



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our ref: FHB/H/24/24
Your ref: CB2/BC/6/16

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17 November 2017

Ms Maisie LAM
Clerk to Bills Committee on Chinese Medicine (Amendment) Bill 2017
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms LAM,

Bills Committee on Chinese Medicine (Amendment) Bill 2017

In response to the request of the Chairman of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 at the meeting on 13 October 2017, the Government has set out the relevant reference materials in the Annex.

The Government noted Members' concerns about issues relating to heavy metal contents and pesticide residues in Chinese herbal medicines. The relevant information is detailed in the Annex. While the Bill does not include proposed amendments concerning the aforementioned matters, the Food and Health Bureau welcome Members' continued discussions and comments raised through other channels.

Yours sincerely,


(James LAM)

for Secretary for Food and Health

Encl.

c.c. Department of Justice (Attn: Ms Mandy NG)
Department of Health (Attn: Dr Edwin TSUI)

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Purpose

This paper sets out the Government's response to the issues raised on the Chinese Medicine (Amendment) Bill 2017 (the Bill) at the Bills Committee meeting on 13 October 2017.

Practising guidelines for Chinese medicine traders

2. With the authority conferred by the Chinese Medicine Ordinance (Cap. 549) (CMO), the Department of Health (DH) provides support to the Chinese Medicine Council of Hong Kong (CMCHK) in monitoring the operation of the trade of Chinese medicines and the sale of Chinese medicines. In this regard, the CMCHK has put in place various systems and measures to safeguard public health. As a start, it implements a licensing regime of Chinese medicines traders to ensure that four types of Chinese medicines traders (i.e. wholesalers of Chinese herbal medicines (Chms), retailers of Chms, manufacturers of proprietary Chinese medicines (pCms) and wholesalers of pCms) must meet the licensing requirements (e.g. the premises are in sanitary condition and suitable facilities for storing Chms are provided in the premises) before they are granted licences. This helps ensure the safety and quality of the Chinese medicines to be sold by them.

3. The CMCHK has also established practising guidelines for the four types of Chinese medicines traders to enhance their practising standards. Contravention of the CMO and/or the practising guidelines by Chinese medicines traders may result in prosecution, disciplinary action by the CMCHK, and cancellation of licences in serious cases. The practising guidelines for the four types of Chinese medicines traders are set out at Appendix 1.

Regulatory standards for pesticide residues and heavy metal contents in Chinese herbal medicines in Hong Kong

4. The standards currently used for testing of pesticide residues and heavy metal contents in Chms sold in Hong Kong, which are related to the testing of 37 pesticide residues and 4 heavy metal contents, are formulated by the CMCHK with reference to other international standards, including those of the World Health Organization (WHO) and those set by different countries or

regions for herbs or raw materials of natural plant preparations. When the standards were being set by the CMCHK, considerations were given to factors like the toxicity, residual effects, popularity and prohibitions or strict restrictions imposed internationally on the import, export and usage in respect of the pesticides and heavy metals. These safety standards are used to regulate all the 605 types of Chms under the CMO (i.e. 31 types from Schedule 1 and 574 types from Schedule 2), but not those mineral Chinese medicines which are known to be originally containing heavy metal(s) as ingredient(s). The safety limits of heavy metal content and pesticides residues in Chms set out by the CMCHK are at Appendix 2.

5. To ensure the safe use of Chms by members of the public, testing of the aforementioned 37 pesticide residues and 4 heavy metal contents are conducted by the CMCHK on Chms for sale in the market.

6. In response to the request of the Chairman of the Bills Committee at the meeting on 28 September 2017 and the enquiries raised in the letter from Dr Hon Helena WONG Pik-wan to the Chairman on 27 September 2017, the Food and Health Bureau has provided the relevant reference materials on 12 October 2017 (at Appendix 3). A detailed account of the procedures and scope of the tests of Chm pesticide residues and heavy metal contents was mentioned in paragraphs 14 to 18 of the above document. These procedures and scope are recognised by the Chinese Medicines Board (CMB) under the CMCHK and the Scientific Committee under the Hong Kong Chinese Materia Medica Standards (HKCMMS) Research Project, and have been uploaded onto the website of CMCHK for reference by the trade.

7. The DH's market surveillance results of Chms from 1 January 2015 to 30 June 2017 were elaborated in paragraph 17 of the above document submitted by the Food and Health Bureau. During the period, the DH collected a total of 1,015 samples for testing. Among these, 53 samples were found to contain pesticide residues in the first stage of testing where further testing in the second stage would be required. Among the 53 samples, the one named Myrrha was found to contain 0.08 mg/kg of DDT in the second stage. Nevertheless, the findings showed that the contents did not exceed the respective maximum residue limits (MRLs). No pesticide residues were found in the remaining 52 samples in the second-stage testing. Therefore, all samples have complied with the safety standards set by the CMCHK. The detailed testing results of the pesticide residues and heavy metal contents in Chms conducted by the DH during market surveillance in 2016 are set out at Appendix 4.

Quality standards for commonly used Chinese herbal medicines by the Hong Kong Chinese Materia Medica Standards

8. To further enhance the quality of Chms in Hong Kong, the HKCMMS Research Project develops reference standards for commonly used Chms. Since 2002, the project has developed reference standards for 275 kinds of Chms, which cover, among other things, the source and description of Chms, identification, extractive, assay, and tests on heavy metals and pesticide residues. Under the HKCMMS Research Project, the International Advisory Board (IAB), which comprised local, Mainland and international renowned experts, is responsible for deciding the content of the HKCMMS, and giving professional advice on the principles, methodologies, parameters and analytical methods for the development of the HKCMMS.

9 As regards heavy metals, the IAB, upon its establishment, endorsed the development of appropriate and practicable standards on the limits of heavy metal contents for each type of Chms according to its uniqueness and usage. Since the introduction of the HKCMMS, the IAB has kept under review and closely monitored the quality standards regarding the limit of heavy metal contents. It has also kept abreast of the requirements on the limits of heavy metal contents adopted by organisations from around the world, such as the U.S. Agency for Toxic Substances and Disease Registry and the Joint FAO/WHO Expert Committee on Food Additives, and the pharmacopoeias of different countries to bring the HKCMMS into alignment with international standards.

10. Besides, the limits of pesticide residues in 20 types of organo-chlorine pesticides which are of wide public concern are also set out in the HKCMMS.

11. The quality limits of heavy metal contents and pesticide residues stipulated in the HKCMMS are applicable to the 267 types of published Chms, excluding the eight types of Chms of mineral origin¹ or certain types of Chms otherwise specified².

12. The quality reference limits of heavy metal content and pesticides residues in Chms set out by the HKCMMS are at Appendix 5.

¹ The 8 types of Chms of mineral origin are Arsenic trioxide, Arsenolite, Calomelas, Cinnabar, Hydrargyri Oxydum Rubrum, Mercurous chloride and mercuric chloride, Orpiment and Realgar.

² According to the HKCMMS (Volume 7), the limits of cadmium contents in the 4 types of Chms including Drynariae Rhizoma, Ilicis Rotundae Cortex, Centellae Herba and Ilicis Cornutae Folium are 2.5 mg/kg, 5.5 mg/kg, 5.5 mg/kg and 6.0 mg/kg respectively.

Comparison of regulatory standards for heavy metals in traditional herbal medicines (including Chinese herbal medicines) on the Mainland and in other countries

13. As mentioned above, the CMCHK has formulated the regulatory MRLs of four heavy metals which are known to be more toxic to human beings (i.e. arsenic, lead, mercury and cadmium). For lead and mercury, the standards are calculated on the basis of the maximum intake per day recommended by the WHO. For arsenic and cadmium, the standards are calculated on the basis of the maximum intake per day or no-observed-adverse-effect level recommended by the U.S. Agency for Toxic Substances and Disease Registry. These safety standards are used to regulate all the 605 types of Chms under the Schedules 1 and 2 of the CMO (except the individual Chms containing relevant heavy metal). While countries around the world have not yet come up with a standardised set of limits for heavy metal contents in traditional Chms, a detailed comparison of the heavy metal MRLs for traditional herbal medicines formulated by the regulatory bodies in other countries are set out at Appendix 6. The latest “Pharmacopoeia of the People’s Republic of China” (2015 edition) issued by the Mainland has set heavy metal MRLs for only 27 types of Chms (at Appendix 7).

14. As regulatory bodies around the world are increasingly concerned about the effect of pesticides residues and heavy metals on human, the CMCHK will from time to time review the standards for pesticide residues and heavy metal contents, as well as the sampling strategy of the market surveillance system to safeguard public health. The CMCHK will take into account the latest development of other regulatory bodies, the advice from the IAB and the industry, and to keep it up-to-date by refining relevant standards and strategies.

Limit of sulphur dioxide in Chms

15. The Food and Health Bureau has already provided its response to the study of testing method for sulphur dioxide residue in Chms and the development of a routine quality monitoring method of Chms in paragraphs 19 and 20 of the document in Appendix 3.

Pharmaceutical manufacturers engaged in the business of manufacturing health food products

16. According to the CMO, manufacture of pCms means the preparation, production, packing or re-packing of the pCms for sale or distribution. Any persons who wish to engage in the business of manufacturing of pCms must

obtain a manufacturer licence in pCms from the CMB under the CMCHK before commencing business. In vetting applications, the CMB will consider whether the applicants have met the basic licensing requirements for running the business, including whether the premises are in good sanitary condition, fittings and equipment are suitable for use in the manufacturing process, adequate and suitable facilities for storage are provided in the premises, steps have been taken to ensure that nothing in the premises may contaminate pCms, and at least two eligible persons are nominated to supervise the manufacturing of pCms.

17. A pCm manufacturer licence only authorises its holder to conduct manufacturing business of pCms in the premises specified. A licensed pCm manufacturer who plans to manufacture non-pCm products (including health products) in his/her licensed premises should make a declaration to the CMB and provide objective justifications for the measures taken to prevent cross contamination as well as their effectiveness, to ensure that the Chinese medicine products manufactured will be free from contamination. Otherwise, the CMB will not approve the licence application from the pCm manufacturer concerned.

18. The DH will carry out investigation and deal with any case of breach of the drug regulatory regime in accordance with law. Disciplinary actions and corresponding enforcement actions will be considered. Cases of possible breach of the food regulatory regime will also be referred to the Food and Environmental Hygiene Department for follow-up action if necessary.

Manpower deployment for the regulation and development of Chinese medicines

19. Currently, the Chinese Medicine Division (CMD) of the DH is led by an Assistant Director (Directorate Pay Scale Point 2). There are 136 civil service posts under the staff establishment of the CMD. The functions of the CMD include enforcement of the CMO, provisions of which mainly include regulation of Chinese medicine practitioners and the use, sale and manufacture of Chinese medicines; provision of professional and administrative support to the CMCHK; setting of standards for some commonly used Chms; Chinese medicine related public health and public education matters; and exchange of information about Chinese medicines with local and overseas institutions or government departments.

20. As announced in “The Chief Executive’s 2017 Policy Address”, the Food and Health Bureau will set up a dedicated policy division for the development

of Chinese medicine. The division, namely the Chinese Medicine Unit, will coordinate and take forward the policies and initiatives featuring the development of Chinese medicine and maintain close liaison with the industry. The Government has proposed that the Chinese Medicine Unit to be headed by an Administrative Officer Staff Grade C. Apart from civil servants, the Chinese Medicine Unit will also employ experienced Chinese medicine practitioner. We will soon seek the approval of the Legislative Council for the staff and funding resources for setting up the dedicated section concerned.

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



Chinese Medicines

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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.

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“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;

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- 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).

- (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.

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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

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- (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.

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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);

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- (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.

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- (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):

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- 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);

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- 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.

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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.

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- (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.

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**Practising Guidelines
for
Manufacturers 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
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.

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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

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- 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.

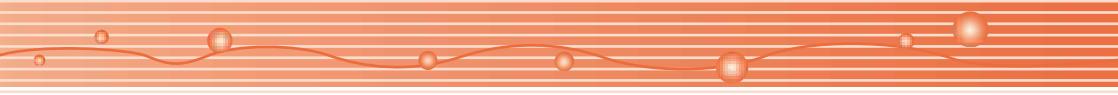
3.2.2 Duties

- (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);

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- (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 毒性中药); 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;

- (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.

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- (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”.

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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.

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7.3 Monitoring of Adverse Reactions of Proprietary Chinese Medicines

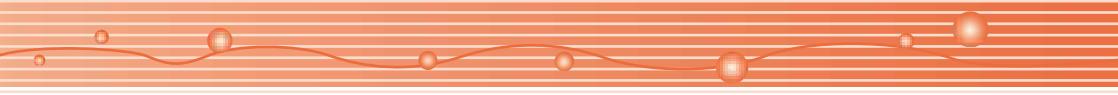
The manufacturers of proprietary Chinese medicines have the responsibility to collect information on all adverse reactions related to their proprietary Chinese medicines, in the course of processing complaints about such products or through other channels. They should communicate such information to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

- 
- 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.

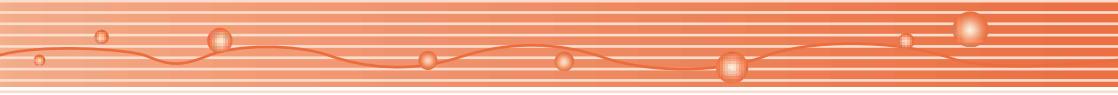
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8.3.2 Transaction Documents (please refer to section 19(3) of the Chinese Medicines Regulation)

- (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.



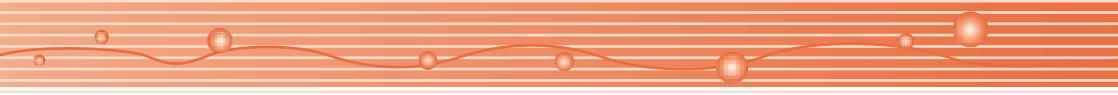
Appendix 1 Manufacture of Proprietary Chinese Medicines Entrusted by a Chinese Medicine Practitioner

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) “须按照中医指示使用”;
 - 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) “须按照中医指示使用”;
 - 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";

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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) “只供中医施用于或供应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 (生附子)
Arsenolite (砒石)	Unprocessed Radix Euphorbiae Fischeriana, Radix Euphorbiae Ebracteolatae or Radix Stellerae (生狼毒)
Calomelas (輕粉)	Unprocessed Radix Kansui (生甘遂)
Cinnabaris (朱砂)	Unprocessed Resina Garcinia Morellae (生藤黃)
Flos Daturae Metelis (洋金花)	Unprocessed Rhizoma Arisaematis (生天南星)
Flos Rhododendri Mollis (閑羊花)	Unprocessed Rhizoma Pinelliae (生半夏)
Huechys (紅娘蟲)	Unprocessed Rhizoma Typhonii or Radix Aconiti Coreani (生白附子(禹白附、關白附))
Hydrargyri Oxydum Rubrum (紅粉)	Unprocessed Semen Euphorbiae (生千金子)
Lytta (青娘蟲)	Unprocessed Semen Hyoscyami (生天仙子)
Mercurous chloride and mercuric chloride (白降丹)	Unprocessed Semen Strychni (生馬錢子)
Mercury (水銀)	Venenum Bufonis (蟾酥)
Mylabris (斑蝥)	
Orpiment (雌黃)	
Radix Aconiti Brachypodi or Radix Aconiti Szechenyian (雪上一枝蒿)	
Radix or Rhizoma Podophylli emodis, or Radix or Rhizoma Dysosmatis (鬼臼(桃耳七、八角蓮))	
Radix Sophorae Tonkinensis (山豆根)	
Realgar (雄黃)	
Unprocessed Fructus Crotonis (生巴豆)	
Unprocessed Radix Aconiti (生川烏)	
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 (蕲蛇)	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 Impatiens (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 Lycoris 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 Brevipedunculæ (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 (火殃簕)	Cornu Saigae Tataricae (羚羊角)

Name	Name
Cortex Dictamni (白鮮皮)	Fluoritum (紫石英)
Cortex Eucommiae (杜仲)	Folium Aconiti Kusnezoffii (草烏葉)
Cortex Fraxini (秦皮)	Folium Apocyni Veneti (羅布麻葉)
Cortex Hibisci (川槿皮)	Folium Artemisiae Argyi (艾葉)
Cortex Ilicis Rotundae (救必應)	Folium Callicarpea Formosanae (紫珠葉)
Cortex Illicii (地楓皮)	Folium et Cacumen Breyniae Fruticosae (黑面神)
Cortex Kadsurae Radicis (紫荊皮)	Folium et Cacumen Murrayae (九里香)
Cortex Lycii (地骨皮)	Folium et Ramulus Evodiae (三叉苦)
Cortex Magnoliae Officinalis (厚樸)	Folium Ginkgo (銀杏葉)
Cortex Meliae (苦棟皮)	Folium Ginseng (人參葉)
Cortex Mori (桑白皮)	Folium Glochidii Eriocarpi (漆大姑)
Cortex Moutan (牡丹皮)	Folium Hibisci Mutabilis (木芙蓉葉)
Cortex Periplocae (香加皮)	Folium Ilicis Cornutae (枸骨葉)
Cortex Phellodendri (黃柏)	Folium Isatidis (大青葉)
Cortex Pseudolaricis (土荊皮)	Folium Lantanae Camarae (馬纓丹)
Cortex Schefflerae Octophyllae (鴨腳木)	Folium Nerii (夾竹桃葉)
Cortex Ulmi Parvifoliae (柳榆皮)	Folium Photinia (石南葉)
Crinis Carbonisatus (血餘炭)	Folium Pini (松毛)
Eupolyphaga seu Steleophaga (土鱉蟲)	Folium Polygoni Tinctorii (蓼大青葉)
Faeces Leporis (望月砂)	Folium Psidii Guajavae (番石榴葉)
Faeces Tropopterori (五靈脂)	Folium Psychotriae Rubrae (山大顏)
Faeces Vespertilionis (夜明砂)	Folium Pterocaryae Stenopterae (楓楊葉)
Flos Albiziae (合歡花)	Folium Pyrrosiae (石韋)
Flos Buddleiae (密蒙花)	Folium Rhododendri Daurici (滿山紅)
Flos Campsis (凌霄花)	Folium Sauropi (龍膽葉)
Flos Celosiae Cristatae (雞冠花)	Folium Sennae (番瀉葉)
Flos Chimonanthi Praecocis (臘梅花)	Folium Viticis Negundo (牡荆葉)
Flos Eriocauli (穀精草)	Fructus Akebiae (預知子)
Flos Farfarae (款冬花)	Fructus Alpiniae Oxyphyllae (益智)
Flos Genkwa (茺花)	Fructus Amomi Rotundus (豆蔻)
Flos Hibisci Rosae-Sinensis (扶桑花)	Fructus Arctii (牛蒡子)
Flos Inulae (旋覆花)	Fructus Aristolochiae (馬兜鈴)
Flos Jasmini (素馨花)	Fructus Aurantii (枳殼)
Flos Magnoliae (辛夷)	Fructus Aurantii Immaturus (枳實)
Flos Magnoliae Officinalis (厚樸花)	
Flos Rosae Chinensis (月季花)	

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Name	Name
Fructus Broussonetiae (楮實子)	Fructus Tritici Levis (浮小麥)
Fructus Bruceae (鴉膽子)	Fructus Tsaoko (草果)
Fructus Carotae (南鶴鱈)	Fructus Ulmi Macrocarpae (蕪荑)
Fructus Carpesii (鶴鱈)	Fructus Viticis (蔓荊子)
Fructus Chebulae (訶子)	Fructus Viticis Negundo (黃荊子)
Fructus Cnidii (蛇床子)	Fructus Xanthii (蒼耳子)
Fructus Coriandri (芫荽子)	Galla Chinensis (五倍子)
Fructus Corni (山茱萸)	Gekko Swinhonis (壁虎)
Fructus Evodiae (吳茱萸)	Gypsum Fibrosum Preparata (煅石膏)
Fructus Fici Pumilae (薜荔果)	Haematurum (赭石)
Fructus Forsythiae (連翹)	Halloysitum Rubrum (赤石脂)
Fructus Galangae (紅豆蔻)	Herba Abri (雞骨草)
Fructus Gleditsiae Abnormalis (豬牙皂)	Herba Achyrantidis Asperae (倒扣草)
Fructus Kochiae (地膚子)	Herba Aeschynomenes Indicae (田皂角)
Fructus Leonuri (茺蔚子)	Herba Agastaches (藿香)
Fructus Ligustri Lucidi (女貞子)	Herba Aglaonematis (廣東萬年青)
Fructus Liquidambaris (路路通)	Herba Agrimoniae (仙鶴草)
Fructus Litseae (華澄茄)	Herba Andrographitis (穿心蓮)
Fructus Malvae (冬葵果)	Herba Antenoritis Neofiliformis (金錢草)
Fructus Nandinae Domesticae (天竺子)	Herba Ardisiae Japonicae (矮地茶)
Fructus Phyllanthi (餘甘子)	Herba Aristolochiae (天仙藤)
Fructus Piperis Longi (華芨)	Herba Aristolochiae Mollissimae (尋骨風)
Fructus Podophylli (小葉蓮)	Herba Artemisiae Annuae (青蒿)
Fructus Polygoni Orientalis (水紅花子)	Herba Artemisiae Anomaliae (劉寄奴)
Fructus Psoraleae (補骨脂)	Herba Artemisiae Scopariae (茵陳)
Fructus Quisqualis (使君子)	Herba Asari (細辛)
Fructus Rosae Laevigatae (金櫻子)	Herba Belladonnae (顛茄草)
Fructus Rubi (覆盆子)	Herba Bidentis Bipinnatae or Herba Bidentis Pilosae (鬼針草)
Fructus Sapindi Mukorossi (無患子)	Herba Blumeae Balsamiferae (大風艾)
Fructus Schisandrae (五味子)	Herba Bryophylli Pinnati (落地生根)
Fructus seu Herba Physalis Pubescens (燈籠草)	Herba Casythaе Filiformis (無根藤)
Fructus Sophorae (槐角)	Herba Catharanthi Rosei (長春花)
Fructus Terminaliae Billericae (毛訶子)	Herba Centellae (積雪草)
Fructus Toosendan (川棟子)	Herba Centipedae (鵝不食草)
Fructus Tribuli (蒺藜)	
Fructus Trichosanthis (瓜萎)	

Name	Name
Herba Chenopodii (土荊芥)	Herba Gynostemmatis (絞股藍)
Herba Cirsii (小薊)	Herba Hedyotidis Chrysotrichae (黃毛耳草)
Herba Cissampelotis (亞乎奴)	Herba Hedyotidis Corymbosae (水綫草)
Herba Cistanches (肉蓯蓉)	Herba Houttuyniae (魚腥草)
Herba Clinopodii (斷血流)	Herba Hyperici (紅旱蓮)
Herba Clinopodii Gracilis (剪刀草)	Herba Hyperici Erecti (小連翹)
Herba Commelinaceae (鴨跖草)	Herba Hyperici Japonici (田基黃)
Herba Corydalis Bungeanae (地丁草)	Herba Inulae (金沸草)
Herba Crotalariae Mucronatae (豬屎豆)	Herba Junci Setchuensis (龍鬚草)
Herba Cymbopogonis (薑香草)	Herba Kulancoes Laciniatae (伽藍菜)
Herba Cynomorii (鎖陽)	Herba Leonuri (益母草)
Herba Damnacanthi (虎刺)	Herba Lespedezae Cuneatae (鐵掃帚)
Herba Dendrobii (石斛)	Herba Lobeliae Chinensis (半邊蓮)
Herba Desmodii Styracifolii (廣金錢草)	Herba Lophatheri (淡竹葉)
Herba Dianthi (瞿麥)	Herba Lycopi (澤蘭)
Herba Dichondrae Repentis (馬蹄金)	Herba Lycopodii (伸筋草)
Herba Duchesneae Indicae (蛇莓)	Herba Lysimachiae (金錢草)
Herba Ecliptae (墨旱蓮)	Herba Malvastri Coromandeliana (黃花棉)
Herba Eleocharitis (通天草)	Herba Melastomatis Candii (野牡丹)
Herba Elephantopi (地膽頭)	Herba Melastomatis Dodecandri (地菍)
Herba Eleusines Indicae (牛筋草)	Herba Orostachyos (瓦松)
Herba Emiliae (一點紅)	Herba Paederiae (雞屎藤)
Herba Ephedrae (麻黃)	Herba Patriniae (敗醬草)
Herba Epimedii (淫羊藿)	Herba Pholidotae Chinensis (石仙桃)
Herba Epimeredis Indicae (防風草)	Herba Phyllanthi Urinariae (葉下珠)
Herba Equiseti Hiemalis (木賊)	Herba Piperis Sarmentosi (假蒟)
Herba Erodii or Herba Geranii (老鶴草)	Herba Plantaginis (車前草)
Herba Eupatorii (佩蘭)	Herba Polygalae Chinensis (大葉金不換)
Herba Euphorbiae Hirtae (飛楊草)	Herba Polygalae Japonicae (瓜子金)
Herba Euphorbiae Humifusae (地錦草)	Herba Polygoni Avicularis (萹蓄)
Herba Euphorbiae Thymifoliae (小飛楊草)	Herba Polygoni Chinensis (火炭母)
Herba Gelsemii Elegantis (斷腸草)	Herba Polygoni Perfoliati (杠板歸)
Herba Gendarussae (小駁骨)	Herba Potentillae Chinensis (委陵菜)
Herba Geranii Caroliniani (野老鶴草)	Herba Potentillae Discoloris (翻白草)
Herba Glechomae (連錢草)	
Herba Gnaphalii Affinis (鼠曲草)	

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Name	Name
Herba Pouzolziae Zeylanicae (霧水葛)	Herba Veronicastri (腹水草)
Herba Pteridis Multifidae (鳳尾草)	Herba Violae (紫花地丁)
Herba Pteridis Semipinnatae (半邊旗)	Herba Visci (槲寄生)
Herba Pyrolae (鹿銜草)	Herba Wedeliae (蟛蜞菊)
Herba Rabdosiae Lophanthoidis (溪黃草)	Herba Zephyranthis Candiae (肝風草)
Herba Ranunculi Japonici (毛茛)	Hirudo (水蛭)
Herba Saginae Japonicae (漆姑草)	Indigo Naturalis (青黛)
Herba Salviae Chinensis (石見穿)	Lapis Chloriti (青礞石)
Herba Salviae Plebeiae (荔枝草)	Lapis Micae Aureus (金礞石)
Herba Sambuci Chinensis (陸英)	Lasiosphaera seu Calvatia (馬勃)
Herba Sarcandrae (腫節風)	Lignum Dalbergiae Odoriferae (降香)
Herba Saussureae Involucratae (雪蓮花)	Lignum Pini Nodi (油松節)
Herba Saxifragae (虎耳草)	Limonium (禹餘糧)
Herba Schizonepetae (荊芥)	Medulla Junci (燈心草)
Herba Scutellariae Barbatae (半枝蓮)	Medulla Stachyuri or Medulla Helwingiae (小通草)
Herba Sedi (垂盆草)	Medulla Tetrapanacis (通草)
Herba Selaginellae (卷柏)	Moschus (麝香)
Herba Selaginellae Doederleinii (石上柏)	Myrrha (沒藥)
Herba Senecionis Scandentis (千里光)	Natrii Sulfas (芒硝)
Herba Setariae Viridis (狗尾草)	Natrii Sulfas Exsiccatus (玄明粉)
Herba seu Radix Amarantri (刺莧菜)	Nidus Vespa (蜂房)
Herba seu Radix Cirsii Japonici (大薊)	Nux Prinsepiae (薤仁)
Herba Sidae Rhombifoliae (黃花母)	Oleum Linderae (香果脂)
Herba Siegesbeckiae (豨莶草)	Olibanum (乳香)
Herba Solani Lyrati (白英)	Omphalia (雷丸)
Herba Solani Nigri (龍葵)	Ootheca Mantidis (桑螵蛸)
Herba Solidaginis (一枝黃花)	Ophicalcitum (花蕊石)
Herba Speranskiae Tuberculatae (珍珠透骨草)	Pericarpium Arecae (大腹皮)
Herba Spirodelae (浮萍)	Pericarpium Trichosanthis (瓜萎皮)
Herba Stephaniae Longae (龜筈篤)	Periostracum Cicadae (蟬蛻)
Herba Swertiae Mileensis (青葉膽)	Petiolus Trachycarpi (棕櫚)
Herba Taxilli (桑寄生)	Pollen Pini (松花粉)
Herba Verbenae (馬鞭草)	Pollen Typhae (蒲黃)
Herba Veronicae (一支香)	Polyporus (豬苓)
	Processed Fructus Crotonis (製巴豆)

Name	Name
Processed Radix Aconiti (製川烏)	Radix Angelicae Pubescentis (獨活)
Processed Radix Aconiti Kusnezoffii (製草烏)	Radix Angelicae Sinensis (當歸)
Processed Radix Aconiti Lateralis (製附子)	Radix Anisodi Tangutici (山莨菪)
Processed Radix Euphorbiae fischeriana, Radix Euphorbiae ebracteolatae, or Radix Stellerae (製狼毒)	Radix Ardisiae Crenatae (朱砂根)
Processed Radix Kansui (製甘遂)	Radix Aristolochiae (青木香)
Processed Resina Garcinia Morellae (製藤黃)	Radix Aristolochiae Fangchi (廣防己)
Processed Rhizoma Arisaematis (製天南星)	Radix Aristolochiae Heterophyllae (漢中防己)
Processed Rhizoma Pinelliae (製半夏)	Radix Arnebiae or Radix Lithospermi (紫草)
Processed Rhizoma Typhonii or Radix Aconiti Corean (製白附子 (禹白附、關白附))	Radix Asparagi (天冬)
Processed Semen Crotonis (巴豆霜)	Radix Asteris (紫菀)
Processed Semen Euphorbiae (製千金子)	Radix Astragali (黃芪)
Processed Semen Hyoscyami (製天仙子)	Radix Aucklandiae (木香)
Processed Semen Strychni (製馬錢子)	Radix Bauhiniae Hupehanae (羊蹄甲)
Pseudobulbus Cremastrae seu Pleiones (山慈姑)	Radix Boehmeriae (苧麻根)
Pumex (浮石)	Radix Bupleuri (柴胡)
Pyrolusitum (無名異)	Radix Celastri Orbiculati (南蛇藤根)
Radix Acanthopanax Senticosi (刺五加)	Radix Changii (明黨參)
Radix Acanthopanax Trifoliatai (三葉五加)	Radix Chloranthi Serrati (及己)
Radix Achyranthis Bidentatae (牛膝)	Radix Clematidis (威靈仙)
Radix Adenophorae (南沙參)	Radix Clerodendri Philippini (臭茉莉)
Radix Aero Fici Microcarpae (榕鬚)	Radix Cocculi Trilobi (木防己)
Radix Ampelopsis (白蔹)	Radix Codonopsis (黨參)
Radix Angelicae Citriodora (香白芷)	Radix Crotonis Crassifolii (雞骨香)

