中華人民共和國香港特別行政區政府總部食物及衞生局
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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22 September 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 17 July 2017 and the enquiry set out in the letter from member Dr Hon Helena Wong Pik-wan to the Chairman dated 11 September 2017, the Government has provided at the Annex the reference materials for the enquiries concerned.

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)

Annex

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Government's response to the issues raised at the Bills Committee meeting on 17 July 2017

Purpose

This paper sets out the Government's response to the issues raised on the Chinese Medicine (Amendment) Bill 2017 at the Bills Committee meeting on 17 July 2017.

Regulation of Chinese medicines traders

(a) List of licensed Chinese medicines traders

2. According to the Chinese Medicine Ordinance (Cap. 549) (CMO), any persons who wish to engage in the business of retail or wholesale of Chinese herbal medicines (Chms), as well as wholesale or manufacturing of proprietary Chinese medicines (pCms), must apply for the relevant licence from the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMCHK). They can commence the business only after obtaining the relevant licence. The lists of licensed Chinese medicines traders have been uploaded on the CMCHK's website (http://www.cmchk.org.hk/pcm/chi/#main_dislist.htm) for public reference.

3. As at 31 July 2017, there were a total of 6,910 licensed Chinese medicines traders. A breakdown by the type of licences is as follows:

Types of Chinese medicines traders	Number
Retailer of Chms	4,688
Wholesaler of Chms	937
Wholesaler of pCms	1,013
Manufacturer of pCms	272[#]
Total	**6,910**

[#] Of which, 18 manufacturers of pCms are also holders of Certificate for Manufacturer (certifying that they follow the requirements of the Good Manufacturing Practice (GMP) in the manufacture and quality control of pCms).

(b) Recall Guidelines for Chinese Medicine Products published by the CMCHK

4. The CMB published the Recall Guidelines for Chinese Medicine Products to assist wholesalers of Chms, wholesalers of pCms and manufacturers of pCms to set up an efficient system for recalling Chinese medicine products, so as to enable as far as practicable the rapid recall of any Chinese medicine products sold or distributed in the event of such products being found to be dangerous, injurious to health or unfit for human consumption. The relevant guidelines are provided at **Annex I**.

Regulation of Chms

(c) Discussion on the maximum permitted limits of heavy metals and pesticide residues of Chms by the International Advisory Board (IAB), and the membership of the IAB

5. The Department of Health (DH) launched the Hong Kong Chinese Materia Medica Standards (HKCMMS) Project in 2002, and has developed the reference standards in respect of the safety and quality of more than 270 kinds of commonly used Chinese Materia Medica.

6. The IAB under the HKCMMS is comprised of local, the Mainland and international renowned experts (the list of membership is provided at **Annex II**). The IAB was established to give advice on the principles, methodologies, parameters and analytical methods for the development of HKCMMS standards. It also identifies suitable research institutions to take up research and laboratory work and determine the target herbs for research, evaluates and endorses the results, and decides the content of the HKCMMS.

7. The IAB will critically examine the results of scientific research in respect of each type of Chm. Based on the results, a set of standards will be developed, setting out the specifications of Chms, which cover the source, description, identification, assay and tests (namely on the limits of heavy metals, pesticide residues, mycotoxins, foreign matter, ash and determination of water). As regards heavy metals, although the IAB has developed general standards on heavy metals (including arsenic, cadmium, lead and mercury) in respect of each type of Chms, the limits of heavy metal contents in Chms will also be adjusted subject to the results of respective scientific research through risk assessment as appropriate. Take the limits of cadmium as an example, according to the existing HKCMMS, the level of cadmium in Chms shall not exceed 1.0mg/kg. Nevertheless, given that a certain amount of cadmium will be absorbed by and retained in certain types of Chms, and taking into account the therapeutic purpose, usage and dosage of different types of Chms, the limits of cadmium in Chms have been adjusted having regard to the results of respective scientific research and risk assessment. The results of relevant researches and methods for setting standards have provided important and local evidence-based information for the development of reference standards on the safety and quality of Chms.

8. The IAB will also timely review the testing methods and limits of heavy metal contents and pesticide residues in Chms.

(d) Information on Market Surveillance of Chms by the DH

(i) Number of Chm samples collected for testing over the past two years, the sources from which such samples were taken and the types of Chms covered by the samples

9. To monitor the quality and safety of the Chms regulated under the CMO, the DH has put in place a market surveillance system under which samples of Chms are collected from the market for testing on a regular basis. At present, the DH adopts a two-pronged approach for testing Chms. Firstly, the DH draws samples of around 45 Chms[1] every

[1] Number of Chm samples to be taken for testing has increased from about 30 to 45 per month starting from February 2017.

month from the market for testing under its regular market surveillance system. Secondly, targeted tests are conducted on Chm samples obtained from other channels, including adverse drug reaction reporting system, public complaints and referrals from other government departments.

10. From January 2015 to the end of June 2017, the number of Chm samples collected by the DH under its regular market surveillance system is as follows:

Year	Regular market surveillance			
	Number of samples taken	Number of Chms involved	Types of Chms involved*	Percentage**
2015	377	377	173	58%
2016	380	380	193	64%
2017 (as at the end of June)	258	258	125	42%

Note：*Some types of samples were collected from the market more than once.

**Based on 300 types of Chms currently available in the local market.

11. From January 2015 to late June 2017, the number of Chm samples^ collected by the DH for targeted tests is as follows:

Year	Targeted test		
	Number of samples taken#	Number of Chms involved^	Types of Chms involved
2015	72	152	77
2016	98	253	76
2017 (as at late June)	31	94	57

Note：#Each sample may contain more than one type of Chms.

^Including Chms listed in Schedules 1 and 2 and other materials of herbal, animal or mineral origin customarily used by the Chinese under the guidance of Chinese medicine theories.

