

**Practising Guidelines  
for  
Wholesalers of  
Proprietary Chinese Medicines**



香港中醫藥管理委員會  
Chinese Medicine Council of Hong Kong

**April 2003**

# Practising Guidelines for Wholesalers of Proprietary Chinese Medicines



香港中醫藥管理委員會  
Chinese Medicine Council of Hong Kong

# Chinese Medicines

## Contents

---

<b>1.</b>	<b>Introduction</b>	<b>1</b>
<b>2.</b>	<b>Interpretation</b>	<b>1</b>
<b>3.</b>	<b>Personnel</b>	<b>3</b>
3.1	Responsibilities of Wholesalers of Proprietary Chinese Medicines	3
3.2	Personnel Engaged in Wholesale Dealing in Proprietary Chinese Medicines	5
<b>4.</b>	<b>Premises</b>	<b>5</b>
4.1	Business Area	5
4.2	Warehouse	6
<b>5.</b>	<b>Scope of Business</b>	<b>6</b>
5.1	Purchase of Proprietary Chinese Medicines	7
5.2	Inspection, Acceptance and Storage of Proprietary Chinese Medicines	7
5.3	Sale or Distribution of Proprietary Chinese Medicines	8
5.4	Transportation of Proprietary Chinese Medicines	8
5.5	Labelling and Package Insert	8
<b>6.</b>	<b>Complaint and Recall System of Proprietary Chinese Medicines</b>	<b>12</b>
6.1	Complaint System	12
6.2	Recall System	13
6.3	Monitoring of Adverse Reactions of Proprietary Chinese Medicines	14
<b>7.</b>	<b>Keeping of Transaction Documents</b>	<b>14</b>
<b>8.</b>	<b>Final Remarks</b>	<b>15</b>

---

# Chinese Medicines

## 1. Introduction

These practising guidelines have been prepared by the Chinese Medicines Board (the Medicines Board) under the Chinese Medicine Council of Hong Kong (the Council) to promote the regularization of the Chinese medicines trade. All people engaged in the trade of wholesale dealing in proprietary Chinese medicines are encouraged to acquire the relevant knowledge and to adhere to professional ethics to ensure the highest standards of practice. The Council wishes to ensure the quality and safety of Chinese medicines, to protect the health of the public, and to boost the confidence of the public in using Chinese medicines.

These practising guidelines provide reference for people concerned to enable them to meet the stated requirements. These guidelines do not include all the matters related to the practising requirements. Rather, they will provide guidance on certain essential subjects. The legislation, including the Chinese Medicine Ordinance, Chinese Medicines Regulation, Chinese Medicine (Fees) Regulation and Chinese Medicines Traders (Regulatory) Regulation, should be taken as the standard for regulation of Chinese medicines traders.

## 2. Interpretation

“Active ingredient”, as prescribed by the Chinese Medicine Ordinance, in relation to a proprietary Chinese medicine, means a substance or compound that is used or is intended to be used in the manufacture of the proprietary Chinese medicine and that contributes to the pharmacological effect or effects of the proprietary Chinese medicine.

“Batch” means a fixed quantity of proprietary Chinese medicine produced in the same continuous production cycle, and having the same nature and quality within specified limits.

“Batch number” means a series of numbers, letters or other symbols, or a series consisting of a combination of numbers, letters and other symbols, used for the purpose of identifying when and by whom the proprietary Chinese medicine is produced.

“Expiry date”, as prescribed by the Chinese Medicines Regulation, in relation to a proprietary Chinese medicine, means the expiry date of the medicine as determined by the manufacturer who produces the medicine, being the date after which the medicine should not be administered.

“Label” includes any statement forming part of or affixed to the container or package of proprietary Chinese medicines.

“Package”, as prescribed by the Chinese Medicine Ordinance,

- (a) means any box, packet or other article in which any proprietary Chinese medicine is enclosed; and
- (b) in the case where such box, packet or other article is enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question.

“Package insert”, as prescribed by the Chinese Medicine Ordinance, means any leaflet, notification or other written material supplied with the package of a proprietary Chinese medicine to provide information in respect of the proprietary Chinese medicine, but does not include a label.

“Proprietary Chinese medicine”, as prescribed by the Chinese Medicine Ordinance, means any proprietary product –

- (a) composed solely of the following as active ingredients –
  - (i) any Chinese herbal medicines; or
  - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
  - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in a finished dose form; and
- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

“Recall” means the remedial measures undertaken by a wholesaler of proprietary Chinese medicines when the proprietary Chinese medicines supplied by him are identified to have quality or safety problems, with a view to preventing such proprietary Chinese medicines that are found to be dangerous, injurious to health, or unfit for human consumption, from further sale or use.