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Name	Name
Radix et Rhizoma Thalictri (馬尾連)	Radix Pseudostellariae (太子參)
Radix et Rhizoma Veratri (藜蘆)	Radix Pterospermi Heterophylli (半楓荷根)
Radix Eupatorii Chinensis (廣東土牛膝)	Radix Pteroxygoni Giraldii (紅藥子)
Radix Euphorbiae Pekinensis (京大戟)	Radix Puerariae (葛根)
Radix Gentianae (龍膽)	Radix Pulsatillae (白頭翁)
Radix Gentianae Macrophyllae (秦艽)	Radix Ranunculus Ternati (貓爪草)
Radix Ginseng (人參)	Radix Rauvolfiae (蘿芙木)
Radix Glehniae (北沙參)	Radix Rehmanniae (地黃)
Radix Hedsyari (紅芪)	Radix Rhapontici (漏蘆)
Radix Helicteris (山芝麻)	Radix Rhodomyrti (崗稔根)
Radix Hemerocallis (萱草根)	Radix Rubiae (茜草)
Radix Ilicis Asprellae (崗梅根)	Radix Salviae Miltiorrhizae (丹參)
Radix Ilicis Pubescens (毛冬青)	Radix Sanguisorbae (地榆)
Radix Inulae (土木香)	Radix Saposhnikoviae (防風)
Radix Isatidis (板藍根)	Radix Scrophulariae (玄參)
Radix Kadsurae Coccineae (黑老虎根)	Radix Scutellariae (黃芩)
Radix Knoxiae (紅大戟)	Radix Semiaquilegiae (天葵子)
Radix Linderae (烏藥)	Radix seu Caulis Derridis Trifoliatae (魚藤)
Radix Liriores (山麥冬)	Radix Sophorae Flavescentis (苦參)
Radix Mirabilis (紫茉莉根)	Radix Stellariae (銀柴胡)
Radix Morindae Officinalis (巴戟天)	Radix Stemonae (百部)
Radix Notoginseng (三七)	Radix Stephaniae Tetrandrae (防己)
Radix Ophiopogonis (麥冬)	Radix Tinosporae (金果欖)
Radix Oryzae Glutinosae (糯稻根)	Radix Trichosanthis (天花粉)
Radix Paeoniae Alba (白芍)	Radix Tripterygii Wilfordii (雷公藤)
Radix Paeoniae Rubra (赤芍)	Radix Valeriana (缬草)
Radix Panacis Quinquefolii (西洋參)	Radix Vitis Adstrictae (野葡萄)
Radix Pandani Tectorii (露兜簕)	Radix Vladimiriae (川木香)
Radix Patriniae Heterophyllae or Radix Patriniae Scabrae (墓頭回)	Radix Wikstroemae (了哥王)
Radix Peucedani (前胡)	Radix Zanthoxyli (兩面針)
Radix Physochlainae (華山參)	Radix Zanthoxyli Avicennae (鷹不泊)
Radix Phytolaccae (商陸)	Ramulus Cinnamomi (桂枝)
Radix Platycodi (桔梗)	Ramulus et Folium Mussaendae Pubescentis (玉葉金花)
Radix Plumbaginis Zeylanicae (白花丹)	
Radix Polygalae (遠志)	
Radix Polygoni Multiflori (何首烏)	

Name	Name
Ramulus et Folium Phyllodii Pulchelli (排錢草)	Rhizoma Curcumae (莪朶) Rhizoma Curcumae Longae (薑黃)
Ramulus et Folium Picrasmae (苦木)	Rhizoma Cynanchi Stauntonii (白前)
Ramulus Euonymi (鬼箭羽)	Rhizoma Cyperi (香附)
Ramulus Mori (桑枝)	Rhizoma Cyrtomii (貫眾)
Ramulus Sambuci Williamsii (接骨木)	Rhizoma Dioscoreae Bulbiferae (黃藥子)
Ramulus Uncariae cum Uncis (鈎藤)	Rhizoma Dioscoreae Cirrhosae (薯莨)
Receptaculum Nelumbinis (蓮房)	Rhizoma Dioscoreae Hypoglaucae (粉草薢)
Resina Draconis (血竭)	Rhizoma Dioscoreae Nipponicae (穿山龍)
Resina Ferulaen (阿魏)	Rhizoma Dioscoreae Septemlobae (綿萆薢)
Resina Liquidambaris (楓香脂)	Rhizoma Dioscoreae Tokoro (山萆薢)
Resina Toxicodendri (乾漆)	Rhizoma Drynariae (骨碎補)
Rhizoma Acori Tatarinowii (石菖蒲)	Rhizoma Dryopteris Crassirhizomae (綿馬貫眾)
Rhizoma Alismatis (澤瀉)	Rhizoma et Radix Baphicacanthis Cusiae (南板藍根)
Rhizoma Anemarrhenae (知母)	Rhizoma et Radix Notopterygii (羌活)
Rhizoma Anemones Altaicae (九節菖蒲)	Rhizoma Gastrodiae (天麻)
Rhizoma Anemones Raddeanae (兩頭尖)	Rhizoma Homalomenae (千年健)
Rhizoma Ardisiae Gigantifoliae (走馬胎)	Rhizoma Ligustici (藁本)
Rhizoma Atractylodis (蒼朮)	Rhizoma Matteucciae (莢果蕨貫眾)
Rhizoma Atractylodis Macrocephalae (白朮)	Rhizoma Menisperm (北豆根)
Rhizoma Belamcandae (射干)	Rhizoma Osmundae (紫萁貫眾)
Rhizoma Bistortae (拳參)	Rhizoma Panacis Japonici (竹節參)
Rhizoma Blechni (烏毛蕨貫眾)	Rhizoma Panacis Majoris (珠子參)
Rhizoma Bletillae (白芨)	Rhizoma Paridis (重樓)
Rhizoma Bolbostemmae (土貝母)	Rhizoma Picrorhizae (胡黃連)
Rhizoma Chuanxiong (川芎)	Rhizoma Polygonati (黃精)
Rhizoma Cibotii (狗脊)	Rhizoma Polygoni Cuspidati (虎杖)
Rhizoma Cimicifugae (升麻)	Rhizoma Corydalis (延胡索)
Rhizoma Coptidis (黃連)	Rhizoma Corydalis Decumbentis (夏天無)
Rhizoma Corydalis (延胡索)	Rhizoma Smilacis Chinensis (菝葜)
Rhizoma Corydalis Decumbentis (夏天無)	Rhizoma Smilacis Glabrae (土茯苓)
Rhizoma Curculiginis (仙茅)	

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Name	Name
Rhizoma Sparganii (三棱)	Semen Myristicae (肉豆蔻)
Rhizoma Wenyujin Concisa (片薑黃)	Semen Nigellae (黑種草子)
Rhizoma Woodwardiae (狗脊貫眾)	Semen Oroxyli (木蝴蝶)
Sal Ammoniacus (礦砂)	Semen Persicae (桃仁)
Scolopendra (蜈蚣)	Semen Pharbitidis (牽牛子)
Scorpio (全蠍)	Semen Plantaginis (車前子)
Semen Abri Precoriori (相思子)	Semen Platycladi (柏子仁)
Semen Abutili (苘麻子)	Semen Ricini (蓖麻子)
Semen Aesculi (婆羅子)	Semen Sinapis (芥子)
Semen Allii Tuberosi (薤菜子)	Semen Sterculiae Lychnophorae (胖大海)
Semen Alpiniae Katsumadai (草豆蔻)	Semen Trichosanthis (瓜萎子)
Semen Arecae (檳榔)	Semen Trigonellae (胡蘆巴)
Semen Astragali Complanati (沙苑子)	Semen Vaccariae (王不留行)
Semen Cassiae (決明子)	Spica Prunellae (夏枯草)
Semen Cassiae Occidentalis (望江南)	Spina Gleditsiae (皂角刺)
Semen Celosiae (青葙子)	Spongilla (紫梢花)
Semen Cuscutae (菟絲子)	Spora Lygodii (海金沙)
Semen Hoveniae (枳椇子)	Stamen Nelumbinis (蓮鬚)
Semen Hydnocarpi (大風子)	Stigma Croci (西紅花)
Semen Impatientis (急性子)	Styrax (蘇合香)
Semen Lepidii or Semen Descurainiae (葶藶子)	Tabanus (蛇蟲)
Semen Lini (亞麻子)	Tremolitum (陽起石)
Semen Momordicae (木鱉子)	

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

$$1 \text{ kilogram} = 1.65347 \text{ catty (sima)}$$

$$100 \text{ gram} = 2.64555 \text{ tael (sima)}$$

$$10 \text{ gram} = 0.264555 \text{ tael (sima)}$$

$$1 \text{ gram} = 0.0264555 \text{ tael (sima)}$$

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

$$1 \text{ catty (sima)} = 0.60478982 \text{ kilogram}$$

$$1 \text{ tael (sima)} = 1/16 \text{ catty} = 37.7994 \text{ gram}$$

$$1 \text{ mace (sima)} = 1/160 \text{ catty} = 3.77994 \text{ gram}$$

$$1 \text{ candareen (sima)} = 1/1600 \text{ catty} = 377.994 \text{ milligram}$$

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

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Practising Guidelines for Wholesalers of Chinese Herbal Medicines



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

April 2003

Practising Guidelines for Wholesalers of Chinese Herbal Medicines



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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 Chinese herbal 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.

2. Interpretation

“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 herbal medicine/processed herbal medicine is supplied to the wholesaler.

“Decolourization” means the change or fading in colour of certain herbal medicines/processed herbal medicines due to exposure to light, or prolonged or improper storage. This may also refer to the production of coloured substances when certain herbal medicines/processed herbal medicines undergo oxidation and polymerization, under the effect of enzymes and oxygen in the air.

“Description” means the characteristics of herbal medicines/processed herbal medicines, which can be examined directly using the sense organs, such as form, size, colour, surface characters, texture, cut surface characters, odour and taste.

“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.

“Label” includes any statement forming part of or affixed to the container or package of herbal medicines/processed herbal medicines.

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

“Loss of Smell” refers to the fact that the volatile oil of certain herbal medicines/processed herbal medicines may easily evaporate under high temperature, causing their aroma to fade.

“Oil secretion” means certain herbal medicines/processed herbal medicines oozing out oil under high temperature, creating an oily shine to the surface. In addition, for some herbal medicines/processed herbal medicines, certain constituents may, in the course of storage, change in composition due to humidity, high temperature, or extended exposure to air, such that their surface may emit an oily shine.

“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. Such treatments are carried out before the herbal medicine is sold or supplied.

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

“Retailing of Chinese herbal medicines” means the selling of any listed Chinese herbal medicines to a person who obtains the same other than for the purpose of wholesale and “retailer of Chinese herbal medicines” shall be construed accordingly.

“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.

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

- (a) a manufacturer; or
- (b) a person who obtains such listed Chinese herbal 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 Chinese herbal medicines” shall be construed accordingly.

3. Personnel

The wholesalers of Chinese herbal medicines play an important role in the prevention of counterfeit herbal medicines/processed herbal medicines or medicines of dubious quality, from entering the retail market through the wholesale process, during the distribution of herbal medicines/processed herbal 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. Wholesalers of Chinese herbal medicines may determine the number of employees and division of labour according to the scope and nature of their business.

3.1 Responsibilities of Wholesalers of Chinese Herbal Medicines

- (1) Should not engage in the dealing of herbal medicines/processed herbal medicines of dubious quality, or suspected to be counterfeit products;
- (2) 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 Chinese herbal 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;

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- 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 endangered species;
 - v. under the Undesirable Medical Advertisements Ordinance (Cap. 231), the restrictions related to the control of advertising of medicines (including herbal medicines and processed herbal 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).

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

3.2 Personnel Engaged in Wholesale Dealing in Chinese Herbal Medicines

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

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3.2.1 Knowledge Requirements

- (1) Basic knowledge of herbal medicines/processed herbal medicines: such as the name (including standard name and other names), species and application;
- (2) Basic knowledge of authentication of herbal medicines/processed herbal medicines: simple identification methods of description such as visual inspection, touching, smelling and tasting, as well as knowledge to determine the medicine's authenticity and quality;
- (3) Relatively deeper understanding of Schedule 1 medicines: for example, basic knowledge of identifying Schedule 1 medicines; and
- (4) Knowledge of managing the medicines warehouse.

3.2.2 Duties

- (1) Identify the authenticity and quality of the herbal medicines/processed herbal medicines being dealt with, to ensure that they conform to the stated specifications;
- (2) Ensure that the herbal medicines are processed according to requirements;
- (3) Take charge of the receipt, dispatch and storage of herbal medicines/processed herbal medicines;
- (4) Ensure the accuracy of the quantity of herbal medicines/processed herbal medicines being stored into, and dispatched from, the warehouse; they should ensure that the medicines are of good quality, the package is stout and the labels are clear; and
- (5) Maintain the cleanliness and hygiene of the premises.

4. Premises

The wholesalers of Chinese herbal medicines should provide suitable premises for the wholesale business in Chinese herbal medicines. They should also set up necessary facilities, and work areas, according to the needs of the business. The layout of the business premises should correspond to the nature and scale of the wholesale business in Chinese herbal medicines. In general, such premises can be divided into two parts – the business area and warehouse. In addition, if there is a need for processing herbal medicines, relevant processing equipment should be available. However, the wholesalers of Chinese herbal medicines may decide on the appropriate layout according to the actual operating conditions.

4.1 Business Area

- (1) Should be maintained in sanitary condition (please refer to section 11(a) of the Chinese Medicines Regulation); and
- (2) Should be equipped with appropriate equipment or apparatus, according to business needs.

4.2 Warehouse

- (1) Should correspond to the scale of the business and to the storage requirements of the herbal medicines/processed herbal medicines (please refer to section 11(b) of the Chinese Medicines Regulation);
- (2) Should be maintained in sanitary condition (please refer to section 11(a) of the Chinese Medicines Regulation);
- (3) To prevent mix-ups and cross-contamination, separate areas dedicated to special functions should be assigned, for example, area for inspecting herbal medicines/processed herbal medicines before storing into warehouse, area for storing different kinds of herbal medicines/processed herbal medicines, area for dispatching goods, area for storing substandard medicines, and area for storing medicines pending further action, etc.; and
- (4) Should be equipped with the following facilities (please refer to section 11(c) of the Chinese Medicines Regulation):

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- 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;
- iv. facilities for control of insects, rodents, humidity, mildew and for the prevention of fire; and
- v. separate storage facilities for Schedule 1 medicines according to business needs.

5. Scope of Business

The scope of business of a wholesaler of Chinese herbal medicines generally involves a number of aspects, including the purchase, inspection, acceptance, storage, sale, distribution and transportation of herbal medicines/processed herbal medicines. Wholesalers of Chinese herbal medicines may also process herbal medicines according to business needs (please see Appendix 1 for details) and sell single Chinese medicine granules for prescription (please see Appendix 2 for details).

5.1 Purchase of Herbal Medicines/Processed Herbal Medicines

- (1) Purchase herbal medicines/processed herbal medicines only from reputable suppliers; and
- (2) Determine the quantity to be purchased for each kind of herbal medicine/processed herbal medicine according to demand, sales volume and inventory status.

5.2 Inspection, Acceptance and Storage of Herbal Medicines/Processed Herbal Medicines

5.2.1 Inspection and Acceptance of Herbal Medicines/Processed Herbal Medicines

- (1) Ensure that the quality of each batch of herbal medicine/processed herbal medicine purchased meets the required standards;

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- (2) When carrying out inspection and acceptance, ensure that the name of the medicines and batch number are properly marked on the container or package of the herbal medicines/processed herbal medicines;
 - (3) Identify the authenticity and quality of the herbal medicines/processed herbal medicines to ensure that they conform to the stated specifications;
 - (4) If the herbal medicines/processed herbal medicines are found to be counterfeit, of poor quality or not conforming to the stated specifications (for example, those showing obvious irregularities such as contamination with mildew, infestation by insects, oil secretion, decolourization, loss of smell, decomposition due to humidity, stickiness etc.), contact the supplier of the herbal medicines/processed herbal medicines as soon as possible for proper remedy; and
 - (5) Assign dedicated staff to inspect and accept deliveries in person for Schedule 1 medicines, or for those herbal medicines/processed herbal medicines that may be easily mixed up with other similar medicines, to avoid any mistakes.

5.2.2 Storage of Herbal Medicines/Processed Herbal Medicines

- (1) Store herbal medicines/processed herbal medicines in containers or packages of good quality;
- (2) After inspection and acceptance, all herbal medicines/processed herbal medicines should be promptly put into the warehouse. The medicines should be stored properly according to their quality and medicinal properties;
- (3) Schedule 1 medicines should be stored effectively separated from other herbal medicines and processed herbal medicines (please refer to section 11(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;
- (4) Store herbal medicines/processed herbal medicines separately from other substances;

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- (5) Each type of herbal medicine/processed herbal medicine should be stored in a separate container, or package, according to its nature and classification (please refer to section 11(e) of the Chinese Medicines Regulation), with its name marked on the container, or package, to prevent mix-ups;
- (6) Ensure that each container and package is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the herbal medicines/processed herbal medicines stored in it (please refer to section 11(f) of the Chinese Medicines Regulation). Choose the most suitable packaging material according to the nature of the herbal medicines/processed herbal medicines; and
- (7) Carry out quality inspections frequently according to the nature of the herbal medicines/processed herbal medicines. If there are any detected changes in quality, take immediate measures (such as exposure to direct sunlight, drying in ovens, or eradication of insects), to minimize changes in quality or loss. In the course of taking such measures, avoid contamination of the herbal medicines/processed herbal medicines.

5.3 Sale or Distribution of Herbal Medicines/Processed Herbal Medicines

- (1) Before dispatching herbal medicines/processed herbal medicines, double-check the name, specification, quantity and batch number;
- (2) Thoroughly inspect the quality of the herbal medicines/processed herbal medicines. Do not dispatch any medicine found to have been infested with insects, contaminated with mildew or adulterated with impurities. At the same time, promptly inspect the herbal medicines/processed herbal medicines from the same batch and take proper action;
- (3) Dispatch herbal medicines/processed herbal medicines according to the “first-in, first-out” principle, to ensure the quality;
- (4) Only dispatch herbal medicines/processed herbal medicines of a quality meeting the required standards;

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- (5) Under general circumstances, only supply processed herbal medicines to retailers of Chinese herbal medicines. If the wholesalers engage in the dealing of pre-packed multiple processed herbal medicines, restrict the scope to the “herbal tea” and “soup ingredients” which are commonly used for health maintenance purposes. Sale of pre-packed multiple processed herbal medicines for therapeutic purposes should be refrained; and
 - (6) Sell or distribute Schedule 1 medicines only to the following persons or entities (please refer to section 12 of the Chinese Medicines Regulation):
 - i. a holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines;
 - ii. a holder of a retailer licence in Chinese herbal medicines in respect of Schedule 1 medicines;
 - iii. a holder of a manufacturer licence;
 - iv. a registered Chinese medicine practitioner;
 - v. a person or an institution exempted under section 158(1) of the Chinese Medicine Ordinance requiring the herbal medicine/processed herbal medicine for the purpose of education or scientific research;
 - vi. a Government department or public officer requiring the herbal medicine/processed herbal medicine for the purpose of public service;
 - vii. a purchaser outside Hong Kong;
 - viii. a hospital or clinic managed and controlled by the Hospital Authority established under section 3(1) of the Hospital Authority Ordinance (Cap. 113); or
 - ix. a hospital within the meaning of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165).

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5.4 Transportation of Herbal Medicines/Processed Herbal Medicines

Ensure that no herbal medicine/processed herbal medicine in possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine (please refer to section 11(h) of the Chinese Medicines Regulation).

5.5 Labelling

- (1) Agree with the supplier on an appropriate, and consistent labelling system, and strictly implement the system;
- (2) Ensure that the label on the containers, or packages, in which a Schedule 1 medicine is stored has the following particulars clearly and distinctly set out and not in any way obscured or obliterated (please refer to section 23 of the Chinese Medicines Regulation):
 - i. the name, at least in Chinese, of the medicine;
 - ii. the name of the wholesale dealer as specified in the wholesaler licence;
 - iii. the batch number of the medicine;
 - iv. a warning containing the Chinese text: 「毒性中藥」 or 「毒性中药」; and
 - v. if the warning referred to in paragraph iv. is to be available in English also, a warning containing the English text: "Toxic Chinese Medicine".

As far as practicable, also state the place where the Schedule 1 medicine was cultivated;

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- (3) Ensure that the label on the containers, or packages, in which other herbal medicines/processed herbal medicines are stored includes, at least in Chinese, the name of the medicine, the batch number and, as far as practicable, the place where the medicine was cultivated. Such particulars should be clearly and distinctly set out and not in any way obscured or obliterated (please refer to section 24 of the Chinese Medicines Regulation);
 - (4) For those medicines listed in Schedule 1 and Schedule 2 of the Chinese Medicine Ordinance, the names used in the schedules should be taken as the standard names. For those medicines not listed in Schedule 1 and Schedule 2, reference should be made orderly to the Pharmacopoeia of the People's Republic of China 《中華人民共和國藥典》, Zhonghua Bencao 《中華本草》, Zhongyao Dacidian 《中藥大辭典》 or Chinese Materia Medica 《中國藥材學》; and
 - (5) Apart from labelling the herbal medicines/processed herbal medicines with their standard names, common names used locally can be included according to practical circumstances. To ensure the correct use of medicines, also include appropriate specifications of the herbal medicines/processed herbal medicines alongside the name of the medicines when necessary to avoid mix-ups.

6. Complaint and Recall System of Herbal Medicines/ Processed Herbal Medicines

The wholesalers of Chinese herbal 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 herbal medicine/processed herbal 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 11(i) 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;

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- (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 herbal medicines/processed herbal medicines, if necessary.

6.2 Recall System

- (1) The wholesalers of Chinese herbal medicines should set up a proper recall system to ensure that they can rapidly recall any herbal medicine/processed herbal medicine identified to have quality or safety problems. In addition, the Medicines Board under the Council may order any wholesaler of Chinese herbal 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 herbal medicine/processed herbal 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 herbal medicines/processed herbal medicines, the 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 herbal medicines/processed herbal medicines and appropriately handle such medicines, for example, by returning, or destroying, such herbal medicines/processed herbal medicines.
- (2) The designated person should first inform the Medicines Board under the Council, before carrying out any recall;

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- (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 herbal medicines/processed herbal 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.

7. Keeping of Records

The wholesalers of Chinese herbal medicines should keep relevant records and transaction documents. Such records and transaction documents should meet the following requirements to enable the tracing of the source and distribution channels of herbal medicines/processed herbal medicines suspected to have problems whenever necessary.

7.1 Purchase and Sales Records of Schedule 1 Medicines of the Chinese Medicine Ordinance

- (1) Ensure that the following particulars in respect of every transaction whereby a Schedule 1 medicine is acquired, received, sold or distributed are recorded within 72 hours after the completion of the transaction:
 - i. the date of the transaction;
 - ii. the nature of the transaction;
 - iii. the name and quantity of the Schedule 1 medicine acquired, received, sold or distributed, as the case may be;
 - iv. the name, address and telephone number of the person who sells or distributes the Schedule 1 medicine to him or the person to whom he sells or distributes the medicine, as the case may be;
 - v. the reference number of the invoice or other document evidencing the transaction; and
 - vi. the balance of the Schedule 1 medicine remaining in possession after the completion of the transaction.

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Such records 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 13(1) and (2) of the Chinese Medicines Regulation); and

- (2) The purchase and sales records of Schedule 1 medicines 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.

7.2 Transaction Documents

- (1) The invoice or other document in respect of every transaction whereby a herbal medicine/processed herbal medicine is acquired, received, 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 13(3), 14(1) and 14(3) of the Chinese Medicines Regulation);
- (2) The relevant invoice or other document should contain the following particulars of the transaction (please refer to sections 13(3) and 14(2) of the Chinese Medicines Regulation):
 - i. the date of the transaction;
 - ii. the nature of the transaction (applicable to Schedule 1 medicines only);
 - iii. the name of the herbal medicine/processed herbal medicine acquired, received, sold or distributed, as the case may be. If necessary, include a text showing the specifications of the medicine;
 - iv. the quantity and batch number of the herbal medicine/processed herbal medicine acquired, received, sold or distributed, as the case may be;

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- v. the name, address and telephone number of the person who sells or distributes the herbal medicine/processed herbal medicine to them or the person to whom they sell or distribute the herbal medicine/processed herbal medicine, as the case may be; and
 - vi. the reference number of the invoice or other document.
- (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 Chinese herbal 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 herbal medicines and processed herbal medicines, and achieve the objective of safeguarding public health.

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Appendix 1 Processing Herbal Medicines

The wholesalers of Chinese herbal medicines may process herbal medicines at the request of the customer. In addition to complying with relevant requirements stated in these guidelines, the following should be observed:

- (1) Persons engaged in the processing should possess the following knowledge:
 - i. basic knowledge of herbal medicines/processed herbal medicines: such as the name (including the standard name and other names), species and application;
 - ii. basic knowledge of authentication of herbal medicines and their processed forms: simple identification methods of description, such as visual inspection, touching, smelling and tasting, as well as knowledge to determine the medicine's authenticity and quality;
 - iii. relatively deeper understanding of Schedule 1 medicines: such as basic knowledge of identifying Schedule 1 medicines; and
 - iv. knowledge of processing herbal medicines.
- (2) The herbal medicines should be processed in accordance with the prescribed processing methods and techniques to ensure safety and quality;
- (3) Before processing, first examine the herbal medicines to ensure that the quality is good;
- (4) Use appropriate equipment, apparatus, container and packaging material in processing (please refer to section 11(g)(i) of the Chinese Medicines Regulation). All staff involved should ensure that the finished product is not contaminated, during the course of processing;
- (5) The processing of Schedule 1 medicines should be carried out by experienced staff, using equipment and tools dedicated to such operation. Such equipment and tools should be thoroughly cleaned after use. Staff who are not involved in the processing work should be prohibited from freely entering the processing area during the course of processing. Impurities separated from Schedule 1 medicines and water or supplementary materials that have been used in the processing of Schedule 1 medicines should be properly disposed of;

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- (6) The processing area should be kept clean and hygienic to avoid contamination of the processed herbal medicines. Smoking, eating, drinking and the storage of personal objects are strictly prohibited. Proper fire prevention facilities should be installed, and special care should be taken in the use and storage of inflammable substances;
 - (7) The processing equipment and apparatus should be kept clean and hygienic. They should be properly maintained and repaired to avoid malfunction or contamination (please refer to section 11(g)(ii) of the Chinese Medicines Regulation);
 - (8) Upon the completion of processing, examine the processed herbal medicines to ensure that the quality meets the required standards (please refer to section 11(g)(iii) of the Chinese Medicines Regulation). The medicines should then be stored directly into clean container, or package, and affixed with appropriate labels, before distribution. Processed herbal medicines that fail to meet the required standards should be disposed of as waste products, and their sale is strictly prohibited;
 - (9) Apart from the appropriate supplementary materials or additives required for processing the herbal medicines, any colouring agents, decolourizing agents, densifying agents or taste modifying agents that are not necessary or do not conform to the specifications should not be used. This is to avoid affecting the normal nature of the medicines, such as appearance, colour, and smell, etc; and
 - (10) A processing record should be made within 72 hours after the completion of processing a herbal medicine. The record should include the following particulars:
 - i. the name and quantity of each type of material (including the herbal medicine or mixture of herbal medicines to be processed) used in the processing;
 - ii. the name and quantity of the processed herbal medicine;
 - iii. the name or description of the processing method;
 - iv. the date of the completion of the processing;
 - v. the examination results of the processed herbal medicine; and

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vi. the name of the person who supervises the processing.

Such records 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 completion of the processing (please refer to sections 11(g)(iv), (v) and (vi) of the Chinese Medicines Regulation). The processing 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.



Appendix 2 Selling Single Chinese Medicine Granules for Prescription

The wholesalers of Chinese herbal medicines may import and sell single Chinese medicine granules for prescription. In addition to complying with relevant requirements stated in these guidelines, the following should be observed:

- (1) Before importing and selling any single Chinese medicine granules for prescription, the wholesalers should submit information about the product to the Medicines Board under the Council to decide whether the product needs to be registered. Information to be submitted includes:
 - i. sample or prototype of the single Chinese medicine granules for prescription (including labelling contents);
 - ii. production permit or certificate issued by the health authority of the place of production;
 - iii. certificate of sales issued by the health authority of the place of production (if applicable);
 - iv. names and quantities of herbal medicine and supplementary materials contained in the single Chinese medicine granules for prescription;
 - v. authentication reports of the relevant herbal medicine;
 - vi. species and place of cultivation of the relevant herbal medicine;
 - vii. production method of the single Chinese medicine granules for prescription (e.g. detailed extraction technique); and
 - viii. extraction ratio of the single Chinese medicine granules for prescription.
- (2) Ensure that the single Chinese medicine granules for prescription being sold complies with the three safety requirements prescribed for registration of proprietary Chinese medicines (i.e. limits of heavy metals or toxic elements, pesticides residue limits and microbial limits);

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- (3) Supply single Chinese medicine granules for prescription only to Chinese medicine practitioners, licensed retailers or wholesalers of Chinese herbal medicines. If the single Chinese medicine granules for prescription contain any Schedule 1 medicine, the said granules should be supplied only to registered Chinese medicine practitioners, licensed retailers or wholesalers of Chinese herbal medicines in respect of Schedule 1 medicines;
- (4) Ensure that the label on the container or package of single Chinese medicine granules for prescription includes the following particulars:
 - i. name of the single Chinese medicine granules for prescription;
 - ii. weight equivalence i.e. the amount of original processed herbal medicine that is equivalent to one gram of the granules;
 - iii. a statement containing the following Chinese text: 「只供中醫處方配發使用」 ;
 - iv. packing specification of the single Chinese medicine granules for prescription;
 - v. normal dosage or maximum dosage of the single Chinese medicine granules for prescription;
 - vi. name of the manufacturer or distributor of the single Chinese medicine granules for prescription; and
 - vii. expiry date of the single Chinese medicine granules for prescription.
- (5) Ensure that the relevant particulars in respect of every transaction whereby a single Chinese medicine granules for prescription containing Schedule 1 medicine, is acquired, received, sold or distributed are recorded. For details, please refer to part 7: Keeping of Records.