12. In 2015, the DH collected a total of 449 Chm samples, of which 70.1% was taken from Chm retailers, 5.3% from Chm wholesalers and 24.6% from other channels (e.g. patients of Chm poisoning, Chinese medicine clinics, etc). In 2016, the DH collected a total of 478 Chm samples, of which 80.9% was taken from Chm retailers and 19.1% from other channels. In 2017 (as at the end of June), the DH collected a total of 289 Chm samples, of which 64.8% was taken from Chm retailers, 18.5% from Chm wholesalers and 16.7% from other channels.

(ii) Testing items, methods and standards

13. Regulatory authorities around the world have not set limits on pesticide residue contents in Chms. The current standards used for testing of pesticide residues and heavy metals contents in Chms sold in Hong Kong 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, for examples the Pharmacopoeia of the People's Republic of China, the

United States Pharmacopoeia and the European Pharmacopoeia. Those standards are related to the testing of 37 pesticide residues (including 20 organochlorine pesticides and 17 organophosphorus pesticides) and 4 heavy metals contents (including lead, arsenic, cadmium and mercury) (see **Annex III**). To monitor the quality and safety of Chms regulated by the CMO, the CMCHK selected the above-mentioned 37 pesticides residues and 4 heavy metals for testing after considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally, with a view to protecting public health.

14. 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 HKCMMS research project. The testing of pesticide residues in Chms is carried out by the Government Laboratory, aiming to see if pesticide residues exist in the decoctions of the Chms, which simulates the condition during human consumption. The tests conducted by the Government Laboratory 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 limits of pesticide residues set by the CMB, no further testing will be conducted, otherwise the second stage tests will be needed to see if pesticide residues exist in the decoctions of the Chms concerned. Therefore, the results of the first stage test are for screening purpose only. It does not mean that the samples concerned will certainly have adverse effects on health. If the results of the second stage tests (i.e. tests of pesticide residues in the decoctions of the Chms) show that the limits of pesticide residues are exceeded, the DH will immediately conduct investigations and the associated risk management procedures.

15. As regards morphological identification of Chms, a standard will be formulated for each medicine, basing on statutory pharmacopoeias and authoritative publications such as the Pharmacopoeia of People's Republic of China, the Chinese Materia Medica and the Chinese Materia Medica Standards in Guangdong Province.

16. Items subject to regular testing include pesticide residues, heavy metal contents and morphological identification. Under the current mechanism, the DH draws about 45 samples of Chms a month for testing. Testing for pesticide residues (including 20 organochlorine pesticides and 17 organophosphorus pesticides) and heavy metal contents (including arsenic, cadmium, lead and mercury), as well as morphological identification, are regularly performed, to ensure that the Chms sold in the market are safe, and that their sources and medicinal parts conform to the descriptions specified in the CMO.

17. Tests for targeted items, which may possibly involve morphological identification, physiochemical testing and testing for adulteration with Western drug ingredients, will be performed according to investigation needs.

(iii) Test results

18. 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[2] in the first stage of testing and needed to be tested in the second stage. The samples covered 21 Chms, namely Myrrha, Fructus Corni,

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[2] The pesticides were DDT(4.12ppm), Dichlorvos (0.2-0.38ppm), Triazophos(0.07-0.13ppm), Isocarbophos (0.08-0.09ppm) and Chlorpyriphos (0.06-5.5ppm).

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 and heavy metal contents in all these Chm samples did not exceed the limits set by the CMB. Details of the findings are summarised in Table 1 and Table 2 below:

Table 1: The number of Chm samples that needed to be tested for pesticide residues in the second stage

Year	Number of samples that needed to be tested in the second stage
2015	15
2016	16
2017 (as at the end of June)	22
Total	**53**

Table 2: Test results of Chm samples for pesticide residues and heavy metal contents

Year	Number of samples	Number of samples that exceeds the limits of pesticide residues	Number of samples that exceeds the limits of heavy metal contents
2015	377	0	0
2016	380	0	0
2017 (as at the end of June)	258	0	0
Total	**1,015**	**0**	**0**

19. As for morphological identification, the DH drew samples of 1,015 Chms from the market for regular testing between 1 January 2015 and 30 June 2017, and found nine samples not in compliance with the requirements. Eight types of Chms were involved, namely Rhizoma Cimicifugae, Radix Acanthopanacis Senticosi, Herba Agastaches, Rhizoma Cyrtomii, Periostracum Cicadae, Radix Stellariae, Lasiosphaera seu Calvatia and Rhizoma Drynariae. According to the testing results, seven samples were commonly used in the region. The DH has followed up with the traders concerned regarding the correct labelling of the relevant Chms. The incident was not related to public health risks. Two other samples were mixed-up products and the cases were referred to the Customs and Excise Department for follow-up action. Details of the testing results are provided in Table 3:

Table 3: Testing results for morphological identification of Chms

Year	Number of samples	Number of samples not in compliance with the morphological identification requirements
2015	377	6
2016	380	1
2017(as at the end of June)	258	2
Total	**1,015**	**9**

(e) Places of origin of imported Chms and practices for suppliers

20. According to the Practising Guidelines for Wholesalers of Chinese Herbal Medicines, wholesalers of Chms should purchase processed herbal medicines only from reputable suppliers. At present, majority of the Chms available in the market of Hong Kong are Chinese medicine decoction pieces imported from the Mainland. Under the Drug Administration Law of the People's Republic of China, the establishment of a drug manufacturer in the Mainland shall be subject to approval by the local drug regulatory department and be granted with the Drug Manufacturing Certificate. Drug manufacturers shall conduct production according to the Good Manufacturing Practice (GMP) for Pharmaceutical Products. The production of Chinese medicine decoction pieces in the Mainland shall also meet the requirements of GMP and be granted with the Drug GMP Certificate after passing the inspection by the local food and drug regulatory department of the respective province, autonomous region or municipality under the China Food and Drug Administration. In addition, the establishment of a wholesaler or retailer of processed herbal medicines in the Mainland shall be granted with the Drug Supply Certificate by the local drug regulatory department, while the wholesaling and retailing of Chinese medicine decoction pieces in the Mainland shall put in place rules and regulations to ensure the quality of drugs.

