2003 年第 229 號法律公告

《〈中藥規例〉(第 549 章，附屬法例 F) 2003 年 (生效日期) (第 2 號) 公告》

現根據《中藥規例》第 1 條，指定 2003 年 12 月 19 日為該規例第 15 及 38 條及附表 3 開始實施的日期。

衞生福利及食物局局長
楊永強

2003 年 10 月 17 日

L.N. 229 of 2003

立法會 CB(2) 251/03-04(03)號文件
LC Paper No. CB(2) 251/03-04(03)

CHINESE MEDICINES REGULATION (CAP. 549 SUB. LEG. F) (COMMENCEMENT) (NO. 2) NOTICE 2003

Under section 1 of the Chinese Medicines Regulation, I appoint 19 December 2003 as the day on which sections 15 and 38 and Schedule 3 to the Regulation shall come into operation.

Dr. E. K. YEOH
Secretary for Health, Welfare and Food

17 October 2003

(*b*) 證明該項交易的發票或其他文件保存在該牌照所關乎的處所內，保存期不得少於自該項交易的日期起計的 2 年。

14. 就附表 2 藥材領有批發商牌照的持牌人的附加職責——備存紀錄

(1) 就附表 2 藥材領有中藥材批發商牌照的持牌人須確保，他藉以獲取、收取、銷售或分銷附表 2 藥材的每項交易均有發票或其他文件證明。

(2) 該持牌人須確保，證明該項交易的發票或其他文件載有關於該項交易的以下詳情——

(*a*) 交易日期；

(*b*) 所獲取、收取、銷售或分銷 (視屬何情況而定) 的藥材的名稱及份量；

(*c*) 以下的人 (視屬何情況而定) 的姓名或名稱、地址及電話號碼——

(i) 向他銷售或分銷該藥材的人；或

(ii) 獲他銷售或分銷該藥材的人；及

(*d*) 該發票或其他文件的參考編號。

(3) 該持牌人亦須確保，證明該項交易的發票或其他文件保存在該牌照所關乎的處所內，保存期不得少於自該項交易的日期起計的 2 年。

第 5 部

中成藥的註冊

15. 就中成藥而須註冊的詳情

就本條例第 121(1)(*b*) 條而言，以下是就任何中成藥而須註冊的詳情——

(*a*) 該成藥的中英文名稱；

(*b*) 該成藥的劑型形式；

(*c*) 該成藥的每種有效成分的名稱及份量；

(*b*) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

14. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 2 medicines—keeping of records

(1) A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 2 medicines shall ensure that every transaction whereby a Schedule 2 medicine is acquired, received, sold or distributed by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction—

(*a*) the date of the transaction;

(*b*) the name and quantity of the medicine acquired, received, sold or distributed, as the case may be;

(*c*) the name, address and telephone number of—

(i) the person who sells or distributes the medicine to him; or

(ii) the person to whom he sells or distributes the medicine,

as the case may be; and

(*d*) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

PART 5

REGISTRATION OF PROPRIETARY CHINESE MEDICINES

15. Particulars to be registered for proprietary Chinese medicines

For the purposes of section 121(1)(*b*) of the Ordinance, the following particulars are required to be registered for a proprietary Chinese medicine—

(*a*) its Chinese and English name;

(*b*) its dose form;

(*c*) the name and quantity of each of its active ingredient;

(*d*) 該成藥的每種賦形劑(如有的話)的名稱及份量；
(*e*) 該成藥的規格說明；
(*f*) 該成藥的主治用途(如有的話)；
(*g*) 該成藥的用量及使用方法；
(*h*) 附加或印刷在該成藥的包裝上的每一份標籤；
(*i*) 為該成藥在香港銷售而供應的說明書；
(*j*) 將會為該成藥在香港境外銷售(如有的話)而供應的每一份說明書；
(*k*) 該成藥的每一位製造商的姓名或名稱及地址；及
(*l*) 該成藥的功能或藥理作用。

第 6 部

製造商牌照的持牌人的職責

16. 製造商牌照的持牌人的一般職責

製造商牌照的持牌人須確保——
(*a*) 該牌照所關乎的處所保持衞生；
(*b*) 在有用以製造中成藥的成分或包裝物料或此兩者在該處所內貯存的情況下，該處所內——
(i) 留有足夠空間；及
(ii) 備有足夠和適當的設施，
以貯存該等成分或包裝物料或此兩者(視屬何情況而定)；
(*c*) 貯存成分或包裝物料或此兩者的設施(如有的話)均保持於良好狀況；
(*d*) 在有任何附表 1 藥材與任何附表 2 藥材或慣常獲華人作藥用的源於植物、動物或礦物的物料貯存在同一處所內的情況下，該附表 1 藥材是與該附表 2 藥材或該物料有效地分開貯存的；
(*e*) 該處所內備有適合在該牌照指明的製造程序中使用的裝置及設備；
(*f*) 在該製造程序中使用的裝置及設備均保持於良好狀況；

(*d*) the name and quantity of each of its excipient (if any);
(*e*) its specification;
(*f*) its indication (if any);
(*g*) its dosage and method of usage;
(*h*) each of its labels to be attached or printed on its package;
(*i*) the package insert to be supplied for its sales inside Hong Kong;
(*j*) each of the package inserts to be supplied for its sales outside Hong Kong (if any);
(*k*) the name and address of each of its manufacturer; and
(*l*) its function or pharmacological action.