Appendix 3: List of Schedule 1 Medicines of the Chinese Medicine Ordinance

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

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Appendix 4: List of Schedule 2 Medicines of the Chinese Medicine Ordinance

Name	Name
Agkistrodon (蕲蛇)	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 Impatiens (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 Lycoris 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 Brevipedunculæ (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 (火殃簕)	Cornu Saigae Tataricae (羚羊角)

Name	Name
Cortex Dictamni (白鮮皮)	Fluoritum (紫石英)
Cortex Eucommiae (杜仲)	Folium Aconiti Kusnezoffii (草烏葉)
Cortex Fraxini (秦皮)	Folium Apocyni Veneti (羅布麻葉)
Cortex Hibisci (川槿皮)	Folium Artemisiae Argyi (艾葉)
Cortex Ilicis Rotundae (救必應)	Folium Callicarpea Formosanae (紫珠葉)
Cortex Illicii (地楓皮)	Folium et Cacumen Breyniae Fruticosae (黑面神)
Cortex Kadsurae Radicis (紫荊皮)	Folium et Cacumen Murrayae (九里香)
Cortex Lycii (地骨皮)	Folium et Ramulus Evodiae (三叉苦)
Cortex Magnoliae Officinalis (厚樸)	Folium Ginkgo (銀杏葉)
Cortex Meliae (苦棟皮)	Folium Ginseng (人參葉)
Cortex Mori (桑白皮)	Folium Glochidii Eriocarpi (漆大姑)
Cortex Moutan (牡丹皮)	Folium Hibisci Mutabilis (木芙蓉葉)
Cortex Periplocae (香加皮)	Folium Ilicis Cornutae (枸骨葉)
Cortex Phellodendri (黃柏)	Folium Isatidis (大青葉)
Cortex Pseudolaricis (土荊皮)	Folium Lantanae Camarae (馬纓丹)
Cortex Schefflerae Octophyllae (鴨腳木)	Folium Nerii (夾竹桃葉)
Cortex Ulmi Parvifoliae (柳榆皮)	Folium Photinia (石南葉)
Crinis Carbonisatus (血餘炭)	Folium Pini (松毛)
Eupolyphaga seu Steleophaga (土鱉蟲)	Folium Polygoni Tinctorii (蓼大青葉)
Faeces Leporis (望月砂)	Folium Psidii Guajavae (番石榴葉)
Faeces Tropopterori (五靈脂)	Folium Psychotriae Rubrae (山大顏)
Faeces Vespertilionis (夜明砂)	Folium Pterocaryae Stenopterae (楓楊葉)
Flos Albiziae (合歡花)	Folium Pyrrosiae (石韋)
Flos Buddleiae (密蒙花)	Folium Rhododendri Daurici (滿山紅)
Flos Campsis (凌霄花)	Folium Sauropi (龍膽葉)
Flos Celosiae Cristatae (雞冠花)	Folium Sennae (番瀉葉)
Flos Chimonanthi Praecocis (臘梅花)	Folium Viticis Negundo (牡荆葉)
Flos Eriocauli (穀精草)	Fructus Akebiae (預知子)
Flos Farfarae (款冬花)	Fructus Alpiniae Oxyphyllae (益智)
Flos Genkwa (茺花)	Fructus Amomi Rotundus (豆蔻)
Flos Hibisci Rosae-Sinensis (扶桑花)	Fructus Arctii (牛蒡子)
Flos Inulae (旋覆花)	Fructus Aristolochiae (馬兜鈴)
Flos Jasmini (素馨花)	Fructus Aurantii (枳殼)
Flos Magnoliae (辛夷)	Fructus Aurantii Immaturus (枳實)
Flos Magnoliae Officinalis (厚樸花)	
Flos Rosae Chinensis (月季花)	

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Name
Fructus Broussonetiae (楮實子)
Fructus Bruceae (鴉膽子)
Fructus Carotae (南鶴鱈)
Fructus Carpesii (鶴鱈)
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 (茺蔚子)
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 (華芨)
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 Pubescens (燈籠草)
Fructus Sophorae (槐角)
Fructus Terminaliae Billericae (毛訶子)
Fructus Toosendan (川棟子)
Fructus Tribuli (蒺藜)
Fructus Trichosanthis (瓜萎)

Name
Fructus Tritici Levis (浮小麥)
Fructus Tsaoko (草果)
Fructus Ulmi Macrocarpae (蕪荑)
Fructus Viticis (蔓荊子)
Fructus Viticis Negundo (黃荊子)
Fructus Xanthii (蒼耳子)
Galla Chinensis (五倍子)
Gekko Swinhonis (壁虎)
Gypsum Fibrosum Preparata (煅石膏)
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 Antenororis Neofiliformis (金錢草)
Herba Ardisiae Japonicae (矮地茶)
Herba Aristolochiae (天仙藤)
Herba Aristolochiae Mollissimae (尋骨風)
Herba Artemisiae Annuae (青蒿)
Herba Artemisiae Anomaliae (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 Casythaе Filiformis (無根藤)
Herba Catharanthi Rosei (長春花)
Herba Centellae (積雪草)
Herba Centipedae (鵝不食草)

Name	Name
Herba Chenopodii (土荊芥)	Herba Gynostemmatis (絞股藍)
Herba Cirsii (小薊)	Herba Hedyotidis Chrysotrichae (黃毛耳草)
Herba Cissampelotis (亞乎奴)	Herba Hedyotidis Corymbosae (水綫草)
Herba Cistanches (肉蓯蓉)	Herba Houttuyniae (魚腥草)
Herba Clinopodii (斷血流)	Herba Hyperici (紅旱蓮)
Herba Clinopodii Gracilis (剪刀草)	Herba Hyperici Erecti (小連翹)
Herba Commelinaceae (鴨跖草)	Herba Hyperici Japonici (田基黃)
Herba Corydalis Bungeanae (地丁草)	Herba Inulae (金沸草)
Herba Crotalariae Mucronatae (豬屎豆)	Herba Junci Setchuensis (龍鬚草)
Herba Cymbopogonis (薑香草)	Herba Kulancoes Laciniatae (伽藍菜)
Herba Cynomorii (鎖陽)	Herba Leonuri (益母草)
Herba Damnacanthi (虎刺)	Herba Lespedezae Cuneatae (鐵掃帚)
Herba Dendrobii (石斛)	Herba Lobeliae Chinensis (半邊蓮)
Herba Desmodii Styracifolii (廣金錢草)	Herba Lophatheri (淡竹葉)
Herba Dianthi (瞿麥)	Herba Lycopi (澤蘭)
Herba Dichondrae Repentis (馬蹄金)	Herba Lycopodii (伸筋草)
Herba Duchesneae Indicae (蛇莓)	Herba Lysimachiae (金錢草)
Herba Ecliptae (墨旱蓮)	Herba Malvastri Coromandeliana (黃花棉)
Herba Eleocharitis (通天草)	Herba Melastomatis Candii (野牡丹)
Herba Elephantopi (地膽頭)	Herba Melastomatis Dodecandri (地菍)
Herba Eleusines Indicae (牛筋草)	Herba Orostachyos (瓦松)
Herba Emiliae (一點紅)	Herba Paederiae (雞屎藤)
Herba Ephedrae (麻黃)	Herba Patriniae (敗醬草)
Herba Epimedii (淫羊藿)	Herba Pholidotae Chinensis (石仙桃)
Herba Epimeredis Indicae (防風草)	Herba Phyllanthi Urinariae (葉下珠)
Herba Equiseti Hiemalis (木賊)	Herba Piperis Sarmentosi (假蒟)
Herba Erodii or Herba Geranii (老鶴草)	Herba Plantaginis (車前草)
Herba Eupatorii (佩蘭)	Herba Polygalae Chinensis (大葉金不換)
Herba Euphorbiae Hirtae (飛楊草)	Herba Polygalae Japonicae (瓜子金)
Herba Euphorbiae Humifusae (地錦草)	Herba Polygoni Avicularis (萹蓄)
Herba Euphorbiae Thymifoliae (小飛楊草)	Herba Polygoni Chinensis (火炭母)
Herba Gelsemii Elegantis (斷腸草)	Herba Polygoni Perfoliati (杠板歸)
Herba Gendarussae (小駁骨)	Herba Potentillae Chinensis (委陵菜)
Herba Geranii Caroliniani (野老鶴草)	Herba Potentillae Discoloris (翻白草)
Herba Glechomae (連錢草)	
Herba Gnaphalii Affinis (鼠曲草)	

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Name	Name
Herba Pouzolziae Zeylanicae (霧水葛)	Herba Veronicastri (腹水草)
Herba Pteridis Multifidae (鳳尾草)	Herba Violae (紫花地丁)
Herba Pteridis Semipinnatae (半邊旗)	Herba Visci (槲寄生)
Herba Pyrolae (鹿銜草)	Herba Wedeliae (蟛蜞菊)
Herba Rabdosiae Lophanthoidis (溪黃草)	Herba Zephyranthis Candiae (肝風草)
Herba Ranunculi Japonici (毛茛)	Hirudo (水蛭)
Herba Saginae Japonicae (漆姑草)	Indigo Naturalis (青黛)
Herba Salviae Chinensis (石見穿)	Lapis Chloriti (青礞石)
Herba Salviae Plebeiae (荔枝草)	Lapis Micae Aureus (金礞石)
Herba Sambuci Chinensis (陸英)	Lasiosphaera seu Calvatia (馬勃)
Herba Sarcandrae (腫節風)	Lignum Dalbergiae Odoriferae (降香)
Herba Saussureae Involucratae (雪蓮花)	Lignum Pini Nodi (油松節)
Herba Saxifragae (虎耳草)	Limonium (禹餘糧)
Herba Schizonepetae (荊芥)	Medulla Junci (燈心草)
Herba Scutellariae Barbatae (半枝蓮)	Medulla Stachyuri or Medulla Helwingiae (小通草)
Herba Sedi (垂盆草)	Medulla Tetrapanacis (通草)
Herba Selaginellae (卷柏)	Moschus (麝香)
Herba Selaginellae Doederleinii (石上柏)	Myrrha (沒藥)
Herba Senecionis Scandentis (千里光)	Natrii Sulfas (芒硝)
Herba Setariae Viridis (狗尾草)	Natrii Sulfas Exsiccatus (玄明粉)
Herba seu Radix Amarantri (刺莧菜)	Nidus Vespa (蜂房)
Herba seu Radix Cirsii Japonici (大薊)	Nux Prinsepiae (薤仁)
Herba Sidae Rhombifoliae (黃花母)	Oleum Linderae (香果脂)
Herba Siegesbeckiae (豨莶草)	Olibanum (乳香)
Herba Solani Lyrati (白英)	Omphalia (雷丸)
Herba Solani Nigri (龍葵)	Ootheca Mantidis (桑螵蛸)
Herba Solidaginis (一枝黃花)	Ophicalcitum (花蕊石)
Herba Speranskiae Tuberculatae (珍珠透骨草)	Pericarpium Arecae (大腹皮)
Herba Spirodelae (浮萍)	Pericarpium Trichosanthis (瓜蒌皮)
Herba Stephaniae Longae (龜筭篤)	Periostracum Cicadae (蟬蛻)
Herba Swertiae Mileensis (青葉膽)	Petiolus Trachycarpi (棕櫚)
Herba Taxilli (桑寄生)	Pollen Pini (松花粉)
Herba Verbenae (馬鞭草)	Pollen Typhae (蒲黃)
Herba Veronicae (一支香)	Polyporus (豬苓)
	Processed Fructus Crotonis (製巴豆)

Name	Name
Processed Radix Aconiti (製川烏)	Radix Angelicae Pubescentis (獨活)
Processed Radix Aconiti Kusnezoffii (製草烏)	Radix Angelicae Sinensis (當歸)
Processed Radix Aconiti Lateralis (製附子)	Radix Anisodi Tangutici (山莨菪)
Processed Radix Euphorbiae fischeriana, Radix Euphorbiae ebracteolatae, or Radix Stellerae (製狼毒)	Radix Ardisiae Crenatae (朱砂根)
Processed Radix Kansui (製甘遂)	Radix Aristolochiae (青木香)
Processed Resina Garcinia Morellae (製藤黃)	Radix Aristolochiae Fangchi (廣防己)
Processed Rhizoma Arisaematis (製天南星)	Radix Aristolochiae Heterophyllae (漢中防己)
Processed Rhizoma Pinelliae (製半夏)	Radix Arnebiae or Radix Lithospermi (紫草)
Processed Rhizoma Typhonii or Radix Aconiti Corean (製白附子 (禹白附、關白附))	Radix Asparagi (天冬)
Processed Semen Crotonis (巴豆霜)	Radix Asteris (紫菀)
Processed Semen Euphorbiae (製千金子)	Radix Astragali (黃芪)
Processed Semen Hyoscyami (製天仙子)	Radix Aucklandiae (木香)
Processed Semen Strychni (製馬錢子)	Radix Bauhiniae Hupehanae (羊蹄甲)
Pseudobulbus Cremastrae seu Pleiones (山慈姑)	Radix Boehmeriae (苧麻根)
Pumex (浮石)	Radix Bupleuri (柴胡)
Pyrolusitum (無名異)	Radix Celastri Orbiculati (南蛇藤根)
Radix Acanthopanax Senticosi (刺五加)	Radix Changii (明黨參)
Radix Acanthopanax Trifoliati (三葉五加)	Radix Chloranthi Serrati (及己)
Radix Achyranthis Bidentatae (牛膝)	Radix Clematidis (威靈仙)
Radix Adenophorae (南沙參)	Radix Clerodendri Philippini (臭茉莉)
Radix Aero Fici Microcarpae (榕鬚)	Radix Cocculi Trilobi (木防己)
Radix Ampelopsis (白蔹)	Radix Codonopsis (黨參)
Radix Angelicae Citriodora (香白芷)	Radix Crotonis Crassifolii (雞骨香)

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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 Hedyosari (紅芪)
Radix Helicteris (山芝麻)
Radix Hemerocallis (萱草根)
Radix Ilicis Asprellae (崗梅根)
Radix Ilicis Pubescens (毛冬青)
Radix Inulae (土木香)
Radix Isatidis (板藍根)
Radix Kadsurae Coccinea (黑老虎根)
Radix Knoxiae (紅大戟)
Radix Linderae (烏藥)
Radix Liriores (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 (露兜簕)
Radix Patriniae Heterophyllae or Radix Patriniae Scabrae (墓頭回)
Radix Peucedani (前胡)
Radix Physochlainae (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 Rauvolfiae (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 (缬草)
Radix Vitis Adstrictae (野葡萄)
Radix Vladimiriae (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	Name
Ramulus et Folium Phyllodii Pulchelli (排錢草)	Rhizoma Curcumae (莪朶) Rhizoma Curcumae Longae (薑黃)
Ramulus et Folium Picrasmae (苦木)	Rhizoma Cynanchi Stauntonii (白前)
Ramulus Euonymi (鬼箭羽)	Rhizoma Cyperi (香附)
Ramulus Mori (桑枝)	Rhizoma Cyrtomii (貫眾)
Ramulus Sambuci Williamsii (接骨木)	Rhizoma Dioscoreae Bulbiferae (黃藥子)
Ramulus Uncariae cum Uncis (鈎藤)	Rhizoma Dioscoreae Cirrhosae (薯莨)
Receptaculum Nelumbinis (蓮房)	Rhizoma Dioscoreae Hypoglaucae (粉草薢)
Resina Draconis (血竭)	Rhizoma Dioscoreae Nipponicae (穿山龍)
Resina Ferulaen (阿魏)	Rhizoma Dioscoreae Septemlobae (綿萆薢)
Resina Liquidambaris (楓香脂)	Rhizoma Dioscoreae Tokoro (山萆薢)
Resina Toxicodendri (乾漆)	Rhizoma Drynariae (骨碎補)
Rhizoma Acori Tatarinowii (石菖蒲)	Rhizoma Dryopteris Crassirhizomae (綿馬貫眾)
Rhizoma Alismatis (澤瀉)	Rhizoma et Radix Baphicacanthis Cusiae (南板藍根)
Rhizoma Anemarrhenae (知母)	Rhizoma et Radix Notopterygii (羌活)
Rhizoma Anemones Altaicae (九節菖蒲)	Rhizoma Gastrodiae (天麻)
Rhizoma Anemones Raddeanae (兩頭尖)	Rhizoma Homalomenae (千年健)
Rhizoma Ardisiae Gigantifoliae (走馬胎)	Rhizoma Ligustici (藁本)
Rhizoma Atractylodis (蒼朮)	Rhizoma Matteucciae (莢果蕨貫眾)
Rhizoma Atractylodis Macrocephalae (白朮)	Rhizoma Menisperm (北豆根)
Rhizoma Belamcandae (射干)	Rhizoma Osmundae (紫萁貫眾)
Rhizoma Bistortae (拳參)	Rhizoma Panacis Japonici (竹節參)
Rhizoma Blechni (烏毛蕨貫眾)	Rhizoma Panacis Majoris (珠子參)
Rhizoma Bletillae (白芨)	Rhizoma Paridis (重樓)
Rhizoma Bolbostemmae (土貝母)	Rhizoma Picrorhizae (胡黃連)
Rhizoma Chuanxiong (川芎)	Rhizoma Polygonati (黃精)
Rhizoma Cibotii (狗脊)	Rhizoma Polygoni Cuspidati (虎杖)
Rhizoma Cimicifugae (升麻)	Rhizoma Saururi or Herba Saururi (三白草)
Rhizoma Coptidis (黃連)	Rhizoma Smilacis Chinensis (菝葜)
Rhizoma Corydalis (延胡索)	Rhizoma Smilacis Glabrae (土茯苓)
Rhizoma Corydalis Decumbentis (夏天無)	
Rhizoma Curculiginis (仙茅)	

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Name	Name
Rhizoma Sparganii (三棱)	Semen Myristicae (肉豆蔻)
Rhizoma Wenyujin Concisa (片薑黃)	Semen Nigellae (黑種草子)
Rhizoma Woodwardiae (狗脊貫眾)	Semen Oroxyli (木蝴蝶)
Sal Ammoniacus (礦砂)	Semen Persicae (桃仁)
Scolopendra (蜈蚣)	Semen Pharbitidis (牽牛子)
Scorpio (全蠍)	Semen Plantaginis (車前子)
Semen Abri Precatorii (相思子)	Semen Platycladi (柏子仁)
Semen Abutili (苘麻子)	Semen Ricini (蓖麻子)
Semen Aesculi (婆羅子)	Semen Sinapis (芥子)
Semen Allii Tuberosi (薤菜子)	Semen Sterculiae Lychnophorae (胖大海)
Semen Alpiniae Katsumadai (草豆蔻)	Semen Trichosanthis (瓜萎子)
Semen Arecae (檳榔)	Semen Trigonellae (胡蘆巴)
Semen Astragali Complanati (沙苑子)	Semen Vaccariae (王不留行)
Semen Cassiae (決明子)	Spica Prunellae (夏枯草)
Semen Cassiae Occidentalis (望江南)	Spina Gleditsiae (皂角刺)
Semen Celosiae (青葙子)	Spongilla (紫梢花)
Semen Cuscutae (菟絲子)	Spora Lygodii (海金沙)
Semen Hoveniae (枳椇子)	Stamen Nelumbinis (蓮鬚)
Semen Hydnocarpi (大風子)	Stigma Croci (西紅花)
Semen Impatientis (急性子)	Styrax (蘇合香)
Semen Lepidii or Semen Descurainiae (葶藶子)	Tabanus (虻蟲)
Semen Lini (亞麻子)	Tremolitum (陽起石)
Semen Momordicae (木鱉子)	

Appendix 5 Purchase and Sales Record of Schedule 1 Medicines of the Chinese Medicine Ordinance (Format for reference)

Name of Schedule 1 Medicine:-

Chinese Medicines

Appendix 6 Processing Record (Format for reference)

Appendix 7: 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

$$1 \text{ kilogram} = 1.65347 \text{ catty (sima)}$$

$$100 \text{ gram} = 2.64555 \text{ tael (sima)}$$

$$10 \text{ gram} = 0.264555 \text{ tael (sima)}$$

$$1 \text{ gram} = 0.0264555 \text{ tael (sima)}$$

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

$$1 \text{ catty (sima)} = 0.60478982 \text{ kilogram}$$

$$1 \text{ tael (sima)} = 1/16 \text{ catty} = 37.7994 \text{ gram}$$

$$1 \text{ mace (sima)} = 1/160 \text{ catty} = 3.77994 \text{ gram}$$

$$1 \text{ candareen (sima)} = 1/1600 \text{ catty} = 377.994 \text{ milligram}$$

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

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**Practising Guidelines
for
Retailers of
Chinese Herbal Medicines**



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

April 2003

Practising Guidelines
for
Retailers of Chinese Herbal Medicines



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 retailing of Chinese herbal 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.

2. Interpretation

“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 processed herbal medicine is supplied to the retailer.

“Contra-indications in pregnancy” means medicines that pregnant women should use with caution. Certain medicines may promote movement of the fetus or even cause miscarriage. Such medicines are usually divided into two types: “strictly prohibited” and “to be administered with caution”.

“Decolourization” means the change or fading in colour of certain processed herbal medicines due to exposure to light, or prolonged or improper storage. This may also refer to the production of coloured substances when certain processed herbal medicines undergo oxidation and polymerization, under the effect of enzymes and oxygen in the air.

“Description” means the characteristics of processed herbal medicines, which can be examined directly using the sense organs, such as form, size, colour, surface characters, texture, cut surface characters, odour and taste.

“Dispense” means the preparation and supply of processed herbal medicines on or in accordance with a prescription given by a Chinese medicine practitioner.

“Dispenser” means a person responsible for the preparation and supply of processed listed Chinese herbal medicines on or in accordance with a prescription given by a Chinese medicine practitioner.

“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.

“Incompatibility of medicine” means reduction or loss of efficacy, or production of toxic effects, when two or more medicines are used in combination.

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

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

“Loss of Smell” refers to the fact that the volatile oil of certain processed herbal medicines may easily evaporate under high temperature, causing their aroma to fade.

“Oil secretion” means certain processed herbal medicines oozing out oil under high temperature, creating an oily shine to the surface. In addition, for some processed herbal medicines, certain constituents may, in the course of storage, change in composition due to humidity, high temperature, or extended exposure to air, such that their surface may emit an oily shine.

“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. Such treatments are carried out before the herbal medicine is being sold or supplied.

“Responsible person”, in relation to the dispensing of processed listed Chinese herbal medicines, means a person responsible for the supervision of dispensing or his deputies –

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- (a) as nominated in an application for a retailer licence under section 114(2)(b) of the Chinese Medicine Ordinance; or
- (b) as notified to the Medicines Board under section 145(2) of the Chinese Medicine Ordinance.

“Retailing of Chinese herbal medicines” means the selling of any listed Chinese herbal medicines to a person who obtains the same other than for the purpose of wholesale, and “retailer of Chinese herbal medicines” shall be construed accordingly.

“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.

“Wholesale dealing of Chinese herbal medicines” means obtaining, or importing, any listed Chinese herbal medicine for the purpose of selling to:

- (a) a manufacturer; or
- (b) a person who obtains such listed Chinese herbal 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 Chinese herbal medicines” shall be construed accordingly.

3. Personnel

The retailing of herbal medicines includes dispensing and selling of processed herbal medicines. It is specialized work, directly affecting the safety and efficacy of processed herbal medicines. Hence, persons engaged in this trade should possess the basic knowledge relevant to their duties, and work conscientiously under proper medicine shop management to safeguard public health. Retailers of Chinese herbal medicines may determine the number of employees and division of labour, according to the scope and nature of their business.

3.1 Responsibilities of Retailers of Chinese Herbal Medicines

- (1) Should not engage in the dealing of processed herbal medicines of dubious quality or suspected to be counterfeit products;

- (2) Provide correct information on processed herbal medicines. Not to engage in false advertising which may mislead customers;
- (3) Supply processed herbal medicines at listed price;
- (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 retailers of Chinese herbal medicines, and the dispensing of Schedule 1 medicines and Schedule 2 medicines;
 - ii. 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;
 - iii. under the Animals and Plants (Protection of Endangered Species) Ordinance (Cap. 187), the restrictions related to the control of endangered species;
 - iv. under the Undesirable Medical Advertisements Ordinance (Cap. 231), the restrictions related to the control of advertising of medicines (including processed herbal medicines);
 - v. under the Waste Disposal Ordinance (Cap. 354), the provisions related to the disposal of waste; and
 - vi. 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).

- (5) Ensure that the premises are in all respects suitable for the retail business in Chinese herbal medicines, such as the provision of adequate space and suitable measuring equipment. At the same time, they should ensure that there is no source of pollution, that may contaminate processed herbal medicines, in the vicinity of the premises;

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- (6) Display the retailer licence in Chinese herbal medicines at a prominent place in the business premises; and
- (7) Properly manage the Chinese medicines retail shop.

3.2 Knowledge Requirements and Duties of Responsible Persons

3.2.1 Knowledge Requirements

- (1) Basic knowledge of processed herbal medicines: such as the names, properties and applications;
- (2) Basic knowledge of preparing processed herbal medicines: such as the principles of incompatibility of medicines (18 types of antagonism and 19 types of mutual inhibition);
- (3) Basic knowledge of the techniques of processing herbal medicines;
- (4) Basic knowledge of authentication of processed herbal medicines: simple identification methods of description such as visual inspection, touching, smelling and tasting, as well as knowledge to determine the medicine's authenticity and quality; and
- (5) Relatively deeper understanding of processed Schedule 1 medicines: for example, basic knowledge of identifying processed Schedule 1 medicines.

3.2.2 Duties

- (1) Check to ensure that the processed herbal medicines purchased, and sold, are of good quality and are suitable for use;
- (2) Handle the prescriptions given by Chinese medicine practitioners with care;
- (3) Guide and supervise the dispensing, decoction and processing of processed herbal medicines; and
- (4) Explain to customers the decoction method of processed herbal medicines, method of usage, contraindications and other matters needing special attention.



3.3 Knowledge Requirements and Duties of Dispensers

3.3.1 Knowledge Requirements

- (1) Basic knowledge of processed herbal medicines: such as the names, properties and applications;
- (2) Basic knowledge of preparing processed herbal medicines;
- (3) Basic knowledge of the techniques of processing herbal medicines;
- (4) Basic knowledge of authentication of processed herbal medicines: simple identification methods of description such as visual inspection, touching, smelling and tasting, as well as knowledge to determine the medicine's authenticity and quality; and
- (5) Basic knowledge of processed Schedule 1 medicines.

3.3.2 Duties

- (1) Assist the responsible person in checking the quality of processed herbal medicines;
- (2) Assist the responsible person in the dispensing, decoction and processing of processed herbal medicines; and
- (3) Assist the responsible person in dispatching processed herbal medicines.

3.4 Duties of Sales Persons

The duties of a sales person should only cover:

- (1) Check the quality of processed herbal medicines purchased and sold;
- (2) Receive, dispatch and store processed herbal medicines; and
- (3) Maintain the cleanliness and hygiene of the premises.

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4. Premises

The retailers of Chinese herbal medicines should provide suitable premises for the retail business in Chinese herbal medicines. They should also set up necessary facilities and work areas according to the needs of the business. The layout of the business premises should correspond to the nature and scale of the retail business in Chinese herbal medicines. In general, such premises can be divided into three parts – the business area, drawers for processed herbal medicines and store-room. In addition, if there is a need for processing herbal medicines, relevant processing equipment should be available. However, retailers of Chinese herbal medicines may decide on the appropriate layout according to the actual operating conditions.

4.1 Business Area

The business area should be maintained in sanitary condition (please refer to section 7(a) of the Chinese Medicines Regulation).

4.1.1 Reception Area of the Shop

The reception area, where customers visit, should not be used for storing sundries.

4.1.2 Retail Counter

- (1) There should be sufficient space and the passageway should be of a suitable width;
- (2) There should be display cabinets of suitable stoutness and size; and
- (3) There should be a suitable area for checking fees and dispatching processed herbal medicines.

4.1.3 Area for Dispensing Processed Herbal Medicines

- (1) Should be close to the area for receiving prescriptions and checking fees, as far as possible, to facilitate checking of the quantities of the processed herbal medicines and the dispatching of medicines;
- (2) The passageway should be of an adequate width (please refer to section 7(e)(i) of the Chinese Medicines Regulation) to facilitate staff in getting and weighing processed herbal medicines;

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- (3) Should be equipped with adequate and suitable facilities (please refer to section 7(e)(ii) of the Chinese Medicines Regulation); and
 - (4) There should be a suitable section for keeping packets of processed herbal medicines awaiting collection by customers.

4.2 Drawers for Processed Herbal Medicines

The drawers should be arranged according to specific patterns and requirements and, in general, on the basis of frequency of use and the nature of the processed herbal medicines. Please refer to the following basic principles:

- (1) Processed herbal medicines having similar therapeutic effects, or which are often used together in the prescriptions, should be placed in neighbouring drawers;
- (2) Processed herbal medicines frequently used should be placed in drawers located in easily accessible positions;
- (3) Medicines of heavier mass (e.g. mineral type of processed herbal medicines) should, preferably, be put in lower drawers;
- (4) Medicines of lighter mass (e.g. herb type of processed herbal medicines) should be placed in relatively larger drawers or in two separate drawers;
- (5) Processed herbal medicines which are incompatible with each other should not be placed in the same drawer or in neighbouring drawers;
- (6) Processed herbal medicines of similar descriptions but having different therapeutic effects, should not be placed in the same drawer;
- (7) Processed herbal medicines having offensive odours should not be placed in the same drawer with other processed herbal medicines; and
- (8) Unprocessed and processed forms of the same type of medicine should not be placed in the same drawer, to avoid mix-ups and misuse.

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4.3 Store-room

- (1) Should correspond to the varieties and quantities of processed herbal medicines being traded (please refer to section 7(b) of the Chinese Medicines Regulation);
- (2) Should be maintained in sanitary condition (please refer to section 7(a) of the Chinese Medicines Regulation); and
- (3) Should be kept cool, dry and well ventilated. Relevant facilities should be provided for the control of insects, rodents, mildew, humidity and contamination (please refer to section 7(c) of the Chinese Medicines Regulation).