21. Licenced Chinese medicines traders in Hong Kong, when carrying on business operations, shall comply with the CMO and the practising guidelines for Chinese medicines traders. To ensure that all Chinese medicine decoction pieces sold in Hong Kong complied with the quality and safety standards, wholesalers of Chms should purchase decoction pieces from holders of Drug GMP Certificate or Drug Supply Certificate granted by the Mainland drug regulatory department or from local licensed wholesalers of Chms. The DH will conduct inspections on the premises of licensed retailers and wholesalers of Chms on a regular basis to ensure their compliance with the requirements of the law and the practicing guidelines.

Regulation of pCms

(f) The membership of the working group for the amendment of the definition of pCms in the CMO

22. The CMO was passed in 1999, under which a regulatory system for Chinese medicine was established to enhance the protection of public health. In the course of examination of the CMO, the Legislative Council had discussed on the content of each provision, including the definition of pCms and the regulatory requirements and mechanism. The provisions finally adopted were widely accepted and supported by the Chinese medicine industry and the community.

23. To strengthen the existing statutory regulation, we are exploring amendments to the definition of pCms in the CMO. As the amendments will involve technical issues and have a wide impact on the business of the Chinese medicines industry, a range of stakeholders will be affected. Hence, the CMB under the CMCHK has established a working group for the amendment of the definition of pCms in the CMO, which comprises Chinese medicine experts, Chinese medicines industry representatives and representatives from the Government Laboratory. The working group is responsible for examining the issue in a holistic manner and providing advice in this regard. The membership of the working group is at **Annex IV**.

(g) Market surveillance mechanism for unregistered pCms by the DH

24. The DH has put in place a market surveillance system to check if there is any sale of unregistered pCms in the market. Through the system to report adverse incidents related to medicines, the public complaint mechanism, visiting the websites of the Mainland and overseas drug regulatory authorities and conducting media monitoring, the DH collects up-to-date and unexpected information on Chinese medicines through different channels to facilitate risk assessment, management and reporting. If deemed necessary, the DH will take follow-up actions to ensure the safety of Chinese medicines and protect public health.

25. The DH also conducts routine inspections and checking of the premises of licensed local Chinese medicines traders, including inspections on the pCm products relating to their business, for ensuring the traders' compliance with the requirements of the relevant legislations and practising guidelines.

26. To enhance the effectiveness of the enforcement actions, the DH will work closely with other Government departments and public bodies, such as the Hong Kong Police Force, the Customs and Excise Department, the Government Laboratory and the Consumer Council, for the exchange of intelligence and the conduct of joint operations when necessary.

27. Through the measures mentioned above, the DH can have a better understanding of the sales of pCms in the market. If substandard or unregistered pCms are found, the DH will take appropriate actions such as prosecuting the traders concerned, requesting the traders concerned to recall the products, referring the cases to the relevant regulatory body for follow-up actions, and issuing relevant press statements.

28. From 1 January 2015 to 31 July 2017, the DH conducted a total of 19,297 inspections. The number of inspections conducted by the DH and the types of licences of the premises concerned are set out at **Annex V**.

(h) Differences between GMP accreditation of pCms in the Mainland and Hong Kong

29. GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to appropriate quality standards, so that a high level of quality and safety for Chinese medicines can be maintained.

30. The GMP certification of pCms in Hong Kong and the Mainland is detailed as follows:

Hong Kong

31. In accordance with the CMO, the CMB under the CMCHK is responsible for formulating and implementing the regulatory measures for pCms and Chms. The DH is responsible for providing professional and administrative support including the GMP certification of pCms.

32. The CMO also provides that any Chinese medicines trader who engages in manufacturing of pCms must apply to the CMB for a licence. A pCm manufacturer with

the respective licence may apply to the CMB for a Certificate for Manufacturer (GMP Certificate), which certifies the manufacturer's compliance with good practices in the manufacture and quality control of pCms. At present, the GMP requirement in respect of pCms in Hong Kong is not mandatory.

33. In 2003, the CMB issued the Hong Kong GMP Guidelines for Proprietary Chinese Medicines, which serve as the standards for implementing pCms GMP, with reference to the relevant GMP guidelines published by the World Health Organization and the Pharmacy and Poisons Board of Hong Kong responsible for the regulation of western medicines. The guidelines are set out in 12 chapters and one appendix, covering quality management in the Chinese medicines manufacturing industry, personnel, premises, equipment, documentation, manufacture, validation, quality control, contract manufacture and test, complaints, product recalls and self-inspection and quality audits as well as sterile pCms in the appendix.

The Mainland

34. In the Mainland, pCms are subject to the regulation of the Law of the People's Republic of China on Pharmaceutical Administration. An applicant for setting up a pharmaceutical production enterprise (producing pharmaceutical products including pCms, Chms, chemical raw material pharmaceuticals and their preparation and antibiotics, etc.) shall seek the approval of the drug supervision and administration departments of the respective government of the province, autonomous region and municipality at its locality, obtain a Pharmaceutical Production Licence and organise production in accordance with the Standards for Quality Control of Pharmaceutical Production. The China Food and Drug Administration takes charge of the administration of GMP certification nationwide, while the food and drug supervision and administration departments of provinces, autonomous regions and municipalities are responsible for carrying out on-site inspections and issuing Drug GMP certificates to GMP-complying enterprises.

35. The Good Manufacturing Practice for Drugs (2010 Revision), which came into effect on 1 March 2011, provides the standards for the implementation of the Mainland GMP. It sets out the basic requirements for manufacturing and quality management of drugs in 14 chapters, namely General Provisions, Quality Management, Organization and Personnel, Premises and Facilities, Equipment, Materials and Products, Qualification and Validation, Documentation Management, Production Management, Quality Control and Quality Assurance, Contract Manufacture and Analysis, Product Distribution and Recalls, Self Inspections, and Supplementary Provisions. Special requirements, which were set out at the annexes, were subsequently published for products such as sterile products, active pharmaceutical ingredients, biological products, Chinese crude drugs and prepared slices of Chinese crude drugs, and the manufacturing and quality management activities. The above standards for the implementation of GMP have been fully implemented in the Mainland.

