立法會 Legislative Council

LC Paper No. CB(2)1207/17-18

(These minutes have been seen by the Administration)

Ref: CB2/BC/6/16

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Minutes of the second meeting held on Thursday, 28 September 2017, at 2:30 pm in Conference Room 1 of the Legislative Council Complex

Members : Hon Alice MAK Mei-kuen, BBS, JP (Chairman)
present Hon Mrs Regina IP LAU Suk-yee, GBS, JP

Hon CHAN Han-pan, JP Dr Hon KWOK Ka-ki

Hon KWOK Wai-keung, JP Dr Hon Elizabeth QUAT, BBS, JP

Hon SHIU Ka-fai

Members : Dr Hon Helena WONG Pik-wan absent Dr Hon Junius HO Kwan-yiu, JP

Dr Hon Pierre CHAN

Public Officers: Mr Howard CHAN, JP

attending Deputy Secretary for Food and Health (Health) 1

Food and Health Bureau

Miss Fiona CHAU

Principal Assistant Secretary for Food and Health (Health) 1

Food and Health Bureau

Dr Edwin TSUI

Assistant Director (Traditional Chinese Medicine)

Department of Health

Mr Stephen YUNG

Senior Pharmacist (Traditional Chinese Medicine) 2

Department of Health

Ms Mandy NG Senior Government Counsel Department of Justice

Attendance by invitation

Ms Karen TANG

The Hong Kong Society of Chinese Medicines

Mr Edward William YAU Fook-wing Vice President

Hong Kong & Kowloon Chinese Medicine Association Limited

Dr Jack PANG Cheung-hi Permanent President

Liberal Party

Mr LEE Chun-keung Vice Party Chair

Hong Kong Ample Love Society Ltd.

Ms TSANG Cheuk-yi Chairlady

The Democratic Party

Mr FUNG Man-tao Community Officer

Hong Kong Medicine Workers General Union (Yee-Shing)

Mr WONG Kwok-cheong 理事長

Hong Kong Chi Chun Tang Herbal Factory Limited

Mr LAU Chor-mo Managing Director

Natural Health Care (HK) Limited

Ms LI Wan-xian Director

Natural Health Care Development Ltd.

Mr Benny LAM Director

Hong Kong Chinese Medicine Manufacturers United Association

Mr LEE Ming-chi 副理事長

Mr Marcus MOK

香港《中醫藥條例》研究委員會

Mr Albert B WONG 委員

Chinese Medicine Merchants Association Ltd.

Mr MONG Hoi-sang Representative

Po Sau Tong Ginseng & Antler Association Hong Kong Limited and Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.

Mr Michael WONG Kam-pui Chairman

The Hong Kong Medicine Dealers' Guild

Mr POON Po-sum Representative

Clerk in attendance

Ms Maisie LAM

Chief Council Secretary (2) 5

Staff in : Mr Bonny LOO

attendance Assistant Legal Adviser 4

Ms Jasmine TAM

Senior Council Secretary (2) 8

Miss Maggie CHIU

Legislative Assistant (2) 5

<u>Action</u>

I. Meeting with deputations and the Administration

[File Ref.: FHB/H/24/24, LC Paper Nos. LS75/16-17, CB(2)1883/16-17(02) to (05), CB(2)2104/16-17(01) to (03) and CB(3)630/16-17]

<u>The Bills Committee</u> deliberated (index of proceedings attached at **Annex**).

2. <u>The Bills Committee</u> received oral representations from 16 deputations on the Bill, and noted five written submissions from organizations not attending the meeting.

Admin

- 3. The Bills Committee requested the Administration to:
 - (a) clarify in writing whether health food products, such as bottled herbal drinks which were claimed to have "heat-clearing" effect, and other prepackaged orally consumed products which contained but were not composed solely of Chinese herbal medicines or materials of herbal, animal or mineral origin customarily used by the Chinese as active ingredients would fall under the regulation of the Bill; and
 - (b) provide a written response to the deputations' views and suggestions in respect of the legal and drafting aspects of the Bill.

Admin

4. The Administration was also requested to provide, before the next meeting of the Bills Committee, a written response to the issues raised in the letter dated 27 September 2017 from Dr Helena WONG (LC Paper No. CB(2)2141/16-17(02)), which was tabled at the meeting.

Action

II. Any other business

- 5. <u>Members</u> agreed that the next meeting of the Bills Committee would be held on Friday, 13 October 2017, at 10:45 am.
- 6. There being no other business, the meeting ended at 4:31 pm.

