

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



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

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Practising Guidelines for Manufacturers of Proprietary Chinese Medicines

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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 manufacture of 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 the regulation of Chinese medicines traders.

For those who intend to follow good practices in manufacture and quality control of proprietary Chinese medicines, please refer to the Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines prepared by the Medicines Board under the Council.

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.

“Cross-contamination” means contamination of an ingredient, intermediate product or proprietary Chinese medicine with another ingredient, intermediate product or proprietary Chinese medicine during the manufacturing process.

“Excipient”, as prescribed by the Chinese Medicines Regulation, in relation to a proprietary Chinese medicine, means a substance or compound that is used or intended to be used in the preparation or production of the medicine but which is not an active ingredient of the medicine.

“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.

“Herbal medicine” means any of the listed Chinese herbal medicine and any other materials of herbal, animal or mineral origin customarily used by the Chinese under the guidance of Chinese medicine theories.

“Ingredient”, as prescribed by the Chinese Medicines Regulation, in relation to a proprietary Chinese medicine, means its active ingredient or excipient.

“Intermediate product”, as prescribed by the Chinese Medicines Regulation, means a substance or compound generated in the course of manufacture of a proprietary Chinese medicine and which is to be used in further preparation or production process of the medicine.

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

“Listed Chinese herbal medicine” means any of the substances specified in Schedule 1 or 2 of the Chinese Medicine Ordinance.

“Manufacture”, as prescribed by the Chinese Medicine Ordinance, in relation to a proprietary Chinese medicine, means the preparation, production, packing or re-packing of the proprietary Chinese medicine for sale or distribution, and “manufacturer” shall be construed accordingly.

“Manufacturing process”, as prescribed by the Chinese Medicines Regulation, in relation to a proprietary Chinese medicine, means the preparation, production, packing or re-packing process of the medicine.

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“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.

“Packing material”, as prescribed by the Chinese Medicines Regulation, in relation to a proprietary Chinese medicine, means a material used for packing or re-packing the medicine.

“Processed herbal medicine” means the processed form of a herbal medicine, which has passed through treatment like cleaning, cutting, roasting or broiling, so as to comply with the prescribed specifications and thus meet the requirements of clinical therapy, dispensing and making preparations.

“Processing” means any type of treatment by means of cleaning, cutting, roasting or broiling applied to a herbal medicine under the guidance of Chinese medicine theories.

“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 manufacturer of proprietary Chinese medicines when the proprietary Chinese medicines/intermediate products supplied by him are identified to have quality or safety problems, with a view to preventing such proprietary Chinese medicines/intermediate products that are found to be dangerous, injurious to health or unfit for human consumption from further sale or use.

“Responsible person”, in relation to the manufacture of proprietary Chinese medicines, means a person responsible for the supervision of the manufacture or his deputies –

- (a) as nominated in an application for a manufacturer licence under section 132(1)(b) of the Chinese Medicine Ordinance; or
- (b) as notified to the Medicines Board under section 145(2) of the Chinese Medicine Ordinance.

“Schedule 1 medicine” means a listed Chinese herbal medicine specified in Schedule 1 of the Chinese Medicine Ordinance.

“Schedule 2 medicine” means a listed Chinese herbal medicine specified in Schedule 2 of the Chinese Medicine Ordinance.

3. Personnel

The manufacture of proprietary Chinese medicines means the whole process of producing a preparation for sale, using processed herbal medicines as major ingredients, together with appropriate excipients and in accordance with prescribed manufacturing process. It is specialized work. The operation during the manufacturing process will directly affect the safety, quality and efficacy of a proprietary Chinese medicine. Hence, persons engaged in this trade should possess the knowledge relevant to their duties, and should work conscientiously under proper factory management. This will ensure the manufacture of proprietary Chinese medicines of good quality, and therefore safeguard public health.

3.1 Responsibilities of Manufacturers of Proprietary Chinese Medicines

- (1) Ensure that there are suitable personnel to undertake the production, packing and management work in the factory;
- (2) Provide appropriate training to staff according to their duties, and ensure that the staff fully understand their duties;
- (3) 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 manufacturers 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 the 36 specified listed Chinese herbal medicines and all 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;
 - vii. under the Trade Descriptions Ordinance (Cap. 362), the restrictions related to the control of counterfeit medicines; and

- viii. under the Pharmacy and Poisons Ordinance (Cap. 138), the restrictions related to the control of medicines containing any western medicine as ingredients. Proprietary Chinese medicines should not contain any western medicine as ingredients.

(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).

- (4) Ensure that the premises are in all respects suitable for the manufacture of proprietary Chinese medicines, such as the provision of adequate space and ensuring that there is no source of pollution that may contaminate proprietary Chinese medicines/intermediate products in the vicinity of the premises. At the same time, they should ensure that the fittings and equipment will not adversely affect the building structure;
- (5) Display the manufacturer licence in proprietary Chinese medicines at a prominent place in the business premises; and
- (6) Properly manage the business of manufacture of proprietary Chinese medicines. Implement the requirements of the law, such as keeping of documents relating to the purchase of ingredients, manufacturing records, sales records and documents.

3.2 Knowledge Requirements and Duties of Responsible Persons

3.2.1 Knowledge Requirements

- (1) Basic knowledge of herbal medicines/processed herbal medicines: such as the names, the place of cultivation, function, and toxicity, as well as the method and techniques of processing of processed herbal medicines;
- (2) Basic knowledge of authenticating herbal medicines/processed herbal medicines: simple identification methods of their characteristics such as visual inspection, touching, smelling and tasting, as well as knowledge to determine the medicine's authenticity and quality;
- (3) Basic techniques and knowledge of the manufacture of proprietary Chinese medicines: such as the principles and methods of manufacture of proprietary Chinese medicines/intermediate products and quality control; and

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- (4) Knowledge of managing factory and proprietary Chinese medicines/intermediate products, in order to ensure the safety and reliability of the proprietary Chinese medicines/intermediate products.

3.2.2 Duties

- (1) Supervise the operation of the manufacturing process (please refer to section 16(k) of the Chinese Medicines Regulation);
- (2) Examine each batch of ingredients to be used in the manufacturing process, before use, to ensure that their identity and quality conform to the specifications and requirements (please refer to section 16(j) of the Chinese Medicines Regulation);
- (3) Ensure that the manufacturing process is carried out in sanitary condition and in accordance with prescribed requirements;
- (4) Ensure that each batch of proprietary Chinese medicine/intermediate product is examined before it is sold or distributed, to ensure that the quality is up to standards (please refer to section 16(m) of the Chinese Medicines Regulation);
- (5) Ensure that a reasonable quantity of control samples are retained for each batch of proprietary Chinese medicine/intermediate product for examination when necessary; and
- (6) Ensure that adequate steps have been taken to prevent contamination of any ingredient, packing material, intermediate product or proprietary Chinese medicine (please refer to section 16(l) of the Chinese Medicines Regulation).