36. The principles laid down in the Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines of Hong Kong are broadly the same as those of the Good Manufacturing Practice for Drugs of the Mainland.

(i) Public and trade consultation on the Chinese Medicine (Amendment) Bill 2017

37. The DH conducted a seven-week public and trade consultation on the proposed legislative amendments from January to February 2017, during which a meeting with 16

Chinese medicines traders associations (see **Annex VI** for the list of attending associations) and six briefing sessions for various types of licensed Chinese medicines traders were convened. The briefing sessions were attended by 164 traders, including 68 pCm wholesalers, 41 pCm manufacturers, 14 Chm wholesalers and 41 Chm retailers. The DH has also released a consultation paper on the Business Consultation e-Platform of the GovHK website, the CMCHK's website and the website of the DH's Chinese Medicine Division, to collect views of the public and the trade.

38. The public and the trade generally recognise the need for legislative amendments and support the legislative proposal. The main reasons for the trade's support of the legislative amendments are: firstly, the proposed amendments will enhance the regulation of illegal Chinese medicines traders without exerting any pressure on law-abiding traders and hence further safeguard public health; secondly, the proposed amendments will not pose additional workload on licensed wholesalers of Chms, licensed wholesalers and manufacturers of pCms as they have already set up a recall system according to the law; and thirdly, the proposed amendments will not affect the daily operation of licensed Chinese medicines traders as they have been very co-operative and are willing to initiate recalls voluntarily.

39. Moreover, the DH received a letter jointly signed by seven Chinese medicines traders associations on 27 February 2017, which indicated support to the proposed amendments and showed their concerns about the operational details. Subsequently, the DH met with the representatives of the associations concerned and explained in detail the operating procedures of the proposal. The DH also stressed that there would be no substantive procedural difference between the proposed and the existing recall actions and the Bill would not require licensed traders to adjust their recall systems already established.

Food and Health Bureau
September 2017

Recall Guidelines for Chinese Medicine Products

Contents

Chapter

1. Introduction

1.1

These guidelines have been prepared by the Chinese Medicines Board ("Medicines Board") of the Chinese Medicine Council of Hong Kong, to assist the wholesalers of Chinese herbal medicines, the wholesalers of proprietary Chinese medicines, and the manufacturers of proprietary Chinese medicines to set up an efficient system of recall for Chinese medicine products, which will, so far as practicable, enable the rapid recall of any Chinese medicine products sold or distributed by them in the event of such medicine being found to be dangerous, injurious to health or unfit for human consumption. In addition, the Medicines Board also wishes that the setting up of a recall system will help to ensure the quality and safety of the Chinese medicine products available in the market, to protect the health of the public and enhance confidence in using Chinese medicines.

1.2

These guidelines do not cover the recall of Chinese medicine products on commercial grounds such as the recall of a product which is about to expire, or which has obtained approval for change to its agent, label, packing or registration particulars.

1.3

These guidelines only provide a guide to recalling Chinese medicine products and do not cover all the details of relevant regulations and practising requirements. For practising requirements for wholesales and manufacturers, please refer to the "Practising Guidelines for Wholesalers of Chinese Herbal Medicines", the "Practising Guidelines for Wholesalers of Proprietary Chinese Medicines" and the "Practising Guidelines for Manufacturers of Proprietary Chinese Medicines", all issued by the Medicines Board. A manufacturer of proprietary Chinese medicines who has obtained the certificate for manufacturer (GMP) may also refer to the "Hong Kong Good Manufacturing Practice for Proprietary Chinese Medicines". Chinese medicines traders should also comply with the relevant legislation. The contents of the relevant provisions shall be subject to the Chinese Medicine Ordinance and its subsidiary legislation.

2. Definitions

The following definitions are applicable to these guidelines only:

"proprietary Chinese medicine"

means, in accordance with the Chinese Medicine Ordinance, 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 human body.

"intermediate product"

means, in accordance with the Chinese Medicines Regulation, 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.

"listed Chinese herbal medicine"

means any of the substances specified in Schedule 1 or Schedule 2 of the Chinese Medicine Ordinance.

"herbal medicine"

means a "listed Chinese herbal medicine" and any materials of herbal, animal or mineral origin customarily used by the Chinese for medical treatment.

“Chinese medicine product”

(a) in relation to a wholesaler of Chinese herbal medicines, means a herbal medicine or single Chinese medicine granules for prescription which are sold or distributed by the wholesaler;
(b) in relation to a manufacturer of proprietary Chinese medicines, means a proprietary Chinese medicine or an intermediate product of a proprietary Chinese medicine which is sold or distributed by the manufacturer;
(c) in relation to a wholesaler of proprietary Chinese medicines, means a proprietary Chinese medicine sold or distributes by the wholesaler.

“Chinese medicines trader”

means a wholesaler of Chinese herbal medicines, a manufacturer of proprietary Chinese medicines or a wholesaler of proprietary Chinese medicines, as the case may be, who is licensed under the Chinese Medicine Ordinance.

“recall”

means the taking of action to resolve existing problems relating to the quality, efficacy or safety of a Chinese medicine product.

“single Chinese medicine granules for prescription”

means any single Chinese medicine granules manufactured by way of extraction and which are dispensed only on a prescription from a Chinese medicine practitioner.

“urgent recall”

means the recovery of a deficient Chinese medicine product which may or will cause significant hazard or danger to a user.

“routine recall”

means the recovery of a deficient Chinese medicine product which may or will cause minor hazard or danger to a user.