5. Scope of Business

The scope of business of a retailer covers, in general, the dispensation and sale of processed herbal medicines, which involves many aspects like verification of prescriptions; preparation; cross-checking; packaging and dispatching; and the purchase, inspection and acceptance as well as the storage of processed herbal medicines. Retailers may also decoct medicines at the request of patients or customers; process herbal medicines according to business needs (please see Appendix 1 for details); prepare or compound preparations for individual patients according to prescriptions given by Chinese medicine practitioners (please see Appendix 2 for details); or dispense single Chinese medicine granules for prescription (please see Appendix 3 for details).

5.1 Dispensation of Processed Herbal Medicines

The dispensation of processed herbal medicines should be conducted under the supervision of a responsible person (please refer to section 7(i) of the Chinese Medicines Regulation).

5.1.1 Verification of Prescriptions

- (1) Contents to be verified include the name and means of contact of the patient; the name, address, contact telephone number and signature of the Chinese medicine practitioner; the name and quantity of the processed herbal medicines, the method of decoction, the method of usage and the date of issue of the prescription;

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- (2) If there is any doubt about the authenticity of the prescription, appropriate measures should be taken immediately to verify the identity of the Chinese medicine practitioner who gave the prescription;
 - (3) If there is any doubt about the name or type of any medicine stated in the prescription, contact the Chinese medicine practitioner who gave the prescription to verify. Do not alter the contents of the prescription arbitrarily;
 - (4) Check to see if the quantity of each processed herbal medicine prescribed is reasonable. If the quantity specified in the prescription is considered to be far exceeding the normal quantity, contact the Chinese medicine practitioner who gave the prescription for confirmation;
 - (5) Check to see if there are incompatibilities of medicines or contraindications in pregnancy. If necessary, ask the Chinese medicine practitioner who gave the prescription to make amendments or obtain his signature for confirmation; and
 - (6) Check the prescription to see if there is any repeated use of a medicine, incorrect medicine name, missing quantity or dosage. If necessary, ask the Chinese medicine practitioner who gave the prescription to make amendments, or obtain his signature for confirmation.

5.1.2 Preparation

- (1) Dispense processed herbal medicines in accordance with the names, number of items and quantities of processed herbal medicines as specified in the prescription given by a Chinese medicine practitioner (please refer to section 109(1)(i) of the Chinese Medicine Ordinance and section 10 of the Chinese Medicines Regulation);
- (2) Should not prepare processed herbal medicines of dubious quality, such as those that have been infested by insects, contaminated with mildew or adulterated with impurities;
- (3) Exercise extra caution when preparing Schedule 1 medicines. If the prescription specifies the use of “raw type”, the medicine in the unprocessed form should be dispensed; if there is no specific requirement for “raw type”, the medicine in the processed form should be dispensed;

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- (4) Use suitable measuring equipment to ensure accuracy in weighing. Always use scales. Never estimate the weight manually. Regularly check and calibrate the measuring equipment (please refer to section 7(f) of the Chinese Medicines Regulation);
- (5) After weighing, the processed herbal medicines should be placed separately and not mixed together in order to facilitate cross-checking;
- (6) Prepare strictly in accordance with the requirements footnoted in the prescription. For processed herbal medicines that should be decocted first, added at a later stage, decocted under wrapping, decocted separately or taken after mixing with water, they should be put in separate packets with proper indication;
- (7) When preparing, take note of the clinical requirements of the Chinese medicine practitioner who gave the prescription. Do not use herbal medicines in the unprocessed form if processed form of the medicines should be used; and
- (8) For processed herbal medicines that should be pounded into pieces, use appropriate apparatus to pound the medicines according to the requirements of the Chinese medicine practitioner who gave the prescription before preparing.

5.1.3 Cross-checking

To avoid any mistakes in preparation and to ensure the safe use of medicines, a rigorous system to cross-check prescriptions should be set up. The system should include the following aspects:

- (1) Check if the processed herbal medicines are the same medicines as specified in the prescription, and verify that the number of items and quantities are correct;
- (2) Check the quality of the processed herbal medicines to determine, for example, if there are any infestation by insects, contamination with mildew or adulteration with impurities;
- (3) For medicines that have been processed, check that the processing has been done thoroughly;

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- (4) Check the processed herbal medicines in the prescription to determine if there are any incompatibilities of medicines or contra-indications in pregnancy; and
 - (5) Verify and check to see if those processed herbal medicines that should be decocted first, added at a later stage, decocted under wrapping, decocted separately, or taken after mixing with water, have been put in separate packets.

5.1.4 Packaging and Dispatching Medicines

- (1) After preparation, processed herbal medicines should be placed in suitable packages;
- (2) Medicines for internal use should be packed separately from those for external use. Never pack the two types of medicines in the same package. Indicate clearly on the package whether the medicine is for internal or external use;
- (3) Clearly mark the name of the patient on the package for easy identification;
- (4) When dispatching the medicines packet, the name of the patient should be asked first. If a number of prescriptions are involved at the same time, additionally use a numbering system, to avoid dispatching the wrong medicines;
- (5) Explain clearly to the person who collects the medicines packet the method of decoction, the method of usage, contraindications and other matters needing special attention; and
- (6) Return the prescription as soon as possible to the person by whom it is presented. Also ensure that the prescription is clearly marked with the following particulars: the date of the dispensation; name, address and telephone number of the retailer of Chinese herbal medicines (please refer to section 7(k) of the Chinese Medicines Regulation). If the prescription contains Schedule 1 medicine, proper records should be made. Please refer to Part 6: Keeping of Records.

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5.1.5 Decoction of Processed Herbal Medicines for Customers

If the retailers of Chinese herbal medicines provide decoction services, they should abide by the following:

- (1) Carry out the decoction according to the instructions specified in the prescription given by the Chinese medicine practitioner;
- (2) Use appropriate apparatus and equipment for decoction, and clean them thoroughly after use;
- (3) Maintain the cleanliness and hygiene of the decoction area at all times;
- (4) To avoid protracted storage of decocted medicines, make every effort to synchronize the time of the completion of decoction, with the time of collection of the medicine by the patient;
- (5) The decocted medicines should be stored in a suitable container, with the patient's name clearly marked on it for identification; and
- (6) Containers filled with decocted medicines should be placed in a hygienic and separate area, to prevent contamination.

5.2 Sale of Single or Multiple Processed Herbal Medicines

Responsible persons or dispensers should advise the customer to consult a Chinese medicine practitioner prior to selling or supplying any single or multiple processed herbal medicines packet under well-established prescriptions. When supplying processed herbal medicines on the basis of a well-established prescription, dispensing staff must take into consideration the interpretation and scope of "practising Chinese medicine" as defined under the Chinese Medicine Ordinance, and comply with the stipulations of section 108(5) of that ordinance.

Apart from pre-packed multiple processed herbal medicines which are commonly used in Hong Kong as "herbal tea" and "soup ingredients" for health maintenance purposes, dispensing staff or sales person should refrain from selling pre-packed multiple processed herbal medicines for therapeutic purposes.



5.2.1 When suggesting well-established prescription, dispensing staff should pay special attention to the following:

- (1) Never recommend any Schedule 1 medicine to customers. Consider carefully to ensure that the quantities and dosage of processed herbal medicines recommended are about the same as the normal dosage for the sake of safety;
- (2) Consider any contra-indications in pregnancy under all circumstances; in the case of multiple processed herbal medicines, consider also the incompatibilities of medicines;
- (3) If the customer's bodily conditions are not clearly known, advise him to consult a Chinese medicine practitioner; and
- (4) Take appropriate measures to record the details of the well-established prescription suggested, such as the names and quantities of the medicines and the contact means of the customer so that if necessary, the customer who uses the medicines can be contacted promptly.

5.2.2 Preparation

If processed herbal medicines are supplied –

- (1) by dispensing staff on the suggested well-established prescription; or
- (2) by dispensing staff or sales person at the request of a customer,

attention should be paid to the following matters -

- i. check to see if the processed herbal medicines have deteriorated in quality, for example, whether there are any infestation by insects, contamination with mildew, or adulteration with impurities;
- ii. use suitable measuring equipment to ensure accuracy in weighing. Always use scales. Never estimate the weight manually. Regularly check and calibrate the measuring equipment;
- iii. after weighing, the processed herbal medicines should be placed separately and not mixed together in order to facilitate cross-checking;

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- iv. for processed herbal medicines which need to be processed, follow the prescribed processing method and processing techniques; and
- v. for processed herbal medicines that should be pounded into pieces, use appropriate apparatus to pound the medicines.

5.2.3 Cross-checking

To avoid any mistake in preparing medicines and to ensure the safe use of medicines, a cross-checking system as far as practicable should be set up. The system should include the following:

- (1) Check to see whether all the required medicines have been included;
- (2) Check the quality of the processed herbal medicines to see, for example, if there are any infestation by insects, contamination with mildew or adulteration with impurities;
- (3) For medicines that have been processed, check that if the processing has been done thoroughly; and
- (4) Check to see if those processed herbal medicines that should be decocted first, added at a later stage, decocted under wrapping, decocted separately, or taken after mixing with water, have been put in separate packets.

5.2.4 Packaging and Dispatching Medicines

- (1) After preparation, processed herbal medicines should be put in suitable packages;
- (2) Medicines for internal use should be packed separately from those for external use. Never pack the two types of medicines in the same package. Indicate clearly on the package whether the medicine is for internal or external use; and
- (3) Explain clearly to customers the method of decoction, the method of usage, contraindications and other matters needing special attention.

5.2.5 Decoction of Processed Herbal Medicines for Customers

- (1) The responsible person should take charge of, or supervise, the decoctions of processed herbal medicines;
- (2) Use appropriate apparatus and equipment for decoction, and clean them thoroughly after use;
- (3) Maintain the cleanliness and hygiene of the decoction area, at all times;
- (4) To avoid protracted storage of decocted medicines, make every effort to synchronize the time of the completion of decoction with the time of collection of the medicines by the customer;
- (5) The decocted medicines should be stored in a suitable container, with the customer's name clearly marked on it for identification; and
- (6) Containers filled with decocted medicines should be placed in a hygienic and separate area, to prevent contamination.

5.3 Purchase of Processed Herbal Medicines

- (1) To ensure the quality of processed herbal medicines, purchase processed herbal medicines from licensed wholesalers of Chinese herbal medicines (please refer to section 7(j) of the Chinese Medicines Regulation); and
- (2) Determine the quantity to be purchased for each kind of processed herbal medicine according to demand, sales volume and inventory status.

5.4 Inspection, Acceptance and Storage of Processed Herbal Medicines

5.4.1 Inspection and Acceptance of Processed Herbal Medicines

- (1) When carrying out inspection and acceptance, ensure that the name of the processed herbal medicines and batch number (provided by the supplier) are clearly stated on the container or package of the medicines. The purchase invoice should also specify the batch number;
- (2) When carrying out inspection and acceptance, ensure that the specifications and shape of the processed herbal medicines are identical to the indications on the label;

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- (3) Check the authenticity and quality of the processed herbal medicines. Do not accept any processed herbal medicine found to be counterfeit, of poor quality or not conforming to the stated specifications, such as those showing obvious irregularities, for example, contamination with mildew, infestation by insects, oil secretion, decolourization, loss of smell, decomposition due to humidity, stickiness etc. Those processed herbal medicines should be returned to the delivery person on the spot. If circumstances do not permit such action (for example, if the delivery person has already left), inform the supplier immediately to arrange for the return of the medicines;
- (4) Check and verify the specifications and number of items of the processed herbal medicines; and
- (5) For processed Schedule 1 medicines or precious herbal medicines, check the quality and quantity in the presence of the delivery person to avoid accepting wrong medicines, insufficient quantity of medicines, or medicines adulterated with counterfeit or substandard ingredient.

5.4.2 Storage of Processed Herbal Medicines

- (1) After inspection and acceptance, all processed herbal medicines should be promptly put into the store-room. The medicines should be stored properly according to their quality and medicinal properties;
- (2) Make suitable arrangements for storing processed herbal medicines into the store-room, so that the principle of “first-in, first-out” can be implemented when dispatching to ensure their quality;
- (3) Processed Schedule 1 medicines should be stored effectively separated from other processed herbal medicines (please refer to section 7(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;
- (4) Store medicines separately from other substances. Medicines for internal use should be stored separately from those for external use;

- (5) Each type of processed herbal medicine should be stored in separate container or package according to its nature and classification (please refer to section 7(g) of the Chinese Medicines Regulation), with its name clearly marked on the container, or package, to prevent mix-ups;
- (6) Ensure that each container and package is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the processed herbal medicines stored in it (please refer to section 7(h)(iii) of the Chinese Medicines Regulation). Choose the most suitable packaging material according to the nature of the processed herbal medicines;
- (7) Regularly clean up the medicine drawers to prevent cross-contamination. The name of the medicines should be clearly marked on each drawer for identification; and
- (8) Carry out quality inspections frequently according to the nature of the processed herbal medicines. If there are any detected changes in quality, take immediate measures (such as exposure to direct sunlight, drying in ovens, or eradication of insects), to minimize changes in quality or loss. In the course of taking such measures, avoid contamination of the processed herbal medicines.

5.5 Labelling

- (1) Ensure each container or package has the name of the processed herbal medicine stored in it being clearly and distinctly set out in a conspicuous position and not in any way obscured or obliterated (please refer to sections 7(h)(i) and 7(h)(ii) of the Chinese Medicines Regulation);
- (2) For those medicines listed in Schedule 1 and Schedule 2 of the Chinese Medicine Ordinance, the names used in the schedules should be taken as the standard names. For those medicines not listed in Schedule 1 and Schedule 2, reference should be made orderly to the Pharmacopoeia of the People's Republic of China 《中華人民共和國藥典》, Zhonghua Bencao 《中華本草》, Zhongyao Dacidian 《中藥大辭典》 or Chinese Materia Medica 《中國藥材學》 ; and

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- (3) Apart from labelling the processed herbal medicines with their standard names, common names used locally can be included, according to practical circumstances. To ensure the correct use of medicines, also include appropriate specifications of the processed herbal medicines, alongside the name of the medicines when necessary, to avoid mix-ups.

6. Keeping of Records

The retailers of Chinese herbal medicines should ensure that the transaction documents and records kept by them meet the following requirements, to enable the tracing of the source and distribution channels of processed herbal medicines suspected to have problems whenever necessary.

6.1 Transaction Documents

- (1) The invoice or other document of every transaction whereby a processed herbal medicine acquired or received should be kept in an organized manner to facilitate checking. Such invoices and documents of the transaction should be retained in the premises to which the retailer licence relates for a period of not less than 2 years from the date of the transaction. (please refer to sections 8(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 8(2) of the Chinese Medicines Regulation):
 - i. the date of the transaction;
 - ii. the name and quantity of the processed herbal medicine acquired or received;
 - iii. the name, address and telephone number of the person who sells or distributes the processed herbal medicine to them; and
 - iv. the reference number of the invoice or other document.
- (3) Such invoices and documents should be kept intact. The information contained should be clear and no arbitrary alteration is allowed.

6.2 Dispensing Records of Schedule 1 Medicines of the Chinese Medicine Ordinance

- (1) Ensure that the following particulars, in respect of each dispensation of processed Schedule 1 medicine, are included in the dispensing records:
 - i. the name and quantity of the processed Schedule 1 medicine dispensed;
 - ii. the name and address of the registered Chinese medicine practitioner who gives the prescription;
 - iii. the name and, if known by the responsible person who supervises the dispensation, the address and telephone number of the person to whom the prescription is given;
 - iv. the date of the dispensation; and
 - v. the name of the responsible person who supervises the dispensation.

The particulars mentioned above should be recorded as soon as reasonably practicable after the dispensation. The responsible person concerned should affix his signature in the dispensing records. The records should be retained in the premises to which the retailer licence relates for a period of not less than 2 years from the date of the dispensation (please refer to section 9 of the Chinese Medicines Regulation); and

- (2) The dispensing 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.

7. Final Remarks

All people engaged in the retailing of Chinese herbal 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 processed herbal medicines and achieve the objective of safeguarding public health.

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Appendix 1 Processing Herbal Medicines

The retailers of Chinese herbal medicines may process herbal medicines according to clinical needs and preparation requirements. In addition to complying with the relevant requirements stated in these guidelines, the following should be observed:

- (1) The herbal medicines should be processed in accordance with the prescribed processing methods and techniques to ensure safety and quality;
- (2) Before processing, first examine the herbal medicines to ensure that the quality is good;
- (3) Use appropriate equipment, apparatus, container and packaging material in processing. All staff involved should ensure that the finished product is not contaminated, during the course of processing;
- (4) The processing of Schedule 1 medicines should be carried out by experienced staff, using equipment and tools dedicated to such operation. Such equipment and tools should be thoroughly cleaned after use. Staff who are not involved in the processing work should be prohibited from freely entering the processing area during the course of processing. Impurities separated from Schedule 1 medicines and water or supplementary materials that have been used in the processing of Schedule 1 medicines, should be properly disposed of;
- (5) The processing area should be kept clean and hygienic to avoid contamination of the processed herbal medicines. Smoking, eating, drinking and the storage of personal objects are strictly prohibited. Proper fire prevention facilities should be installed, and special care should be taken in the use and storage of inflammable substances;
- (6) The processing equipment and apparatus should be kept clean and hygienic. They should be properly maintained and repaired to avoid malfunction or contamination;
- (7) Upon the completion of processing, examine the processed herbal medicines to ensure that the quality meets the required standards. The medicines should then be stored directly into clean container, or package, and affixed with appropriate labels. Processed herbal medicines that fail to meet the required standards should be disposed of as waste products, and their sale is strictly prohibited; and

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- (8) A processing record should be made within 72 hours after the completion of processing a herbal medicine. The record should include the following particulars:
- i. the name and quantity of each type of material (including the herbal medicine or mixture of herbal medicines to be processed) used in the processing;
 - ii. the name and quantity of the processed herbal medicine;
 - iii. the name or description of the processing method;
 - iv. the date of the completion of the processing;
 - v. the examination results of the processed herbal medicine; and
 - vi. the name of the person who supervises the processing.

Such records should be retained in the premises to which the retailer licence relates for a period of not less than 2 years from the date of the completion of the processing. The processing 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.

Chinese Medicines

Appendix 2 Preparing or Compounding Preparations

The retailers of Chinese herbal medicines may prepare or compound preparations for individual patient according to a prescription given by a Chinese medicine practitioner. However, this should be done in accordance with the relevant stipulations under the Chinese Medicine Ordinance. Apart from complying with the relevant requirements stated in these guidelines, the following should be observed:

- (1) Staff responsible for preparing, or compounding, the preparations should be conversant with the preparation, or compounding techniques, quality requirements and operation of the equipment. They should also observe good personal hygiene, to prevent contamination of the medicines;
- (2) The area for preparing, or compounding, preparations should meet the hygiene standards, and be kept clean and tidy;
- (3) Apparatus for preparing, or compounding preparations, such as containers, measuring equipment and other equipment, should be kept clean and should function accurately. Separate sets of apparatus should be used for preparing or compounding, preparations containing processed Schedule 1 medicines, medicines for internal use or medicines for external use. Cross usage is strictly prohibited;
- (4) To prevent error and confusion, never assign one person or one team of people to prepare or compound two different preparations at the same time;
- (5) The responsible person should take charge of, or supervise, the whole preparation or compounding process. Extra caution should be taken when preparing, or compounding, preparations containing processed Schedule 1 medicines;
- (6) Ensure the quality of the finished products;
- (7) The finished products should be stored in a suitable package affixed with the correct label for identification. The label should basically contain the patient's name, the name and quantity of each constituent specified in the prescription given by the Chinese medicine practitioner, the method of usage and dosage as specified in the prescription, the name and address of the retailer, the date of preparing, or compounding the preparation, and matters needing special attention; and

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- (8) Mark the date of dispensation, and the name, address and telephone number of the retailer, on the prescription and return it to the patient. For prescription containing Schedule 1 medicines, ensure that particulars of the dispensation are recorded. Please refer to Part 6: Keeping of Records.

Chinese Medicines

Appendix 3: Dispensing Single Chinese Medicine Granules for Prescription

The retailers of Chinese herbal medicines may dispense single Chinese medicine granules for prescription according to prescription given by Chinese medicine practitioners. Apart from complying with the relevant requirements stated in these guidelines, the following should be observed:

- (1) Purchase single Chinese medicine granules for prescription only from licensed wholesalers of Chinese herbal medicines;
- (2) In the case where a patient is unable to present a prescription given by a Chinese medicine practitioner, the retailers should not sell any single Chinese medicine granules for prescription to him;
- (3) Dispense the single Chinese medicine granules for prescription only according to the requirements stated in the prescription;
- (4) Ensure that the label on the container or package of single Chinese medicine granules for prescription includes the following particulars:
 - i. name of the single Chinese medicine granules for prescription;
 - ii. weight equivalence i.e. the amount of original processed herbal medicine that is equivalent to one gram of the granules;
 - iii. a statement containing the following Chinese text: 「只供中醫處方配發使用」 ;
 - iv. packing specification of the single Chinese medicine granules for prescription;
 - v. normal dosage, or maximum dosage, of the single Chinese medicine granules for prescription;
 - vi. name of the manufacturer, or distributor, of the single Chinese medicine granules for prescription; and
 - vii. expiry date of the single Chinese medicine granules for prescription.

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- (5) Ensure that the relevant particulars in respect of dispensation of single Chinese medicine granules for prescription containing Schedule 1 medicine are recorded. For details, please refer to part 6: Keeping of Records.

Chinese Medicines

Appendix 4: List of Schedule 1 Medicines of the Chinese Medicine Ordinance

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

Appendix 5: List of Schedule 2 Medicines of the Chinese Medicine Ordinance

Name	Name
Agkistrodon (蕲蛇)	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 Impatiens (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 Lycoris 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 Brevipedunculæ (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 (火殃簕)	Cornu Saigae Tataricae (羚羊角)

Chinese Medicines

Name	Name
Cortex Dictamni (白鮮皮)	Fluoritum (紫石英)
Cortex Eucommiae (杜仲)	Folium Aconiti Kusnezoffii (草烏葉)
Cortex Fraxini (秦皮)	Folium Apocyni Veneti (羅布麻葉)
Cortex Hibisci (川槿皮)	Folium Artemisiae Argyi (艾葉)
Cortex Ilicis Rotundae (救必應)	Folium Callicarpea Formosanae (紫珠葉)
Cortex Illicii (地楓皮)	Folium et Cacumen Breyniae Fruticosae (黑面神)
Cortex Kadsurae Radicis (紫荊皮)	Folium et Cacumen Murrayae (九里香)
Cortex Lycii (地骨皮)	Folium et Ramulus Evodiae (三叉苦)
Cortex Magnoliae Officinalis (厚樸)	Folium Ginkgo (銀杏葉)
Cortex Meliae (苦棟皮)	Folium Ginseng (人參葉)
Cortex Mori (桑白皮)	Folium Glochidii Eriocarpi (漆大姑)
Cortex Moutan (牡丹皮)	Folium Hibisci Mutabilis (木芙蓉葉)
Cortex Periplocae (香加皮)	Folium Ilicis Cornutae (枸骨葉)
Cortex Phellodendri (黃柏)	Folium Isatidis (大青葉)
Cortex Pseudolaricis (土荊皮)	Folium Lantanae Camarae (馬纓丹)
Cortex Schefflerae Octophyllae (鴨腳木)	Folium Nerii (夾竹桃葉)
Cortex Ulmi Parvifoliae (柳榆皮)	Folium Photinia (石南葉)
Crinis Carbonisatus (血餘炭)	Folium Pini (松毛)
Eupolyphaga seu Steleophaga (土鱉蟲)	Folium Polygoni Tinctorii (蓼大青葉)
Faeces Leporis (望月砂)	Folium Psidii Guajavae (番石榴葉)
Faeces Tropopterori (五靈脂)	Folium Psychotriae Rubrae (山大顏)
Faeces Vespertilionis (夜明砂)	Folium Pterocaryae Stenopterae (楓楊葉)
Flos Albiziae (合歡花)	Folium Pyrrosiae (石韋)
Flos Buddlejae (密蒙花)	Folium Rhododendri Daurici (滿山紅)
Flos Campsis (凌霄花)	Folium Sauropi (龍膽葉)
Flos Celosiae Cristatae (雞冠花)	Folium Sennae (番瀉葉)
Flos Chimonanthi Praecocis (臘梅花)	Folium Viticis Negundo (牡荆葉)
Flos Eriocauli (穀精草)	Fructus Akebiae (預知子)
Flos Farfarae (款冬花)	Fructus Alpiniae Oxyphyllae (益智)
Flos Genkwa (茺花)	Fructus Amomi Rotundus (豆蔻)
Flos Hibisci Rosae-Sinensis (扶桑花)	Fructus Arctii (牛蒡子)
Flos Inulae (旋覆花)	Fructus Aristolochiae (馬兜鈴)
Flos Jasmini (素馨花)	Fructus Aurantii (枳殼)
Flos Magnoliae (辛夷)	Fructus Aurantii Immaturus (枳實)
Flos Magnoliae Officinalis (厚樸花)	
Flos Rosae Chinensis (月季花)	

Name	Name
Fructus Broussonetiae (楮實子)	Fructus Tritici Levis (浮小麥)
Fructus Bruceae (鴉膽子)	Fructus Tsaoko (草果)
Fructus Carotae (南鶴蟲)	Fructus Ulmi Macrocarpae (蕪荑)
Fructus Carpesii (鶴蟲)	Fructus Viticis (蔓荊子)
Fructus Chebulae (訶子)	Fructus Viticis Negundo (黃荊子)
Fructus Cnidii (蛇床子)	Fructus Xanthii (蒼耳子)
Fructus Coriandri (芫荽子)	Galla Chinensis (五倍子)
Fructus Corni (山茱萸)	Gekko Swinhonis (壁虎)
Fructus Evodiae (吳茱萸)	Gypsum Fibrosum Preparata (煅石膏)
Fructus Fici Pumilae (薜荔果)	Haematum (赭石)
Fructus Forsythiae (連翹)	Halloysitum Rubrum (赤石脂)
Fructus Galangae (紅豆蔻)	Herba Abri (雞骨草)
Fructus Gleditsiae Abnormalis (豬牙皂)	Herba Achyrantidis Asperae (倒扣草)
Fructus Kochiae (地膚子)	Herba Aeschynomenes Indicae (田皂角)
Fructus Leonuri (茺蔚子)	Herba Agastaches (藿香)
Fructus Ligustri Lucidi (女貞子)	Herba Aglaonematis (廣東萬年青)
Fructus Liquidambaris (路路通)	Herba Agrimoniae (仙鶴草)
Fructus Litseae (華澄茄)	Herba Andrographitis (穿心蓮)
Fructus Malvae (冬葵果)	Herba Antenoritis Neofiliformis (金錢草)
Fructus Nandinae Domesticae (天竺子)	Herba Ardisiae Japonicae (矮地茶)
Fructus Phyllanthi (餘甘子)	Herba Aristolochiae (天仙藤)
Fructus Piperis Longi (華芨)	Herba Aristolochiae Mollissimae (尋骨風)
Fructus Podophylli (小葉蓮)	Herba Artemisiae Annuae (青蒿)
Fructus Polygoni Orientalis (水紅花子)	Herba Artemisiae Anomaliae (劉寄奴)
Fructus Psoraleae (補骨脂)	Herba Artemisiae Scopariae (茵陳)
Fructus Quisqualis (使君子)	Herba Asari (細辛)
Fructus Rosae Laevigatae (金櫻子)	Herba Belladonnae (顛茄草)
Fructus Rubi (覆盆子)	Herba Bidentis Bipinnatae or Herba Bidentis Pilosae (鬼針草)
Fructus Sapindi Mukorossi (無患子)	Herba Blumeae Balsamiferae (大風艾)
Fructus Schisandrae (五味子)	Herba Bryophylli Pinnati (落地生根)
Fructus seu Herba Physalis Pubescens (燈籠草)	Herba Casythaе Filiformis (無根藤)
Fructus Sophorae (槐角)	Herba Catharanthi Rosei (長春花)
Fructus Terminaliae Billericae (毛訶子)	Herba Centellae (積雪草)
Fructus Toosendan (川棟子)	Herba Centipedae (鵝不食草)
Fructus Tribuli (蒺藜)	
Fructus Trichosanthis (瓜萎)	

Chinese Medicines

Name	Name
Herba Chenopodii (土荊芥)	Herba Gynostemmatis (絞股藍)
Herba Cirsii (小薊)	Herba Hedyotidis Chrysotrichae (黃毛耳草)
Herba Cissampelotis (亞乎奴)	Herba Hedyotidis Corymbosae (水綫草)
Herba Cistanches (肉蓯蓉)	Herba Houttuyniae (魚腥草)
Herba Clinopodii (斷血流)	Herba Hyperici (紅旱蓮)
Herba Clinopodii Gracilis (剪刀草)	Herba Hyperici Erecti (小連翹)
Herba Commelinace (鴨跖草)	Herba Hyperici Japonici (田基黃)
Herba Corydalis Bungeanae (地丁草)	Herba Inulae (金沸草)
Herba Crotalariae Mucronatae (豬屎豆)	Herba Junci Setchuensis (龍鬚草)
Herba Cymbopogonis (薑香草)	Herba Kulancoes Laciniatae (伽藍菜)
Herba Cynomorii (鎖陽)	Herba Leonuri (益母草)
Herba Damnacanthi (虎刺)	Herba Lespedezae Cuneatae (鐵掃帚)
Herba Dendrobii (石斛)	Herba Lobeliae Chinensis (半邊蓮)
Herba Desmodii Styracifolii (廣金錢草)	Herba Lophatheri (淡竹葉)
Herba Dianthi (瞿麥)	Herba Lycopi (澤蘭)
Herba Dichondrae Repentis (馬蹄金)	Herba Lycopodii (伸筋草)
Herba Duchesneae Indicae (蛇莓)	Herba Lysimachiae (金錢草)
Herba Ecliptae (墨旱蓮)	Herba Malvastri Coromandeliana (黃花棉)
Herba Eleocharitis (通天草)	Herba Melastomatis Candii (野牡丹)
Herba Elephantopi (地膽頭)	Herba Melastomatis Dodecandri (地菍)
Herba Eleusines Indicae (牛筋草)	Herba Orostachyos (瓦松)
Herba Emiliae (一點紅)	Herba Paederiae (雞屎藤)
Herba Ephedrae (麻黃)	Herba Patriniae (敗醬草)
Herba Epimedii (淫羊藿)	Herba Pholidotae Chinensis (石仙桃)
Herba Epimeredis Indicae (防風草)	Herba Phyllanthi Urinariae (葉下珠)
Herba Equiseti Hiemalis (木賊)	Herba Piperis Sarmentosi (假蒟)
Herba Erodii or Herba Geranii (老鶴草)	Herba Plantaginis (車前草)
Herba Eupatorii (佩蘭)	Herba Polygalae Chinensis (大葉金不換)
Herba Euphorbiae Hirtae (飛楊草)	Herba Polygalae Japonicae (瓜子金)
Herba Euphorbiae Humifusae (地錦草)	Herba Polygoni Avicularis (萹蓄)
Herba Euphorbiae Thymifoliae (小飛楊草)	Herba Polygoni Chinensis (火炭母)
Herba Gelsemii Elegantis (斷腸草)	Herba Polygoni Perfoliati (杠板歸)
Herba Gendarussae (小駁骨)	Herba Potentillae Chinensis (委陵菜)
Herba Geranii Caroliniani (野老鶴草)	Herba Potentillae Discoloris (翻白草)
Herba Glechomae (連錢草)	
Herba Gnaphalii Affinis (鼠曲草)	