4. Factory

The manufacturers of proprietary Chinese medicines should provide suitable premises for the manufacture, examination and storage of proprietary Chinese medicines/intermediate products. The factory should fulfill the following requirements:

- (1) Should be maintained in sanitary condition (please refer to section 16(a) of the Chinese Medicines Regulation);

- (2) The area of the factory should correspond to the scale of the manufacturing process;
- (3) The layout of the factory should be reasonably devised in accordance with the requirements of the manufacturing process, to prevent cross-contamination;
- (4) Should be equipped with the following facilities (please refer to sections 16(c), (h) and (i) of the Chinese Medicines Regulation):
 - i. facilities for detecting and regulating the temperature and humidity;
 - ii. facilities for ventilation, drainage 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) The area of the laboratory should correspond to the scale of the examination work. The examination of ingredients, proprietary Chinese medicines or intermediate products may be commissioned to reputable examination institutions according to the practical circumstances and examination condition;
- (6) The warehouse in the factory should correspond to the storage quantities and storage requirements of the materials (please refer to sections 16(b) and (g) of the Chinese Medicines Regulation); and
- (7) The ingredients, intermediate products, proprietary Chinese medicines and packing materials, etc., should be stored separately in the warehouse, to prevent mix-ups and contamination.

5. Fittings and Equipment

The manufacturers of proprietary Chinese medicines should provide suitable fittings and equipment. Their design, model and installation should conform with the requirements of the manufacturing process. Such fittings and equipment should be easy to operate, clean and maintain (please refer to section 16(e) of the Chinese Medicines Regulation).

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- (1) The design and installation of the fittings and equipment used for manufacturing proprietary Chinese medicines or generating intermediate products, should be suitable for the operation to be performed. All such fittings and equipment should be easy to clean, to prevent cross-contamination;
- (2) Fittings and equipment used for quality control should be suitable for the process to be performed, accurate, and reliable;
- (3) Before using any fitting and equipment, first check if it is functioning properly;
- (4) Manufacturers should arrange regular maintenance, and inspection for all fittings and equipment (please refer to section 16(f) of the Chinese Medicines Regulation); and
- (5) Defective fittings and equipment should not be used. Notices should be affixed on them to indicate the damage.

6. Scope of Business

The manufacture of proprietary Chinese medicines generally involves the production for sale of preparations using herbal medicines, processed herbal medicines or extracts of herbal medicines/processed herbal medicines together with appropriate excipients and in accordance with the prescribed manufacturing process. As such, it is very important for a manufacturer of proprietary Chinese medicines to maintain stringent manufacturing process and management of proprietary Chinese medicines/intermediate products. The main processes involved in the manufacture and management of proprietary Chinese medicines may include:

- (1) Purchase, inspection, acceptance, storage and dispatch of ingredients;
- (2) Production, packing, quality control, storage, sale, distribution and transportation of proprietary Chinese medicines; and/or
- (3) Generation, quality control, storage, sale, distribution and transportation of intermediate products.

6.1 Purchase of Ingredients

Ingredients should only be purchased from reputable suppliers.

6.2 Inspection and Acceptance of Ingredients

- (1) Inspect each batch of ingredients purchased and identify its authenticity and quality to ensure that it meets the requirements. Do not accept ingredients found to be of poor quality, containing impurities, deteriorated in quality, or of an unacceptable standard;
- (2) Staff responsible for inspection and acceptance should carefully check the quantity of the Schedule 1 medicines and ensure that the name of the supplier, the name and batch number of the medicines are properly marked on the containers or packages, together with a warning, at least in Chinese, stating “Toxic Chinese Medicine” (毒性中藥 or 毒性中藥); and
- (3) If the quality of an ingredient is dubious, store it separately and contact the supplier as soon as possible for proper remedy.

6.3 Storage of Ingredients

- (1) After inspection and acceptance, all ingredients should be put promptly into the warehouse and stored in conditions that conform to the prescribed requirements;
- (2) Each kind of ingredients should be stored according to its nature and classification, with its name clearly marked to prevent mix-ups; and
- (3) Schedule 1 medicines should be stored effectively separated from other herbal medicines and processed herbal medicines (please refer to section 16(d) of the Chinese Medicines Regulation). Each kind of Schedule 1 medicine should be individually packed, and affixed with an appropriate label, to prevent mix-ups.

6.4 Dispatch of Ingredients

- (1) Accurately weigh the ingredients according to the complete formulation. Set up a double-check system to ensure accuracy and reliability;

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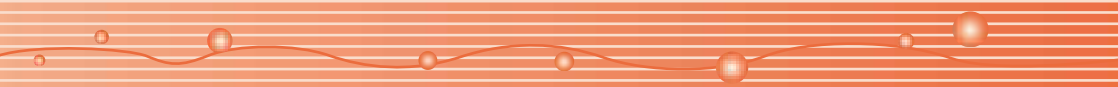
- (2) Examine the quality of the ingredients and promptly take action if any ingredient is found to have deteriorated in quality; and
- (3) Dispatch ingredients in chronological order according to the date of storing into the warehouse. In general, adopt the principle of “first-in, first-out” or “first-expired, first-out” to prevent the protracted storage of ingredients.

6.5 Production of Proprietary Chinese Medicines or Generation of Intermediate Products

- (1) Ensure that the premises, fittings and equipment have been cleaned properly before carrying out the production of proprietary Chinese medicines, or the generation of intermediate products;
- (2) Should be carried out according to the prescribed manufacturing process and records should be kept accordingly; and
- (3) Use appropriate fittings, equipment, apparatus and containers to ensure that the proprietary Chinese medicines/intermediate products will not be contaminated during the manufacturing process.

6.6 Packing of Proprietary Chinese Medicines

- (1) Upon inspection and acceptance, the packing materials of proprietary Chinese medicines should be stored separately to prevent mix-ups;
- (2) Dispatch packing materials according to the requirements of the packing process. Set up a double-check system to ensure accuracy;
- (3) Ensure that the premises, fittings and equipment have been cleaned properly, before packing;
- (4) Carry out packing according to the packing process and make records accordingly;
- (5) Check the packed proprietary Chinese medicines to ensure the absence of errors;

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- (6) The manufacturers 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);
- (7) 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;

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- viii. its expiry date; and
 - ix. its batch number.
- (8) 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.
- (9) 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);
- (10) 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);
- (11) The manufacturers 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 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.

- (12) The manufacturers 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.

6.7 Quality Control

- (1) There should be adequate facilities and operational procedures for the quality control of ingredients, intermediate products, proprietary Chinese medicines and the manufacturing processes. The quality control work may be commissioned to reputable examination institutions according to the practical circumstances and examination condition;
- (2) Examine each batch of ingredients used in the manufacturing process, the proprietary Chinese medicine produced and the intermediate product generated, to ensure that the quality of such proprietary Chinese medicine/intermediate product conforms to the requirements;
- (3) Retain the control sample of each batch of intermediate product which has been sold, under suitable conditions of storage, from the date on which the batch of product is generated until the expiry of 2 years from the date of the last transaction in the batch of product (please refer to section 16(r) of the Chinese Medicines Regulation); and
- (4) Retain the control sample of each batch of proprietary Chinese medicine manufactured in the course of manufacture, under suitable conditions of storage, from the date of the manufacture until the expiry of 2 years from the expiry date of the batch of medicine (please refer to section 16(s) of the Chinese Medicines Regulation).