3. Recall System

3.1

Wholesalers and manufacturers of Chinese medicine products shall, for the purpose of complying with the provisions of the Chinese Medicines Regulation, set up and maintain a recall system. This system will enable the rapid and, so far as practicable, complete recall of any Chinese medicine products sold or distributed by them in the event that the product is found to be dangerous, injurious to health or unfit for human consumption.

3.2

The recall system should be revised from time to time in the light of the actual situation. In the course of a recall, a wholesaler or a manufacturer should take into consideration practical factors such as its scope of the business, the nature of the Chinese medicine product concerned and the needs of customers as well as changes in relevant conditions and undertake suitable corresponding action.

3.3

The recall system should be clearly set out in writing and notified to the personnel performing a recall. The relevant trader should also inform its personnel concerned of the latest changes to the recall system. A Chinese medicines trader is required to take necessary steps to ensure that the details of the latest recall system are promulgated and that the affected personnel are notified that the arrangement is in place.

4. Responsibility

4.1

The prime responsibilities of a Chinese medicines trader are to decide whether to recall a deficient Chinese medicine product, to assign personnel to carry out a recall, and to determine the scope of a recall, having regard to the danger that the product may cause.

4.2

The Medicines Board will assume a role in communication and coordination in the course of a recall, and it will monitor the recall actions and assess their progress and effectiveness. If necessary, the Medicines Board may discuss recall strategy with Chinese medicines traders and undertake corresponding action.

5. Recall Procedures

5.1 – Receipt of Complaints

5.1.1

A Chinese medicines trader should keep on file a record of any complaint received about its Chinese medicine products (including reports on its products of the Medicines Board, such as a test report) alleging that its products are found to be deficient. The records may contain the following information:

(1) Details of the problem
   (i) name, telephone number and facsimile number of the person reporting the problem;
   (ii) date of report;
   (iii) physical location and nature of the problem;
   (iv) number of similar reports received;
   (v) Investigation results and test result of suspected and other samples; and
   (vi) other relevant factors.

(2) Details of the product

(i) product name and description including batch number, expiry date (if any) and date of manufacture (for proprietary Chinese medicine only);

(ii) quantity of the batch and date released;

(iii) sales network (e.g. for local sales or for export);

(iv) number of complaints received;

(v) registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only);

(vi) contact number and facsimile number of the manufacturer/supplier.

5.1.2

The Chinese medicines trader should assign or appoint appropriate personnel to handle the complaints and make available to them the details of the complaints.

5.2 – Assessment of Recall

5.2.1

The responsible person as assigned or appointed by the Chinese medicines trader should determine whether a recall is "urgent" or "routine" based on the nature of complaints and the potential hazard or danger the deficient products may cause to users. If the hazard is significant, an "urgent" recall is required;

5.2.2

In assessing a deficient product, the responsible person should consider whether the deficient product would, when used by or in contact with human beings, cause short-term, curable or minor health problems to them or cause severe adverse effect on human bodies or even lead to death. The responsible person may seek expert opinion in making this assessment;

5.2.3

The responsible person should classify a recall of products (an example of "Classification of Recall" is provided at Appendix 1) and determine promptly whether or not to initiate recall actions;

5. Recall Procedures

5.2.4

When a single batch of a product is found to be deficient, the responsible person should consider whether products of other batches are to be examined, to ascertain if they have been affected.

5.3 – Recall Actions

5.3.1

Once a Chinese medicines trader has decided to initiate recall actions, he should promptly notify the Medicines Board by telephone at 2319 5119 and then inform the Medicines Board of the details of the actions by facsimile (Facsimile number: 2319 2664).

5.3.2

The Chinese medicines trader should deliver a recall notice containing the following information to the Medicines Board (an example of a "Recall Notice" is provided at Appendix 2):

(i) name, position and telephone number or facsimile number of the person responsible for the recall;
(ii) date of complaint first received, and date of decision made to initiate recall actions;
(iii) name, address and telephone number of the complainant (if these can be provided);
(iv) name of the product to be recalled;
(v) registration number or receipt number of application for proprietary Chinese medicines registration of the product to be recalled (for proprietary Chinese medicine only);
(vi) description of the complaint;
(vii) scope of distribute of the product;
(viii) plan and logistic of the recall;
(ix) expected time of complaint of recall actions;
(x) "Classification of Recall"; and
(xi) any other relevant information.

5.3.3

In the meantime, the Chinese medicines trader should also notify in writing all organizations or parties to which the recalled products have been supplied directly. The notification should be written in the following manner:

(i) be clear and concise;
(ii) clearly specify the name, dose form or type, pack size and batch number (if any) of the product, and any other information which may help to identify the product;
(iii) specify the registration number or receipt number of application for proprietary Chinese medicines registration of the product (for proprietary Chinese medicine only);
(iv) contain a warning for immediate removal of the product form supply or use;
(v) specify the "Classification of Recall" and clearly explain the reason(s) for the recall and the hazard(s) involved (if any);
(vi) suggest that if any of the recalled products could have been re-supplied to another organization, such organization and the manufacturer and/or wholesaler concerned should be notified of the recall;
(vii) explain how the products can be returned to the Chinese medicines trader.

If the Chinese medicines trader considers it necessary, he may make a wider publication of the recall actions (e.g. by making announcements through the media).

5.3.4

The Chinese medicines trader may send personnel to contact the organizations or parties concerned to assist in returning the products to the suppliers;

5.3.5

The Chinese medicines trader should set up telephone and facsimile hotlines to answer enquiries.

5.4 - Supervision of Recall

The relevant Chinese medicines trader should monitor the effectiveness and progress of the recall, to ensure that the deficient products are recovered within the proposed period of time.

5.5 – Recall Report

5.5.1

In the course of a recall, the parties concerned should, upon the request of the Medicines Board, submit an interim report (an example of an "Interim Report" is provided at Appendix 3) to enable the Medicines Board to assess the progress and effectiveness of the recall actions. The interim report should contain the following information:

(i) the number of organizations which have been supplied with the products, and the quantity of the products supplied;
(ii) the quantity of the products recalled;
(iii) the date and method of recall known to such organizations;
(iv) the number of organizations which have responded;
(v) the names of those organizations which have not responded; and
(vi) the estimated proposed time schedule for completion of the recall.