Council Business Division 2
<u>Legislative Council Secretariat</u>
12 April 2018

Proceedings of the second meeting of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 held on Thursday, 28 September 2017, at 2:30 pm in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker	Subject(s)/Discussion	Action required		
Agenda it	Agenda item I: Meeting with deputations and the Administration				
000840 - 001217	Chairman	Opening remarks			
001218 - 001527	Ms Karen TANG	Presentation of views (LC Paper No. CB(2)2104/16-17(04))			
001528 - 001833	The Hong Kong Society of Chinese Medicines	Presentation of views (LC Paper No. CB(2)2104/16-17(05))			
001834 - 002156	Hong Kong & Kowloon Chinese Medicine Association Limited	Presentation of views (LC Paper No. CB(2)2104/16-17(06))			
002157 - 002440	Liberal Party	Presentation of views			
002441 - 002733	Hong Kong Ample Love Society Ltd.	Presentation of views			
002734 - 003035	The Democratic Party	Presentation of views (LC Paper No. CB(2)2117/16-17(03))			
003036 - 003255	Hong Kong Medicine Workers General Union (Yee-Shing)	Presentation of views			
003256 - 003618	Hong Kong Chi Chun Tang Herbal Factory Limited	Presentation of views (LC Paper No. CB(2)2104/16-17(07))			
003619 - 003900	Natural Health Care (HK) Limited	Presentation of views (LC Paper No. CB(2)2117/16-17(01))			
003901 - 004226	Natural Health Care Development Ltd.	Presentation of views (LC Paper No. CB(2)2128/16-17(01))			
004227 - 004524	Hong Kong Chinese Medicine Manufacturers United Association	Presentation of views (LC Paper No. CB(2)2104/16-17(08))			
004525 - 004832	Mr Marcus MOK	Presentation of views			
004833 - 005142	香港《中醫藥條 例》研究委員會	Presentation of views (LC Paper No. CB(2)2117/16-17(02)) (LC Paper No. CB(2)2141/16-17(01))			

Time marker	Speaker	Subject(s)/Discussion	Action required
005143 - 005447	Chinese Medicine Merchants Association Ltd.	Presentation of views (LC Paper No. CB(2)2104/16-17(12))	
005448 - 005645	Po Sau Tong Ginseng & Antler Association Hong Kong Limited and Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.	Presentation of views (LC Paper No. CB(2)2104/16-17(12))	
005646 - 005957	The Hong Kong Medicine Dealers' Guild	Presentation of views (LC Paper No. CB(2)2128/16-17(02))	
005958 - 011110	Chairman Admin	The Administration's response as follows: (a) in the light of the Court of First Instance's judgment in a judicial review case ("the court judgment in question") that the Director of Health or the Deputy Director of Health (collectively and individually referred to as "the Director") had no lawful power under the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") to order recall of Chinese medicines or related products which might pose threats to public health, the Administration considered it necessary to address the above lacuna by amending the Ordinance and its subsidiary legislation in a timely manner to empower the Director to issue a Chinese medicine safety order ("CMSO") to prohibit the sale of a Chinese medicine or related product and/or to recall such product on the grounds specified in the proposed new sections 138C and 138D of the Ordinance; (b) wholesalers of Chinese herbal medicines, wholesalers of proprietary Chinese medicines ("pCm") and manufacturers of pCms had already been required by law to set up and maintain a system of control to enable the recall of the Chinese medicine products sold or distributed by the licence holder concerned for public health purposes. The Chinese Medicines Board ("CMB") of the Chinese Medicine Council of Hong Kong had published the Recall Guidelines for Chinese Medicine Products ("the Recall Guidelines") in 2005 to assist these licensed Chinese medicine traders to set up the recall system. The Bill, if passed, would not impose additional compliance burden on licensed traders as in practice there would be no substantive procedural difference between the proposed and the existing recall actions. However, it would enable the Director to direct any person, including an unlicensed trader and a shell company, to stop selling and/or to recall from the market any Chinese medicines or related products with public health risk, failing which the person would be subject to prosecution and upon conviction be liable to a maximum penalty of a level 6 fine (i.e. \$100,000) an	