6.8 Storage of Proprietary Chinese Medicines/Intermediate Products

- (1) Each batch of proprietary Chinese medicines/intermediate products should be stored separately from other substances. They can be sold or distributed only after they have been inspected and found to be of the required standard. They should then be promptly stored in the prescribed condition and area;
- (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 each container and package of intermediate product generated, or proprietary Chinese medicine manufactured in the course of manufacture is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the products or medicines (please refer to section 16(o) of the Chinese Medicines Regulation); and
- (4) Proprietary Chinese medicines/intermediate products returned by customers should be stored separately. They should only be sold or distributed again after being found to meet the standards after inspection.

6.9 Sale or Distribution of Proprietary Chinese Medicines/Intermediate Products

- (1) Do not sell or distribute expired proprietary Chinese medicines manufactured (please refer to section 16(n) of the Chinese Medicines Regulation);
- (2) Verify the name, specification and quantity of the proprietary Chinese medicines/intermediate products according to the purchase order or dispatch slip, before sale or distribution. Make proper records and retain relevant documents; and
- (3) Sell or distribute proprietary Chinese medicines in chronological order according to the expiry date, i.e. “first-expired, first-out”.

6.10 Transportation of Proprietary Chinese Medicines/Intermediate Products

- (1) Ensure that the proprietary Chinese medicines manufactured, or intermediate products generated, 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 proprietary Chinese medicines/intermediate products (please refer to section 16(p) of the Chinese Medicines Regulation); and
- (2) Take care when conveying, loading and unloading proprietary Chinese medicines/intermediate products. Place the medicines/products in the exact way indicated by the sign on the external package.

7. Complaint and Recall System of Proprietary Chinese Medicines/Intermediate Products

The manufacturers 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/ intermediate product sold or distributed, in the event of the medicine/product being found to be dangerous, injurious to health, or unfit for human consumption (please refer to section 16(q) of the Chinese Medicines Regulation).

7.1 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 distributors, if necessary.

7.2 Recall System

- (1) The manufacturers of proprietary Chinese medicines should set up a proper recall system to ensure that they can rapidly recall any proprietary Chinese medicine/intermediate product identified to have quality or safety problems. In addition, the Medicines Board under the Council may order any manufacturer 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/intermediate product;
 - 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/intermediate products, their distribution channels and any other information related to the recall;
 - iv. the designated person should promptly inform the customers and consumers of the recall arrangements; and
 - v. the designated person should properly store the recalled proprietary Chinese medicines/intermediate products and appropriately handle such medicines, for example, by destroying such proprietary Chinese medicines/intermediate products.
- (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/intermediate products 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.

7.3 Monitoring of Adverse Reactions of Proprietary Chinese Medicines

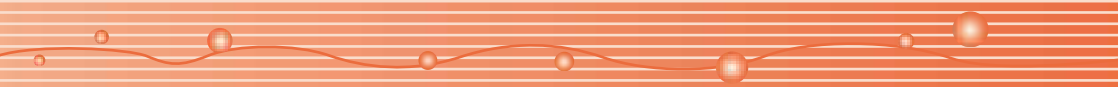
The manufacturers of proprietary Chinese medicines have the responsibility to collect information on all adverse reactions related to their proprietary Chinese medicines, in the course of processing complaints about such products or through other channels. They should communicate such information to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

8. Keeping of Records

The manufacturers of proprietary Chinese medicines should make proper records and/or retain relevant documents of purchasing ingredients, operation of manufacturing process, and sale or distribution of proprietary Chinese medicines/intermediate products, to facilitate checking whenever necessary.

8.1 Documents of Purchase of Ingredients (Please refer to section 17 of the Chinese Medicines Regulation)

- (1) The invoice or other document in respect of every transaction whereby an ingredient is acquired or received should be kept in an organized manner to facilitate checking;
- (2) The relevant invoice or other document should contain the following particulars of the transaction:
 - i. the date of the transaction;
 - ii. the name and quantity of the batch of ingredient acquired or received;
 - iii. the name, address and telephone number of the person who sells or distributes the batch of ingredient to them; and
 - iv. the reference number of the invoice or other document.
- (3) The invoices and other documents related to the transaction should be retained in the premises to which the manufacturer licence relates from the date of the transaction –

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- i. in the case where a batch of intermediate product is generated from the batch of ingredient, until the expiry of 2 years from the date of generation of the batch of product; or
 - ii. in the case where a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, until the expiry of 2 years from the expiry date of the batch of medicine.
- (4) Where two or more batches of intermediate product or proprietary Chinese medicine are generated or manufactured, as the case may be, from the batch of ingredient and they have different dates of generation or expiry dates, as the case may be, the invoice or other document should be retained until the expiry of 2 years from the latest of such dates of generation or expiry dates, as the case may be;
 - (5) Where a batch of intermediate product is generated and a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, the invoice or other document should be retained until the expiry of 2 years from the latter of the dates referred to in paragraph 8.1(3)i. or ii.; and
 - (6) Such invoices and documents should be kept intact. The information contained should be clear and no arbitrary alteration is allowed.

8.2 Manufacturing Records (Please refer to section 18 of the Chinese Medicines Regulation)

- (1) Ensure that the following particulars in respect of each manufacturing process are recorded:
 - i. the name of the intermediate product generated or proprietary Chinese medicine manufactured from the manufacturing process, or both, as the case may be;
 - ii. the quantity of the batch of intermediate product or proprietary Chinese medicine, or both, as the case may be;
 - iii. the expiry date and batch number of the batch of medicine (applicable only where a proprietary Chinese medicine is manufactured from the manufacturing process);

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- iv. the name and quantity of each ingredient or packing material used in the manufacturing process;
- v. a description of each manufacturing method used; and
- vi. the date on which the manufacturing process-
 - (A) begins; and
 - (B) is completed.

The particulars mentioned in paragraph 8.2(1)ii. and vi. (B) should be recorded within 72 hours after the manufacturing process is completed. The other particulars should be recorded within 72 hours after the manufacturing process begins.

- (2) The manufacturing records should be retained in the premises to which the manufacturer licence relates from the date of preparation of the record –
 - i. in the case where the record relates to a batch of intermediate product, until the expiry of 2 years from the date of the last transaction in the batch of product or the date when the batch of product is used up by the licence holder, whichever is later;
 - ii. in the case where the record relates to a batch of proprietary Chinese medicine, until the expiry of 2 years from the expiry date of the batch of medicine; or
 - iii. in the case where the record relates to a batch of intermediate product and proprietary Chinese medicine, until the expiry of 2 years from the latter of the dates referred to in paragraph 8.2(2)i. or ii.
- (3) Ensure that the manufacturing records are kept in an organized manner, the handwriting is legible, the contents are true and the data are accurate. No arbitrary destruction or alteration is allowed.

8.3 Transaction Records and Documents

8.3.1 Transaction Records (please refer to sections 19(1) and (2) of the Chinese Medicines Regulation)

- (1) Ensure that where any batch of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is sold or distributed, the following particulars of such transaction are recorded within 72 hours after the completion of the transaction:
 - i. the date of the transaction;
 - ii. the name and quantity of the batch of intermediate product or proprietary Chinese medicine, as the case may be;
 - iii. the name, address and telephone number of the person to whom the batch of intermediate product or proprietary Chinese medicine is sold or distributed, as the case may be;
 - iv. the batch number of the batch of medicine (applicable only where the transaction relates to a proprietary Chinese medicine); and
 - v. the reference number of the invoice or other document evidencing the transaction.
- (2) The transaction records should be retained in the premises to which the manufacturer licence relates from the date of preparation of the record -
 - i. in the case where the transaction relates to a batch of intermediate product, until the expiry of 2 years from the date of the transaction; or
 - ii. in the case where the transaction relates to a batch of proprietary Chinese medicine, until the expiry of 2 years from the expiry date of the batch of medicine.
- (3) The transaction records should be kept in an organized manner and be easy to check. They should be kept intact and the information contained should be clear. No arbitrary alteration is allowed.