5.5.2

On completion of a recall, the Chinese medicines trader should compile a final report (an example of a "Final Report" is provided at Appendix 4) and submit that to the Medicines Board. The final report should contain the following information:

(i) the names of organizations or parties being requested to return the recalled products;
(ii) the quantity of the products distributed;
(iii) the quantity of the products recalled;
(iv) the results of the investigation into the causes of the deficiencies of the products;
(v) their decision(s) on handling the recalled products; and
(vi) the measures to be taken to prevent any recurrence of similar problem(s).

5.5.3

In the course of a recall, the Chinese medicines trader should appropriately handle any information received which is of a commercially sensitive and personnel nature. The Chinese medicines trader should also maintain properly the relevant documents and/or records for inspection, when necessary.

6. Conclusion

6.1

These Guidelines are intended to provide assistance to Chinese medicines traders to conduct an effective recall of Chinese medicine products. These Guidelines are subject to amendment in the light of actual experience in operation and changes to the social environment.

6.2

Each recall action is a unique exercise. In preparing a recall strategy, there are a number of factors that need to be considered, including the nature of the problem; the number of complaints received; customer safety; sales or distribution networks; recall procedures; and resources.

6.3

The Chinese medicines trader should maintain good communication and cooperation with the Medicines Board, to enable effective and rapid recall of a deficient Chinese medicine product. This is with a view to ensuring the quality and safety of the Chinese medicine products available in the market and to protecting public health.

The Chinese Medicines Board of
the Chinese Medicine Council of Hong Kong

September 2005

Appendix 1

Example of "Recall Classification"

The purpose of stating a "Recall Classification" is to foster better understanding among the Chinese medicines traders and between the Chinese medicines traders and the Medicines Board of the seriousness of the problem that gave rise to a recall. According to the extent of hazard posed by a deficient Chinese medicine product, recalls may be generally classified as follows:

Class 1

When a product is potentially life-threatening, or could cause a serious risk to health.

Examples:

- wrong product (its label and ingredients are of a different product)
- right product but of wrong quantities of ingredients, which may result in serious medical consequences
- proprietary Chinese medicine with wrong active ingredients which may result in serious medical consequences.

Class 2

When a deficient product could cause illness or inappropriate treatment, but does not fall within Class 1.

Examples:

- with labelling errors, such as incorrect or incomplete information on the label description
- omission or incorrect information on the description of the package insert
- deviation from the quality specification.

Class 3

When a deficient product may not cause significant hazard to health, but withdrawal may be initiated for other reasons.

Examples:

- with packaging errors, such that mistakes or omissions are found in the batch number or expiry date
- discoloration which does not affect the efficacy of the product or where the seal of the package is damaged.

Appendix 2

Example of "Recall Notice for Chinese Medicine Products"

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong (Fax Number: 2319 2664)

Our company has decided to initiate the recall of_____.
Details of this recall are as follows:

(1) Details of the Company

(1) Licence number of Chinese medicines trader:
(2) Name of Chinese medicines trader:
(3) Name and position of person responsible for the recall:
(4) Telephone number:
(5) Facsimile number:
E-mail address / website (if any):
(6) Enquiry hotline (if any):

(2) Background information on the recall

(1) Date and time of receipt of complaint:
(2) Details of the organization or person which made the complaint (subject to consent of the complainant):
(3) Description of Complaint:

(3) Details of recalled product

(1) Name of product:			
(2) Type of product (put a ✓ in the appropriate box):	Chinese herbal medicine ☐	Proprietary Chinese medicine ☐	☐ others_____
(3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only):			
(4) Package specifications:			
(5) Scope of distribution, in brief:			

(4) Details of recall actions

(1) Batch number of affected product (if applicable):			
(2) Quantity supplied before the recall:			
(3) Reasons for recall:			
(4) Classification of recall (put a ✓ in the appropriate box)	Class 1 ☐	Class 2 ☐	Class 3 ☐
(5) Plan and logistics of recall actions:			
(6) Expected time of completion of recall:			
(7) Other relevant information:			

(if the space provided is insufficient, supplementary sheets may be added.)

_____

Signature of responsible person

Date:_____ _____

Company chop

Appendix 3

Example of "Interim Report on Recall of Chinese Medicine Products"

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong (Fax Number: 2319 2664)

Our company hereby submits this interim report on the recall of _____ by virtue of the information provided below:

(1) Details of the Company

(1) Licence number of Chinese medicines trader:
(2) Name and address of Chinese medicines trader:
(3) Name and position of the person responsible for the recall:
(4) Telephone number:
(5) Facsimile number:
E-mail address / website (if any):
(6) Enquiry hotline (if any):

(2) Details of recalled product

(1) Name of product:			
(2) Type of product (put a ✓ in the appropriate box):	Chinese herbal medicine ☐	Proprietary Chinese medicine ☐	☐ others _____
(3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only):			
(4) Package specifications:			

(3) Details of progress of the recall

(1) Number of organizations supplied with the product:
(2) Quantity of products supplied:
(3) Date and method of recall known to the above organizations:
(4) Number of organizations which have responded:
(5) Quantity of products recalled:
(6) Name of organization which have not responded:
(7) Time schedule for recall actions, and expected time of completion:

(If the space provided is insufficient, supplementary sheets may be added.)