Name	Name
Herba Pouzolziae Zeylanicae (霧水葛)	Herba Veronicastri (腹水草)
Herba Pteridis Multifidae (鳳尾草)	Herba Violae (紫花地丁)
Herba Pteridis Semipinnatae (半邊旗)	Herba Visci (槲寄生)
Herba Pyrolae (鹿銜草)	Herba Wedeliae (蟛蜞菊)
Herba Rabdosiae Lophanthoidis (溪黃草)	Herba Zephyranthis Candiae (肝風草)
Herba Ranunculi Japonici (毛茛)	Hirudo (水蛭)
Herba Saginae Japonicae (漆姑草)	Indigo Naturalis (青黛)
Herba Salviae Chinensis (石見穿)	Lapis Chloriti (青礞石)
Herba Salviae Plebeiae (荔枝草)	Lapis Micae Aureus (金礞石)
Herba Sambuci Chinensis (陸英)	Lasiosphaera seu Calvatia (馬勃)
Herba Sarcandrae (腫節風)	Lignum Dalbergiae Odoriferae (降香)
Herba Saussureae Involucratae (雪蓮花)	Lignum Pini Nodi (油松節)
Herba Saxifragae (虎耳草)	Limonium (禹餘糧)
Herba Schizonepetae (荊芥)	Medulla Junci (燈心草)
Herba Scutellariae Barbatae (半枝蓮)	Medulla Stachyuri or Medulla Helwingiae (小通草)
Herba Sedi (垂盆草)	Medulla Tetrapanacis (通草)
Herba Selaginellae (卷柏)	Moschus (麝香)
Herba Selaginellae Doederleinii (石上柏)	Myrrha (沒藥)
Herba Senecionis Scandentis (千里光)	Natrii Sulfas (芒硝)
Herba Setariae Viridis (狗尾草)	Natrii Sulfas Exsiccatus (玄明粉)
Herba seu Radix Amarantri (刺莧菜)	Nidus Vespa (蜂房)
Herba seu Radix Cirsii Japonici (大薊)	Nux Prinsepiae (薤仁)
Herba Sidae Rhombifoliae (黃花母)	Oleum Linderae (香果脂)
Herba Siegesbeckiae (豨莶草)	Olibanum (乳香)
Herba Solani Lyrati (白英)	Omphalia (雷丸)
Herba Solani Nigri (龍葵)	Ootheca Mantidis (桑螵蛸)
Herba Solidaginis (一枝黃花)	Ophicalcitum (花蕊石)
Herba Speranskiae Tuberculatae (珍珠透骨草)	Pericarpium Arecae (大腹皮)
Herba Spirodelae (浮萍)	Pericarpium Trichosanthis (瓜萎皮)
Herba Stephaniae Longae (龜筈篤)	Periostracum Cicadae (蟬蛻)
Herba Swertiae Mileensis (青葉膽)	Petiolus Trachycarpi (棕櫚)
Herba Taxilli (桑寄生)	Pollen Pini (松花粉)
Herba Verbenae (馬鞭草)	Pollen Typhae (蒲黃)
Herba Veronicae (一支香)	Polyporus (豬苓)
	Processed Fructus Crotonis (製巴豆)

Chinese Medicines

Name	Name
Processed Radix Aconiti (製川烏)	Radix Angelicae Pubescentis (獨活)
Processed Radix Aconiti Kusnezoffii (製草烏)	Radix Angelicae Sinensis (當歸)
Processed Radix Aconiti Lateralis (製附子)	Radix Anisodi Tangutici (山莨菪)
Processed Radix Euphorbiae fischeriana, Radix Euphorbiae ebracteolatae, or Radix Stellerae (製狼毒)	Radix Ardisiae Crenatae (朱砂根)
Processed Radix Kansui (製甘遂)	Radix Aristolochiae (青木香)
Processed Resina Garcinia Morellae (製藤黃)	Radix Aristolochiae Fangchi (廣防己)
Processed Rhizoma Arisaematis (製天南星)	Radix Aristolochiae Heterophyllae (漢中防己)
Processed Rhizoma Pinelliae (製半夏)	Radix Arnebiae or Radix Lithospermii (紫草)
Processed Rhizoma Typhonii or Radix Aconiti Corean (製白附子 (禹白附、關白附))	Radix Asparagi (天冬)
Processed Semen Crotonis (巴豆霜)	Radix Asteris (紫菀)
Processed Semen Euphorbiae (製千金子)	Radix Astragali (黃芪)
Processed Semen Hyoscyami (製天仙子)	Radix Aucklandiae (木香)
Processed Semen Strychni (製馬錢子)	Radix Bauhiniae Hupehanae (羊蹄甲)
Pseudobulbus Cremastrae seu Pleiones (山慈姑)	Radix Boehmeriae (苧麻根)
Pumex (浮石)	Radix Bupleuri (柴胡)
Pyrolusitum (無名異)	Radix Celastri Orbiculati (南蛇藤根)
Radix Acanthopanax Senticosi (刺五加)	Radix Changii (明黨參)
Radix Acanthopanax Trifoliatai (三葉五加)	Radix Chloranthi Serrati (及己)
Radix Achyranthis Bidentatae (牛膝)	Radix Clematidis (威靈仙)
Radix Adenophorae (南沙參)	Radix Clerodendri Philippini (臭茉莉)
Radix Aero Fici Microcarpae (榕鬚)	Radix Cocculi Trilobi (木防己)
Radix Ampelopsis (白蔹)	Radix Codonopsis (黨參)
Radix Angelicae Citriodora (香白芷)	Radix Crotonis Crassifolii (雞骨香)

Name	Name
Radix et Rhizoma Thalictri (馬尾連)	Radix Pseudostellariae (太子參)
Radix et Rhizoma Veratri (藜蘆)	Radix Pterospermi Heterophylli (半楓荷根)
Radix Eupatorii Chinensis (廣東土牛膝)	Radix Pteroxygoni Giraldii (紅藥子)
Radix Euphorbiae Pekinensis (京大戟)	Radix Puerariae (葛根)
Radix Gentianae (龍膽)	Radix Pulsatillae (白頭翁)
Radix Gentianae Macrophyllae (秦艽)	Radix Ranunculus Ternati (貓爪草)
Radix Ginseng (人參)	Radix Rauvolfiae (蘿芙木)
Radix Glehniae (北沙參)	Radix Rehmanniae (地黃)
Radix Hedsyari (紅芪)	Radix Rhapontici (漏蘆)
Radix Helicteris (山芝麻)	Radix Rhodomyrti (崗稔根)
Radix Hemerocallis (萱草根)	Radix Rubiae (茜草)
Radix Ilicis Asprellae (崗梅根)	Radix Salviae Miltorrhizae (丹參)
Radix Ilicis Pubescens (毛冬青)	Radix Sanguisorbae (地榆)
Radix Inulae (土木香)	Radix Saposhnikoviae (防風)
Radix Isatidis (板藍根)	Radix Scrophulariae (玄參)
Radix Kadsurae Coccineae (黑老虎根)	Radix Scutellariae (黃芩)
Radix Knoxiae (紅大戟)	Radix Semiaquilegiae (天葵子)
Radix Linderae (烏藥)	Radix seu Caulis Derridis Trifoliatae (魚藤)
Radix Liriores (山麥冬)	Radix Sophorae Flavescentis (苦參)
Radix Mirabilis (紫茉莉根)	Radix Stellariae (銀柴胡)
Radix Morindae Officinalis (巴戟天)	Radix Stemonae (百部)
Radix Notoginseng (三七)	Radix Stephaniae Tetrandrae (防己)
Radix Ophiopogonis (麥冬)	Radix Tinosporae (金果欖)
Radix Oryzae Glutinosae (糯稻根)	Radix Trichosanthis (天花粉)
Radix Paeoniae Alba (白芍)	Radix Tripterygii Wilfordii (雷公藤)
Radix Paeoniae Rubra (赤芍)	Radix Valerianae (纈草)
Radix Panacis Quinquefolii (西洋參)	Radix Vitis Adstrictae (野葡萄)
Radix Pandani Tectorii (露兜簕)	Radix Vladimiriae (川木香)
Radix Patriniae Heterophyllae or Radix Patriniae Scabrae (墓頭回)	Radix Wikstroemae (了哥王)
Radix Peucedani (前胡)	Radix Zanthoxyli (兩面針)
Radix Physochlainae (華山參)	Radix Zanthoxyli Avicennae (鷹不泊)
Radix Phytolaccae (商陸)	Ramulus Cinnamomi (桂枝)
Radix Platycodi (桔梗)	Ramulus et Folium Mussaendae Pubescentis (玉葉金花)
Radix Plumbaginis Zeylanicae (白花丹)	
Radix Polygalae (遠志)	
Radix Polygoni Multiflori (何首烏)	

Chinese Medicines

Name	Name
Ramulus et Folium Phyllodii Pulchelli (排錢草)	Rhizoma Curcumae (莪朶) Rhizoma Curcumae Longae (薑黃)
Ramulus et Folium Picrasmae (苦木)	Rhizoma Cynanchi Stauntonii (白前)
Ramulus Euonymi (鬼箭羽)	Rhizoma Cyperi (香附)
Ramulus Mori (桑枝)	Rhizoma Cyrtomii (貫眾)
Ramulus Sambuci Williamsii (接骨木)	Rhizoma Dioscoreae Bulbiferae (黃藥子)
Ramulus Uncariae cum Uncis (鈎藤)	Rhizoma Dioscoreae Cirrhosae (薯莨)
Receptaculum Nelumbinis (蓮房)	Rhizoma Dioscoreae Hypoglaucae (粉草薢)
Resina Draconis (血竭)	Rhizoma Dioscoreae Nipponicae (穿山龍)
Resina Ferulaen (阿魏)	Rhizoma Dioscoreae Septemlobae (綿萆薢)
Resina Liquidambaris (楓香脂)	Rhizoma Dioscoreae Tokoro (山萆薢)
Resina Toxicodendri (乾漆)	Rhizoma Drynariae (骨碎補)
Rhizoma Acori Tatarinowii (石菖蒲)	Rhizoma Dryopteris Crassirhizomae (綿馬貫眾)
Rhizoma Alismatis (澤瀉)	Rhizoma et Radix Baphicacanthis Cusiae (南板藍根)
Rhizoma Anemarrhenae (知母)	Rhizoma et Radix Notopterygii (羌活)
Rhizoma Anemones Altaicae (九節菖蒲)	Rhizoma Gastrodiae (天麻)
Rhizoma Anemones Raddeanae (兩頭尖)	Rhizoma Homalomenae (千年健)
Rhizoma Ardisiae Gigantifoliae (走馬胎)	Rhizoma Ligustici (藁本)
Rhizoma Atractylodis (蒼朮)	Rhizoma Matteucciae (莢果蕨貫眾)
Rhizoma Atractylodis Macrocephalae (白朮)	Rhizoma Menisperm (北豆根)
Rhizoma Belamcandae (射干)	Rhizoma Osmundae (紫萁貫眾)
Rhizoma Bistortae (拳參)	Rhizoma Panacis Japonici (竹節參)
Rhizoma Blechni (烏毛蕨貫眾)	Rhizoma Panacis Majoris (珠子參)
Rhizoma Bletillae (白芨)	Rhizoma Paridis (重樓)
Rhizoma Bolbostemmae (土貝母)	Rhizoma Picrorhizae (胡黃連)
Rhizoma Chuanxiong (川芎)	Rhizoma Polygonati (黃精)
Rhizoma Cibotii (狗脊)	Rhizoma Polygoni Cuspidati (虎杖)
Rhizoma Cimicifugae (升麻)	Rhizoma Saururi or Herba Saururi (三白草)
Rhizoma Coptidis (黃連)	Rhizoma Smilacis Chinensis (菝葜)
Rhizoma Corydalis (延胡索)	Rhizoma Smilacis Glabrae (土菝葜)
Rhizoma Corydalis Decumbentis (夏天無)	
Rhizoma Curculiginis (仙茅)	

Name	Name
Rhizoma Sparganii (三棱)	Semen Myristicae (肉豆蔻)
Rhizoma Wenyujin Concisa (片薑黃)	Semen Nigellae (黑種草子)
Rhizoma Woodwardiae (狗脊貫眾)	Semen Oroxyli (木蝴蝶)
Sal Ammoniacus (礦砂)	Semen Persicae (桃仁)
Scolopendra (蜈蚣)	Semen Pharbitidis (牽牛子)
Scorpio (全蠍)	Semen Plantaginis (車前子)
Semen Abri Precatori (相思子)	Semen Platycladi (柏子仁)
Semen Abutili (苘麻子)	Semen Ricini (蓖麻子)
Semen Aesculi (婆羅子)	Semen Sinapis (芥子)
Semen Allii Tuberosi (薤菜子)	Semen Sterculiae Lychnophorae (胖大海)
Semen Alpiniae Katsumadai (草豆蔻)	Semen Trichosanthis (瓜萎子)
Semen Arecae (檳榔)	Semen Trigonellae (胡蘆巴)
Semen Astragali Complanati (沙苑子)	Semen Vaccariae (王不留行)
Semen Cassiae (決明子)	Spica Prunellae (夏枯草)
Semen Cassiae Occidentalis (望江南)	Spina Gleditsiae (皂角刺)
Semen Celosiae (青葙子)	Spongilla (紫梢花)
Semen Cuscutae (菟絲子)	Spora Lygodii (海金沙)
Semen Hoveniae (枳椇子)	Stamen Nelumbinis (蓮鬚)
Semen Hydnocarpi (大風子)	Stigma Croci (西紅花)
Semen Impatientis (急性子)	Styrax (蘇合香)
Semen Lepidii or Semen Descurainiae (蕓薹子)	Tabanus (虻蟲)
Semen Lini (亞麻子)	Tremolitum (陽起石)
Semen Momordicae (木鱉子)	

Chinese Medicines

Appendix 6 Dispensing Record of Schedule 1 Medicines of the Chinese Medicine Ordinance (Format for reference)

Appendix 7 Processing Record (Format for reference)

Chinese Medicines

Appendix 8: 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

$$1 \text{ kilogram} = 1.65347 \text{ catty (sima)}$$

$$100 \text{ gram} = 2.64555 \text{ tael (sima)}$$

$$10 \text{ gram} = 0.264555 \text{ tael (sima)}$$

$$1 \text{ gram} = 0.0264555 \text{ tael (sima)}$$

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

$$1 \text{ catty (sima)} = 0.60478982 \text{ kilogram}$$

$$1 \text{ tael (sima)} = 1/16 \text{ catty} = 37.7994 \text{ gram}$$

$$1 \text{ mace (sima)} = 1/160 \text{ catty} = 3.77994 \text{ gram}$$

$$1 \text{ candareen (sima)} = 1/1600 \text{ catty} = 377.994 \text{ milligram}$$

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

Notes



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

Appendix 2

Safety limits of heavy metals content and pesticides residues in Chinese herbal medicines set out by the Chinese Medicine Council of Hong Kong

Limits of organochlorine pesticide residues

	Chinese name	English name	Test parameters (20 items in total)	Maximum residue limit (mg/kg)
1	艾氏劑及狄氏劑	Aldrin & Dieldrin	Sum of Aldrin and Dieldrin	0.05
2	氯丹	Chlordane	Sum of <i>cis</i> -chlordane, <i>trans</i> -chlordane and oxychlordane	0.05
3	滴滴涕	DDT	Sum of <i>p,p'</i> -DDT, <i>o,p'</i> -DDT, <i>p,p'</i> -DDE and <i>p,p'</i> -TDE	1.0
4	異狄氏劑	Endrin	endrin	0.05
5	七氯	Heptachlor	Sum of heptachlor and heptachlor epoxide	0.05
6	六氯苯	Hexachlorobenzene	hexachlorobenzene	0.1
7	六六六	Hexachlorocyclohexane	Sum of α -, β - and δ -isomers	0.3
8	林丹	Lindane	lindane	0.6
9	五氯硝基苯	Quintozone	Sum of quintozone, pentachloroaniline and methyl pentachlorophenyl sulphide	1.0

Limits of organophosphate pesticide residues

	Chinese name	English name	Maximum residue limit
1	滴滴畏	Dichlorvos	Should not be detected
2	甲胺磷	Methamidophos	
3	滴百蟲	Trichlorphon	
4	氧樂果	Omethoate	
5	二嗪磷	Diazinon	
6	樂果	Dimethoate	
7	馬拉硫磷	Malathion	
8	水胺硫磷	Isocarbophos	
9	三唑磷	Triazophos	
10	對硫磷	Parathion	
11	甲基對硫磷	Parathion-methyl	
12	久效磷	Monocrotophos	
13	磷胺	Phoshamidon	
14	毒死蜱	Chlorpyriphos	
15	乙酰甲胺磷	Acephate	
16	乙硫磷	Ethion	
17	殺撲磷	Methidathion	

Limits of heavy metals

Chinese name	English name	Maximum permitted level (total intake)
砷	Arsenic	1,500 mcg/day
鎘	Cadmium	3,500 mcg/dose
鉛	Lead	179 mcg/day
汞	Mercury	36 mcg/day



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our ref: FHB/H/24/24
Your ref: CB2/BC/6/16

Tel no: 3509 8956
Fax no: 2840 0467

12 October 2017

Ms Maisie LAM
Clerk to Bills Committee on Chinese Medicine (Amendment) Bill 2017
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms LAM,

Bills Committee on Chinese Medicine (Amendment) Bill 2017

In response to the request of the Chairman of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 at the meeting on 28 September 2017 and the enquiries raised in the letter from Dr Hon Helena WONG Pik-wan to the Chairman on 27 September 2017, the Government has set out the relevant reference materials in the Annex.

Yours sincerely,

A handwritten signature in black ink, appearing to read "J".

(James LAM)
for Secretary for Food and Health

Encl.

c.c. Department of Justice (Attn: Ms Mandy NG)
Department of Health (Attn: Dr Edwin TSUI)

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Purpose

This paper sets out the Government's response to the issues raised on the Chinese Medicine (Amendment) Bill 2017 (the Bill) at the Bills Committee meeting on 28 September 2017 and the enquiries made by Dr Hon Helena WONG Pik-wan in her letter to the Chairman of the Bills Committee on 27 September 2017.

(a) Classification of Proprietary Chinese Medicines

2. According to the Chinese Medicine Ordinance (Cap. 549) (CMO), products that fall within the definition of proprietary Chinese medicines (pCms) must be registered by the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMCHK) before they can be imported, or manufactured and/or sold in Hong Kong. The CMO provides that pCms are defined as any proprietary products which conform to the following descriptions:

- (a) composed solely of the following as active ingredients:-
 - (i) any Chinese herbal medicines (Chms); or
 - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
 - (iii) any medicines and materials as mentioned in (i) and (ii) above 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 diseases or any symptoms of a disease in human being, or for the regulation of the functional states of the human body.

3. Products that fall within the definition of pCms or pharmaceutical products under the CMO or the Pharmacy and Poisons Ordinance (Cap. 138) must fulfil the relevant requirements in respect of safety, quality and efficacy, and be registered according to the relevant regulations before they can be sold in Hong Kong. As mentioned above, products which are composed solely of any Chms as active ingredients, formulated in a finished dose form and used for treatment are regulated by the CMO. For products containing medicinal ingredients or presented as having properties for treating or preventing diseases in human beings or animals, they are regulated by the PPO and must meet the relevant requirements in respect of safety, quality and efficacy before they can be registered. Such medicines should also be labelled with particulars such as ingredients, dosage and usage directions. The Department of Health (DH) exercises the power imposed by relevant ordinances to regulate the concerned medicines.

4. Products that do not fall within the definition of pCms under the CMO or pharmaceutical products under the PPO are not required to be registered under the relevant ordinances. According to the Public Health and Municipal Services Ordinance (Cap 132), products that fulfill the definition of "food" are regulated by that ordinance. The claims of

these products are also subject to the regulation of the Trade Description Ordinance (Cap. 362). Moreover, to protect the public from being induced by medical or health claims to seek improper self-medication, which may result in delay in seeking treatment, the Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits the publication of any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for the purpose of prevention or treatment of certain diseases or conditions specified in the schedules to that ordinance.

5. Therefore, products not composing solely of Chms as active ingredients do not meet the definition of pCms under the CMO. For bottled drinks or herbal teas (e.g. Spica Prunellae) generally sold in the market with neither indication of method of usage and dosage nor medicinal claims, they are also not regulated by the CMO.

(b) Response to deputations' views and suggestions in respect of the Bill

The lack of a person responsible for recall

6. According to the current CMO, only three types of Chinese medicines traders (i.e. wholesale dealers in Chms, wholesalers of pCms and manufacturers of pCms) are required to set up a recall system according to their licensing requirements to enable the rapid recall of the relevant Chinese medicine products as far as practicable when necessary. However, if the relevant Chinese medicine products are held by people other than the above three types of Chinese medicines traders, or the licensed Chinese medicines traders concerned refuse to recall the products, they will not be held legally responsible for not conducting the recall. Formulated to deal with the above situation, the Bill allows the DH to issue a Chinese medicine safety order to any organisation or person found to be held responsible for the recall during investigation of the Chinese medicine incident.

Principles and mechanism of the issue of Chinese medicine safety orders by the Director of Health

7. The legislative proposals contained in the Bill seek to confer powers on the Director of Health (DoH) to prohibit the sale of Chinese medicines and other substances or compounds generated in the course of manufacture of pCms or to recall such products in specified circumstances, with a view to further protecting public health. Clauses 138C and 138D of the Bill have set out in detail the specified circumstances, that is the DoH may issue a Chinese medicine safety order when he/she has reasonable grounds to believe that: (1) the Chms, pCms and/or intermediate products¹ will be dangerous or injurious to health, or unfit for use by human beings; (2) the Chinese medicine safety order is necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; (3) the related product has been sold or distributed in contravention of the CMO, such as Chms being sold or distributed without licence, unregistered pCms being sold, pCms being sold without a package insert which complied with the prescribed requirements, and pCms being sold were in a package not being labelled in the prescribed manner. From the previous recall cases which might relate to public health, we can see that all of the cases had to be supported by sufficient objective evidence, for examples, the laboratory report proved that the Chinese medicine products concerned had contained harmful substances and consumption by members of the public might be dangerous or harmful to their health, or the

¹ For the definition of “intermediate product”, please refer to paragraph 13.

Chinese medicine products concerned showed *prima facie* evidence of illegal sale, before the DH could take appropriate action, including the issue of a press release and relevant prosecution action. On making Chinese medicine safety orders in the future, the DH will process the recall cases based on the same criteria.

8. Moreover, as there is possibility that relevant traders may not be able to recall all the Chinese medicines concerned, statutory defences are provided in section 138L of the Bill. What would constitute a reasonable excuse is considered on a case-by-case basis. Generally speaking, it will be deemed a reasonable excuse if the product concerned has already been consumed, or has been destroyed at the retail outlet due to damage. To ensure the fair and just handling of all cases, the Bill also introduces an appeal mechanism to allow a person bound by a Chinese medicine safety order to appeal against the decision of the DoH.

9. As the grounds for the issue of Chinese medicine safety order are set out in the proposed new sections 138C and 138D of the Bill, to avoid duplication with the requirements set out in these sections, consequential amendments have been made to sections 11(i) and 16(q) of the Chinese Medicines Regulation by removing the requirement of recall of any product “being found to be dangerous, injurious to health or unfit for human consumption”. After the Bill is passed by the Legislative Council and enacted, the CMB will amend the relevant practicing guidelines and recall guidelines to set out the circumstances and grounds for recall.

10. A deputation has proposed amending clauses 138C and 138D of the Bill (see paragraph 7 above) to include “a possibility of danger to public health that still cannot be removed when using under the guidance of a registered Chinese medicine practitioner” as a specified condition for the DoH to issue a Chinese medicine safety order. As it is not necessary for Chms and pCms currently for sale in the market to be prescribed by a registered Chinese medicine practitioner and the public can use those medicines according to their own body constitution and illnesses, we consider it more comprehensive and appropriate to adopt “to prevent or reduce a possibility of danger to public health” (clauses 138C and 138D of the Bill) as one of the grounds for making a Chinese medicine safety order.

Procedures for recalling Chinese medicine products

11. To assist the industry to set up an effective recall system for Chinese medicine products, the CMB prepared in 2005 the “Recall Guidelines for Chinese Medicine Products” for Chinese medicines traders. During a recall, the Chinese medicines trader concerned should maintain good communication and co-operation with the DH to enable effective and rapid recall of a deficient Chinese medicine products, and proper disposal of the recalled product. This could help ensure the safety and quality of Chinese medicine products available in the market and safeguard public health. For enforcement of Chinese medicine safety orders in the future, the DH will adopt the same approach by discussing the details of the enforcement method and the timeframe with the person subject to the Chinese medicine safety order in each case. To minimise the risk that may arise from deficient products, recalls are usually carried out in the shortest time practicable. To ensure the safety and quality of Chinese medicine products available in the market and safeguard public health, it is necessary to handle each recall action as a unique exercise and formulate appropriate recall methods by taking into account the nature of the problem, the sales or distribution networks and the detailed assessment of deficient products concerned.

Service of Chinese medicine safety orders

12. To ensure that the Chinese medicine safety orders will be enforced in practice, the Bill has covered various arrangements for their service, including delivery to the individuals personally, leaving them at the relevant addresses or delivery by post or registered post. The DH will ensure that Chinese medicine safety orders are served in the most reasonable way. In general, the Chinese medicine safety orders are delivered to the individuals personally to facilitate discussion of implementation details. Chinese medicine safety orders will only be left at the relevant addresses mentioned in clause 159 of the Bill, or delivered by post or registered post when the persons concerned refuse to receive the Chinese medicine safety orders, or when it is unable to enter the premises of the businesses concerned.

Definition of “intermediate product”

13. In clause 7 of the Bill, we have proposed to amend the definition of “intermediate product” from “a substance or component that is generated in the course of manufacture of a pCm and which is to be used in the further preparation or production process” to “a substance or component that is generated in the course of manufacture of a pCm and that is intended for use in the further preparation or production process”. After review, we consider that the phrases “and which is to be used in” and “and that is intended for use in” are similar in meaning. To avoid misunderstanding, we will propose a committee stage amendment to adopt the definition of “intermediate product” stipulated by the current CMO, that is “a substance or component that is generated in the course of manufacture of a pCm and which is to be used in the further preparation or production process”.

(c) Response to the enquiries made by Dr Hon Helena WONG Pik-wan in her letter to the Chairman of the Bills Committee

Pesticide residues

14. At present, the regulatory bodies in the world have not formulated a standardised set of pesticide maximum residue limits (MRLs) for Chms. According to the Pharmacopoeia of the People’s Republic of China, 2015 Edition, Volume 1 (PPRC), the Mainland has set MRLs for up to 16 organochlorine pesticides (OCPs) for four types of Chms (namely Radix et Rhizoma Glycyrrhizae, Radix Astragali, Radix Panacis Quinquefolii and Radix Ginseng)². Those 16 OCPs have already been included in the 37 pesticide residues that will be tested for in the 605 types of Chms listed in Schedules 1 and 2 to the CMO in Hong Kong. According to the Taiwan Herbal Pharmacopeia, 2nd Edition (THP), Taiwan has set MRLs for up to 11 OCPs for 16 types of Chms³. Both places have not set MRLs for organophosphorus

² The PPRC has only set 9 MRLs for OCPs for Radix et Rhizoma Glycyrrhizae and Radix Astragali; and 16 MRLs for OCPs for Radix Panacis Quinquefolii and Radix Ginseng. The relevant OCPs are: Total Hexachlorocyclohexane (the sum of α-BHC, β-BHC, γ-BHC and δ-BHC), Total DDT (the sum of p,p'-DDE, p,p'-DDD, o,p'-DDT and pp'-DDT), Quintozene, Hexachlorobenzene, Heptachlor (the sum of heptachlor and heptachlor epoxide), Aldrin and Chlordane (the sum of cis- and trans-chlordane and oxychlordane).

³ The THP has only set MRLs for OCPs for 16 types of Chms (Radix Ginseng, Jujubae Fructus, Fructus Corni, Radix et Rhizoma Glycyrrhizae, Cinnamon Bark, Radix Panacis Quinquefolii, Cortex Moutan, Loquat Leaf, Hedysarum Root, Ramulus Cinnamomi, Herba Asari, Tangerine Peel, Folium Sennae, Perillae Folium, Astragalus Root and Radix Polygalae); 11 MRLs for OCPs for Radix Panacis Quinquefolii, Radix Ginseng, Radix et Rhizoma Glycyrrhizae, Hedysarum Root, Astragalus Root and Folium Sennae; and 8 MRLs for OCPs for the remaining 10 types of Chms.

pesticides (OPPs). The European Union, the United Kingdom and the United States have set MRLs for some pesticides for medicinal plants and formulations. The European Pharmacopoeia 8.6 and the British Pharmacopoeia 2016 have set MRLs for 105 pesticides while the United States Pharmacopoeia 39 has set MRL for 106 pesticides, which include the MRLs for both OCPs and OPPs.

15. The current MRLs used in Hong Kong for testing of pesticide residues in Chms sold locally are formulated by the CMCHK with reference to other international standards, including those of the World Health Organization and those set by different countries or regions on herbs or raw materials of natural plant preparations. Those MRLs are related to the testing residues of 37 OCPs and OPPs (see Annex I). The MRLs are applicable to all the 605 types of Chms listed respectively in Schedules 1 and 2 regulated by the CMO. To monitor the quality and safety of Chms regulated by the CMO, the CMCHK has chosen to test the residues of the above-mentioned 37 pesticides after considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally, with a view to protecting public health.