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8.3.2 Transaction Documents (please refer to section 19(3) of the Chinese Medicines Regulation)

- (1) The invoice or other document in respect of every transaction whereby a proprietary Chinese medicine/intermediate product is 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 manufacturer licence relates, from the date of the transaction until the expiry of 2 years from the dates referred to in paragraph 8.3.1(2)i. or ii., as the case may be;
- (2) The invoice or other document should contain the particulars referred to in paragraph 8.3.1(1); and
- (3) Such invoices and documents should be kept intact. The information contained should be clear and no arbitrary alteration is allowed.

9. Final Remarks

All people engaged in the manufacture of 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.

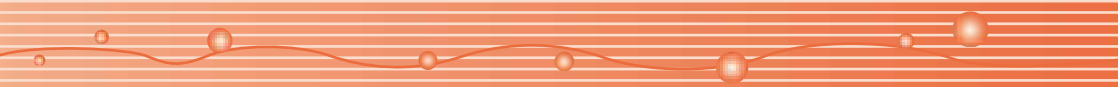
Appendix 1 Manufacture of Proprietary Chinese Medicines Entrusted by a Chinese Medicine Practitioner

The manufacturers of proprietary Chinese medicines may be entrusted by a Chinese medicine practitioner to manufacture proprietary Chinese medicines in accordance with a prescription given by him for administering, or supplying, the medicine to his patients. In addition to complying with the relevant requirements stated in the Chinese Medicine Ordinance and these guidelines, the following should be observed:

- (1) Submit a written notification to the Medicines Board under the Council at least 1 working day before the day on which the manufacturing process of the medicine begins. The written notification should contain the following particulars (please refer to sections 37(1)(c) and (2) of the Chinese Medicines Regulation):
 - i. the quantity of the proprietary Chinese medicine to be manufactured;
 - ii. the names and quantities of each ingredient listed in the prescription;
 - iii. its dose form;
 - iv. the name and address of the Chinese medicine practitioner; and
 - v. the date on which the Chinese medicine practitioner entrusts the manufacturer to manufacture the proprietary Chinese medicine.
- (2) The notification should be accompanied by a written undertaking given by the Chinese medicine practitioner, stating that the medicine will only be administered or supplied to the following persons (please refer to section 37(3) of the Chinese Medicines Regulation) –
 - i. 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
 - ii. in the case where the medicine is for external application only, a patient or patients under his direct care.
- (3) Manufacture the proprietary Chinese medicine in accordance with the prescription given by the Chinese medicine practitioner (please refer to section 37(1)(a)(ii) of the Chinese Medicines Regulation);

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- (4) If the prescription is given by a Chinese medicine practitioner to a patient under his direct care, and the prescription indicates that the medicine is for internal application, or both internal and external application, the label on the package of the medicine should include the following particulars, at least in Chinese (please refer to section 26(4)(d) of the Chinese Medicines Regulation):
- i. the name and address of the Chinese medicine practitioner;
 - ii. the name and address of the manufacturer who produces the medicine;
 - iii. its batch number;
 - iv. the date on which it is produced;
 - v. its dose form;
 - vi. its packing specification;
 - vii. its expiry date;
 - viii. the name and quantity of each ingredient listed in the prescription;
 - ix. a statement containing the following Chinese text –
 - (A) “須按照中醫指示使用”； or
 - (B) “須按照中医指示使用”；
 - x. if the statement referred to in paragraph ix. is to be available in English also, a statement containing the English text: “To be used only in accordance with the instructions of a Chinese medicine practitioner”;
 - xi. a statement containing the following Chinese text –
 - (A) “只供中醫施用於或供應予獲開給本成藥的處方，並且是由他直接治理的病人”； or
 - (B) “只供中医施用于或供应予获开给本成药的处方，并且是由他直接治理的病人”； and

- 
- xii. if the statement referred to in paragraph xi. is to be available in English also, a statement containing the English text: “To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to the patient to whom the prescription of this medicine is given and who is under his direct care.”
- (5) If the medicine is to be administered, or supplied, to a patient or patients under the direct care of the Chinese medicine practitioner, and the prescription indicates that the medicine is for external application only, the label on the package of the medicine should include the following particulars, at least in Chinese (please refer to section 26(4) (e) of the Chinese Medicines Regulation):
- i. the name and address of the Chinese medicine practitioner;
 - ii. the name and address of the manufacturer who produces the medicine;
 - iii. its batch number;
 - iv. the date on which it is produced;
 - v. its dose form;
 - vi. its packing specification;
 - vii. its expiry date;
 - viii. the name and quantity of each ingredient listed in the prescription;
 - ix. a statement containing the following Chinese text -
 - (A) “須按照中醫指示使用”; or
 - (B) “須按照中醫指示使用”;
 - x. if the statement referred to in paragraph ix. is to be available in English also, a statement containing the English text: “To be used only in accordance with the instructions of a Chinese medicine practitioner”;

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- xi. a statement containing the following Chinese text -
 - (A) “只供中醫施用於或供應予由他直接治理的病人”； or
 - (B) “只供中醫施用於或供應予由他直接治理的病人”；
- xii. if the statement referred to in paragraph xi. is to be available in English also, a statement containing the English text: “To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to a patient or patients under his direct care”;
- xiii. a statement containing the Chinese text: “只供外用”； and
- xiv. if the statement referred to in paragraph xiii. is to be available in English also, a statement containing the English text: “For external application only”.

Appendix 2: List of Schedule 1 Medicines of the Chinese Medicine Ordinance

Name	Name
Arsenic trioxide (砒霜)	Unprocessed Radix Aconiti Lateralis
Arsenolite (砒石)	(生附子)
Calomelas (輕粉)	Unprocessed Radix Euphorbiae
Cinnabaris (朱砂)	Fischerianae, Radix Euphorbiae
Flos Daturae Metelis (洋金花)	Ebracteolatae or Radix Stellerae
Flos Rhododendri Mollis (關羊花)	(生狼毒)
Huechys (紅娘蟲)	Unprocessed Radix Kansui (生甘遂)
Hydrargyri Oxydum Rubrum (紅粉)	Unprocessed Resina Garcinia Morellae
Lytta (青娘蟲)	(生藤黃)
Mercurous chloride and mercuric chloride	Unprocessed Rhizoma Arisaematis
(白降丹)	(生天南星)
Mercury (水銀)	Unprocessed Rhizoma Pinelliae
Mylabris (斑蝥)	(生半夏)
Orpiment (雌黃)	Unprocessed Rhizoma Typhonii or Radix
Radix Aconiti Brachypodi or Radix	Aconiti Coreani
Aconiti Szechenyiani (雪上一枝蒿)	(生白附子(禹白附、關白附))
Radix or Rhizoma Podophylli emodis, or	Unprocessed Semen Euphorbiae
Radix or Rhizoma Dysosmatis	(生千金子)
(鬼白(桃耳七、八角蓮))	Unprocessed Semen Hyoscyami
Radix Sophorae Tonkinensis (山豆根)	(生天仙子)
Realgar (雄黃)	Unprocessed Semen Strychni
Unprocessed Fructus Crotonis (生巴豆)	(生馬錢子)
Unprocessed Radix Aconiti (生川烏)	Venenum Bufonis (蟾酥)
Unprocessed Radix Aconiti Kusnezoffii	
(生草烏)	

