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

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,

(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

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 products[1] 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) <u>Response to the enquiries made by Dr Hon Helena WONG Pik-wan in her letter to the Chairman of the Bills Committee</u>

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 Chms[3]. 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 Chms[4] 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 *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	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 1st 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
									0.21
			2						0.07
									0.07
				1					0.26
5	Rhizoma Alismatis	2							1.7
									2.1
			1						5.5
				3				0.07	3
								0.13	3.6
									3.6
6	Herba Plantaginis	2							0.11
									0.14
			2						0.11
									0.13
				2					0.07
									0.10
7	Fructus Aurantii Immaturus	2							0.09
									0.11
			4						0.10
									0.11
									0.12
									0.13
				2					0.09
									0.10
8	Herba Ecliptae	1							0.15
9	Semen Astragali Complanati	1							0.09
10	Herba Artemisiae Scopariae	1							0.09
			1						0.10
				2					0.10
									0.53
11	Radix Adenophorae	1							0.7
			1						0.15
12	Rhizoma et Radix Notopterygii		1			0.2			
13	Fructus Kochiae		1					0.09	
14	Rhizoma Atractylodis Macrocephalae		1						0.17
15	Herba Scutellariae Barbatae		1						0.08
16	Rhizoma Chuanxiong			4				0.08	
									0.31
									1.30
									1.40
17	Herba Violae			2					0.17
									0.18
18	Radix Asteris			2					0.07
									0.08
19	Herba Leonuri			1					0.2
20	Folium Sauropi			1					0.13
21	Flos Campsis			1					0.06
	Sub-total	15	16	22					
	Total		**53**						