Time marker	Speaker	Subject(s)/Discussion	Action required
		(c) as regards the regulation of products which did not fall within the definition of pCms under the Ordinance and hence would not be subject to the registration requirement (or the proposed CMSO regime), CMB had set up a working group ("CMB working group") to explore amendments to the definition of pCms under the Ordinance. Subject to the recommendations to be made by the CMB working group and the view of CMB in this regard, the Administration would consult the Chinese medicine sector and report to the Panel on Health Services ("the Panel") on the way forward; and	
		(d) the Administration would continue to gauge the views of the Chinese medicine sector on the long-term development of Chinese medicine in Hong Kong through the Chinese Medicine Development Committee. This apart, a dedicated unit was proposed to be set up under the Food and Health Bureau ("FHB") to oversee the policy matters in this regard.	
011111 - 011703	Chairman Mrs Regina IP Admin	In reply to Mrs Regina IP's enquiry, the Administration advised that a total of 11 cases of recall actions had been carried out by relevant licensed traders in 2015-2016 under the recall system they had set up. The recall actions were carried out satisfactorily.	
		On Mrs Regina IP's questioning of the need for introducing the legislative proposals given that the trade had been cooperative in recalling the products if the circumstances so dictated, the Administration reiterated the need of the legislative proposals in the light of the court judgment in question and the fact that there was at present no provision under the law requiring an unlicensed trader to, as directed by the Director, stop selling or recall any Chinese medicine or related product which might pose health threats.	
		Mrs Regina's enquiry about the mechanism put in place by the Department of Health ("DH") to monitor the quality and safety of Chinese medicines and related products supplied in the market, and the resources devoted by the Administration to promoting the development of the Chinese medicine industry.	
		The Administration's response as follows:	
		(a) under DH's respective market surveillance systems for Chinese herbal medicines and pCms, samples of Chinese herbal medicines were collected from the market for testing on a regular basis and inspections were carried out to check if there was any sale of unregistered pCms in the market. DH had also established an adverse Chinese medicines reaction reporting system, and had maintained liaison with the Mainland and overseas drug regulatory authorities for timely exchange of information about the safety and quality of Chinese medicines; and	
		(b) there were at present around 200 staff members working under the Chinese Medicine Division of DH, which was	

Time marker	Speaker	Subject(s)/Discussion	Action required
		mainly responsible for, among others, the regulation and standard setting of Chinese medicine. A dedicated Chinese Medicine Unit was also proposed to be set up under FHB.	20quil tu
011704 - 012443	Chairman Mr SHIU Ka-fai Admin	Mr SHIU Ka-fai's concern about whether a wholesaler of Chinese medicine products served with a CMSO would be held liable if the distributor(s) involved could not be reached and hence the wholesaler was unable to request the retailers concerned to return the recalled products; and his worry about possible delay in returning such products if the retailers concerned were not notified of the recall action under the aforesaid situation. The Administration's explanations as follows:	
		(a) after the passage of the Bill, DH would, as in the past, request relevant Chinese medicines traders to take recall actions through administrative means. According to the Recall Guidelines, a wholesaler of Chinese medicine products should maintain good communication and cooperate with DH to enable effective and rapid recall of a deficient Chinese medicine product. A CMSO would only be issued when the trader concerned refused or failed to recall the product;	
		(b) for enforcement of CMSO in future, DH would continue to discuss with the organization/person subject to a CMSO the method and timeframe of recall for each case. Where necessary, DH would issue a press release to alert the public and Chinese medicine traders to the CMSO made. If a retailer to whom the CMSO was not specifically addressed refused or failed without reasonable excuse to return the recalled products to the wholesaler subject to a CMSO, the Director might issue a CMSO to that particular retailer to prohibit the sale of and recall the product concerned; and	
		(c) for the purpose of the defence under the proposed new section 138L of the Ordinance, it would constitute a reasonable excuse for failing or refusing to comply with a CMSO if the person charged adduced sufficient evidence to raise an issue that the product concerned had already been consumed or disposed of due to damage, or he or she was unable to reach the distributors or retailers concerned after using all practicable means, and the contrary was not proved by the prosecution beyond reasonable doubt.	
012444 - 013152	Chairman Mr CHAN Han-pan Admin	Mr CHAN Han-pan's remark that while he noted that the deputations generally did not object to the Bill, the proposed legislative amendments had not addressed the various long-standing concern of the Chinese medicines trade. His enquiries and the Administration's replies regarding (a) the way forward for the review of the definition of pCms being carried out by the CMB working group; and (b) the timetable for a comprehensive review of the Ordinance to address, among others, the trade's call for introducing more classification categories of pCms with different levels of safety and quality testing requirements.	