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Appendix 3: List of Schedule 2 Medicines of the Chinese Medicine Ordinance

Name	Name
Agkistrodon (蕘蛇)	Caulis Fibraureae (黃藤)
Arisaema cum Bile (膽南星)	Caulis Gneti (買麻藤)
Aspongopus (九香蟲)	Caulis Hederae Sinensis (常春藤)
Asteriscus Pseudosciaenae (魚腦石)	Caulis Impatientis (透骨草)
Benzoinum (安息香)	Caulis Lonicerae (忍冬藤)
Bombyx Batryticatus (僵蠶)	Caulis Mahoniae (功勞木)
Bulbus Fritillariae Cirrhosae (川貝母)	Caulis Perillae (紫蘇梗)
Bulbus Fritillariae Hupehensis (湖北貝母)	Caulis Piperis Kadsurae (海風藤)
Bulbus Fritillariae Pallidiflorae (伊貝母)	Caulis Polygoni Multiflori (首烏藤)
Bulbus Fritillariae Thunbergii (浙貝母)	Caulis Sargentodoxae (大血藤)
Bulbus Fritillariae Ussuriensis (平貝母)	Caulis Sinomenii (青風藤)
Bulbus Lycoridis Radiatae (石蒜)	Caulis Spatholobi (雞血藤)
Cacumen Platycladi (側柏葉)	Caulis Tinosporae (寬根藤)
Cacumen Securinegae Suffruticosae (葉底珠)	Caulis Trachelospermi (絡石藤)
Cacumen Tamaricis (西河柳)	Cera Chinensis (蟲白蠟)
Calamina (爐甘石)	Colla Corii Asini (阿膠)
Calculus Bovis (牛黃)	Concha Arcae (瓦楞子)
Calculus Equi (馬寶)	Concha Haliotidis (石決明)
Calyx seu Fructus Physalis (錦燈籠)	Concha Margaritifera Usta (珍珠母)
Caulis Akebiae (木通)	Concha Mauritiae Arabicae (紫貝齒)
Caulis Ampelopsis Brevipedunculae (山葡萄)	Concha Meretricis seu Cyclinae (蛤殼)
Caulis Aristolochiae Manshuriensis (關木通)	Concretio Silicea Bambusae (天竺黃)
Caulis Bambusae in Taeniam (竹茹)	Cordyceps (冬蟲夏草)
Caulis Clematidis Armandii (川木通)	Corium Erinacei seu Hemiechianus (刺猬皮)
Caulis Entadae (過江龍)	Cornu Bubali (水牛角)
Caulis Erycibes (丁公藤)	Cornu Cervi (鹿角)
Caulis et Folium Piperis Hancei (山蒟)	Cornu Cervi Degelatinatum (鹿角霜)
Caulis et Folium Schefflerae Arboricolae (七葉蓮)	Cornu Cervi Pantotrichum (鹿茸)
Caulis Euphorbiae Antiquori (火殃筊)	Cornu Saigae Tataricae (羚羊角)
	Cortex Acanthopanax (五加皮)
	Cortex Ailanthi (椿皮)
	Cortex Albiziae (合歡皮)
	Cortex Cinchonae (金雞納皮)

Name
Cortex Dictamnii (白鮮皮)
Cortex Eucommiae (杜仲)
Cortex Fraxini (秦皮)
Cortex Hibisci (川槿皮)
Cortex Ilicis Rotundae (救必應)
Cortex Illicii (地楓皮)
Cortex Kadsurae Radicis (紫荊皮)
Cortex Lycii (地骨皮)
Cortex Magnoliae Officinalis (厚樸)
Cortex Meliae (苦楝皮)
Cortex Mori (桑白皮)
Cortex Moutan (牡丹皮)
Cortex Periplocae (香加皮)
Cortex Phellodendri (黃柏)
Cortex Pseudolaricis (土荊皮)
Cortex Schefflerae Octophyllae (鴨腳木)
Cortex Ulmi Parvifoliae (榔榆皮)
Crinis Carbonisatus (血餘炭)
Eupolyphaga seu Steleophaga (土鱉蟲)
Faeces Leporis (望月砂)
Faeces Trogloteri (五靈脂)
Faeces Vespertilionis (夜明砂)
Flos Albiziae (合歡花)
Flos Buddlejae (密蒙花)
Flos Campsis (凌霄花)
Flos Celosiae Cristatae (雞冠花)
Flos Chimonanthe Praecocis (臘梅花)
Flos Eriocauli (穀精草)
Flos Farfarae (款冬花)
Flos Genkwa (芫花)
Flos Hibisci Rosae-Sinensis (扶桑花)
Flos Inulae (旋覆花)
Flos Jasmini (素馨花)
Flos Magnoliae (辛夷)
Flos Magnoliae Officinalis (厚樸花)
Flos Rosae Chinensis (月季花)

Name
Fluoritum (紫石英)
Folium Aconiti Kusnezoffii (草烏葉)
Folium Apocyni Veneti (羅布麻葉)
Folium Artemisiae Argyi (艾葉)
Folium Callicarpae Formosanae (紫珠葉)
Folium et Cacumen Breyniae Fruticosae (黑面神)
Folium et Cacumen Murrayae (九里香)
Folium et Ramulus Evodiae (三叉苦)
Folium Ginkgo (銀杏葉)
Folium Ginseng (人參葉)
Folium Glochidii Eriocarpi (漆大姑)
Folium Hibisci Mutabilis (木芙蓉葉)
Folium Ilicis Cornutae (柃木葉)
Folium Isatidis (大青葉)
Folium Lantanae Camarae (馬纓丹)
Folium Nerii (夾竹桃葉)
Folium Photiniae (石南葉)
Folium Pini (松毛)
Folium Polygoni Tinctorii (蓼大青葉)
Folium Psidii Guajavae (番石榴葉)
Folium Psychotriae Rubrae (山大顏)
Folium Pterocarya Stenopterae (楓楊葉)
Folium Pyrrosiae (石韋)
Folium Rhododendri Daurici (滿山紅)
Folium Sauropi (龍脷葉)
Folium Sennae (番瀉葉)
Folium Vitis Negundo (牡荊葉)
Fructus Akebiae (預知子)
Fructus Alpiniae Oxyphyllae (益智)
Fructus Amomi Rotundus (豆蔻)
Fructus Arctii (牛蒡子)
Fructus Aristolochiae (馬兜鈴)
Fructus Aurantii (枳殼)
Fructus Aurantii Immaturus (枳實)