_____ _____

Date: **Company chop and signature of responsible person**

Appendix 4

Example of "Final Report on Recall of Chinese Medicine Products"

To: Chinese Medicines Board of the Chinese Medicine Council of Hong Kong (Fax Number: 2319 2664)

Our company hereby submits this final report on the recall of _____ by virtue of the information provided below:

(1) Details of the Company

(1) Licence number of Chinese medicines trader:
(2) Name and address of Chinese medicines trader:
(3) Name and position of person responsible for the recall:
(4) Telephone number:
(5) Facsimile number:
E-mail address / website (if any):
(6) Enquiry hotline (if any):

(2) Details of recalled product

(1) Name of product:			
(2) Type of product (put a ✓ in the appropriate box):	Chinese herbal medicine ☐	Proprietary Chinese medicine ☐	☐ others _____
(3) Registration number or receipt number of application for proprietary Chinese medicines registration (for proprietary Chinese medicine only):			
(4) Package specifications:			

(3) Summary of the recall

(1) Number of organizations or person requested for return of product:
(2) Total quantity of products distributed:
(3) Total quantity of products recalled:
(4) Results of investigation into the cause(s) for deficient products:
(5) Handling method(s) of the recalled products:
(6) Measures to prevent recurrence of similar problem:

(If the space provided is insufficient, supplementary sheets may be added.)

_____ _____

Date: **Company chop and signature of responsible person**

Annex II

Current Member List of International Advisory Board of Hong Kong Chinese Materia Medica Standards
(as of 31 July 2017)

Dr. Samantha ATKINSON	--	Deputy Director, Inspection, Enforcement & Standards Division Secretary and Scientific Director, BP Commission Medicines & Healthcare products Regulatory Agency, United Kingdom	--
Prof. Dr. Rudolf BAUER	鮑儒德教授	Professor in Pharmacognosy, Head, Institute of Pharmaceutical Sciences, Department of Pharmacognosy, TCM Research Center Graz, University of Graz, Austria	--
Dr. Joseph M. BETZ	--	Director, Analytical Methods and Reference Materials Program, Office of Dietary Supplements, National Institutes of Health, United States	--
Prof. David BRIGGS	戴维伯瑞格思教授	Adjunct Professor, The National Institute of Complementary Medicine, Western Sydney University, Australia	--
Prof. Nuntavan BUNYAPRAPHATSARA	--	Professor Emeritus of Pharmacognosy, Faculty of Pharmacy, Mahidol University, Thailand; and Consultant on medicinal plants at the Thailand Research Fund	--
Dr. Constance CHAN, JP	陳漢儀醫生,太平紳士	Director of Health, The Government of the Hong Kong Special Administrative Region (Chairperson of IAB)	香港特別行政區政府 衞生署署長 (國際專家委員會主席)
Prof. Kelvin K. C. CHAN	陳金泉教授	Adjunct Professor at the National Institute of Complementary Medicine, Western Sydney University, and Faculty of Science, University of Technology Sydney, Australia; and Visiting Professor at the School of Pharmacy & Biomolecular Sciences, Liverpool John Moores University, United Kingdom	--
Dr. Peter CHAN	陳嘉廉博士	Director General, Health Evaluation Directorate, Pest Management Regulatory Agency, Health Canada, Canada	--
Prof. CHE Chun-tao	車鎮濤教授	Norman R. Farnsworth Professor of Pharmacognosy; and Director, WHO Collaborating Center for Traditional Medicine, College of Pharmacy, University of Illinois	--

		at Chicago, United States	
Prof. Harry H.S. FONG	鄺洪生教授	Professor Emeritus of Pharmacognosy, Department of Medicinal Chemistry and Pharmacognosy, College of Pharmacy, University of Illinois at Chicago, United States	--
Prof. em. Dr. Gerhard FRANZ	--	Chairman of the European TCM-Working Party, EDQM-Strasbourg, France; and Department of Pharmacy, University of Regensburg, Regensburg, Germany	--
Dr. Yukihiro GODA	--	Head, Division of Drugs, National Institute of Health Sciences, Japan	--
Prof. HUANG Luqi	黃璐琦教授	Vice-President, China Academy of Chinese Medical Sciences; and Director, National Resource Center for Chinese Materia Medica, The People's Republic of China	中華人民共和國 中國中醫科學院常務副院長 中國中醫科學院中藥資源中心主任
Dr. Cindy LAI, JP	黎潔廉醫生, 太平紳士	Deputy Director of Health, The Government of the Hong Kong Special Administrative Region	香港特別行政區政府 衞生署副署長
Dr. Gerard LEE	--	Member, British Pharmacopoeia Commission, United Kingdom	--
Prof. LIN Ruichao	林瑞超教授	Professor, Dean of School of Chinese Materia Medica, Beijing University of Chinese Medicine, The People's Republic of China	中華人民共和國 北京中醫藥大學中藥學院院長
Prof. MA Shuangcheng	馬雙成教授	Director, Institute for Control of Chinese Traditional Medicine and Ethnic Medicine, National Institutes for Food and Drug Control, China Food and Drug Administration, The People's Republic of China	中華人民共和國國家食品藥品監督管理總局 中國食品藥品檢定研究院中藥民族藥檢定所所長
Ms. SHI Shang-mei	石上梅女士	Director, Division of Traditional Chinese Medicine, Chinese Pharmacopoeia Commission, The People's Republic of China	中華人民共和國國家藥典委員會 中藥標準處處長
Prof. Monique S.J. SIMMONDS	--	Deputy Director of Science, Royal Botanic Gardens, Kew, United Kingdom	--
Dr. SIN Wai-	單慧媚	Government Chemist,	香港特別行政

mei, JP	博士, 太平紳士	Government Laboratory, The Government of the Hong Kong Special Administrative Region	區政府 政府化驗所政府化驗師
Dr. WANG Xiaopin M. D.	王笑頻 司長	Director General, Office of Hong Kong, Macau and Taiwan Affairs, Department of International Cooperation, State Administration of Traditional Chinese Medicine, The People's Republic of China	中華人民共和國國家中醫藥管理局 國際合作司港澳台辦公室司長
Dr. WEI Feng	魏鋒博士	Director of Department of Chinese Materia Medica, Institute for Control of Chinese Traditional Medicine and Ethnic Medicine, National Institutes for Food and Drug Control, China Food and Drug Administration, The People's Republic of China	中華人民共和國國家食品藥品監督管理總局 中國食品藥品檢定研究院中藥民族藥檢定所 中藥材室主任
Prof. ZHAO Zhongzhen, MH	趙中振 教授, MH	Associate Dean and Chair Professor, School of Chinese Medicine, Hong Kong Baptist University	香港浸會大學 中醫藥學院副院長及講座教授