PART 6

DUTIES OF HOLDERS OF MANUFACTURER LICENCES

16. General duties of holders of manufacturer licences

A holder of a manufacturer licence shall ensure that—
(*a*) the premises to which the licence relates are maintained in sanitary condition;
(*b*) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are stored in the premises—
(i) adequate space; and
(ii) adequate and suitable facilities,
for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;
(*c*) the facilities (if any) for storing ingredients or packing materials, or both, as the case may be, are maintained in good condition;
(*d*) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;
(*e*) fittings and equipment suitable for use in the manufacturing process specified in the licence are provided in the premises;
(*f*) the fittings and equipment used in the manufacturing process are maintained in good condition;

(*b*) 該成藥——

(i) 是供內服或供內服兼外用，並會施用於或供應予由該中醫直接治理並獲開給該處方的病人的；或

(ii) 是只供外用，並會施用於或供應予由該中醫直接治理的病人的；及

(*c*) 中藥組在該成藥的製造程序開始當日最少一個工作天前，自有關製造商處收到包括第 (2) 款所列的詳情及附有第 (3) 款提述的承諾書的書面通知。

(2) 第 (1)(*c*) 款提述的通知書須載有——

(*a*) 將會製造的中成藥的份量；

(*b*) 有關處方中列出的每一種成分的名稱及份量；

(*c*) 該成藥的劑型形式；

(*d*) 有關註冊或表列中醫的姓名及地址；及

(*e*) 該中醫委託有關製造商製造該成藥的日期。

(3) 第 (1)(*c*) 款提述的通知書須附有有關註冊或表列中醫向有關製造商發出的承諾書，承諾有關中成藥只會施用於或供應予以下人士——

(*a*) (如該成藥是只供內服或供內服兼外用的) 由他直接治理並獲開給該處方的病人；或

(*b*) (如該成藥是只供外用的) 由他直接治理的一名或多於一名的病人。

第 13 部

表格

38. 中成藥銷售證明書

根據本條例第 130(1) 條發出的證明書須符合附表 3 訂明的格式。

(*b*) the medicine is—

(i) for internal application or both internal and external application, and the medicine is to be administered or supplied to the patient to whom the prescription is given and who is under the direct care of the Chinese medicine practitioner; or

(ii) for external application only, and the medicine is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner; and

(*c*) the Medicines Board has received from the manufacturer, at least 1 working day before the day on which the manufacturing process of the medicine begins, a written notification including the particulars set out in subsection (2) and being accompanied by an undertaking referred to in subsection (3).

(2) A notification referred to in subsection (1)(*c*) shall include—

(*a*) the quantity of the medicine to be manufactured;

(*b*) the names and quantities of each ingredient listed in the prescription;

(*c*) its dose form;

(*d*) the name and address of the registered or listed Chinese medicines practitioner; and

(*e*) the date on which the Chinese medicine practitioner entrusts the manufacturer to manufacture the proprietary Chinese medicine.

(3) A notification referred to in subsection (1)(*c*) shall be accompanied by a written undertaking given by the registered or listed Chinese medicine practitioner to the manufacturer, stating that the medicine will only be administered or supplied to—

(*a*) (in the case where the medicine is for internal application or both internal and external application) the patient to whom the prescription is given and who is under his direct care; or

(*b*) (in the case where the medicine is for external application only) a patient or patients under his direct care.

PART 13

FORMS

38. Certificate of sale of proprietary Chinese medicine

A certificate issued under section 130(1) of the Ordinance shall be in the form prescribed in Schedule 3.

[附屬法例]

附表 3　[第 38 條]

中成藥銷售證明書

《中醫藥條例》
(第 549 章)

中成藥銷售證明書

中成藥名稱：(中文) _____

(英文) _____

劑型形式：_____

包裝規格說明：_____

有效成分的名稱及份量(為該成藥在香港銷售而須供應的說明書中列明者)：_____

_____

_____

製造商的姓名或名稱：_____

_____

製造商的地址：_____

_____

現證明——

(*a*) 本證明書指明的中成藥已根據《中醫藥條例》第 121 條註冊；

證明書編號：_____

註冊日期：_____

(*b*) 製造該中成藥所在的香港處所經定期視察；

(*c*) 其他述明(如適用的話)：_____

_____

本證明書指明的中成藥獲准在香港銷售。

本證明書有效期直至 _____ 為止。

發出日期：_____

_____ 代行
中藥組

香港特別行政區

[Subsidiary]

SCHEDULE 3　[s. 38]

CERTIFICATE OF SALE OF PROPRIETARY CHINESE MEDICINE

CHINESE MEDICINE ORDINANCE
(Chapter 549)

CERTIFICATE OF SALE OF PROPRIETARY CHINESE MEDICINE

Name of the proprietary Chinese medicine: (Chinese) _____

(English) _____

Dose form: _____

Packing specification: _____

Names and quantities of its active ingredients (as set out in a package insert of the medicine required to be supplied for its sales in Hong Kong): _____

_____

Manufacturer(s) name: _____

Address: _____

_____

It is certified that—

(*a*) the proprietary Chinese medicine specified in this Certificate is registered under section 121 of the Chinese Medicine Ordinance;

Certificate no.: _____

Date of registration: _____

(*b*) the premises in Hong Kong in which the proprietary Chinese medicine is manufactured are subject to regular inspections;

(*c*) other statements (if applicable): _____

_____

The proprietary Chinese medicine is allowed to be sold in Hong Kong.

This Certificate is valid until _____.

Date of issue: _____

_____
for Chinese Medicines Board

Hong Kong Special Administrative Region