16. Unless specified otherwise, most of the Chinese medicines mentioned in Part 1 of the Pharmacopoeia of the People's Republic of China 2015 are to be taken in the form of a decoction while certain medicines can be taken directly after being grounded into powder. Currently, the testing of pesticide residues in Chms is carried out by the Government Laboratory. The tests involve two stages. In the first stage, preliminary tests are conducted on Chinese medicine decoction pieces. If the test results are found in compliance with the pesticide MRLs set by the CMB, no further testing will be conducted; if otherwise, the second stage tests will be conducted to evaluate the level of pesticide residues existed in the decoctions of the Chms concerned (not applicable if the Chm concerned "can be directly taken after being grounded into powder", a condition as mentioned in Part 1 of the Pharmacopoeia of the People's Republic of China 2015). Therefore, the results of the first-stage testing are for screening purpose only. It does not mean that the samples concerned must have adverse effects on health. If the results of the second-stage testing show that the pesticide residual levels have exceeded the MRLs, the DH will immediately conduct investigations and take the corresponding risk management.

17. The testing of pesticide residues in the decoction of Chm is considered to be a closer simulation of condition during human consumption which is more appropriate for human risk assessment. The procedures and scope of the tests are recognised by the CMB under the CMCHK and the Scientific Committee under the Hong Kong Chinese Materia Medica Standards (HKCMMS) research project. From 1 January 2015 to 30 June 2017, the DH collected a total of 1,015 Chm samples for testing during its regular market surveillance. Among these, 53 samples were found to contain pesticide residues in the first stage of testing and needed to be tested in the second stage. The samples covered 21 Chms, namely Myrrha, Fructus Corni, Rhizoma Chuanxiong, Herba Scutellariae Barbatae, Rhizoma Atractylodis Macrocephalae, Fructus Kochiae, Semen Astragali Complanati, Herba Plantaginis, Rhizoma et Radix Notopterygii, Radix Adenophorae, Fructus Aurantii Immaturus, Flos Campsis, Cortex Mori, Herba Leonuri, Herba Artemisiae Scopariae, Fructus Cnidii, Herba Violae, Radix Asteris, Herba Ecliptae, Rhizoma Alismatis and Folium Sauropi. Findings of the second-stage testing proved that pesticide residues in all these Chm samples did not exceed the MRLs set by the CMB. The results of the 53 samples in the first-stage testing are set out in Annex II.

Heavy metals and toxic elements

18. The standards currently used for testing the limits of heavy metal and toxic element contents in Chms sold in Hong Kong are formulated by the CMCHK with reference to other relevant international standards. The standards are calculated on the basis of maximum intake per day or dose to assess the impacts on human beings. Chms are different from food in that the use of Chms and their medication are based on personal physical conditions and medical needs, and Chms are normally not taken daily like food. As regulatory authorities around the world are increasingly concerned about the possible effects of heavy metals on the health of human beings, the CMB of the CMCHK will review the limits and scope of heavy metal contents in Chms, as well as the sampling strategy of the market surveillance system from time to time to safeguard public health.

Sulphur dioxide

19. Sulphur dioxide released from the burning of sulphur can be used in fumigation to keep Chms out of pests and mould, thus allowing easy storage of the Chms. Chms fumigated by sulphur will have more vivid colours and smell sour. According to Part 1 of the Pharmacopoeia of the People's Republic of China 2015, the sulphur dioxide residues in Chms and decoction pieces (except minerals tablets) should not exceed 150 ppm, while the limit of sulphur dioxide residue in the 10 specified types of Chms⁴ and their decoction pieces is 400 ppm.

20. During the research work for the compilation of HKCMMS Volume 9, the International Advisory Board proposed to include the testing of sulphur dioxide residue. At present, the HKCMMS is studying the method of testing sulphur dioxide residue contained in Chms. Samples of relevant herbal medicines will be collected for testing. It is expected that the HKCMMS Volume 9 will be released in 2018-2019, and the CMB will then consult the industry again on the proposal of adopting the testing method for sulphur dioxide residue promulgated by the HKCMMS as a routine quality monitoring method of Chms.

Good Manufacturing Practice for drugs

21. In Hong Kong, the regulatory regime of the pCms and that of the pharmaceutical products were formulated in different time, and the manufacturers of these products have different historical backgrounds. The CMO stipulates that anyone who wishes to engage in the manufacturing business of pCms must apply for a licence from the CMB. Manufacturers holding a pCm manufacturer licence may apply to the CMB for a certificate for manufacturer, certifying that he/she follows the requirements of GMP in the manufacture and quality control of pCms. Currently, the GMP system for pCms is not mandatory in Hong Kong.

22. For pharmaceutical products, the Pharmacy and Poisons Ordinance stipulates that anyone who wishes to engage in the manufacturing business of any pharmaceutical product must apply for a licence from the Pharmacy and Poisons Board. In 1995, the GMP system was introduced as one of the licensing requirements for manufacturers of pharmaceutical

⁴ According to Pharmacopoeia of the People's Republic of China 2015, except as otherwise provided in other provisions, the limit of sulphur dioxide residue in general Chms and decoction pieces (except minerals) is no more than 150 ppm: Rhizoma Dioscoreae, Radix Achyranthis Bidentatae, Arrowroot, Radix Asparagi, Rhizoma Gastrodiae, Radix Trichosanthis, Rhizoma Bletillae, Radix Paeoniae Alba, Radix Paeoniae Alba, Rhizoma Atractylodis Macrocephalae and Radix Codonopsis. The limit of sulphur dioxide residue in 10 types of Chms and their decoction pieces is no more than 400 ppm.

products with a grace period in place until 2002 after which the requirement of GMP system has been fully implemented.

23. To ensure the safety of pCms and enhance their quality, and to keep up with international trends of developing GMP for medicines, the CMB agreed in 2011 to adopt GMP as an approval requirement for local pCm manufacturers. It is understood that the industry is generally concerned about the requirements for implementing the GMP which include the financial resource involved, the availability of suitable manufacturing plants and the necessary technical support. The CMB and the DH have maintained close communication with the industry on the timetable and specific arrangements for the full implementation of GMP for pCms, and have assisted the industry in raising the manufacturing standard through various means and channels. The Government is still in the process of consulting the industry as to the specific timetable for the implementation of mandatory GMP requirement for pCms. In striking a balance between the capability of the industry and public interest, and on the premise of safeguarding public interest, the Government will work out a practical timetable for the implementation of GMP in a progressive manner.

Regulatory standards for routine surveillance and HKCMMS standards

24. At present, the regulatory standards for Chms in Hong Kong focus on ensuring public safety. If pesticide residues or heavy metal contents in any Chm samples are found to exceed the limits set by the CMCHK, which may cause injuries to health after human consumption, risk management and follow-up actions would be taken immediately. On the other hand, the HKCMMS standards are set as reference standards on the quality of individual Chms, which are thus more stringent than the regulatory standards for Chms. In the future, the Government will continue to closely monitor the situation of the market, and will conduct timely review of the regulatory standards for Chms, balancing the views of the industry and public safety.

Other matters

25. Matters regarding places of origin of imported Chms, practices for suppliers and import/export control of Chms have already been covered in the letter issued by the Food and Health Bureau on 22 September 2017.

Annex 1**Limits of pesticide residues in Chinese herbal medicines****(1) Limits of organochlorine pesticide residues (20 items in total)**

	Chinese name	English name	Test parameters (20 items in total)	Maximum residue limit
1.	艾氏劑及狄氏劑	Aldrin & Dieldrin	Sum of Aldrin and Dieldrin	0.05
2.	氯丹	Chlordane	Sum of <i>cis</i> -chlordane, <i>trans</i> -chlordane and oxychlordane	0.05
3.	滴滴涕	DDT	Sum of <i>p,p'</i> -DDT, <i>o,p'</i> -DDT, <i>p,p'</i> -DDE and <i>p,p'</i> -TDE	1.0
4.	異狄氏劑	Endrin	endrin	0.05
5.	七氯	Heptachlor	Sum of heptachlor and heptachlor	0.05
6.	六氯苯	Hexachlorobenzene	hexachlorobenzene	0.1
7.	六六六	Hexachlorocyclohexane	Sum of α -, β - and δ -isomers	0.3
8.	林丹	Lindane	lindane	0.6
9.	五氯硝基苯	Quintozene	Sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide	1.0

(2) Limits of organophosphate pesticide residues (17 items in total)

	Chinese name	English name	Maximum residue limit
1	滴滴畏	Dichlorvos	Should not be detected
2	甲胺磷	Methamidophos	
3	滴百蟲	Trichlorphon	
4	氧樂果	Omethoate	
5	二嗪磷	Diazinon	
6	樂果	Dimethoate	
7	馬拉硫磷	Malathion	
8	水胺硫磷	Isocarbophos	
9	三唑磷	Triazophos	
10	對硫磷	Parathion	
11	甲基對硫磷	Parathion-methyl	
12	久效磷	Monocrotophos	
13	磷胺	Phosphamidon	
14	毒死蜱	Chlorpyriphos	
15	乙酰甲胺磷	Acephate	
16	乙硫磷	Ethion	
17	殺撲磷	Methidathion	

Annex 2

Detailed testing results for the 53 Chinese herbal medicines samples which were found to contain pesticides in the first-stage testing (Unit: ppm)

	Name of Chinese herbal medicines	Number of samples			Organochlorine	Organophosphate			
		2015	2016	2017 1 st half	DDT	Dichlorvos	Isocarbophos	Triazophos	Chlorpyriphos
1	Myrrha	1			4.12				
2	Cortex Mori	1				0.38			
3	Fructus Corni	1					0.09		
			1					0.83	
				1			0.08	0.09	0.06
4	Fructus Cnidii	2							0.38
			2						0.21
				2					0.07
					1				0.07
									0.26
5	Rhizoma Alismatis	2							1.7
			1						2.1
				3					5.5
								0.07	3
								0.13	3.6
6	Herba Plantaginis	2							0.11
			2						0.14
				2					0.11
									0.13
									0.07
7	Fructus Aurantii Immaturus	2							0.10
			4						0.09
				2					0.11
									0.10
									0.11
8	Herba Ecliptae	1							0.12
9	Semen Astragali Complanati	1							0.13
10	Herba Artemisiae Scopariae	1							0.09
			1						0.10
				2					0.10
11	Radix Adenophorae	1							0.53
			1						0.7
12	Rhizoma et Radix Notopterygii		1			0.2			0.15
13	Fructus Kochiae		1						0.09
14	Rhizoma Atractylodis Macrocephalae		1						0.09
15	Herba Scutellariae Barbatae		1						0.17
16	Rhizoma Chuanxiong			4					0.08
									0.31
									1.30
									1.40
17	Herba Violae			2					0.17
18	Radix Asteris			2					0.18
19	Herba Leonuri			1					0.07
20	Folium Sauropi			1					0.08
21	Flos Campsis			1					0.2
	Sub-total	15	16	22					0.13
	Total		53						0.06

Result of First stage and Second Stage Testing of Heavy Metals in Chinese Herbal Medicines Samples (Year 2016)(Unit: mg/kg)

	Name of Chm	First Stage Testing Result				Second Stage Testing Result			
		Arsenic (Permitted level: 1500 mcg/day)	Cadmium (Permitted level: 3 500 mcg/dose)	Lead (Permitted level: 179 mcg/day)	Mercury (Permitted level: 36 mcg/day)	Arsenic (Permitted level: 1 500 mcg/day)	Cadmium (Permitted level: 3 500 mcg/dose)	Lead (Permitted level: 179 mcg/day)	Mercury (Permitted level: 36 mcg/day)
1	Faeces Tropopterori	2	2.1	34	0.12	NA	NA	BRL	NA
2	Radix Notoginseng	2.2	0.2	0.4	BRL	NA	NA	NA	NA
3	Radix Notoginseng	1.1	0.24	0.76	BRL	NA	NA	NA	NA
4	Rhizoma Sparganii	0.11	BRL	0.2	BRL	NA	NA	NA	NA
5	Rhizoma Sparganii	BRL	BRL	0.22	BRL	NA	NA	NA	NA
6	Rhizoma Homalomenae	0.13	2.2	3.7	BRL	NA	NA	NA	NA
7	Rhizoma Homalomenae	0.29	2.4	5.3	BRL	NA	NA	NA	NA
8	Rhizoma Homalomenae	BRL	1.3	1.2	BRL	NA	NA	NA	NA
9	Rhizoma Smilacis Glabrae	BRL	BRL	0.53	BRL	NA	NA	NA	NA
10	Rhizoma Smilacis Glabrae	BRL	BRL	0.41	BRL	NA	NA	NA	NA
11	Radix et Rhizoma Rhei	0.13	BRL	0.55	BRL	NA	NA	NA	NA
12	Radix et Rhizoma Rhei	BRL	BRL	0.11	BRL	NA	NA	NA	NA
13	Pericarpium Arecae	BRL	0.11	0.21	BRL	NA	NA	NA	NA
14	Pericarpium Arecae	BRL	BRL	0.12	BRL	NA	NA	NA	NA
15	Pericarpium Arecae	BRL	BRL	0.13	BRL	NA	NA	NA	NA
16	Fructus Ligustri Lucidi	0.14	BRL	0.77	BRL	NA	NA	NA	NA
17	Fructus Ligustri Lucidi	0.47	BRL	0.98	BRL	NA	NA	NA	NA
18	Fructus Ligustri Lucidi	BRL	BRL	0.52	BRL	NA	NA	NA	NA
19	Fructus Ligustri Lucidi	0.13	BRL	0.53	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

Remarks: The unit of the detected value for testing of heavy metal content is mg/kg, which represents the amount of heavy metal (in mg) contained in 1 kg of Chinese herbal medicine. The detected value should multiply by the recommended maximum amount of the respective Chinese herbal medicine to be consumed per day or per dose (subject to the type of heavy metal) to calculate the intake of respective heavy metal per day or per dose (subject to the type of heavy metal).

20	Fructus Corni	BRL	BRL	0.22	BRL	NA	NA	NA	NA
21	Fructus Corni	BRL	BRL	0.26	BRL	NA	NA	NA	NA
22	Fructus Corni	BRL	BRL	0.57	BRL	NA	NA	NA	NA
23	Fructus Corni	0.33	BRL	0.73	BRL	NA	NA	NA	NA
24	Caulis Ampelopsis Brevipedunculae	0.27	0.21	2.2	BRL	NA	NA	NA	NA
25	Rhizoma Chuanxiong	0.27	0.72	1.1	BRL	NA	NA	NA	NA
26	Radix Salviae Miltorrhizae	0.21	0.13	0.64	BRL	NA	NA	NA	NA
27	Fructus Schisandrae	BRL	BRL	0.16	BRL	NA	NA	NA	NA
28	Fructus Schisandrae	0.12	BRL	0.71	BRL	NA	NA	NA	NA
29	Galla Chinensis	BRL	0.12	7.4	BRL	NA	NA	NA	NA
30	Rhizoma Cimicifugae	0.31	0.12	1.4	BRL	NA	NA	NA	NA
31	Radix Asparagi	BRL	BRL	0.39	BRL	NA	NA	NA	NA
32	Radix Asparagi	0.15	BRL	0.24	BRL	NA	NA	NA	NA
33	Radix Asparagi	0.87	0.29	1.2	BRL	NA	NA	NA	NA
34	Radix Trichosanthis	BRL	BRL	0.11	BRL	NA	NA	NA	NA
35	Radix Trichosanthis	0.12	BRL	BRL	BRL	NA	NA	NA	NA
36	Rhizoma Gastrodiae	BRL	BRL	1.8	BRL	NA	NA	NA	NA
37	Rhizoma Gastrodiae	0.15	0.44	0.25	BRL	NA	NA	NA	NA
38	Rhizoma Gastrodiae	0.2	0.66	0.38	BRL	NA	NA	NA	NA
39	Radix Pseudostellariae	BRL	0.37	2	BRL	NA	NA	NA	NA
40	Radix Pseudostellariae	BRL	0.18	0.98	BRL	NA	NA	NA	NA
41	Radix Pseudostellariae	BRL	0.23	1.2	BRL	NA	NA	NA	NA
42	Radix Morindae Officinalis	0.29	0.12	2.1	BRL	NA	NA	NA	NA
43	Flos Rosae Chinensis	0.15	BRL	0.39	BRL	NA	NA	NA	NA
44	Herba Equiseti Hiemalis	BRL	BRL	0.4	BRL	NA	NA	NA	NA
45	Herba Equiseti Hiemalis	0.43	1.2	1.1	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

46	Semen Oroxyli	0.41	BRL	BRL	BRL	NA	NA	NA	NA
47	Semen Oroxyli	0.34	BRL	0.14	BRL	NA	NA	NA	NA
48	Radix Ilicis Pubescentis	0.2	BRL	BRL	BRL	NA	NA	NA	NA
49	Hirudo	BRL	BRL	0.37	BRL	NA	NA	NA	NA
50	Herba Polygoni Chinensis	1.1	0.2	2.9	BRL	NA	NA	NA	NA
51	Herba Polygoni Chinensis	0.3	BRL	0.75	BRL	NA	NA	NA	NA
52	Fructus Arctii	0.19	BRL	0.24	BRL	NA	NA	NA	NA
53	Fructus Arctii	BRL	0.11	BRL	BRL	NA	NA	NA	NA
54	Radix Achyranthis Bidentatae	BRL	BRL	0.13	BRL	NA	NA	NA	NA
55	Radix Achyranthis Bidentatae	0.13	BRL	0.18	BRL	NA	NA	NA	NA
56	Semen Vaccariae	0.2	0.11	0.3	BRL	NA	NA	NA	NA
57	Rhizoma Curculiginis	0.18	0.52	3.4	BRL	NA	NA	NA	NA
58	Radix Glehniae	BRL	BRL	BRL	0.16	NA	NA	NA	NA
59	Radix Glehniae	BRL	BRL	0.18	BRL	NA	NA	NA	NA
60	Herba Scutellariae Barbatae	0.66	0.22	2.1	BRL	NA	NA	NA	NA
61	Radix Scrophulariae	0.21	0.18	0.48	BRL	NA	NA	NA	NA
62	Radix Scrophulariae	0.12	BRL	0.29	BRL	NA	NA	NA	NA
63	Fructus Trichosanthis	0.19	BRL	0.73	BRL	NA	NA	NA	NA
64	Fructus Trichosanthis	BRL	BRL	0.48	BRL	NA	NA	NA	NA
65	Semen Trichosanthis	BRL	BRL	0.22	BRL	NA	NA	NA	NA
66	Pericarpium Trichosanthis	BRL	BRL	0.49	BRL	NA	NA	NA	NA
67	Concha Arcae	BRL	0.29	0.56	BRL	NA	NA	NA	NA
68	Concha Arcae	0.27	BRL	0.21	BRL	NA	NA	NA	NA
69	Concha Arcae	0.51	BRL	0.18	BRL	NA	NA	NA	NA
70	Rhizoma Bletillae	BRL	BRL	0.41	BRL	NA	NA	NA	NA
71	Rhizoma Atractylodis Macrocephalae	BRL	0.27	BRL	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

72	Rhizoma Atractylodis Macrocephalae	BRL	0.24	0.39	BRL	NA	NA	NA	NA
73	Cortex Dictamni	0.12	BRL	0.18	BRL	NA	NA	NA	NA
74	Cortex Dictamni	0.11	BRL	0.26	BRL	NA	NA	NA	NA
75	Concha Haliotidis	0.18	BRL	0.27	BRL	NA	NA	NA	NA
76	Concha Haliotidis	0.18	BRL	0.33	BRL	NA	NA	NA	NA
77	Concha Haliotidis	0.17	BRL	0.3	BRL	NA	NA	NA	NA
78	Concha Haliotidis	0.2	BRL	0.92	BRL	NA	NA	NA	NA
79	Herba Dendrobii	0.19	0.23	2.4	BRL	NA	NA	NA	NA
80	Rhizoma Acori Tatarinowii	0.72	0.16	1.1	BRL	NA	NA	NA	NA
81	Rhizoma Acori Tatarinowii	3.1	0.1	1.6	BRL	NA	NA	NA	NA
82	Scorpio	0.57	0.67	0.21	0.19	NA	NA	NA	NA
83	Cortex Albiziae	0.16	0.11	2.6	BRL	NA	NA	NA	NA
84	Cortex Albiziae	BRL	0.12	1.8	BRL	NA	NA	NA	NA
85	Cortex Albiziae	0.17	0.12	2.2	BRL	NA	NA	NA	NA
86	Cortex Albiziae	BRL	0.13	2.1	BRL	NA	NA	NA	NA
87	Cortex Albiziae	BRL	0.11	2	BRL	NA	NA	NA	NA
88	Cortex Lycii	0.53	0.14	1.3	BRL	NA	NA	NA	NA
89	Radix Rehmanniae	0.26	0.2	1.5	BRL	NA	NA	NA	NA
90	Radix Rehmanniae	0.31	BRL	0.6	BRL	NA	NA	NA	NA
91	Radix Sanguisorbae	1.5	1.2	6.2	BRL	NA	NA	NA	NA
92	Fructus Kochiae	BRL	0.11	0.22	BRL	NA	NA	NA	NA
93	Herba Euphorbiae Humifusae	BRL	BRL	0.67	BRL	NA	NA	NA	NA
94	Radix Stemoneae	0.5	0.45	0.46	BRL	NA	NA	NA	NA
95	Radix Stemoneae	0.47	BRL	0.23	0.1	NA	NA	NA	NA
96	Caulis Bambusae in Taeniam	0.63	BRL	0.19	BRL	NA	NA	NA	NA
97	Caulis Bambusae in Taeniam	BRL	BRL	0.38	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

98	Caulis Bambusae in Taeniam	BRL	0.24	0.37	BRL	NA	NA	NA	NA
99	Herba Cistanches	0.12	BRL	0.26	BRL	NA	NA	NA	NA
100	Herba Cistanches	0.14	BRL	0.38	BRL	NA	NA	NA	NA
101	Folium Artemisiae Argyi	0.35	0.74	2.8	BRL	NA	NA	NA	NA
102	Folium Artemisiae Argyi	0.43	0.66	3.3	BRL	NA	NA	NA	NA
103	Crinis Carbonisatus	5	0.31	20	BRL	NA	NA	NA	NA
104	Crinis Carbonisatus	3.9	0.25	15	BRL	NA	NA	NA	NA
105	Radix Panacis Quinquefolii	BRL	BRL	0.18	BRL	NA	NA	NA	NA
106	Herba Lycopodii	1.2	0.3	5.1	BRL	NA	NA	NA	NA
107	Herba Lycopodii	1.5	0.39	3.8	BRL	NA	NA	NA	NA
108	Radix Polygoni Multiflori	BRL	BRL	0.31	BRL	NA	NA	NA	NA
109	Radix Polygoni Multiflori	0.25	BRL	0.16	BRL	NA	NA	NA	NA
110	Fructus Evodiae	BRL	0.21	0.69	BRL	NA	NA	NA	NA
111	Fructus Evodiae	0.1	0.21	0.74	BRL	NA	NA	NA	NA
112	Caulis Lonicerae	0.31	0.12	2	BRL	NA	NA	NA	NA
113	Caulis Lonicerae	BRL	0.3	1.4	BRL	NA	NA	NA	NA
114	Caulis Lonicerae	0.24	0.14	1	0.15	NA	NA	NA	NA
115	Cortex Eucommiae	BRL	0.11	1.1	BRL	NA	NA	NA	NA
116	Cortex Eucommiae	BRL	BRL	0.28	BRL	NA	NA	NA	NA
117	Cortex Eucommiae	BRL	0.15	0.34	BRL	NA	NA	NA	NA
118	Myrrha	0.51	BRL	1.2	BRL	NA	NA	NA	NA
119	Myrrha	0.25	BRL	0.86	BRL	NA	NA	NA	NA
120	Myrrha	0.33	BRL	0.91	BRL	NA	NA	NA	NA
121	Semen Astragali Complanati	BRL	BRL	0.11	BRL	NA	NA	NA	NA
122	Cortex Moutan	BRL	BRL	0.1	BRL	NA	NA	NA	NA
123	Cortex Moutan	BRL	BRL	0.12	BRL	NA	NA	NA	NA
124	Fructus Amomi Rotundus	0.13	BRL	0.27	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

125	Fructus Amomi Rotundus	0.2	BRL	0.29	BRL	NA	NA	NA	NA
126	Halloysitum Rubrum	2.5	0.19	15	BRL	NA	NA	NA	NA
127	Radix Paeoniae Rubra	BRL	BRL	0.11	BRL	NA	NA	NA	NA
128	Radix Paeoniae Rubra	BRL	BRL	0.14	BRL	NA	NA	NA	NA
129	Semen Plantaginis	0.17	0.19	0.24	BRL	NA	NA	NA	NA
130	Semen Plantaginis	0.17	0.2	0.38	BRL	NA	NA	NA	NA
131	Herba Plantaginis	0.59	BRL	2.5	BRL	NA	NA	NA	NA
132	Herba Plantaginis	0.83	0.1	3.6	BRL	NA	NA	NA	NA
133	Flos Magnoliae	BRL	BRL	1	BRL	NA	NA	NA	NA
134	Radix Stephaniae Tetrandrae	0.2	BRL	1.6	BRL	NA	NA	NA	NA
135	Radix Stephaniae Tetrandrae	0.17	BRL	1.4	BRL	NA	NA	NA	NA
136	Radix Saposhnikoviae	0.18	0.1	0.31	BRL	NA	NA	NA	NA
137	Radix Saposhnikoviae	0.22	0.1	0.42	BRL	NA	NA	NA	NA
138	Olibanum	BRL	BRL	0.15	BRL	NA	NA	NA	NA
139	Olibanum	BRL	BRL	0.12	BRL	NA	NA	NA	NA
140	Olibanum	BRL	0.24	1.1	BRL	NA	NA	NA	NA
141	Semen Lini	BRL	0.65	BRL	BRL	NA	NA	NA	NA
142	Herba Eupatorii	0.13	0.1	0.87	BRL	NA	NA	NA	NA
143	Herba Eupatorii	0.77	0.26	1.5	BRL	NA	NA	NA	NA
144	Fructus Quisqualis	BRL	0.34	BRL	0.16	NA	NA	NA	NA
145	Radix Acanthopanacis Senticosi	BRL	BRL	0.18	BRL	NA	NA	NA	NA
146	Rhizoma Corydalis	BRL	0.13	0.27	BRL	NA	NA	NA	NA
147	Rhizoma Corydalis	BRL	0.1	0.19	BRL	NA	NA	NA	NA
148	Radix Isatidis	0.2	BRL	0.17	BRL	NA	NA	NA	NA
149	Processed Radix Astragali	0.17	BRL	0.12	BRL	NA	NA	NA	NA
150	Rhizoma Cibotii	BRL	0.13	3.8	BRL	NA	NA	NA	NA

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NA: Not applicable (不適用)

151	Rhizoma Cibotii	BRL	0.11	9.1	BRL	NA	NA	NA	NA
152	Rhizoma Anemarrhenae	BRL	BRL	0.15	BRL	NA	NA	NA	NA
153	Rhizoma Anemarrhenae	0.12	0.21	0.14	BRL	NA	NA	NA	NA
154	Rhizoma et Radix Notopterygii	0.23	0.19	0.4	BRL	NA	NA	NA	NA
155	Rhizoma et Radix Notopterygii	0.33	0.17	0.7	BRL	NA	NA	NA	NA
156	Rhizoma et Radix Notopterygii	0.3	0.21	0.6	BRL	NA	NA	NA	NA
157	Rhizoma et Radix Notopterygii	0.48	0.18	0.71	BRL	NA	NA	NA	NA
158	Semen Sinapis	BRL	0.12	BRL	BRL	NA	NA	NA	NA
159	Rhizoma Polygoni Cuspidati	0.12	0.26	0.68	BRL	NA	NA	NA	NA
160	Rhizoma Polygoni Cuspidati	1.5	0.41	3.2	BRL	NA	NA	NA	NA
161	Rhizoma Polygoni Cuspidati	0.14	0.11	0.44	BRL	NA	NA	NA	NA
162	Herba Lysimachiae	0.42	BRL	1.5	BRL	NA	NA	NA	NA
163	Fructus Rosae Laevigatae	BRL	BRL	0.38	BRL	NA	NA	NA	NA
164	Fructus Rosae Laevigatae	BRL	BRL	0.31	BRL	NA	NA	NA	NA
165	Semen Celosiae	BRL	BRL	0.14	BRL	NA	NA	NA	NA
166	Radix Peucedani	0.22	0.96	0.66	BRL	NA	NA	NA	NA
167	Radix Peucedani	0.3	1	0.51	BRL	NA	NA	NA	NA
168	Radix Adenophorae	0.23	0.61	0.51	BRL	NA	NA	NA	NA
169	Radix Adenophorae	0.26	0.68	1.5	BRL	NA	NA	NA	NA
170	Cortex Magnoliae Officinalis	BRL	BRL	2.7	BRL	NA	NA	NA	NA
171	Cortex Magnoliae Officinalis	BRL	BRL	2.6	BRL	NA	NA	NA	NA
172	Flos Magnolisa Officinalis	BRL	BRL	0.1	BRL	NA	NA	NA	NA
173	Radix Clematidis	0.38	0.13	0.58	BRL	NA	NA	NA	NA
174	Radix Clematidis	0.44	0.15	1.7	BRL	NA	NA	NA	NA
175	Fructus Aurantii	0.21	BRL	0.82	BRL	NA	NA	NA	NA
176	Fructus Aurantii	0.11	BRL	1	BRL	NA	NA	NA	NA
177	Fructus Aurantii Immaturus	BRL	BRL	0.34	BRL	NA	NA	NA	NA

