵地址 E-mail address: |
| | | | |
| 聯絡電話 Contact telephone no.: | | | 傳真號碼 Fax no.: |
| | | | |
| | | | |

| 丙部分 Part C | 詳情 Details | | | | |
|---|--|--|--|--|--|
| 獲得有關中成藥的目的: The purpose(s) of acquiring proprietary Chinese medicine(s): 教育 □ 科學研究 □ Scientific research | | | | | |
| 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) | | | |
| 中成藥進口 Import of proprietar Chinese medicines | у 🗆 | | | | |
| 中成藥製造 Manufacture of prop Chinese medicines | rietary 🗆 | | | | |
| 其他 Others | | | | | |
| | 教育或科研項目的名稱(如適用): Title of the educational project or scientific research (if applicable): | | | | |
| 教育或科研項目的內容: Content of the educational project or scientific research: | | | | | |
| 需要有關中成藥的名稱(或種類)及其數量: Name (or kind) and quantity of proprietary Chinese medicine(s) to be acquired: | | | | | |
| 需要有關中成藥的原因: The reason(s) of acquiring the concerned proprietary Chinese medicine(s): | | | | | |
| 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的人士所負責的工作範圍及性質: Please give details on the duties and responsibilities of the person(s) involved in the above-mentioned project: | | | | | |
| | | | | | |
| 由 | | 總時間: etion of the educational project or scientific research: 至至 | | | |
| From | | to | | | |

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

| 丙部分 Part C (| | 詳情 Details | | |
|---|-------------|---|--|--|
| 本人已附上以下文件作審批申請之用: | | | | |
| I attach | the followi | ng documents for approval of the application: | | |
| (i) | | 請表(表格 E1B) mpleted application form (Form E1B) | | |
| (ii) | Proof that | 「教育或科研工作項目負責人」處理申請的文件 the person responsible for the educational project or scientific research has prized by the institution to handle the application. | | |
| (iii) | | 或科研項目的地址證明文件 ddress where the educational project or scientific research is carried out. | | |
| (iv) | List of equ | 與進行教育或科研項目相關的設備及設施文件 sipment and facilities used for carrying out the educational project or scientific the institution. | | |
| (v) | Details of | 與的中藥教育或科研的詳情,包括研究或教學課程的大綱 the educational project or scientific research of Chinese medicines carried out by tion, including the research protocol or teaching curriculum. | | |
| (vi) | | 科研工作項目負責人」的身份證明文件副本 lentity of the person responsible for the educational project or scientific | | |
| (vii) | | 科研工作項目負責人」相關學歷的證明文件副本 cademic qualification(s) of the person responsible for the educational project or research. | | |
| (viii) | Proof of re | 科研工作項目負責人」相關執業經驗的證明(如有) elevant practical experience of the person responsible for the educational project ic research (if any). | | |
| (ix) | Copy of pr | 或表列中醫的證明文件,或有限制註冊證明書副本 (如有) ractising certificate of registered Chinese Medicine Practitioner or "Notification Chinese medicine practitioner"; or certificate of limited registration (if any). | | |
| (x) | | 及藥物測試證明書副本(如適用) ne certificate for clinical trial and medicinal test (if applicable). | | |
| 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. | | | | |

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| 丁 | 部 | 分 |
|----|-----|---|
| Pa | art | D |

聲明(人士或機構必須填寫)

Declaration (To be completed by person or institution)

1. 本人謹此聲明,已閱讀並理解申請須知內的要求#,以及就本人所知及所信,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 have read through and understood the Guidelines# and 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.

- 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.
- 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.

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,其他個人資料祗 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.

| 申請機構負責人簽署: Signature of the responsible person of the institution: | (代表申請機構簽署) (Signing for and on behalf of the institution) | |
|--|---|-----------|
| 申請機構負責人的姓名(正楷): | | (中文) |
| Name of responsible person of the institution (in Block letters): | | (English) |
| 申請機構名稱: | | (中文) |
| Name of Institution: | | (English) |
| 機構的蓋章: Stamp of the institution: 日期: Date: | | |

[#] 見「與教育或科研有關的人士或機構根據《中醫藥條例》第 158(1)條豁免有關中藥材/中成藥的製造/中成藥的批發條文規限的申請須知」(上稱申請須知)內的要求。Refer to the requirements of the "Guidelines on application of exemption in relation to Chinese herbal medicines or manufacturer licence or wholesaler licence in proprietary Chinese medicines by a person or institution concerned with education or scientific research in accordance with section 158(1) of the Chinese Medicine Ordinance" ("the Guidelines").

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,請與衞生署中醫藥規管辦公室聯絡(電話號碼: 2319 5119)。
 - If an applicant wishes to amend or inquire personal information after submission of the application form, please contact the Chinese Medicine Regulatory Office of Department of Health (telephone no. 2319 5119).
- 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.