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Name
Fructus Broussonetiae (栲實子)
Fructus Bruceae (鴉膽子)
Fructus Carotae (南鶴虱)
Fructus Carpesii (鶴虱)
Fructus Chebulae (訶子)
Fructus Cnidii (蛇床子)
Fructus Coriandri (芫荽子)
Fructus Corni (山茱萸)
Fructus Evodiae (吳茱萸)
Fructus Fici Pumilae (薜荔果)
Fructus Forsythiae (連翹)
Fructus Galangae (紅豆蔻)
Fructus Gleditsiae Abnormalis (豬牙皂)
Fructus Kochiae (地膚子)
Fructus Leonuri (芫薺子)
Fructus Ligustri Lucidi (女貞子)
Fructus Liquidambaris (路路通)
Fructus Litseae (華澄茄)
Fructus Malvae (冬葵果)
Fructus Nandinae Domesticae (天竺子)
Fructus Phyllanthi (餘甘子)
Fructus Piperis Longi (華芫)
Fructus Podophylli (小葉蓮)
Fructus Polygoni Orientalis (水紅花子)
Fructus Psoraleae (補骨脂)
Fructus Quisqualis (使君子)
Fructus Rosae Laevigatae (金櫻子)
Fructus Rubi (覆盆子)
Fructus Sapindi Mukorossi (無患子)
Fructus Schisandrae (五味子)
Fructus seu Herba Physalis Pubescentis (燈籠草)
Fructus Sophorae (槐角)
Fructus Terminaliae Billericae (毛訶子)
Fructus Toosendan (川楝子)
Fructus Tribuli (蒺藜)
Fructus Trichosanthis (瓜蒌)

Name
Fructus Triticis Levis (浮小麥)
Fructus Tsaoko (草果)
Fructus Ulmi Macrocarpae (蕪荑)
Fructus Vitis (蔓荊子)
Fructus Vitis Negundo (黃荊子)
Fructus Xanthii (蒼耳子)
Galla Chinensis (五倍子)
Gekko Swinhonis (壁虎)
Gypsum Fibrosum Preparata (煨石膏)
Haematitum (赭石)
Halloysitum Rubrum (赤石脂)
Herba Abri (雞骨草)
Herba Achyranthis Asperae (倒扣草)
Herba Aeschynomenes Indicae (田皂角)
Herba Agastaches (藿香)
Herba Aglaonematis (廣東萬年青)
Herba Agrimoniae (仙鶴草)
Herba Andrographitis (穿心蓮)
Herba Antenoronis Neofiliformis (金縷草)
Herba Ardisiae Japonicae (矮地茶)
Herba Aristolochiae (天仙藤)
Herba Aristolochiae Mollissimae (尋骨風)
Herba Artemisiae Annuae (青蒿)
Herba Artemisiae Anomalaе (劉寄奴)
Herba Artemisiae Scopariae (茵陳)
Herba Asari (細辛)
Herba Belladonnae (顛茄草)
Herba Bidentis Bipinnatae or Herba Bidentis Pilosae (鬼針草)
Herba Blumeae Balsamiferae (大風艾)
Herba Bryophylli Pinnati (落地生根)
Herba Casythae Filiformis (無根藤)
Herba Catharanthi Rosei (長春花)
Herba Centellae (積雪草)
Herba Centipedaе (鶴不食草)

Name

Herba Chenopodii (土荊芥)
Herba Cirsii (小薊)
Herba Cissampelotis (亞乎奴)
Herba Cistanches (肉蓯蓉)
Herba Clinopodii (斷血流)
Herba Clinopodii Gracilis (剪刀草)
Herba Commelinae (鴨跖草)
Herba Corydalis Bungeanae (地丁草)
Herba Crotalariae Mucronatae (豬屎豆)
Herba Cymbopogonis (藜香草)
Herba Cynomorii (鎖陽)
Herba Damnacanthi (虎刺)
Herba Dendrobii (石斛)
Herba Desmodii Styracifolii (廣金錢草)
Herba Dianthi (瞿麥)
Herba Dichondrae Repentis (馬蹄金)
Herba Duchesneae Indicae (蛇莓)
Herba Ecliptae (墨旱蓮)
Herba Eleocharitis (通天草)
Herba Elephantopi (地膽頭)
Herba Eleusines Indicae (牛筋草)
Herba Emiliae (一點紅)
Herba Ephedrae (麻黃)
Herba Epimedii (淫羊藿)
Herba Epimeredis Indicae (防風草)
Herba Equiseti Hiemalis (木賊)
Herba Erodii or Herba Geranii (老鸛草)
Herba Eupatorii (佩蘭)
Herba Euphorbiae Hirtae (飛楊草)
Herba Euphorbiae Humifusae (地錦草)
Herba Euphorbiae Thymifoliae
(小飛楊草)
Herba Gelsemii Elegantis (斷腸草)
Herba Gendarussae (小駁骨)
Herba Geranii Caroliniani (野老鸛草)
Herba Glechomae (連錢草)
Herba Gnaphalii Affinis (鼠曲草)

Name

Herba Gynostemmatis (絞股藍)
Herba Hedyotidis Chrysotrichae
(黃毛耳草)
Herba Hedyotidis Corymbosae (水綫草)
Herba Houttuyniae (魚腥草)
Herba Hyperici (紅旱蓮)
Herba Hyperici Erecti (小連翹)
Herba Hyperici Japonici (田基黃)
Herba Inulae (金沸草)
Herba Junci Setchuensis (龍鬚草)
Herba Kulanchoes Laciniatae (伽藍菜)
Herba Leonuri (益母草)
Herba Lespedezae Cuneatae (鐵掃帚)
Herba Lobeliae Chinensis (半邊蓮)
Herba Lophatheri (淡竹葉)
Herba Lycopi (澤蘭)
Herba Lycopodii (伸筋草)
Herba Lysimachiae (金錢草)
Herba Malvastris Coromandeliani
(黃花棉)
Herba Melastomatis Candii (野牡丹)
Herba Melastomatis Dodecandri (地茶)
Herba Orostachyos (瓦松)
Herba Paderiae (雞屎藤)
Herba Patriniae (敗醬草)
Herba Pholidotae Chinensis (石仙桃)
Herba Phyllanthi Urinariae (葉下珠)
Herba Piperis Sarmentosi (假蒟)
Herba Plantaginis (車前草)
Herba Polygalae Chinensis
(大葉金不換)
Herba Polygalae Japonicae (瓜子金)
Herba Polygoni Avicularis (篇蓄)
Herba Polygoni Chinensis (火炭母)
Herba Polygoni Perfoliati (杠板歸)
Herba Potentillae Chinensis (委陵菜)
Herba Potentillae Discoloris (翻白草)

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Name
Herba Pouzolziae Zeylanicae (霧水葛)
Herba Pteridis Multifidae (鳳尾草)
Herba Pteridis Semipinnatae (半邊旗)
Herba Pyrolae (鹿銜草)
Herba Rabdosiae Lophanthoidis (溪黃草)
Herba Ranunculi Japonici (毛茛)
Herba Saginae Japonicae (漆姑草)
Herba Salviae Chinensis (石見穿)
Herba Salviae Plebeiae (荔枝草)
Herba Sambuci Chinensis (陸英)
Herba Sarcandrae (腫節風)
Herba Saussureae Involucratae (雪蓮花)
Herba Saxifragae (虎耳草)
Herba Schizonepetae (荊芥)
Herba Scutellariae Barbatae (半枝蓮)
Herba Sedi (垂盆草)
Herba Selaginellae (卷柏)
Herba Selaginellae Doederleinii (石上柏)
Herba Senecionis Scandentis (千里光)
Herba Setariae Viridis (狗尾草)
Herba seu Radix Amaranthi (刺莧菜)
Herba seu Radix Cirsii Japonici (大薊)
Herba Sidae Rhombifoliae (黃花母)
Herba Siegesbeckiae (豨薟草)
Herba Solani Lyrati (白英)
Herba Solani Nigri (龍葵)
Herba Solidaginis (一枝黃花)
Herba Speranskiae Tuberculatae (珍珠透骨草)
Herba Spirodelaе (浮萍)
Herba Stephaniae Longae (糞箕蕨)
Herba Swertiae Mileensis (青葉膽)
Herba Taxilli (桑寄生)
Herba Verbenae (馬鞭草)
Herba Veronicae (一支香)