# Chinese Medicines

“Wholesale dealing in proprietary Chinese medicines” means obtaining or importing any proprietary Chinese medicine for the purpose of selling to:

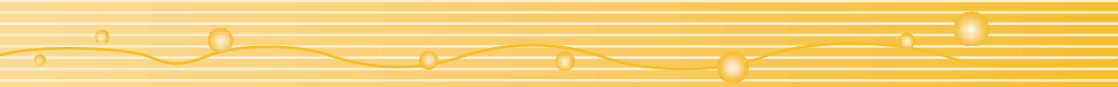
- (a) a manufacturer; or
- (b) a person who obtains such proprietary Chinese medicine for the purpose of selling again, supplying, or causing to supply, such medicine to a third party in the course of business or activity carried out by that person and “wholesaler of proprietary Chinese medicines” shall be construed accordingly.

## 3. Personnel

The wholesalers of proprietary Chinese medicines play an important role in the prevention of counterfeit proprietary Chinese medicines or medicines of dubious quality from entering the retail market through the wholesale process, during the distribution of proprietary Chinese medicines in the market. Hence, persons engaged in this trade should possess the basic knowledge relevant to their duties and work conscientiously, under proper business management, to safeguard public health.

### 3.1 Responsibilities of Wholesalers of Proprietary Chinese Medicines

- (1) Should not sell proprietary Chinese medicine which is not registered with the Medicines Board under the Council (please refer to section 119(1) of the Chinese Medicine Ordinance);
- (2) Should not engage in the dealing of proprietary Chinese medicines of dubious quality, or suspected to be counterfeit products;
- (3) Should not sell or distribute proprietary Chinese medicines after the expiry date;
- (4) Implement and comply with the prescribed codes of practice and relevant laws, such as:
  - i. under the Chinese Medicine Ordinance (Cap. 549), the provisions related to the wholesalers of proprietary Chinese medicines, and the provisions related to the registration, labelling and package insert of proprietary Chinese medicines;

- 
- ii. under the Import and Export Ordinance (Cap. 60), the restrictions related to the import, and export control, of proprietary Chinese medicines;
  - iii. under the Public Health and Municipal Services Ordinance (Cap. 132), the restrictions related to the suitability of medicines for human consumption, and the affixing of false label;
  - iv. under the Animals and Plants (Protection of Endangered Species) Ordinance (Cap. 187), the restrictions related to the control of proprietary Chinese medicines containing endangered species;
  - v. under the Undesirable Medical Advertisements Ordinance (Cap. 231), the restrictions related to the control of advertising of medicines (including proprietary Chinese medicines);
  - vi. under the Waste Disposal Ordinance (Cap. 354), the provisions related to the disposal of waste; and
  - vii. under the Trade Descriptions Ordinance (Cap. 362), the restrictions related to the control of counterfeit medicines.

(Please refer to the various ordinances for details. The full text of the ordinances can be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910 or downloaded from the Internet: [www.justice.gov.hk](http://www.justice.gov.hk) ).

- (5) Ensure that the premises are in all respects suitable for the wholesale business in proprietary Chinese medicines, such as the provision of adequate space. At the same time, they should ensure that there is no source of pollution that may contaminate proprietary Chinese medicines, in the vicinity of the premises;
- (6) Display the wholesaler licence in proprietary Chinese medicines at a prominent place in the business premises; and
- (7) Properly manage the business of wholesale dealing in proprietary Chinese medicines.

# Chinese Medicines

## 3.2 Personnel Engaged in Wholesale Dealing in Proprietary Chinese Medicines

The wholesalers of proprietary Chinese medicines should employ personnel with the following knowledge and duties:

### 3.2.1 Knowledge Requirements

- (1) Adequate knowledge of the proprietary Chinese medicines being traded, such as names, specifications, expiry date, storage instructions, method of usage and other related matters; and
- (2) Adequate knowledge of warehouse management, such as inspection, acceptance, storage and dispatch of proprietary Chinese medicines and other related matters.

### 3.2.2 Duties

- (1) Ensure the accuracy of the quantities of proprietary Chinese medicines being stored into, and dispatched from, the warehouse. Also they should ensure that the medicines are of good quality and that the medicines are affixed with appropriate labels and attached with appropriate package inserts;
- (2) Ensure that the proprietary Chinese medicines are stored under suitable conditions; and
- (3) Maintain the cleanliness and hygiene of the premises.