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178	Fructus Aurantii Immaturus	BRL	BRL	0.26	BRL	NA	NA	NA	NA
179	Fructus Aurantii Immaturus	0.13	BRL	0.12	BRL	NA	NA	NA	NA
180	Semen Platycladi	BRL	BRL	0.76	BRL	NA	NA	NA	NA
181	Concha Margaritifera Usta	BRL	0.92	0.95	BRL	NA	NA	NA	NA
182	Concha Margaritifera Usta	BRL	BRL	0.58	BRL	NA	NA	NA	NA
183	Concha Margaritifera Usta	0.2	BRL	0.68	BRL	NA	NA	NA	NA
184	Semen Sterculiae Lychnoporae	0.99	BRL	BRL	BRL	NA	NA	NA	NA
185	Semen Sterculiae Lychnoporae	BRL	0.82	BRL	BRL	NA	NA	NA	NA
186	Radix Sophorae Flavescentis	2.2	0.22	2.1	0.2	NA	NA	NA	NA
187	Caulis Polygoni Multiflori	0.74	0.46	1.6	BRL	NA	NA	NA	NA
188	Caulis Polygoni Multiflori	0.2	0.25	0.88	BRL	NA	NA	NA	NA
189	Caulis Polygoni Multiflori	BRL	0.21	0.51	BRL	NA	NA	NA	NA
190	Caulis Polygoni Multiflori	0.36	0.37	1.4	BRL	NA	NA	NA	NA
191	Rhizoma Cyperi	BRL	BRL	0.14	BRL	NA	NA	NA	NA
192	Rhizoma Cyperi	0.1	BRL	0.13	BRL	NA	NA	NA	NA
193	Spica Prunellae	0.19	BRL	1.1	BRL	NA	NA	NA	NA
194	Spica Prunellae	0.22	BRL	1.1	BRL	NA	NA	NA	NA
195	Rhizoma Belamcandae	0.26	0.7	0.59	BRL	NA	NA	NA	NA
196	Radix Cynanchi Paniculati	0.11	0.1	0.54	BRL	NA	NA	NA	NA
197	Radix Bupleuri	0.23	BRL	0.42	BRL	NA	NA	NA	NA
198	Radix Bupleuri	0.41	BRL	0.8	BRL	NA	NA	NA	NA
199	Radix Bupleuri	0.29	BRL	0.46	BRL	NA	NA	NA	NA
200	Radix Bupleuri	0.32	BRL	0.59	BRL	NA	NA	NA	NA
201	Ramulus Cinnamomi	0.18	0.24	0.85	BRL	NA	NA	NA	NA
202	Ramulus Cinnamomi	0.11	0.43	1.5	BRL	NA	NA	NA	NA
203	Cortex Mori	0.88	BRL	2.4	BRL	NA	NA	NA	NA
204	Cortex Mori	0.88	BRL	2.6	BRL	NA	NA	NA	NA

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205	Ramulus Mori	BRL	BRL	0.47	BRL	NA	NA	NA	NA
206	Ramulus Mori	BRL	BRL	0.42	BRL	NA	NA	NA	NA
207	Herba Taxilli	BRL	BRL	0.89	BRL	NA	NA	NA	NA
208	Herba Taxilli	0.16	0.23	2.9	BRL	NA	NA	NA	NA
209	Ootheca Mantidis	0.35	BRL	2.7	BRL	NA	NA	NA	NA
210	Radix Platycodi	BRL	0.1	0.14	BRL	NA	NA	NA	NA
211	Radix Platycodi	BRL	BRL	0.18	BRL	NA	NA	NA	NA
212	Bulbus Fritillariae Thunbergii	BRL	0.1	0.42	BRL	NA	NA	NA	NA
213	Bulbus Fritillariae Thunbergii	BRL	0.22	0.17	BRL	NA	NA	NA	NA
214	Radix Linderae	0.42	1.6	4.7	BRL	NA	NA	NA	NA
215	Radix Linderae	0.3	1.2	2.8	BRL	NA	NA	NA	NA
216	Fructus Alpiniae Oxyphyllae	BRL	BRL	0.16	BRL	NA	NA	NA	NA
217	Fructus Alpiniae Oxyphyllae	BRL	BRL	0.12	BRL	NA	NA	NA	NA
218	Radix Gentianae Macrophyllae	0.93	BRL	0.23	BRL	NA	NA	NA	NA
219	Flos Jasmini	0.15	0.19	0.31	BRL	NA	NA	NA	NA
220	Radix Rubiae	2.2	0.5	2.8	BRL	NA	NA	NA	NA
221	Radix Rubiae	2.3	0.4	2	BRL	NA	NA	NA	NA
222	Herba Artemisiae Scopariae	2.2	0.3	3.8	BRL	NA	NA	NA	NA
223	Herba Artemisiae Scopariae	1.6	1.3	4.2	BRL	NA	NA	NA	NA
224	Fructus Tsaoko	BRL	0.12	0.23	BRL	NA	NA	NA	NA
225	Lasiosphaera seu Calvatia	4.8	1.2	7.4	4.6	NA	NA	NA	NA
226	Lasiosphaera seu Calvatia	6	0.43	5.7	1.1	NA	NA	NA	NA
227	Herba Verbenae	0.36	BRL	1	BRL	NA	NA	NA	NA
228	Cacumen Platycladi	0.31	BRL	2.9	BRL	NA	NA	NA	NA
229	Flos Buddlejae	0.37	BRL	1.7	BRL	NA	NA	NA	NA
230	Flos Buddlejae	0.38	0.16	2.6	BRL	NA	NA	NA	NA
231	Radix Ilicis Asprellae	BRL	0.13	0.17	BRL	NA	NA	NA	NA

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232	Radix Ilicis Asprellae	BRL	BRL	0.32	BRL	NA	NA	NA	NA
233	Herba Lophatheri	0.2	0.16	2.4	BRL	NA	NA	NA	NA
234	Herba Lophatheri	0.34	0.16	3.3	BRL	NA	NA	NA	NA
235	Herba Epimedii	0.74	0.35	5.5	BRL	NA	NA	NA	NA
236	Herba Epimedii	0.38	0.11	2.2	0.12	NA	NA	NA	NA
237	Rhizoma Curcumae	0.11	0.37	2.9	BRL	NA	NA	NA	NA
238	Fructus Cnidii	0.68	0.21	2.8	BRL	NA	NA	NA	NA
239	Fructus Cnidii	0.91	0.11	1.9	BRL	NA	NA	NA	NA
240	Fructus Cnidii	0.24	0.33	0.9	BRL	NA	NA	NA	NA
241	Medulla Tetrapanacis	BRL	2.9	0.29	BRL	NA	NA	NA	NA
242	Medulla Tetrapanacis	BRL	3.7	0.57	BRL	NA	NA	NA	NA
243	Fructus Forsythiae	0.42	0.11	1.7	BRL	NA	NA	NA	NA
244	Fructus Forsythiae	0.15	BRL	1.5	BRL	NA	NA	NA	NA
245	Fructus Forsythiae	0.12	BRL	1.3	BRL	NA	NA	NA	NA
246	Herba Houttuyniae	2.3	BRL	7	0.12	NA	NA	NA	NA
247	Herba Houttuyniae	0.35	0.47	1.8	BRL	NA	NA	NA	NA
248	Cornu Cervi Degelatinatum	0.12	BRL	0.4	BRL	NA	NA	NA	NA
249	Herba Pyrolae	0.27	BRL	1.2	BRL	NA	NA	NA	NA
250	Radix Ophiopogonis	0.26	0.19	0.14	BRL	NA	NA	NA	NA
251	Radix Ophiopogonis	0.3	0.24	0.13	BRL	NA	NA	NA	NA
252	Herba Ephedrae	0.19	BRL	0.4	BRL	NA	NA	NA	NA
253	Herba Ephedrae	0.26	BRL	0.79	BRL	NA	NA	NA	NA
254	Radix Ephedrae	0.42	0.11	2.6	BRL	NA	NA	NA	NA
255	Fructus Broussonetiae	BRL	BRL	0.16	BRL	NA	NA	NA	NA
256	Folium Sennae	0.37	BRL	0.33	BRL	NA	NA	NA	NA
257	Fluoritum	1.5	0.19	9.8	BRL	NA	NA	NA	NA
258	Radix Asteris	0.31	0.14	0.56	BRL	NA	NA	NA	NA

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259	Radix Asteris	0.33	0.13	0.57	BRL	NA	NA	NA	NA
260	Radix Asteris	0.3	0.14	0.48	BRL	NA	NA	NA	NA
261	Caulis Perillae	0.14	0.11	0.67	BRL	NA	NA	NA	NA
262	Caulis Perillae	BRL	0.11	0.63	BRL	NA	NA	NA	NA
263	Caulis Perillae	0.11	0.2	0.77	BRL	NA	NA	NA	NA
264	Caulis Perillae	0.11	0.17	0.74	BRL	NA	NA	NA	NA
265	Semen Cuscutae	0.31	BRL	0.47	BRL	NA	NA	NA	NA
266	Semen Cuscutae	0.92	BRL	1.3	BRL	NA	NA	NA	NA
267	Concha Meretricis seu Cyclinae	BRL	0.74	3.7	BRL	NA	NA	NA	NA
268	Concha Meretricis seu Cyclinae	0.14	BRL	BRL	BRL	NA	NA	NA	NA
269	Fructus Chebulae	BRL	BRL	1.4	BRL	NA	NA	NA	NA
270	Radix Scutellariae	0.12	0.17	0.36	BRL	NA	NA	NA	NA
271	Radix Scutellariae	0.16	BRL	0.24	BRL	NA	NA	NA	NA
272	Radix Astragali	0.17	BRL	BRL	BRL	NA	NA	NA	NA
273	Rhizoma Polygonati	0.29	BRL	0.73	BRL	NA	NA	NA	NA
274	Rhizoma Polygonati	0.49	BRL	0.59	BRL	NA	NA	NA	NA
275	Rhizoma Polygonati	0.49	0.34	0.36	BRL	NA	NA	NA	NA
276	Rhizoma Polygonati	0.36	BRL	0.42	BRL	NA	NA	NA	NA
277	Rhizoma Dioscoreae Bulbiferae	0.16	0.1	0.57	BRL	NA	NA	NA	NA
278	Folium et Cacumen Breyniae Fruticosae	BRL	3.3	0.4	BRL	NA	NA	NA	NA
279	Radix Angelicae Sinensis	0.19	BRL	0.21	BRL	NA	NA	NA	NA
280	Radix Angelicae Sinensis	0.15	BRL	0.14	BRL	NA	NA	NA	NA
281	Radix Puerariae	BRL	BRL	0.17	BRL	NA	NA	NA	NA
282	Radix Puerariae	BRL	BRL	0.12	BRL	NA	NA	NA	NA

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283	Nidus Vespaee	1.5	0.56	16	BRL	NA	NA	NA	NA
284	Fructus Psoraleae	0.25	BRL	0.67	BRL	NA	NA	NA	NA
285	Fructus Psoraleae	BRL	BRL	0.38	BRL	NA	NA	NA	NA
286	Fructus Liquidambaris	0.62	0.21	2.2	BRL	NA	NA	NA	NA
287	Fructus Liquidambaris	0.34	0.15	1.1	BRL	NA	NA	NA	NA
288	Fructus Liquidambaris	0.95	0.29	6	BRL	NA	NA	NA	NA
289	Fructus Liquidambaris	0.5	BRL	2.2	BRL	NA	NA	NA	NA
290	Caulis Entadae	BRL	BRL	0.97	BRL	NA	NA	NA	NA
291	Semen Allii Tuberosi	BRL	BRL	0.13	BRL	NA	NA	NA	NA
292	Fructus Akebiae	BRL	BRL	0.12	BRL	NA	NA	NA	NA
293	Fructus Sophorae	BRL	BRL	0.15	BRL	NA	NA	NA	NA
294	Fructus Sophorae	BRL	BRL	0.24	BRL	NA	NA	NA	NA
295	Fructus Tribuli	0.14	0.19	0.12	BRL	NA	NA	NA	NA
296	Fructus Tribuli	BRL	0.12	BRL	BRL	NA	NA	NA	NA
297	Processed Radix Aconiti Lateralis	0.2	BRL	0.41	BRL	NA	NA	NA	NA
298	Processed Radix Aconiti Lateralis	0.39	BRL	0.71	BRL	NA	NA	NA	NA
299	Herba Siegesbeckiae	0.13	0.16	3.9	BRL	NA	NA	NA	NA
300	Radix Polygalae	0.59	BRL	0.86	BRL	NA	NA	NA	NA
301	Radix Polygalae	0.32	BRL	0.48	BRL	NA	NA	NA	NA
302	Herba Ecliptae	2.4	6.2	9.6	BRL	NA	NA	NA	NA
303	Herba Ecliptae	0.37	0.65	0.94	BRL	NA	NA	NA	NA
304	Caulis Tinosporae	0.14	BRL	0.96	BRL	NA	NA	NA	NA
305	Caulis Tinosporae	0.14	BRL	1.1	BRL	NA	NA	NA	NA
306	Caulis Tinosporae	BRL	BRL	0.89	BRL	NA	NA	NA	NA
307	Caulis Tinosporae	BRL	BRL	0.78	BRL	NA	NA	NA	NA

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308	Receptaculum Nelumbinis	0.17	BRL	0.23	BRL	NA	NA	NA	NA
309	Receptaculum Nelumbinis	0.23	BRL	0.26	BRL	NA	NA	NA	NA
310	Stamen Nelumbinis	BRL	BRL	0.16	BRL	NA	NA	NA	NA
311	Fructus Viticis	BRL	BRL	1.2	BRL	NA	NA	NA	NA
312	Fructus Viticis	BRL	BRL	0.13	BRL	NA	NA	NA	NA
313	Polyporus	0.55	0.75	2.1	BRL	NA	NA	NA	NA
314	Polyporus	0.39	0.48	0.85	BRL	NA	NA	NA	NA
315	Polyporus	BRL	0.42	0.31	BRL	NA	NA	NA	NA
316	Rhizoma Alismatis	0.12	0.12	0.13	BRL	NA	NA	NA	NA
317	Herba Lycopi	BRL	BRL	0.69	BRL	NA	NA	NA	NA
318	Radix Angelicae Pubescentis	0.14	BRL	0.2	BRL	NA	NA	NA	NA
319	Radix Angelicae Pubescentis	0.2	BRL	0.25	BRL	NA	NA	NA	NA
320	Radix Ranunculus Ternati	0.93	0.12	2	BRL	NA	NA	NA	NA
321	Radix Ranunculus Ternati	BRL	BRL	0.13	BRL	NA	NA	NA	NA
322	Radix Gentianae	1.1	0.5	0.68	0.35	NA	NA	NA	NA
323	Rhizoma Curcumae Longae	0.11	0.72	2.8	BRL	NA	NA	NA	NA
324	Rhizoma Curcumae Longae	BRL	0.3	6.7	BRL	NA	NA	NA	NA
325	Herba Dianthi	0.44	0.4	1.2	BRL	NA	NA	NA	NA
326	Herba Dianthi	0.41	1.8	1.1	BRL	NA	NA	NA	NA
327	Rhizoma Ligustici	0.65	0.21	1.5	BRL	NA	NA	NA	NA
328	Rhizoma Ligustici	0.49	0.17	1.1	BRL	NA	NA	NA	NA
329	Rhizoma Ligustici	0.22	BRL	0.28	BRL	NA	NA	NA	NA
330	Fructus Rubi	0.11	0.24	0.43	BRL	NA	NA	NA	NA
331	Fructus Rubi	0.3	0.74	0.71	BRL	NA	NA	NA	NA
332	Herba Cynomorii	0.19	BRL	0.14	BRL	NA	NA	NA	NA

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333	Herba Cynomorii	0.16	BRL	0.25	BRL	NA	NA	NA	NA
334	Caulis Spatholobi	BRL	BRL	0.46	BRL	NA	NA	NA	NA
335	Caulis Spatholobi	BRL	BRL	0.44	BRL	NA	NA	NA	NA
336	Caulis Spatholobi	0.19	BRL	0.75	BRL	NA	NA	NA	NA
337	Caulis Spatholobi	0.58	BRL	0.74	BRL	NA	NA	NA	NA
338	Herba Paederiae	BRL	BRL	1	BRL	NA	NA	NA	NA
339	Herba Centipedae	2.1	2.4	7	BRL	NA	NA	NA	NA
340	Radix Codonopsis	0.25	0.13	0.28	BRL	NA	NA	NA	NA
341	Radix Codonopsis	0.13	0.25	0.19	BRL	NA	NA	NA	NA
342	Radix Dipsaci	0.7	0.67	1.4	BRL	NA	NA	NA	NA
343	Radix Curcumae	0.18	BRL	0.27	BRL	NA	NA	NA	NA
344	Radix Curcumae	0.18	BRL	0.34	BRL	NA	NA	NA	NA
345	Semen Trichosanthis	BRL	BRL	BRL	BRL	NA	NA	NA	NA
346	Fructus Arctii	BRL	BRL	BRL	BRL	NA	NA	NA	NA
347	Caulis Clematidis Armandii	BRL	BRL	BRL	BRL	NA	NA	NA	NA
348	Fructus Alpiniae Oxyphyllae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
349	Fructus Arctii	BRL	BRL	BRL	BRL	NA	NA	NA	NA
350	Fructus Chebulae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
351	Nux Prinsepiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
352	Nux Prinsepiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
353	Radix Gentianae Macrophyllae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
354	Fructus Toosendan	BRL	BRL	BRL	BRL	NA	NA	NA	NA
355	Radix Paeoniae Alba	BRL	BRL	BRL	BRL	NA	NA	NA	NA
356	Radix Paeoniae Alba	BRL	BRL	BRL	BRL	NA	NA	NA	NA
357	Fructus Toosendan	BRL	BRL	BRL	BRL	NA	NA	NA	NA

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358	Fructus Tsaoko	BRL	BRL	BRL	BRL	NA	NA	NA	NA
359	Radix Pseudostellariae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
360	Olibanum	BRL	BRL	BRL	BRL	NA	NA	NA	NA
361	Semen Arecae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
362	Semen Cassiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
363	Radix Sophorae Flavescentis	BRL	BRL	BRL	BRL	NA	NA	NA	NA
364	Semen Cassiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
365	Semen Arecae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
366	Semen Persicae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
367	Semen Platycladi	BRL	BRL	BRL	BRL	NA	NA	NA	NA
368	Cortex Phellodendri	BRL	BRL	BRL	BRL	NA	NA	NA	NA
369	Semen Trichosanthis	BRL	BRL	BRL	BRL	NA	NA	NA	NA
370	Radix Astragali	BRL	BRL	BRL	BRL	NA	NA	NA	NA
371	Cortex Phellodendri	BRL	BRL	BRL	BRL	NA	NA	NA	NA
372	Rhizoma Smilacis Glabrae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
373	Radix Astragali	BRL	BRL	BRL	BRL	NA	NA	NA	NA
374	Fructus Aurantii Immaturus	BRL	BRL	BRL	BRL	NA	NA	NA	NA
375	Fructus Chebulae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
376	Fructus Chebulae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
377	Nux Prinsepiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
378	Radix Changii	BRL	BRL	BRL	BRL	NA	NA	NA	NA
379	Nux Prinsepiae	BRL	BRL	BRL	BRL	NA	NA	NA	NA
380	Semen Persicae	BRL	BRL	BRL	BRL	NA	NA	NA	NA

BRL: Below reporting limit (低於報告限值)

NA: Not applicable (不適用)

Result of First Stage Testing of Pesticide Residues in Chinese Herbal Medicines Samples (Year 2016) (Unit: mg/kg)

	Name of Chinese herbal medicines	Organochlorine										Organophosphate (Permitted level: Should not be detected)												
		Dieldrin	DDT (Permitted level: 1.0)	Heptachlor (Permitted level: 0.05)	Hexachlorobenzene (Permitted level: 0.1)	Hexachlorocyclohexane (Permitted level: 0.3)	Quintozene (Permitted level: 1.0)	Lindan (Permitted level: 0.6)	Dichlorvos	Trichlorfon	Chlorpyrifos	Malathion	Dimethoate	Diazinon	Isocarbophos	Triazophos	Parathion	Parathion-methyl	Monocrotophos	Phosphamidon	Chlorpyrifos	Acephate	Ethion	Methidation
1	Nidus Vespa	BRL	BRL	0.02	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
2	Radix Rehmmanniae	BRL	BRL	0.03	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
3	Radix Panacis Quinquefolii	BRL	BRL	0.24	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
4	Herba Dianthi	BRL	BRL	BRL	BRL	BRL	0.02	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
5	Herba Artemisiae Scopariae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.1	BRL	BRL	BRL
6	Herba Artemisiae Scopariae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.1	BRL	BRL	BRL
7	Radix Notoginseng	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.03	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
8	Radix Notoginseng	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.06	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
9	Rhizoma et Radix Notopterygii	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.2	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL
10	Fructus Kochiae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.09	BRL	BRL	BRL	BRL	BRL	BRL	BRL
11	Fructus Corni	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.83	BRL	BRL	BRL	BRL	BRL	BRL	BRL
12	Fructus Cnidii	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.07	BRL	BRL	BRL
13	Fructus Cnidii	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.07	BRL	BRL	BRL
14	Fructus Aurantii Immaturus	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.12	BRL	BRL	BRL
15	Fructus Aurantii Immaturus	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.13	BRL	BRL	BRL
16	Fructus Aurantii Immaturus	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.12	BRL	BRL	BRL
17	Fructus Aurantii Immaturus	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.10	BRL	BRL	BRL
18	Rhizoma Alismatis	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	5.5	BRL	BRL	BRL
19	Rhizoma Atractylodis Macrocephalae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.17	BRL	BRL	BRL
20	Herba Plantaginis	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.11	BRL	BRL	BRL
21	Herba Plantaginis	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.13	BRL	BRL	BRL
22	Herba Scutellariae Barbatae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.08	BRL	BRL	BRL
23	Radix Adenophorae	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	0.15	BRL	BRL	BRL

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

24	Herba Cistanches	BRL																					
25	Radix Bupleuri	BRL																					
26	Rhizoma Curcumae	BRL																					
27	Rhizoma Cyperi	BRL																					
28	Rhizoma Curcumae Longae	BRL																					
29	Semen Trichosanthis	BRL																					
30	Fructus Evodiae	BRL																					
31	Fructus Alpiniae Oxyphyllae	BRL																					
32	Fructus Amomi Rotundus	BRL																					
33	Fructus Arctii	BRL																					
34	Fructus Aurantii	BRL																					
35	Radix Bupleuri	BRL																					
36	Myrrha	BRL																					
37	Olibanum	BRL																					
38	Rhizoma Cimicifugae	BRL																					
39	Caulis Clematidis Armandii	BRL																					
40	Fructus Aurantii	BRL																					
41	Myrrha	BRL																					
42	Olibanum	BRL																					
43	Herba Lycopi	BRL																					
44	Herba Centipedae	BRL																					
45	Herba Cistanches	BRL																					
46	Radix Asparagi	BRL																					
47	Cortex Albiziae	BRL																					
48	Rhizoma Dioscoreae Bulbiferae	BRL																					
49	Fructus Evodiae	BRL																					
50	Fructus Alpiniae Oxyphyllae	BRL																					
51	Fructus Arctii	BRL																					
52	Radix Asteris	BRL																					
53	Rhizoma Cyperi	BRL																					
54	Fructus Akebiae	BRL																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

55	Radix Curcumae	BRL																						
56	Caulis Polygoni Multiflori	BRL																						
57	Fructus Forsythiae	BRL																						
58	Floritum	BRL																						
59	Radix Stephaniae Tetrandrae	BRL																						
60	Fructus Forsythiae	BRL																						
61	Fructus Corni	BRL																						
62	Fructus Chebulae	BRL																						
63	Pericarpium Arecae	BRL																						
64	Rhizoma Homalomenae	BRL																						
65	Rhizoma Gastrodiae	BRL																						
66	Rhizoma et Radix Notopterygii	BRL																						
67	Caulis Polygoni Multiflori	BRL																						
68	Radix Curcumae	BRL																						
69	Herba Dianthi	BRL																						
70	Herba Cynomorii	BRL																						
71	Herba Cynomorii	BRL																						
72	Radix Codonopsis	BRL																						
73	Rhizoma et Radix Notopterygii	BRL																						
74	Rhizoma Ligustici	BRL																						
75	Fructus Corni	BRL																						
76	Fructus Chebulae	BRL																						
77	Radix Stephaniae Tetrandrae	BRL																						
78	Pericarpium Arecae	BRL																						
79	Rhizoma Homalomenae	BRL																						
80	Radix Codonopsis	BRL																						
81	Radix Astragali	BRL																						
82	Processed Radix Astragali	BRL																						
83	Herba Ecliptae	BRL																						
84	Herba Ephedrae	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

85	Herba Epimedii	BRL																						
86	Ramulus Mori	BRL																						
87	Radix Dipsaci	BRL																						
88	Radix et Rhizoma Rhei	BRL																						
89	Cortex Dictamni	BRL																						
90	Cortex Eucommiae	BRL																						
91	Caulis Tinosporae	BRL																						
92	Rhizoma Polygonati	BRL																						
93	Rhizoma Polygoni Cuspidati	BRL																						
94	Rhizoma Smilacis	BRL																						
95	Nux Prinsepiae	BRL																						
96	Fructus Ligustris Lucidi	BRL																						
97	Fructus Liquidambaris	BRL																						
98	Radix Ephedrae	BRL																						
99	Herba Ecliptae	BRL																						
100	Herba Ephedrae	BRL																						
101	Herba Epimedii	BRL																						
102	Ramulus Mori	BRL																						
103	Radix et Rhizoma Rhei	BRL																						
104	Cortex Dictamni	BRL																						
105	Cortex Eucommiae	BRL																						
106	Caulis Tinosporae	BRL																						
107	Rhizoma Polygonati	BRL																						
108	Rhizoma Polygoni Cuspidati	BRL																						
109	Rhizoma Smilacis	BRL																						
110	Nux Prinsepiae	BRL																						
111	Fructus Ligustris Lucidi	BRL																						
112	Fructus Liquidambaris	BRL																						
113	Radix Glehniae	BRL																						
114	Herba Euphorbiae Humifusae	BRL																						
115	Radix Ilicis Asprellae	BRL																						
116	Fructus Sophorae	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

117	Concha Margaritifera Usta	BRL																						
118	Herba Siegesbeckiae	BRL																						
119	Radix Gentianae Macrophyliae	BRL																						
120	Radix Glehniae	BRL																						
121	Radix Ilicis Asprellae	BRL																						
122	Radix Ilicis Pubescens	BRL																						
123	Caulis Bambusae in Taeniam	BRL																						
124	Fructus Psoraleae	BRL																						
125	Fructus Quisqualis	BRL																						
126	Fructus Rosae Laevigatae	BRL																						
127	Fructus Rubi	BRL																						
128	Fructus Schisandrae	BRL																						
129	Concha Arcae	BRL																						
130	Concha Haliotidis	BRL																						
131	Concha Meretricis seu Cyclinae	BRL																						
132	Concha Margaritifera Usta	BRL																						
133	Radix Gentianae Macrophyliae	BRL																						
134	Caulis Bambusae in Taeniam	BRL																						
135	Fructus Psoraleae	BRL																						
136	Fructus Rosae Laevigatae	BRL																						
137	Fructus Rubi	BRL																						
138	Fructus Schisandrae	BRL																						
139	Concha Arcae	BRL																						
140	Fructus Sophorae	BRL																						
141	Concha Haliotidis	BRL																						
142	Cortex Eucommiae	BRL																						
143	Herba Houttuyniae	BRL																						
144	Radix Linderae	BRL																						
145	Radix Ophiopogonis	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

146	Caulis Spatholobi	BRL																				
147	Caulis Perillae	BRL																				
148	Fructus Toosendan	BRL																				
149	Fructus Trichosanthis	BRL																				
150	Fructus Tsaoko	BRL																				
151	Fructus Viticis	BRL																				
152	Semen Celosiae	BRL																				
153	Radix Achyranthis Bidentatae	BRL																				
154	Radix Achyranthis Bidentatae	BRL																				
155	Caulis Perillae	BRL																				
156	Radix Ophiopogonis	BRL																				
157	Fructus Tribuli	BRL																				
158	Radix Paeoniae Alba	BRL																				
159	Caulis Lonicerae	BRL																				
160	Herba Dendrobii	BRL																				
161	Fructus Tribuli	BRL																				
162	Herba Houttuyniae	BRL																				
163	Radix Linderae	BRL																				
164	Radix Paeoniae Alba	BRL																				
165	Caulis Spatholobi	BRL																				
166	Fructus Toosendan	BRL																				
167	Fructus Trichosanthis	BRL																				
168	Crinis Carbonisatus	BRL																				
169	Fructus Tsaoko	BRL																				
170	Fructus Viticis	BRL																				
171	Radix Morindae Officinalis	BRL																				
172	Caulis Lonicerae	BRL																				
173	Radix Polygalae	BRL																				
174	Herba Lophatheri	BRL																				
175	Herba Lycopodii	BRL																				
176	Radix Paeoniae Rubra	BRL																				
177	Cortex Magnoliae Officinalis	BRL																				

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

178	Radix Peucedani	BRL																			
179	Radix Platycodi	BRL																			
180	Rhizoma Atractylodis Macrocephalae	BRL																			
181	Bulbus Fritillariae Thunbergii	BRL																			
182	Rhizoma Acori Tatarinowii	BRL																			
183	Rhizoma Anemarrhenae	BRL																			
184	Rhizoma Anemarrhenae	BRL																			
185	Flos Magnoliae	BRL																			
186	Rhizoma Belamcandae	BRL																			
187	Scorpio	BRL																			
188	Flos Rosae Chinensis	BRL																			
189	Flos Magnoliae Officinalis	BRL																			
190	Flos Jasmini	BRL																			
191	Radix Peucedani	BRL																			
192	Radix Polygalae	BRL																			
193	Rhizoma Chuanxiong	BRL																			
194	Pericarpium Trichosanthis	BRL																			
195	Herba Lophatheri	BRL																			
196	Herba Lycopodii	BRL																			
197	Cortex Magnoliae Officinalis	BRL																			
198	Radix Platycodi	BRL																			
199	Bulbus Fritillariae Thunbergii	BRL																			
200	Rhizoma Acori Tatarinowii	BRL																			
201	Polyporus	BRL																			
202	Radix Paeoniae Rubra	BRL																			
203	Herba Polygoni Chinensis	BRL																			
204	Radix Polygoni Multiflori	BRL																			
205	Herba Eupatorii	BRL																			
206	Radix Pseudostellariae	BRL																			
207	Flos Buddleiae	BRL																			
208	Radix Puerariae	BRL																			