Annex III

Limits of pesticide residues and heavy metals contents in Chinese herbal medicines

(1) Limits of organochlorine pesticide residues

	Chinese name	English name	Test parameters (20 types 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*-chlordane, *trans*-chlordane and oxychlordane	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

(2) 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	Phosphamidon	
14	毒死蜱	Chlorpyriphos	
15	乙酰甲胺磷	Acephate	
16	乙硫磷	Ethion	
17	殺撲磷	Methidathion	

(3) Limits of heavy metals and toxic elements contents

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

Annex IV

Member List of Working Group of Amendment of the Definition of Proprietary Chinese Medicines under the Chinese Medicine Ordinance

Chairman		2 persons	Dr. TSUI Lok-kin, Edwin	Assistant Director (TCM) of the Department of Health
			Mr. CHAN Wai-ho, Jacob	Executive President of the Hong Kong Chinese Medicine Industry Association Limited
Member	Experts of Chinese medicine	4 persons	Professor BIAN Zhaoxiang	Associate Vice-President of the Hong Kong Baptist University
			LAM Kar-wing Chinese medicine practitioner	Member of the Chinese Medicine Council of Hong Kong
			CHAN Wing-kwong Chinese medicine practitioner	Member of the Chinese Medicines Committee under the Chinese Medicines Board
			Dr. Yi Bin FENG	Associate Director of the School of Chinese Medicine of the University of Hong Kong
	Person from Trade of Chinese medicines	7 persons	Mr. TING Wing-fai	Member of the Chinese Medicine Council of Hong Kong
			Mr. LI Chun-man, Thomson	Member of the Chinese Medicines Committee under the Chinese Medicines Board
			Mr. YAU Fook-wing, Edward William	Vice-Chairman of the Hong Kong Society of Chinese Medicines
			Mr. LIN Hei-hing	Chairman of the Hong Kong Federation of Chinese Medicine Sector Limited
			Mr. WONG Cho-hang, Stanley	Alternate member of the Chinese Medicines Committee under the Chinese Medicines Board
			Mr. POON Po-sum	Chairman of the Hong Kong Medicine Dealers Guild
			Dr. Timothy TAM	Chairman of the Modernized Chinese Medicine International Association
	Government Laboratory representative	1 person	Ms. TSOI Sau-ching	Senior Chemist
		Total 14 persons		

Annex V

Breakdown of inspections conducted by the Department of Health with respect to the types of licence on the related premises

Year 2015	Retailers of Chinese Herbal Medicines	Wholesalers of Chinese Herbal Medicines	Wholesalers of Proprietary Chinese Medicines	Manufacturers of Proprietary Chinese Medicines	**Total**
January	336	66	112	61	**575**
February	331	41	98	24	**494**
March	387	80	97	73	**637**
April	421	48	81	29	**579**
May	423	52	70	27	**572**
June	465	61	85	42	**653**
July	436	87	93	43	**659**
August	390	70	66	29	**555**
September	364	67	68	40	**539**
October	405	68	106	25	**604**
November	485	75	108	45	**713**
December	524	64	138	40	**766**
Sub-total	**4967**	**779**	**1122**	**478**	**7,346**

Year 2016	Retailers of Chinese Herbal Medicines	Wholesalers of Chinese Herbal Medicines	Wholesalers of Proprietary Chinese Medicines	Manufacturers of Proprietary Chinese Medicines	**Total**
January	495	94	90	27	**706**
February	363	97	124	21	**605**
March	401	121	134	36	**692**
April	338	83	147	49	**617**
May	410	116	92	31	**649**
June	405	100	116	45	**666**
July	433	74	83	39	**629**
August	446	70	98	41	**655**
September	349	66	102	33	**550**
October	309	52	84	26	**471**
November	405	66	93	33	**597**
December	343	53	86	26	**508**
Sub-total	**4697**	**992**	**1249**	**407**	**7,345**

Year 2017 (as at end of June)	Retailers of Chinese Herbal Medicines	Wholesalers of Chinese Herbal Medicines	Wholesalers of Proprietary Chinese Medicines	Manufacturers of Proprietary Chinese Medicines	**Total**
January	290	51	120	33	**494**
February	396	73	111	25	**605**
March	454	80	110	32	**676**
April	456	83	93	32	**664**
May	546	81	114	37	**778**
June	524	92	91	40	**747**
July	449	102	60	31	**642**
Sub-total	**3115**	**562**	**699**	**230**	**4,606**

Annex VI

List of Chinese Medicines Traders Associations attended the Consultation Meeting on "Chinese Medicine (Amendment) Bill 2017" Trade Consultation

	Name of Association
1	Hong Kong & Kowloon Chinese Medicine Merchants Association
2	Modernized Chinese Medicine International Association
3	Hong Kong Chinese Prepared Medicine Traders Association
4	Hong Kong Chinese Patent Medicine Manufacturers' Association
5	International General Chinese Herbalists and Medicine Professionals Association Limited
6	Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Limited
7	The Hong Kong Federation of Chinese Medicine Sector Limited
8	Hong Kong Chinese Medicine Industry Association Limited
9	The Hong Kong Medicine Dealers Guild
10	Hong Kong Chinese Medicine Manufactures United Association
11	Po Sau Tong Ginseng & Antler Association Hong Kong Limited
12	Hong Kong Chinese Medicine Merchants Association
13	The Hong Kong Society of Chinese Medicines
14	Hong Kong Chinese Medicine Employees Association
15	Hong Kong Chinese Medicine Pharmacists Association
16	The Hong Kong Pharmaceutical Manufacturers Association Limited