Name
Herba Veronicastris (腹水草)
Herba Violaе (紫花地丁)
Herba Visci (槲寄生)
Herba Wedeliae (螞蟥菊)
Herba Zephyranthis Candidae (肝風草)
Hirudo (水蛭)
Indigo Naturalis (青黛)
Lapis Chloriti (青礞石)
Lapis Micae Aureus (金礞石)
Lasiosphaera seu Calvatia (馬勃)
Lignum Dalbergiae Odoriferae (降香)
Lignum Pini Nodi (油松節)
Limonium (禹餘糧)
Medulla Junci (燈心草)
Medulla Stachyuri or Medulla Helwingiae (小通草)
Medulla Tetrapanacis (通草)
Moschus (麝香)
Myrrha (沒藥)
Natrii Sulfas (芒硝)
Natrii Sulfas Exsiccatus (玄明粉)
Nidus Vespaе (蜂房)
Nux Prinsepieae (薤仁)
Oleum Linderae (香果脂)
Olibanum (乳香)
Omphalia (雷丸)
Ootheca Mantidis (桑螵蛸)
Ophicalcitur (花蕊石)
Pericarpium Arecae (大腹皮)
Pericarpium Trichosanthis (瓜蒌皮)
Periostracum Cicadae (蟬蛻)
Petiolus Trachycarpi (棕櫚)
Pollen Pini (松花粉)
Pollen Typhae (蒲黃)
Polyporus (豬苓)
Processed Fructus Crotonis (製巴豆)

Name
Processed Radix Aconiti (製川烏)
Processed Radix Aconiti Kusnezoffii (製草烏)
Processed Radix Aconiti Lateralis (製附子)
Processed Radix Euphorbiae fischerianae, Radix Euphorbiae ebracteolatae, or Radix Stellerae (製狼毒)
Processed Radix Kansui (製甘遂)
Processed Resina Garcinia Morellae (製藤黃)
Processed Rhizoma Arisaematis (製天南星)
Processed Rhizoma Pinelliae (製半夏)
Processed Rhizoma Typhonii or Radix Aconiti Corean (製白附子 (禹白附、關白附))
Processed Semen Crotonis (巴豆霜)
Processed Semen Euphorbiae (製千金子)
Processed Semen Hyoscyami (製天仙子)
Processed Semen Strychni (製馬錢子)
Pseudobulbus Cremastrae seu Pleiones (山慈菇)
Pumex (浮石)
Pyrolusitum (無名異)
Radix Acanthopanax Senticosus (刺五加)
Radix Acanthopanax Trifoliati (三葉五加)
Radix Achyranthis Bidentatae (牛膝)
Radix Adenophorae (南沙參)
Radix Aerialis Ficus Microcarpa (榕鬚)
Radix Ampelopsis (白薇)
Radix Angelicae Citriodora (香白芷)

Name
Radix Angelicae Pubescentis (獨活)
Radix Angelicae Sinensis (當歸)
Radix Anisodi Tangutici (山茱萸)
Radix Ardisiae Crenatae (朱砂根)
Radix Aristolochiae (青木香)
Radix Aristolochiae Fangchi (廣防己)
Radix Aristolochiae Heterophyllae (漢中防己)
Radix Arnebiae or Radix Lithospermi (紫草)
Radix Asparagi (天冬)
Radix Asteris (紫菀)
Radix Astragali (黃芪)
Radix Aucklandiae (木香)
Radix Bauhiniae Hupehanae (羊蹄甲)
Radix Boehmeriae (苧麻根)
Radix Bupleuri (柴胡)
Radix Celastris Orbiculati (南蛇藤根)
Radix Changii (明黨參)
Radix Chloranthi Serrati (及己)
Radix Clematidis (威靈仙)
Radix Clerodendri Philippini (臭茉莉)
Radix Cocculi Trilobi (木防己)
Radix Codonopsis (黨參)
Radix Crotonis Crassifolii (雞骨香)
Radix Curcumae (鬱金)
Radix Cyathulae (川牛膝)
Radix Cynanchi Atrati (白薇)
Radix Cynanchi Auriculati (白首烏)
Radix Cynanchi Paniculati (徐長卿)
Radix Cynoglossi Amabilis (接骨草)
Radix Dichroae (常山)
Radix Dipsaci (續斷)
Radix Echinopsis (禹州漏蘆)
Radix Ephedrae (麻黃根)
Radix et Rhizoma Nardostachyos (甘松)
Radix et Rhizoma Rhei (大黃)

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Name
Radix et Rhizoma Thalictri (馬尾連)
Radix et Rhizoma Veratri (藜蘆)
Radix Eupatorii Chinensis (廣東土牛膝)
Radix Euphorbiae Pekinensis (京大戟)
Radix Gentianae (龍膽)
Radix Gentianae Macrophyllae (秦艽)
Radix Ginseng (人參)
Radix Glehniae (北沙參)
Radix Hedysari (紅芪)
Radix Helicteris (山芝麻)
Radix Hemerocallis (萱草根)
Radix Ilicis Asprellae (崗梅根)
Radix Ilicis Pubescentis (毛冬青)
Radix Inulae (土木香)
Radix Isatidis (板藍根)
Radix Kadsurae Coccineae (黑老虎根)
Radix Knoxiae (紅大戟)
Radix Linderae (烏藥)
Radix Liriopes (山麥冬)
Radix Mirabilis (紫茉莉根)
Radix Morindae Officinalis (巴戟天)
Radix Notoginseng (三七)
Radix Ophiopogonis (麥冬)
Radix Oryzae Glutinosae (糯稻根)
Radix Paeoniae Alba (白芍)
Radix Paeoniae Rubra (赤芍)
Radix Panacis Quinquefolii (西洋參)
Radix Pandani Tectorii (露兜筋)
Radix Patriniae Heterophyllae or Radix Patriniae Scabrae (墓頭回)
Radix Peucedani (前胡)
Radix Physoclainae (華山參)
Radix Phytolaccae (商陸)
Radix Platycodi (桔梗)
Radix Plumbaginis Zeylanicae (白花丹)
Radix Polygalae (遠志)
Radix Polygoni Multiflori (何首烏)