## 4. Premises

The wholesalers of proprietary Chinese medicines should provide suitable premises for the wholesale business in proprietary Chinese medicines. In general, such premises can be divided into two parts – the business area and warehouse. Relevant contents are as follows:

### 4.1 Business Area

- (1) Should be maintained in sanitary condition (please refer to section 20(a) of the Chinese Medicines Regulation); and

- (2) If necessary, set up display cabinets that correspond to the scale of business.

## 4.2 Warehouse

- (1) Should correspond to the scale of the business and to the storage requirements of the proprietary Chinese medicines (please refer to section 20(b) of the Chinese Medicines Regulation);
- (2) Should be maintained in sanitary condition (please refer to section 20(a) of the Chinese Medicines Regulation);
- (3) Should implement appropriate measures to prevent contamination and mix-ups; and
- (4) Should be equipped with the following facilities (please refer to section 20(c) of the Chinese Medicines Regulation):
  - i. facilities for detecting and regulating the temperature and humidity;
  - ii. facilities for ventilation and for the obstruction of direct sunlight;
  - iii. adequate lighting facilities; and
  - iv. facilities for the control of insects, rodents, humidity, mildew and for the prevention of fire.

## 5. Scope of Business

The wholesale dealing in proprietary Chinese medicines refers to the trade in which proprietary Chinese medicine is transacted in bulk. The scope of business includes import and export, or sale of proprietary Chinese medicines in Hong Kong, or both activities. All proprietary Chinese medicines should be registered with the Medicines Board under the Council before they can be sold or distributed in Hong Kong. When re-exporting proprietary Chinese medicines, the wholesalers should keep complete records of the proprietary Chinese medicines properly, to facilitate checking.

# Chinese Medicines

## 5.1 Purchase of Proprietary Chinese Medicines

Purchase proprietary Chinese medicines from reputable suppliers.

## 5.2 Inspection, Acceptance and Storage of Proprietary Chinese Medicines

### 5.2.1 Inspection and Acceptance of Proprietary Chinese Medicines

- (1) Check the name, specifications, batch number, quantity and expiry date of each batch of proprietary Chinese medicine purchased against the invoice, and ensure that the packages of the proprietary Chinese medicines to be stored into the warehouse are intact; and
- (2) Store proprietary Chinese medicines of dubious quality separately. Contact the supplier of such medicines as soon as possible for proper remedy.

### 5.2.2 Storage of Proprietary Chinese Medicines

- (1) After inspection and acceptance, the proprietary Chinese medicines should be stored in the warehouse promptly according to the storage instructions as prescribed by the producer;
- (2) Proprietary Chinese medicines should be stored according to their classification. Medicines of a nature that affect each other should be stored separately. Medicines for internal use should be stored separately from those for external use. Medicines with names and packages that may be easily mixed up should be stored separately;
- (3) Ensure that all proprietary Chinese medicines sold or distributed are packed using materials that are sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicines (please refer to section 20(e) of the Chinese Medicines Regulation); and
- (4) Proprietary Chinese medicines returned by customers should be stored separately. They should only be sold or distributed again after being found to meet the standards after inspection.

### **5.3 Sale or Distribution of Proprietary Chinese Medicines**

- (1) Ensure that no proprietary Chinese medicine is sold or distributed after the expiry date (please refer to section 20(d) of the Chinese Medicines Regulation);
- (2) Verify the name, specification and quantity of the proprietary Chinese medicines, according to the purchase order or dispatch slip, before sale or distribution; and
- (3) Sell or distribute proprietary Chinese medicines in chronological order according to the expiry date, i.e. “first expired, first-out”.

### **5.4 Transportation of Proprietary Chinese Medicines**

- (1) Ensure that proprietary Chinese medicines are consigned for transport under suitable arrangements. Such arrangements are made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicines (please refer to section 20(f) of the Chinese Medicines Regulation); and
- (2) Take care when conveying, loading and unloading proprietary Chinese medicines. Place the medicines in the exact way indicated by the sign on the external package.