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

209	Olibanum	BRL																						
210	Receptaculum Nelumbinis	BRL																						
211	Radix Rehmanniae	BRL																						
212	Herba Polygoni Chinensis	BRL																						
213	Radix Polygoni Multiflori	BRL																						
214	Radix Pseudostellariae	BRL																						
215	Radix Puerariae	BRL																						
216	Radix Ranunculus Ternati	BRL																						
217	Rhizoma Bletillae	BRL																						
218	Rhizoma Cibotii	BRL																						
219	Rhizoma Corydalis	BRL																						
220	Rhizoma Curculiginis	BRL																						
221	Receptaculum Nelumbinis	BRL																						
222	Stamen Nelumbinis	BRL																						
223	Semen Allii Tuberosi	BRL																						
224	Myrrha	BRL																						
225	Olibanum	BRL																						
226	Semen Lini	BRL																						
227	Herba Eupatorii	BRL																						
228	Flos Buddlejae	BRL																						
229	Rhizoma Cibotii	BRL																						
230	Rhizoma Corydalis	BRL																						
231	Radix Ranunculus Ternati	BRL																						
232	Radix Pseudostellariae	BRL																						
233	Radix Salviae Miltiorrhizae	BRL																						
234	Radix Saposhnikoviae	BRL																						
235	Radix Scrophulariae	BRL																						
236	Radix Sophorae Flavescentis	BRL																						
237	Semen Arecae	BRL																						
238	Semen Cassiae	BRL																						
239	Semen Cuscutae	BRL																						
240	Spica Prunellae	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

241	Radix Stemonae	BRL																			
242	Radix Rubiae	BRL																			
243	Semen Astragali Complanati	BRL																			
244	Halloysitum Rubrum	BRL																			
245	Radix Scutellariae	BRL																			
246	Cacumen Platycladi	BRL																			
247	Rhizoma Curcumae Longae	BRL																			
248	Herba Pyrolae	BRL																			
249	Radix Sanguisorbae	BRL																			
250	Radix Rubiae	BRL																			
251	Radix Scutellariae	BRL																			
252	Radix Sophorae Flavescentis	BRL																			
253	Radix Stemonae	BRL																			
254	Semen Cassiae	BRL																			
255	Radix Saposhnikoviae	BRL																			
256	Radix Scrophulariae	BRL																			
257	Semen Cuscutae	BRL																			
258	Radix Pseudostellariae	BRL																			
259	Semen Arecae	BRL																			
260	Spica Prunellae	BRL																			
261	Radix Trichosanthis	BRL																			
262	Cortex Albiziae	BRL																			
263	Rhizoma Homalomenae	BRL																			
264	Semen Platycladi	BRL																			
265	Semen Sinapis	BRL																			
266	Semen Sterculiae Lychnoporae	BRL																			
267	Rhizoma Spargani	BRL																			
268	Radix Clematidis	BRL																			
269	Ramulus Cinnamomi	BRL																			
270	Rhizoma Ligustici	BRL																			
271	Cortex Albiziae	BRL																			
272	Rhizoma Gastrodiae	BRL																			

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

273	Rhizoma Spargani	BRL																			
274	Semen Oroxyl	BRL																			
275	Radix Clematidis	BRL																			
276	Rhizoma et Radix Notopterygii	BRL																			
277	Radix Trichosanthis	BRL																			
278	Semen Plantaginis	BRL																			
279	Caulis Polygoni Multiflori	BRL																			
280	Semen Persicae	BRL																			
281	Semen Platycladi	BRL																			
282	Semen Sterculiae Lychnoporae	BRL																			
283	Herba Lysimachiae	BRL																			
284	Rhizoma Gastrodiae	BRL																			
285	Ramulus Cinnamomi	BRL																			
286	Caulis Polygoni Multiflori	BRL																			
287	Rhizoma Ligustici	BRL																			
288	Semen Oroxyl	BRL																			
289	Semen Plantaginis	BRL																			
290	Herba Taxillii	BRL																			
291	Folium Artemisiae Argyi	BRL																			
292	Radix Angelicae Pubescens	BRL																			
293	Cortex Moutan	BRL																			
294	Cortex Phellodendri	BRL																			
295	processed Radix Aconiti Lateralis	BRL																			
296	Caulis Tinosporae	BRL																			
297	Rhizoma Polygonati	BRL																			
298	Rhizoma Polygoni Cuspidati	BRL																			
299	Semen Trichosanthis	BRL																			
300	Fructus Alpiniae Oxyphyllae	BRL																			
301	Fructus Arctii	BRL																			
302	Concha Arcae	BRL																			

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

303	Concha Haliotidis	BRL																			
304	Concha Margaritifera Usta	BRL																			
305	Concha Meretricis seu Cyclinae	BRL																			
306	Herba Taxilli	BRL																			
307	Folium Artemisiae Argyi	BRL																			
308	Radix Astragali	BRL																			
309	Radix Angelicae Pubescens	BRL																			
310	Cortex Moutan	BRL																			
311	Cortex Phellodendri	BRL																			
312	processed Radix Aconiti Lateralis	BRL																			
313	Caulis Tinosporae	BRL																			
314	Rhizoma Polygonati	BRL																			
315	Semen Trichosanthis	BRL																			
316	Fructus Amomi Rotundus	BRL																			
317	Fructus Arctii	BRL																			
318	Concha Haliotidis	BRL																			
319	Rhizoma Smilacis	BRL																			
320	Radix Astragali	BRL																			
321	Radix Adenophorae	BRL																			
322	Cortex Mori	BRL																			
323	Medulla Tetrapanacis	BRL																			
324	Radix Angelicae Sinensis	BRL																			
325	Fructus Corni	BRL																			
326	Fructus Chebulae	BRL																			
327	Herba Verbenae	BRL																			
328	Fructus Cnidii	BRL																			
329	Fructus Chebulae	BRL																			
330	Pericarpium Arecae	BRL																			
331	Fructus Broussonetiae	BRL																			
332	Caulis Entadae	BRL																			
333	Caulis Bambusae in Taeniam	BRL																			

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

334	Caums Ampelopsis Brevipeduncula	BRL																						
335	Radix Acanthopanaxis Senticosi	BRL																						
336	Radix Angelicae Sinensis	BRL																						
337	Medulla Tetrapanaxis	BRL																						
338	Cortex Mori	BRL																						
339	Folium et Cacumen Breyoniae Fruticosae	BRL																						
340	Faeces Trogopteroni	BRL																						
341	Herba Paederiae	BRL																						
342	Ootheca Mantidis	BRL																						
343	Hirudo	BRL																						
344	Galla Chinensis	BRL																						
345	Crinis Carbonisatus	BRL																						
346	Cornu Cervi Degelatinatum	BRL																						
347	Fructus Forsythiae	BRL																						
348	Radix Asparagi	BRL																						
349	Radix Asteris	BRL																						
350	Cortex Albiziae	BRL																						
351	Radix Bupleuri	BRL																						
352	Caulis Spatholobi	BRL																						
353	Fructus Ligustri Lucidi	BRL																						
354	Nux Prinsepiae	BRL																						
355	Herba Equiseti Hiemalis	BRL																						
356	Folium Sennae	BRL																						
357	Radix Changii	BRL																						
358	Radix Bupleuri	BRL																						
359	Cortex Albiziae	BRL																						
360	Radix Asparagi	BRL																						
361	Radix Asteris	BRL																						
362	Caulis Perillae	BRL																						
363	Caulis Spatholobi	BRL																						
364	Nux Prinsepiae	BRL																						
365	Fructus Ligustri Lucidi	BRL																						
366	Fructus Liquidambaris	BRL																						
367	Polyporus	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

368	Radix Gentianae	BRL																						
369	Herba Equiseti Hiemalis	BRL																						
370	Caulis Perillae	BRL																						
371	Radix Cynanchi Paniculati	BRL																						
372	Fructus Liquidambaris	BRL																						
373	Lasiosphaera seu Calvata	BRL																						
374	Caulis Lonicerae	BRL																						
375	Radix Isatidis	BRL																						
376	Semen Vaccariae	BRL																						
377	Polyporus	BRL																						
378	Cortex Lycii	BRL																						
379	Semen Persicae	BRL																						
380	Lasiosphaera seu Calvata	BRL																						

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

Result of Second Stage Testing of Pesticide Residues in Chinese Herbal Medicines Samples (Year 2016) (Unit: mg/kg)

	Name of Chinese herbal medicines	Aldrin and dieldrin (Permitted level: 0.05)	Organochlorine												Organophosphate (Permitted level: Should not be detected)												Meditation
			DDE	DDT	Heptachlor	Heptachlor (Permitted level: 0.1)	Hexachlorobenzene (Permitted level: 0.1)	Hexachlorocyclohexane (Permitted level: 0.3)	Quintozone (Permitted level: 1.0)	Lindan (Permitted level: 0.6)	Dichlorvos	Methamidophos	Trichlorphon	o-methoate	Diazinon	Dimethoate	Malathion	Isocarbophos	Triazophos	Parathion	Parathion-methyl	Monocrotophos	Phosphanidon	Chlorpyriphos	Acephate	Ethion	
1	Nidus Vesiae	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
2	Radix Rehmanniae	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
3	Radix Panacis Quinquefolii	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
4	Herba Dianthi	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
5	Herba Artemisiae Scopariae	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
6	Herba Artemisiae Scopariae	NA	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
7	Radix Notoginseng	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
8	Radix Notoginseng	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
9	Rhizoma et Radix Notopterygii	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
10	Fructus Kochiae	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
11	Fructus Corni	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
12	Fructus Cnidii	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
13	Fructus Cnidii	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
14	Fructus Aurantii Immaturus	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
15	Fructus Aurantii Immaturus	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
16	Fructus Aurantii Immaturus	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
17	Fructus Aurantii Immaturus	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
18	Rhizoma Alismatis	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
19	Rhizoma Attractylodis Macrocephalae	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
20	Herba Plantaginis	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
21	Herba Plantaginis	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
22	Herba Scutellariae Barbatae	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	
23	Radix Adenophorae	NA	NA	NA	NA	NA	NA	NA	NA	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	BRL	

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

24	Herba Cistanches	NA																					
25	Radix Bupleuri	NA																					
26	Rhizoma Curcumae	NA																					
27	Rhizoma Cyperi	NA																					
28	Rhizoma Curcumae Longae	NA																					
29	Semen Trichosanthis	NA																					
30	Fructus Evodiae	NA																					
31	Fructus Alpiniae Oxyphyllae	NA																					
32	Fructus Amomi Rotundus	NA																					
33	Fructus Arctii	NA																					
34	Fructus Aurantii	NA																					
35	Radix Bupleuri	NA																					
36	Myrrha	NA																					
37	Olibanum	NA																					
38	Rhizoma Cimicifugae	NA																					
39	Caulis Clematidis Armandii	NA																					
40	Fructus Aurantii	NA																					
41	Myrrha	NA																					
42	Olibanum	NA																					
43	Herba Lycopi	NA																					
44	Herba Centipedae	NA																					
45	Herba Cistanches	NA																					
46	Radix Asparagi	NA																					
47	Cortex Albiziae	NA																					
48	Rhizoma Dioscoreae Bulbiferae	NA																					
49	Fructus Evodiae	NA																					
50	Fructus Alpiniae Oxyphyllae	NA																					
51	Fructus Arctii	NA																					
52	Radix Asteris	NA																					
53	Rhizoma Cyperi	NA																					
54	Fructus Akebiae	NA																					
55	Radix Curcumae	NA																					
56	Caulis Polygoni Multiflori	NA																					
57	Fructus Forsythiae	NA																					
58	Floritum	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

59	Radix Stephaniae Tetrandrae	NA																					
60	Fructus Forsythiae	NA																					
61	Fructus Corni	NA																					
62	Fructus Chebulae	NA																					
63	Pericarpium Arecae	NA																					
64	Rhizoma Homalomenae	NA																					
65	Rhizoma Gastrodiae	NA																					
66	Rhizoma et Radix Notopterygii	NA																					
67	Caulis Polygoni Multiflori	NA																					
68	Radix Curcumae	NA																					
69	Herba Dianthi	NA																					
70	Herba Cynomorii	NA																					
71	Herba Cynomorii	NA																					
72	Radix Codonopsis	NA																					
73	Rhizoma et Radix Notopterygii	NA																					
74	Rhizoma Ligustici	NA																					
75	Fructus Corni	NA																					
76	Fructus Chebulae	NA																					
77	Radix Stephaniae Tetrandrae	NA																					
78	Pericarpium Arecae	NA																					
79	Rhizoma Homalomenae	NA																					
80	Radix Codonopsis	NA																					
81	Radix Astragali	NA																					
82	Processed Radix Astragali	NA																					
83	Herba Ecliptae	NA																					
84	Herba Ephedrae	NA																					
85	Herba Epimedii	NA																					
86	Ramulus Mori	NA																					
87	Radix Dipsaci	NA																					
88	Radix et Rhizoma Rhei	NA																					
89	Cortex Dictamni	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

90	Cortex Eucommiae	NA																				
91	Caulis Tinosporae	NA																				
92	Rhizoma Polygonati	NA																				
93	Rhizoma Polygoni Cuspidati	NA																				
94	Rhizoma Smilacis Glabrae	NA																				
95	Nux Prinsepiae	NA																				
96	Fructus Ligustri Lucidi	NA																				
97	Fructus Liquidambaris	NA																				
98	Radix Ephedrae	NA																				
99	Herba Ecliptae	NA																				
100	Herba Ephedrae	NA																				
101	Herba Epimedii	NA																				
102	Ramulus Mori	NA																				
103	Radix et Rhizoma Rhei	NA																				
104	Cortex Dictamni	NA																				
105	Cortex Eucommiae	NA																				
106	Caulis Tinosporae	NA																				
107	Rhizoma Polygonati	NA																				
108	Rhizoma Polygoni Cuspidati	NA																				
109	Rhizoma Smilacis Glabrae	NA																				
110	Nux Prinsepiae	NA																				
111	Fructus Ligustri Lucidi	NA																				
112	Fructus Liquidambaris	NA																				
113	Radix Glehniae	NA																				
114	Herba Euphorbiae Humifusae	NA																				
115	Radix Ilicis Asprellae	NA																				
116	Fructus Sophorae	NA																				
117	Concha Margaritifera Usta	NA																				
118	Herba Siegesbeckiae	NA																				
119	Radix Gentianae Macrophylla	NA																				
120	Radix Glehniae	NA																				

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

121	Radix Ilicis Asprellae	NA																					
122	Radix Ilicis Pubescentis	NA																					
123	Caulis Bambusae in Taeniam	NA																					
124	Fructus Psoraleae	NA																					
125	Fructus Quisqualis	NA																					
126	Fructus Rosae Laevigatae	NA																					
127	Fructus Rubi	NA																					
128	Fructus Schisandrae	NA																					
129	Concha Arcae	NA																					
130	Concha Haliotidis	NA																					
131	Concha Meretricis seu Cyclinae	NA																					
132	Concha Margaritifera Usta	NA																					
133	Radix Gentianae Macrophyllae	NA																					
134	Caulis Bambusae in Taeniam	NA																					
135	Fructus Psoraleae	NA																					
136	Fructus Rosae Laevigatae	NA																					
137	Fructus Rubi	NA																					
138	Fructus Schisandrae	NA																					
139	Concha Arcae	NA																					
140	Fructus Sophorae	NA																					
141	Concha Haliotidis	NA																					
142	Cortex Eucommiae	NA																					
143	Herba Houttuyniae	NA																					
144	Radix Linderae	NA																					
145	Radix Ophiopogonis	NA																					
146	Caulis Spatholobi	NA																					
147	Caulis Perillae	NA																					
148	Fructus Toosendan	NA																					
149	Fructus Trichosanthis	NA																					
150	Fructus Tsaoko	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

151	Fructus Viticis	NA																					
152	Semen Celosiae	NA																					
153	Radix Achyranthis Bidentatae	NA																					
154	Radix Achyranthis Bidentatae	NA																					
155	Caulis Perillae	NA																					
156	Radix Ophiopogonis	NA																					
157	Fructus Tribuli	NA																					
158	Radix Paeoniae Alba	NA																					
159	Caulis Lonicerae	NA																					
160	Herba Dendrobii	NA																					
161	Fructus Tribuli	NA																					
162	Herba Houttuyniae	NA																					
163	Radix Linderae	NA																					
164	Radix Paeoniae Alba	NA																					
165	Caulis Spatholobi	NA																					
166	Fructus Toosendan	NA																					
167	Fructus Trichosanthis	NA																					
168	Crinis Carbonisatus	NA																					
169	Fructus Tsaoko	NA																					
170	Fructus Viticis	NA																					
171	Radix Morindae Officinalis	NA																					
172	Caulis Lonicerae	NA																					
173	Radix Polygalae	NA																					
174	Herba Lophatheri	NA																					
175	Herba Lycopodii	NA																					
176	Radix Paeoniae Rubra	NA																					
177	Cortex Magnoliae Officinalis	NA																					
178	Radix Peucedani	NA																					
179	Radix Platycodi	NA																					
180	Rhizoma Atractylodis Macrocephalae	NA																					
181	Bulbus Fritillariae Thunbergii	NA																					
182	Rhizoma Acori Tatarinowii	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

183	Rhizoma Anemarrhenae	NA																					
184	Rhizoma Anemarrhenae	NA																					
185	Flos Magnoliae	NA																					
186	Rhizoma Belamcandae	NA																					
187	Scorpio	NA																					
188	Flos Rosae Chinensis	NA																					
189	Flos Magnolia Officinalis	NA																					
190	Flos Jasmini	NA																					
191	Radix Peucedani	NA																					
192	Radix Polygalae	NA																					
193	Rhizoma Chuanxiong	NA																					
194	Pericarpium Trichosanthis	NA																					
195	Herba Lophatheri	NA																					
196	Herba Lycopodii	NA																					
197	Cortex Magnoliae Officinalis	NA																					
198	Radix Platycodi	NA																					
199	Bulbus Fritillariae Thunbergii	NA																					
200	Rhizoma Acori Tatarinowii	NA																					
201	Polyporus	NA																					
202	Radix Paeoniae Rubra	NA																					
203	Herba Polygoni Chinensis	NA																					
204	Radix Polygoni Multiflori	NA																					
205	Herba Eupatorii	NA																					
206	Radix Pseudostellariae	NA																					
207	Flos Buddleiae	NA																					
208	Radix Puerariae	NA																					
209	Olibanum	NA																					
210	Receptaculum Nelumbinis	NA																					
211	Radix Rehmanniae	NA																					
212	Herba Polygoni Chinensis	NA																					
213	Radix Polygoni Multiflori	NA																					
214	Radix Pseudostellariae	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

215	Radix Puerariae	NA																					
216	Radix Ranunculus Ternati	NA																					
217	Rhizoma Bletillae	NA																					
218	Rhizoma Cibotii	NA																					
219	Rhizoma Corydalis	NA																					
220	Rhizoma Curculiginis	NA																					
221	Receptaculum Nelumbinis	NA																					
222	Stamen Nelumbinis	NA																					
223	Semen Allii Tuberosi	NA																					
224	Myrrha	NA																					
225	Olibanum	NA																					
226	Semen Lini	NA																					
227	Herba Eupatorii	NA																					
228	Flos Buddleiae	NA																					
229	Rhizoma Cibotii	NA																					
230	Rhizoma Corydalis	NA																					
231	Radix Ranunculus Ternati	NA																					
232	Radix Pseudostellariae	NA																					
233	Radix Salviae Miltiorrhizae	NA																					
234	Radix Saposhnikoviae	NA																					
235	Radix Scrophulariae	NA																					
236	Radix Sophorae Flavescentis	NA																					
237	Semen Arecae	NA																					
238	Semen Cassiae	NA																					
239	Semen Cuscutae	NA																					
240	Spica Prunellae	NA																					
241	Radix Stemoneae	NA																					
242	Radix Rubiae	NA																					
243	Semen Astragali Complanati	NA																					
244	Halloysitum Rubrum	NA																					
245	Radix Scutellariae	NA																					
246	Cacumen Platycladi	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

247	Rhizoma Curcumae Longae	NA																				
248	Herba Pyrolae	NA																				
249	Radix Sanguisorbae	NA																				
250	Radix Rubiae	NA																				
251	Radix Scutellariae	NA																				
252	Radix Sophorae Flavescens	NA																				
253	Radix Stemoneae	NA																				
254	Semen Cassiae	NA																				
255	Radix Saposhnikoviae	NA																				
256	Radix Scrophulariae	NA																				
257	Semen Cuscutae	NA																				
258	Radix Pseudostellariae	NA																				
259	Semen Arecae	NA																				
260	Spica Prunellae	NA																				
261	Radix Trichosanthis	NA																				
262	Cortex Albiziae	NA																				
263	Rhizoma Homalomenae	NA																				
264	Semen Platycladi	NA																				
265	Semen Sinapis	NA																				
266	Semen Sterculiae Lychnoporae	NA																				
267	Rhizoma Sparganii	NA																				
268	Radix Clematidis	NA																				
269	Ramulus Cinnamomi	NA																				
270	Rhizoma Ligustici	NA																				
271	Cortex Albiziae	NA																				
272	Rhizoma Gastrodiae	NA																				
273	Rhizoma Sparganii	NA																				
274	Semen Oroxyli	NA																				
275	Radix Clematidis	NA																				
276	Rhizoma et Radix Notopterygii	NA																				
277	Radix Trichosanthis	NA																				

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

278	Semen Plantaginis	NA																					
279	Caulis Polygoni Multiflori	NA																					
280	Semen Persicae	NA																					
281	Semen Platycladi	NA																					
282	Semen Sterculiae Lychnoporae	NA																					
283	Herba Lysimachiae	NA																					
284	Rhizoma Gastrodiae	NA																					
285	Ramulus Cinnamomi	NA																					
286	Caulis Polygoni Multiflori	NA																					
287	Rhizoma Ligustici	NA																					
288	Semen Oroxyli	NA																					
289	Semen Plantaginis	NA																					
290	Herba Taxilli	NA																					
291	Folium Artemisiae Argyi	NA																					
292	Radix Angelicae Pubescentis	NA																					
293	Cortex Moutan	NA																					
294	Cortex Phellodendri	NA																					
295	processed Radix Aconiti Lateralis	NA																					
296	Caulis Tinosporae	NA																					
297	Rhizoma Polygonati	NA																					
298	Rhizoma Polygoni Cuspidati	NA																					
299	Semen Trichosanthis	NA																					
300	Fructus Alpiniae Oxyphyllae	NA																					
301	Fructus Arctii	NA																					
302	Concha Arcæ	NA																					
303	Concha Haliotidis	NA																					
304	Concha Margaritifera Usta	NA																					
305	Concha Meretricis seu Cyclinae	NA																					
306	Herba Taxilli	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

307	Folium Artemisiae Argyi	NA																					
308	Radix Astragali	NA																					
309	Radix Angelicae Pubescens	NA																					
310	Cortex Moutan	NA																					
311	Cortex Phellodendri	NA																					
312	processed Radix Aconiti Lateralis	NA																					
313	Caulis Tinosporae	NA																					
314	Rhizoma Polygonati	NA																					
315	Semen Trichosanthis	NA																					
316	Fructus Amomi Rotundus	NA																					
317	Fructus Arctii	NA																					
318	Concha Haliotidis	NA																					
319	Rhizoma Smilacis Glabrae	NA																					
320	Radix Astragali	NA																					
321	Radix Adenophorae	NA																					
322	Cortex Mori	NA																					
323	Medulla Tetrapanacis	NA																					
324	Radix Angelicae Sinensis	NA																					
325	Fructus Corni	NA																					
326	Fructus Chebulae	NA																					
327	Herba Verbena	NA																					
328	Fructus Cnidii	NA																					
329	Fructus Chebulae	NA																					
330	Pericarpium Arecae	NA																					
331	Fructus Broussonetiae	NA																					
332	Caulis Entadae	NA																					
333	Caulis Bambusae in Taeniam	NA																					
334	Caulis Ampelopsis Brevipedunculæ	NA																					
335	Radix Acanthopanax Senticosi	NA																					
336	Radix Angelicae Sinensis	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

337	Medulla Tetrapanacis	NA																					
338	Cortex Mori	NA																					
339	Folium et Cacumen Breyniae Fruticosae	NA																					
340	Faeces Trogopteroni	NA																					
341	Herba Paederiae	NA																					
342	Ootheca Mantidis	NA																					
343	Hirudo	NA																					
344	Galla Chinensis	NA																					
345	Crinis Carbonisatus	NA																					
346	Cornu Cervi Degelatinatum	NA																					
347	Fructus Forsythiae	NA																					
348	Radix Asparagi	NA																					
349	Radix Asteris	NA																					
350	Cortex Albiziae	NA																					
351	Radix Bupleuri	NA																					
352	Caulis Spatholobi	NA																					
353	Fructus Ligustri Lucidi	NA																					
354	Nux Prinsepiae	NA																					
355	Herba Equiseti Hiemalis	NA																					
356	Folium Sennae	NA																					
357	Radix Changii	NA																					
358	Radix Bupleuri	NA																					
359	Cortex Albiziae	NA																					
360	Radix Asparagi	NA																					
361	Radix Asteris	NA																					
362	Caulis Perillae	NA																					
363	Caulis Spatholobi	NA																					
364	Nux Prinsepiae	NA																					
365	Fructus Ligustri Lucidi	NA																					
366	Fructus Liquidambaris	NA																					
367	Polyporus	NA																					
368	Radix Gentianae	NA																					
369	Herba Equiseti Hiemalis	NA																					
370	Caulis Perillae	NA																					
371	Radix Cynanchi Paniculati	NA																					

BRL: Below reporting limit (低於報告限值) NA: Not applicable (不適用)

372	Fructus Liquidambaris	NA																						
373	Lasiosphaera seu Calvatia	NA																						
374	Caulis Lonicerae	NA																						
375	Radix Isatidis	NA																						
376	Semen Vaccariae	NA																						
377	Polyporus	NA																						
378	Cortex Lycii	NA																						
379	Semen Persicae	NA																						
380	Lasiosphaera seu Calvatia	NA																						

Appendix 5

Quality reference limits of heavy metals content and pesticides residues in Chinese herbal medicines set out by the Hong Kong Chinese Materia Medica Standards

Limits of organochlorine pesticide residues

	Chinese name	English name	Test parameters (20 items in total)	Maximum residue limit (mg/kg)
1	艾氏劑及狄氏劑	Aldrin & Dieldrin	Sum of Aldrin and Dieldrin	0.05
2	氯丹	Chlordane	Sum of cis-chlordanne, trans-chlordanne and oxychlordanne	0.05
3	滴滴涕	DDT	Sum of p,p'-DDT, o,p'-DDT, p,p'-DDE and p,p'-TDE	1.0
4	異狄氏劑	Endrin	endrin	0.05
5	七氯	Heptachlor	Sum of heptachlor and heptachlor epoxide	0.05
6	六氯苯	Hexachlorobenzene	hexachlorobenzene	0.1
7	六六六	Hexachlorocyclohexane	Sum of α-, β- and δ-isomers	0.3
8	林丹	Lindane	lindane	0.6
9	五氯硝基苯	Quintozene	Sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide	1.0

Limits of heavy metals

Chinese name	English name	Limit (Not more than)
砷	Arsenic	2.0 mg/kg
鎘	Cadmium	1.0 mg/kg*
鉛	Lead	5.0 mg/kg
汞	Mercury	0.2 mg/kg

*According to the Hong Kong Chinese Materia Medica Standards (Voumve 7), the limits for cadmium in 4 raw herbs including Rhizoma Drynariae, Cortex Ilicis Rotundae, Herba Centellae and Folium Ilicis Cornutae are not more than 2.5 mg/kg, 5.5 mg/kg, 5.5 mg/g and 6.0 mg/kg respectively.

Appendix 6

Comparison of regulation of heavy metals in other places

Country / Region	Scope	Total heavy metals content limit (mg/kg)	Individual heavy metal content limit (mg/kg)				
			Lead	Cadmium	Arsenic	Mercury	Copper
China	27 herbal medicine	10-40	5-10	0.3-5	2-20	0.1-1	20
ASEAN (Except Singapore)	Traditional herbal medicines and health supplements	Not applicable	10	0.3	5	0.5	Not applicable
Singapore	Traditional herbal medicines	Not applicable	20	Not applicable	5	0.5	150

Appendix 7

The requirement of heavy metals content limits in the “Chinese Pharmacopoeia 2015”

	Herbs	Total heavy metal content limit (mg/kg)	Individual heavy metal content limit (mg/kg)				
			Lead	Cadmium	Arsenic	Mercury	Copper
1	山楂 (Crataegi Fructus)	Not applicable	5	0.3	2	0.2	20
2	丹參 (Radix Salviae Miltiorrhizae)	Not applicable	5	0.3	2	0.2	20
3	水蛭(Hirudo)	Not applicable	10	1	5	1	Not applicable
4	甘草(Glycyrrhizae Radix et Rhizoma)	Not applicable	5	0.3	2	0.2	20
5	石膏(Gypsum Fibrosum)	10	Not applicable	Not applicable	2	Not applicable	Not applicable
6	煅石膏 (Gypsum Fibrosum Preparata)	10	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
7	白芍 (Radix Paeoniae Alba)	Not applicable	5	0.3	2	0.2	20
8	白礬(Alumen)	20	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
9	玄明粉 (Natrii Sulfas Exsiccatus)	20	Not applicable	Not applicable	20	Not applicable	Not applicable
10	地龍(Pheretima)	30	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
11	西瓜霜(Mirabilitum Praeparatum)	10	Not applicable	Not applicable	10	Not applicable	Not applicable
12	西洋參(Radix Panacis Quinquefolii)	Not applicable	5	0.3	2	0.2	20
13	冰片(合成龍腦)(Borneolum Syntheticum)	5	Not applicable	Not applicable	2	Not applicable	Not applicable
14	牡蠣(Ostreae Concha)	Not applicable	5	0.3	2	0.2	20
15	龜甲膠(Testudinis Carapacis et Plastri Colla)	30	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
16	阿膠(Colla Corii Asini)	Not applicable	5	0.3	2	0.2	20
17	昆布(Laminariae Thallus Eckloniae Thallus)	Not applicable	5	4	Not applicable	0.1	20
18	金銀花(Lonicerae Japonicae Flos)	Not applicable	5	0.3	2	0.2	20
19	珍珠(Margarita)	Not applicable	5	0.3	2	0.2	20
20	枸杞子(Lycii Fructus)	Not applicable	5	0.3	2	0.2	20
21	海螵蛸(Sepiae Endoconcha)	Not applicable	5	5	10	0.2	20
22	海藻(Sargassum)	Not applicable	5	4	Not applicable	0.1	20
23	黃芪(Radix Astragali)	Not applicable	5	0.3	2	0.2	20
24	鹿角膠(Cervi Cornus Colla)	30	Not applicable	Not applicable	2	Not applicable	Not applicable
25	蛤殼(Concha Meretricis seu Cyclinae)	Not applicable	5	0.3	2	0.2	20
26	滑石粉(Talci Pulvis)	40	Not applicable	Not applicable	2	Not applicable	Not applicable
27	蜂膠(Propolis)	Not applicable	8	Not applicable	Not applicable	Not applicable	Not applicable