Time marker	Speaker	Subject(s)/Discussion	Action required
		Mr CHAN Han-pan urged the Administration to make reference to the recommendations of the Subcommittee on Issues Relating to the Development of Chinese Medicine formed in the Fifth Legislative Council, and gauge extensively the views of the trade in conducting an overall review of the Ordinance.	required
013153 - 013716	Chairman Dr KWOK Ka-ki Admin	While expressing support for the Bill, Dr KWOK Ka-ki was concerned about the lack of regulation on those health products claiming to contain Chinese medicine materials and have beneficial effects on health.	
		The Administration's advice that the labels and advertisements of orally consumed products, except those customarily consumed only as food or drink, with health claims were regulated under the Undesirable Medical Advertisements Ordinance (Cap. 231). As regards the regulation of products which contained Chinese medicines but did not fall within the definition of pCms under the Ordinance, the CMB working group was reviewing the definition of pCms.	
		In response to Dr KWOK Ka-ki's follow-up enquiry, the Administration advised that while there were no representatives from the Consumer Council or patients' associations in the CMB working group, the recommendations to be made by the working group would be considered by CMB which comprised, among others, representatives from the Chinese medicines practice and the Chinese medicines trade, and lay persons representing the interests of the general public and consumers. Subject to CMB's views, extensive consultations with the relevant stakeholders would be conducted on any proposed amendment to the definition of pCms.	
013717 - 014149	Chairman Admin	In reply to the Chairman's enquiry about the Administration's target time frame for setting up a dedicated Chinese medicine unit under FHB and completing the review of the definition of pCms, the Administration advised that its plan was to seek funding approval for the directorate staffing proposals for the Chinese medicine unit to be set up under FHB and to consult the trade on CMB's proposed amendments to the definition of pCms within the current legislative session.	
		The Chairman's remark that the Administration should address the concerns raised by members and deputations over the need for an overall review of the Ordinance and the development of Chinese medicine in Hong Kong; and her request for the Administration to provide, before the next meeting of the Bills Committee, a written response to the issues raised in the letter dated 27 September 2017 from Dr Helena WONG (LC Paper No. CB(2)2141/16-17(02), which was tabled at the meeting.	Admin
014150 - 014811	Chairman Mr SHIU Ka-fai Admin	In response to Mr SHIU Ka-fai's enquiry about whether health products which were composed mainly of Chinese medicine materials and adulterated with other materials or substances (e.g. vitamins) would be subject to a CMSO made under the Bill, the Administration reiterated that only those products falling within the existing definition of pCms under the Ordinance would be subject to a CMSO. The CMB working group was examining amendments to the definition of pCms.	

Time	Speaker	Subject(s)/Discussion	Action
marker			required
014812 - 015040	Chairman Mr CHAN Han-pan Admin	On Mr CHAN Han-pan's enquiry about how shareholders of a limited company subject to a CMSO would be held liable if the company had already wound up its business, the Administration advised that the Bill allowed the Director to issue a CMSO to any organization or person found to be held responsible for the product concerned. DH might also issue a press release to inform the public and traders of the making of the CMSO.	
		Referring to the submission from Hong Kong Chinese Medicine Pharmacists Association (LC Paper No. CB(2)2104/16-17(09)), Mr CHAN Han-pan enquired about the mechanism to be put in place to ensure that CMSO would only be made on reasonable grounds. The Administration advised that the Bill had provided for an appeal mechanism to allow a person or an organization aggrieved by a CMSO to appeal to the Court of First Instance against the Director's decision.	
015041 - 020311	Chairman Mr SHIU Ka-fai Mr CHAN Han-pan Admin	Mr SHIU Ka-fai and Mr CHAN Han-pan's reiteration of the need to address the lack of regulation on the sale of health products which resembled pCms in their ingredients and packaging but were not required to meet the stringent registration requirements applicable to pCms.	
		The Chairman's request for the Administration to (a) clarify in writing the following issue raised by Mr SHIU Ka-fai: whether health food products, such as bottled herbal drinks which were claimed to have "heat-clearing" effect, and other prepackaged orally consumed products which contained but were not composed solely of Chinese herbal medicines or materials of herbal, animal or mineral origin customarily used by the Chinese as active ingredients would fall under the regulation of the Bill; and (b) provide a written response to the deputations' views and suggestions in respect of the legal and drafting aspects of the Bill.	Admin
Agenda it	Agenda item II: Any other business		
020312 - 020454	Chairman Hong Kong Medicine Workers General Union (Yee-Shing)	Date of next meeting The Chairman's remark that issues relating to the review of the Ordinance and the development of Chinese medicine could be followed up at the forum of the Panel.	

Council Business Division 2 <u>Legislative Council Secretariat</u> 12 April 2018