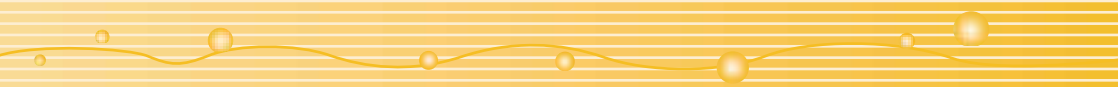
### **5.5 Labelling and Package Insert**

#### **5.5.1 Labelling**

- (1) The wholesalers of proprietary Chinese medicines should ensure that the proprietary Chinese medicines sold in Hong Kong comply with the regulations on labelling as prescribed by the Chinese Medicine Ordinance. They should ensure that the proprietary Chinese medicines sold in Hong Kong or in their possession for the purpose of selling in Hong Kong have the particulars on the label of the package being clearly and distinctly set out and not in any way obscured or obliterated (please refer to section 26 (1) of the Chinese Medicines Regulation);

# Chinese Medicines

- (2) Except as otherwise provided, a label on a package of a proprietary Chinese medicine, whether being the outermost package to be sold or distributed to an ultimate user of the medicine or otherwise, should include the following particulars, at least in Chinese (please refer to section 26 (2) of the Chinese Medicines Regulation):
- i. the name of the medicine;
  - ii. (A) (if the medicine is composed of less than 3 kinds of active ingredients) the name of each kind of active ingredient; or  
(B) (if the medicine is composed of 3 or more kinds of active ingredients) the names of more than half of the total number of kinds of active ingredients;
  - iii. the name of the country or territory in which the medicine is produced;
  - iv. the registration number of the medicine as specified in its certificate of registration;
  - v. (A) (if the package is the outermost package) the name of the holder of the certificate of registration of the medicine as specified in the certificate; or  
(B) (if the package is not the outermost package) either the particulars set out in paragraph v.(A) or the name of the manufacturer who produces the medicine;
  - vi. its packing specification;
  - vii. its dosage and method of usage;
  - viii. its expiry date; and
  - ix. its batch number.

- 
- (3) If a package of a proprietary Chinese medicine is in the form of a strip pack, blister pack or similar article and not being the outermost package to be sold or distributed to an ultimate user of the medicine, the label on the package of such medicine should include the following particulars, at least in Chinese (please refer to section 26(3) (a) of the Chinese Medicines Regulation):
- i. the name of the medicine;
  - ii. the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine;
  - iii. its expiry date;
  - iv. its packing specification; and
  - v. its batch number.
- (4) If a package of a proprietary Chinese medicine is in the form of an ampoule, vial or similar receptacle, with not more than 10 ml capacity or equivalent, and not being the outermost package to be sold or distributed to an ultimate user of the medicine, the label on the package of such medicine should include, at least in Chinese, the name of the medicine (please refer to section 26(3) (b) of the Chinese Medicines Regulation);
- (5) If a package of a proprietary Chinese medicine contains a single dose in the form of a pill and not being the outermost package to be sold or distributed to an ultimate user of the medicine, the label on the package of such medicine should include, at least in Chinese, the name of the medicine (please refer to section 26(3) (c) of the Chinese Medicines Regulation); and
- (6) The wholesalers of proprietary Chinese medicines who export or have in their possession for the purpose of exporting a proprietary Chinese medicine manufactured in Hong Kong should ensure that a label on the outermost package of the medicine likely to be sold or distributed to an ultimate user of the medicine includes the particulars listed below. Such particulars should be clearly and distinctly set out and not in any way obscured or obliterated (please refer to section 27 of the Chinese Medicines Regulation):

- i. the name of the medicine;
- ii. the name of the holder of the certificate of registration of the medicine as specified in the certificate; and
- iii. the registration number of the medicine as specified in its certificate of registration.

## 5.5.2 Package Insert

The wholesalers of proprietary Chinese medicines should ensure that the proprietary Chinese medicines sold in Hong Kong comply with the regulations on package insert as prescribed by the Chinese Medicine Ordinance. They should ensure that the package insert of the proprietary Chinese medicines sold in Hong Kong or have in their possession for the purpose of selling in Hong Kong includes the particulars listed below, being clearly and distinctly set out and not in any way obscured or obliterated, and at least in Chinese (please refer to section 28 of the Chinese Medicines Regulation):

- i. the name of the medicine;
- ii. (A) (if the medicine is composed of less than 3 kinds of active ingredients) the name of each kind of active ingredient and its quantity; or  
(B) (if the medicine is composed of 3 or more kinds of active ingredients) the names of more than half of the total number of kinds of active ingredients and their respective quantities;
- iii. either the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine;
- iv. its dosage and method of usage;
- v. its functions and pharmacological action;
- vi. its indications (if any);
- vii. its contra-indications (if any);

- viii. its side-effects (if any);
- ix. its toxic effects (if any);
- x. the precautions to be taken regarding its use (if any);
- xi. its storage instructions; and
- xii. its packing specification.