Name
Radix Pseudostellariae (太子參)
Radix Pterospermi Heterophylli (半楓荷根)
Radix Pteroxygoni Giraldii (紅藥子)
Radix Puerariae (葛根)
Radix Pulsatillae (白頭翁)
Radix Ranunculus Ternati (貓爪草)
Radix Rauwolfiae (蘿芙木)
Radix Rehmanniae (地黃)
Radix Rhapontici (漏蘆)
Radix Rhodomyrti (崗稔根)
Radix Rubiae (茜草)
Radix Salviae Miltiorrhizae (丹參)
Radix Sanguisorbae (地榆)
Radix Saposhnikoviae (防風)
Radix Scrophulariae (玄參)
Radix Scutellariae (黃芩)
Radix Semiaquilegiae (天葵子)
Radix seu Caulis Derridis Trifoliatae (魚藤)
Radix Sophorae Flavescentis (苦參)
Radix Stellariae (銀柴胡)
Radix Stemonae (百部)
Radix Stephaniae Tetrandrae (防己)
Radix Tinosporae (金果欖)
Radix Trichosanthis (天花粉)
Radix Tripterygii Wilfordii (雷公藤)
Radix Valerianae (纈草)
Radix Vitis Adstrictae (野葡萄)
Radix Vladimiriiae (川木香)
Radix Wikstroemae (了哥王)
Radix Zanthoxyli (兩面針)
Radix Zanthoxyli Avicennae (鷹不泊)
Ramulus Cinnamomi (桂枝)
Ramulus et Folium Mussaendae Pubescentis (玉葉金花)

Name
Ramulus et Folium Phyllodii Pulchelli (排錢草)
Ramulus et Folium Picrasmae (苦木)
Ramulus Euonymi (鬼箭羽)
Ramulus Mori (桑枝)
Ramulus Sambuci Williamsii (接骨木)
Ramulus Uncariae cum Uncis (鈎藤)
Receptaculum Nelumbinis (蓮房)
Resina Draconis (血竭)
Resina Ferulaen (阿魏)
Resina Liquidambaris (楓香脂)
Resina Toxicodendri (乾漆)
Rhizoma Acori Tatarinowii (石菖蒲)
Rhizoma Alismatis (澤瀉)
Rhizoma Anemarrhenae (知母)
Rhizoma Anemones Altaicae (九節菖蒲)
Rhizoma Anemones Raddeanae (兩頭尖)
Rhizoma Ardisiae Gigantifoliae (走馬胎)
Rhizoma Atractylodis (蒼朮)
Rhizoma Atractylodis Macrocephalae (白朮)
Rhizoma Belamcandae (射干)
Rhizoma Bistortae (拳參)
Rhizoma Blechni (烏毛蕨貫眾)
Rhizoma Bletillae (白及)
Rhizoma Bolbostemmae (土貝母)
Rhizoma Chuanxiong (川芎)
Rhizoma Cibotii (狗脊)
Rhizoma Cimicifugae (升麻)
Rhizoma Coptidis (黃連)
Rhizoma Corydalis (延胡索)
Rhizoma Corydalis Decumbentis (夏天無)
Rhizoma Curculiginis (仙茅)

Name
Rhizoma Curcumae (莪朮)
Rhizoma Curcumae Longae (薑黃)
Rhizoma Cynanchi Stauntonii (白前)
Rhizoma Cyperi (香附)
Rhizoma Cyrtomii (貫眾)
Rhizoma Dioscoreae Bulbiferae (黃藥子)
Rhizoma Dioscoreae Cirrhosae (薯蕷)
Rhizoma Dioscoreae Hypoglaucae (粉萆薢)
Rhizoma Dioscoreae Nipponicae (穿山龍)
Rhizoma Dioscoreae Septemlobae (縮萆薢)
Rhizoma Dioscoreae Tokoro (山萆薢)
Rhizoma Drynariae (骨碎補)
Rhizoma Dryopteris Crassirhizomae (綿馬貫眾)
Rhizoma et Radix Baphicacanthis Cusiae (南板藍根)
Rhizoma et Radix Notopterygii (羌活)
Rhizoma Gastrodiae (天麻)
Rhizoma Homalomenae (千年健)
Rhizoma Ligustici (藜蘆)
Rhizoma Matteucciae (莢果蕨貫眾)
Rhizoma Menispermii (北豆根)
Rhizoma Osmundae (紫萁貫眾)
Rhizoma Panacis Japonici (竹節參)
Rhizoma Panacis Majoris (珠子參)
Rhizoma Paridis (重樓)
Rhizoma Picrorhizae (胡黃連)
Rhizoma Polygonati (黃精)
Rhizoma Polygoni Cuspidati (虎杖)
Rhizoma Saururi or Herba Saururi (三白草)
Rhizoma Smilacis Chinensis (菝葜)
Rhizoma Smilacis Glabrae (土茯苓)

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Name
Rhizoma Sparganii (三棱)
Rhizoma Wenyujin Concisa (片薑黃)
Rhizoma Woodwardiae (狗脊貫眾)
Sal Ammoniacus (礞砂)
Scolopendra (蜈蚣)
Scorpio (全蠍)
Semen Abri Precatorii (相思子)
Semen Abutili (苘麻子)
Semen Aesculi (娑羅子)
Semen Allii Tuberosi (韭菜子)
Semen Alpiniae Katsumadai (草豆蔻)
Semen Arecae (檳榔)
Semen Astragali Complanati (沙苑子)
Semen Cassiae (決明子)
Semen Cassiae Occidentalis (望江南)
Semen Celosiae (青葙子)
Semen Cuscutae (菟絲子)
Semen Hoveniae (枳椇子)
Semen Hydnocarpi (大風子)
Semen Impatientis (急性子)
Semen Lepidii or Semen Descurainiae (葶藶子)
Semen Lini (亞麻子)
Semen Momordicae (木鱉子)

Name
Semen Myristicae (肉豆蔻)
Semen Nigellae (黑種草子)
Semen Oroxyli (木蝴蝶)
Semen Persicae (桃仁)
Semen Pharbitidis (牽牛子)
Semen Plantaginis (車前子)
Semen Platycladi (柏子仁)
Semen Ricini (蓖麻子)
Semen Sinapis (芥子)
Semen Sterculiae Lychnophorae (胖大海)
Semen Trichosanthis (瓜蒌子)
Semen Trigonellae (胡蘆巴)
Semen Vaccariae (王不留行)
Spica Prunellae (夏枯草)
Spina Gleditsiae (皂角刺)
Spongilla (紫梢花)
Spora Lygodii (海金沙)
Stamen Nelumbinis (蓮鬚)
Stigma Croci (西紅花)
Styrax (蘇合香)
Tabanus (蛇蟲)
Tremolitus (陽起石)

Appendix 4: Weight Conversion Table

All weight units in the metric system, i.e. the weight units of kilograms, grams or milligrams should be used. The retail market in Hong Kong also customarily uses the catty (*sima*), tael (*sima*), mace (*sima*) and candareen (*sima*) as measuring units. In addition, the weight units customarily used in Hong Kong are different from those used in the mainland market.

(I) Conversion between the metric units and weight units customarily used in Hong Kong

1 kilogram = 1.65347 *catty (sima)*

100 gram = 2.64555 *tael (sima)*

10 gram = 0.264555 *tael (sima)*

1 gram = 0.0264555 *tael (sima)*

(II) Conversion between the weight units customarily used in Hong Kong and metric units

1 *catty (sima)* = 0.60478982 kilogram

1 *tael (sima)* = 1/16 *catty* = 37.7994 gram

1 *mace (sima)* = 1/160 *catty* = 3.77994 gram

1 *candareen (sima)* = 1/1600 *catty* = 377.994 milligram

(Remarks: please refer to the Weights and Measures Ordinance (Cap. 68) for details of this weight conversion.)



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