## **6. Complaint and Recall System of Proprietary Chinese Medicines**

The wholesalers of proprietary Chinese medicines should set up and maintain a system of complaint and recall to enable the rapid and, so far as practicable, complete recall of any proprietary Chinese medicine sold or distributed, in the event of the medicine being found to be dangerous, injurious to health, or unfit for human consumption (please refer to section 20(g) of the Chinese Medicines Regulation).

### **6.1 Complaint System**

- (1) Set up a complaint handling system;
- (2) Record, in detail, all information related to complaints, and conduct appropriate investigation;
- (3) Record, in detail, the result of investigation and follow-up action;
- (4) Conduct regular and comprehensive review of the complaint records. If a problem is found to occur repeatedly, launch a full-scale study and investigation; and
- (5) Communicate the related information to the relevant suppliers of the proprietary Chinese medicines, if necessary.

## 6.2 Recall System

- (1) The wholesalers of proprietary Chinese medicines should set up a proper recall system to ensure that they can rapidly recall any proprietary Chinese medicine identified to have quality or safety problems. In addition, the Medicines Board under the Council may order any wholesaler of proprietary Chinese medicines to carry out recall when necessary. An appropriate recall system should include the following:
  - i. set up the recall procedures to enable the effective and rapid recall of any proprietary Chinese medicine;
  - ii. assign a designated person to perform and coordinate the recall;
  - iii. the designated person should be fully acquainted with all information related to the proprietary Chinese medicines, the distribution channels and any other information related to the recall;
  - iv. the designated person should promptly inform the customers or consumers of the recall arrangements; and
  - v. the designated person should properly store the recalled proprietary Chinese medicines and appropriately handle such medicines, for example, by returning or destroying such proprietary Chinese medicines.
- (2) The designated person should first inform the Medicines Board under the Council, before carrying out any recall;
- (3) During the course of recall, the designated person should report the progress of the recall to the Medicines Board under the Council regularly, including the quantity of the proprietary Chinese medicines sold, distributed and recalled, respectively, for the evaluation of the effectiveness of the recall; and
- (4) The designated person should inform local, mainland and overseas suppliers and customers of the recall.

### 6.3 Monitoring of Adverse Reactions of Proprietary Chinese Medicines

The wholesalers of proprietary Chinese medicines have the responsibility to collect information on all adverse reactions related to their proprietary Chinese medicines, in the course of processing complaints about such products or through other channels. They should communicate such information to the Medicines Board under the Council as soon as possible.

## 7. Keeping of Transaction Documents

The wholesalers of proprietary Chinese medicines should ensure that the transaction documents of the proprietary Chinese medicines meet the following requirements to enable the tracing of the source and distribution channels of proprietary Chinese medicines suspected to have problems whenever necessary.

- (1) The invoice or other document in respect of every transaction whereby a proprietary Chinese medicine is acquired, received, exported, sold or distributed should be kept in an organized manner to facilitate checking. Such invoices and documents should be retained in the premises to which the wholesaler licence relates for a period of not less than 2 years from the date of the transaction (please refer to sections 21(1) and (3) of the Chinese Medicines Regulation);
- (2) The relevant invoice or other document should contain the following particulars of the transaction (please refer to section 21(2) of the Chinese Medicines Regulation):
  - i. the date of the transaction;
  - ii. the name and quantity of the proprietary Chinese medicine acquired, received, exported, sold or distributed, as the case may be;
  - iii. the name, address and telephone number of the person who imports, sells or distributes the medicine to them, or the person to whom they export, sell or distribute the medicine, as the case may be; and
  - iv. the reference number of the invoice or other document.

# Chinese Medicines

- (3) Such invoices and documents should be kept intact. The information contained should be clear and no arbitrary alteration is allowed.

## **8. Final Remarks**

All people engaged in the wholesale dealing in proprietary Chinese medicines should follow these guidelines in operating their business. To keep pace with and facilitate development of the trade, these guidelines will be revised as appropriate based on actual operational experiences and any changes in the social circumstances. This would further improve the quality of proprietary Chinese medicines, and achieve the objective of safeguarding public health.



**Secretariat of the Chinese Medicine Council of Hong Kong**  
37/F, Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong