

立法會
Legislative Council

LC Paper No. CB(2)1921/17-18
(These minutes have been
seen by the Administration)

Ref : CB2/BC/6/16

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Minutes of the fifth meeting
held on Monday, 22 January 2018, at 2:30 pm
in Conference Room 2 of the Legislative Council Complex

Members present : Hon Alice MAK Mei-kuen, BBS, JP (Chairman)
Hon Mrs Regina IP LAU Suk-ye, GBS, JP
Hon CHAN Han-pan, JP
Dr Hon KWOK Ka-ki
Dr Hon Helena WONG Pik-wan
Dr Hon Junius HO Kwan-yiu, JP
Hon SHIU Ka-fai
Dr Hon Pierre CHAN

Members absent : Hon KWOK Wai-keung, JP
Dr Hon Elizabeth QUAT, BBS, JP

Public Officers attending : Mr Howard CHAN, JP
Deputy Secretary for Food and Health (Health) 1
Food and Health Bureau

Miss Grace KWOK
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 : Liberal Party
by invitation

Mr WONG Ka-kei
Central Committee Member

Hong Kong Chinese Medicine Industry Association

Ms Karen TANG Mui-fun
Chairman

The Hong Kong Society of Chinese Medicines

Mr Edward William YAU Fook-wing
Vice President

Hong Kong Medicine Workers General Union (Yee-Shing)

Mr WONG Kwok-cheong
理事長

Clerk in : Ms Maisie LAM
attendance Chief Council Secretary (2) 5

Staff in : Mr Bonny LOO
attendance Assistant Legal Adviser 4

Ms Priscilla LAU
Council Secretary (2) 5

Ms Louisa YU
Legislative Assistant (2) 10

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I. Meeting with deputations and the Administration
[LC Paper Nos. CB(2)703/17-18(01) to (03)]

The Bills Committee deliberated (index of proceedings attached at **Annex**).

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2. The Bills Committee received further oral representations from four deputations on the Bill, and noted a written submission from an organization not attending the meeting.

II. Meeting with the Administration

[LC Paper Nos. CB(2)1883/16-17(02) to (04), CB(2)703/17-18(04) to (05) and CB(3)630/16-17]

Continuation of clause-by-clause examination of the Bill

3. Members noted that the Administration proposed moving the following amendments to the Bill:

- (a) replace the words "intended for use" in the definition of "intermediate product" as provided for in the proposed section 138A of the Chinese Medicine Ordinance (Cap. 549) ("the CM Ordinance") with the words "to be used";
- (b) replace "證明" by "確立" in subsection (1) and replace "已證明" by "已確立" in subsection (2) of the Chinese text of the proposed section 138L of the CM Ordinance; and
- (c) repeal the finality provision in the existing section 141(3) of the CM Ordinance.

Admin

4. The Bills Committee requested the Administration to provide after the meeting a full set of the draft amendments to be proposed by the Administration to the Bill for onward circulation to members of the Bills Committee for consideration.

5. The Bills Committee completed clause-by-clause examination of the Chinese text of the Bill.

Follow-up actions required of the Administration

Admin

6. The Bills Committee requested the Administration to provide the following information in writing:

- (a) in respect of the licensing requirements under the Chinese Medicines Regulation (Cap. 549F) that licensed Chinese medicines traders had the duty to set up and maintain a system

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of control to enable the rapid and, so far as practicable, complete recall of the Chinese medicine products sold or distributed by the licence holder concerned, provide information on the composition and functions of the Chinese Medicines Board ("CMB") which was the licensing authority, in particular its work in relation to the system of control referred above;

- (b) provide information on the mechanism put in place by the Department of Health, including inspections conducted, to ensure that the licensed wholesalers of Chinese herbal medicines had purchased herbal medicines or processed herbal medicines only from reputable suppliers as required in the Practising Guidelines for Wholesalers of Chinese Herbal Medicines, and any disciplinary actions taken by CMB and/or prosecutions instituted against the non-complying wholesalers; and
- (c) in respect of herbal teas containing Chinese medicines ingredients which were sold in Chinese herbal tea shops that were subject to the regulation of the Public Health and Municipal Services Ordinance (Cap. 132), provide information on:
 - (i) the number of inspections and sample testing, if any, carried out by the Food and Environmental Hygiene Department in 2017 to ensure that these herbal teas were fit for human consumption; and
 - (ii) the number of cases where the herbal teas concerned were found unfit for human consumption and the prosecutions instituted.

Legislative timetable

7. Members agreed to the Chairman's suggestion that subject to any views members might have on the draft amendments to be proposed by the Administration to the Bill and the Administration's response to issues raised at this meeting, the Bills Committee would hold no further meeting. Members further agreed that if no further meeting needed to be held, the Bills Committee would complete scrutiny of the Bill. The Bills Committee would then report its deliberations to the House Committee.

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[*Post-meeting note:* The draft amendments to be proposed by the Administration to the Bill and the Administration's response to issues raised at this meeting were circulated vide LC Paper Nos. CB(2)864/17-18(01) and CB(2)887/17-18(01) on 9 and 15 February 2018 respectively for members' consideration. No views from members had been received by the specified deadlines.]

8. The Bills Committee noted the Administration's intention to resume the Second Reading debate on the Bill at a Council meeting in March 2018. No members raised objection.

III. Any other business

9. There being no other business, the meeting ended at 4:24 pm.

Council Business Division 2
Legislative Council Secretariat
7 August 2018

**Proceedings of the fifth meeting of
the Bills Committee on Chinese Medicine (Amendment) Bill 2017
held on Monday, 22 January 2018, at 2:30 pm
in Conference Room 2 of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
<i>Agenda item I: Meeting with deputations and the Administration</i>			
000540 - 000844	Chairman	Opening remarks	
000845 - 001137	Liberal Party	Presentation of views	
001138 - 001449	Hong Kong Chinese Medicine Industry Association	Presentation of views (LC Paper No. CB(2)703/17-18(01))	
001450 - 001723	The Hong Kong Society of Chinese Medicines	Presentation of views (LC Paper No. CB(2)703/17-18(02))	
001724 - 002020	Hong Kong Medicine Workers General Union (Yee-Shing)	Presentation of views	
002021 - 002527	Chairman Admin	The Administration's response to the major concerns and issues raised by the deputations: (a) the Bill empowered the Director of Health to issue a Chinese medicine safety order ("CMSO") to direct any person, including licensed traders and unlicensed traders, to stop selling and/or to recall from the market any Chinese medicines or related products with public health risk; and (b) the Chinese Medicines Board ("CMB") had set up a working group comprising Chinese medicine experts, representatives from the Chinese medicines industry and representative from the Government Laboratory to explore amendments to the definition of proprietary Chinese medicine ("pCm") under the Chinese Medicine Ordinance (Cap. 549) ("the CM Ordinance").	
002528 - 003125	Chairman Mr CHAN Han-pan Admin	Mr CHAN Han-pan's expression of support for the legislative proposal; and his call for the Administration to allow holders of a pCm being issued with a Notice of confirmation of transitional registration of pCm (i.e. HKP) to sell out the stocks bearing a HKP label and package insert when the pCm concerned was issued with a Certificate of registration of pCm (i.e. HKC) so as to avoid unnecessary wastage arising from a product recall after the passage of the Bill. The Administration's advice that a product holder who was granted HKC status had to indicate to CMB a preferred effective date for the HKC of the product, which should be within 12 months after being notified of the granting of the HKC status. A product holder who failed to complete the replacement of old	

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		packaging label and insert for the product concerned before the effective date could apply to CMB for extending the deadline for up to another twelve months. CMB would discuss at its meeting to be held by end of January 2018 the option to allow the co-existence of HKP and HKC for the same pCm for a short period of time when all existing stocks bearing a HKP label and package insert were closer to selling out.	
003126 - 003331	Chairman Mr SHIU Ka-fai Hong Kong Medicine Workers General Union (Yee-Shing) Admin	Mr SHIU Ka-fai's advice that the industry supported in principle the legislative proposal. In response to the representative of the Hong Kong Medicine Workers General Union (Yee-Shing), the Administration advised that apart from pCms and intermediate products, CMSO also covered Chinese herbal medicines.	
003332 - 004803	Chairman Dr Helena WONG The Hong Kong Society of Chinese Medicines Admin Mr CHAN Han-pan Hong Kong Chinese Medicine Industry Association	<p>Dr Helena WONG's concern that health products currently not regulated under the CM Ordinance would not be subject to CMSO if the Bill was passed; and Mr CHAN Han-pan concern about the lack of regulation over health products and the manufacturing of health products by licensed pCm manufacturer on their licensed premises.</p> <p>At Dr Helena WONG and Mr CHAN Han-pan's invitations, representative of the Hong Kong Society of Chinese Medicines expressed concern about the lack of effective regulation over those health products which did not fall within the definition of pCms under the CM Ordinance but contained Chinese herbal medicines; and representative of the Hong Kong Chinese Medicine Industry Association considered that the existence of such products created unfairness to traders manufacturing registered pCm products which had devoted much effort and resources to meet the registration requirements.</p> <p>The Administration's response that:</p> <p>(a) CMB had set up a working group to review the pCm definition. Subject to the recommendations to be made by the working group and the view of CMB, consultations would be conducted on any proposed amendments to the definition of pCm in the CM Ordinance. The Administration would, as and when appropriate, propose the relevant legislative amendments in a separate legislative exercise. It should be noted that the Public Health and Municipal Services Ordinance (Cap. 132) provided general protection for purchasers of food and drugs that did not fall within the definition of pCm under the CM Ordinance but fulfilled the definition of "food" under the Public Health and Municipal Services Ordinance. This apart, the labels and advertisements of products with health claims were regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231); and</p> <p>(b) a licensed pCm manufacturer which manufactured non-pCm products in the licensed premises had to ensure that the Chinese medicine products manufactured therein would be free from contamination.</p>	

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004804 - 010044	Chairman Dr Helena WONG Admin Hong Kong Chinese Medicine Industry Association	<p>In response to Dr Helena WONG, the Administration and the representative of the Hong Kong Chinese Medicine Industry Association respectively elaborated on what constituted "intermediate product" and the import of intermediate products.</p> <p>On Dr Helena WONG's enquiry about the regulatory measures over intermediate products which would be used in the further preparation or production process of pCms, the Administration advised that pCm manufacturers had to ensure the safety and quality of all materials, including intermediate products, used in the production of pCms. The Department of Health ("DH") had also put in place a market surveillance system to monitor the quality and safety of pCms.</p>	
<i>Agenda item II: Meeting with the Administration</i>			
010045 - 010217	Chairman Admin	Briefing by the Administration on its response to the follow-up actions arising from the discussion at the meeting on 21 November 2017 [LC Paper No. CB(2)703/17-18(05)].	
010218 - 010353	Chairman Dr Helena WONG Admin	Dr Helena WONG's request for the Administration to provide information on the number of inspection and sample testing carried out by the Food and Environment Hygiene Department in 2017 to ensure that herbal teas containing Chinese medicines ingredients sold in the Chinese herbal tea shops were fit for human consumption, and the number of cases where the herbal teas concerned were found unfit for human consumption and the prosecutions instituted.	Admin
010354 - 010424	Chairman	Continuation of clause-by-clause examination of the Bill	
010425 - 011314	Chairman Admin Dr KWOK Ka-ki	<p><u>Examination of clause 4</u></p> <p><i>Proposed section 138J of the CM Ordinance</i></p> <p>On Dr KWOK Ka-ki's concern over the regulation of Chinese herbal tea drinks and intermediate products, the Administration elaborated on its response as set out in paragraphs 2 to 7 in the Annex to LC Paper No. CB(2)703/17-18(05). Dr KWOK Ka-ki held the view that DH should conduct random sample test to monitor the safety of intermediate products being used by local pCm manufacturers.</p>	
011315 - 011634	Chairman Admin ALA4	<p><i>Proposed sections 138K and 138L of the CM Ordinance</i></p> <p>Legal Adviser to the Bills Committee's remarks that:</p> <p>(a) under the proposed 138F of the CM Ordinance, a CMSO would only be binding on a person from the time it was served on the person, and under the proposed section 138K of the CM Ordinance, non-compliance with a CMSO would only constitute an offence if the person who failed to comply with it was bound by the order; and</p> <p>(b) at his suggestion as set out under item (v) of LC Paper No. CB(2)1883/16-17(03), the Administration would propose</p>	

Time marker	Speaker	Subject(s)/Discussion	Action required
		<p>an amendment to the proposed section 138L of the CM Ordinance to replace "證明" by "確立" in subsection (1) and replace "已證明" by "已確立" in subsection (2).</p>	
011635 - 011959	<p>Chairman Admin ALA4 Dr Helena WONG</p>	<p><u>Examination of clause 5</u></p> <p>Legal Adviser to the Bills Committee's remarks that in response to his comments as set out under item (1) of LC Paper No. CB(2)1883/16-17(03), the Administration would propose an amendment to repeal the finality provision in the existing section 141(3) of the CM Ordinance.</p>	
012000 - 012408	<p>Chairman Admin ALA4</p>	<p><u>Examination of clause 6</u></p> <p>Legal Adviser to the Bills Committee drew to members' attention that the Chinese text of the proposed section 159(3) of the CM Ordinance rendered "the second day after the day" as "當日起計的第三日", which had the same meaning despite the use of different language.</p>	
012409 - 013429	<p>Chairman Admin ALA4 Dr Helena WONG</p>	<p><u>Examination of clause 7</u></p> <p>Dr Helena WONG's enquiry and the Administration as well as the Legal Adviser to the Bills Committee's elaboration on the proposed definition of "intermediate product" as provided for in the proposed section 138A of the CM Ordinance and the amendment to be proposed by the Administration to replace the words "intended for use" in the definition with "to be used" as appeared in the existing section 2 of the Chinese Medicines Regulation (Cap. 549F).</p>	
013430 - 014625	<p>Chairman Admin Dr Helena WONG</p>	<p><u>Examination of clause 8</u></p> <p>Dr Helena WONG's enquiry and the Administration's advice on the measures being put in place to monitor the quality and safety of Chinese herbal medicines and intermediate products as well as the mechanism to recall from the market any Chinese herbal medicines and intermediate products which might pose threats to public health.</p> <p>Dr Helena WONG's request for the Administration to provide information on the mechanism put in place by DH to ensure that the licensed wholesalers of Chinese herbal medicines had purchased herbal medicines or processed herbal medicines only from reputable suppliers as required in the Practising Guidelines for Wholesalers of Chinese Herbal Medicines, and the disciplinary actions taken by CMB and/or prosecutions instituted against the non-complying wholesalers.</p>	Admin
014626 - 014808	<p>Chairman Admin</p>	<p><u>Examination of clauses 9 and 10</u></p>	
014809 - 014949	<p>Chairman Admin</p>	<p><u>Examination of clauses 11 and 12</u></p> <p>In response to the Chairman's enquiry, the Administration's advice that clauses 11 and 12 proposed to repeal section 35 of</p>	

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		the Chinese Medicine Practitioners (Registration) Regulation (Cap. 549C) and Part IV of the Chinese Medicine Practitioners (Discipline) Regulation (Cap. 549D) as the proposed section 159 of the CM Ordinance had already provided for the time at which a notice or order was taken as having been served or given in specified circumstances.	
014950 - 015559	Chairman Dr Helena WONG ALA4 Admin	<p>While noting that CMB had published the Recall Guidelines for Chinese Medicine Products ("the Recall Guidelines") to assist the licensed Chinese medicines traders concerned to set up the recall system, Dr Helena WONG was of the view that the procedures for the traders to recall a Chinese medicine product should preferably be set out in the law.</p> <p>The Administration's response that being the licensing and regulatory authority, CMB was statutorily empowered to impose licensing conditions on the relevant Chinese medicines traders and promulgate various practising guidelines for compliance by the traders concerned. It was considered appropriate to set out the recalling procedures in the Recall Guidelines which would facilitate amendments more efficiently as and when necessary.</p> <p>Dr Helena WONG requested the Administration to provide in writing information on the composition and functions of CMB. Pointing out that the subject "Regulation of Chinese medicines" was listed on the list of outstanding items for discussion by the Panel on Health Services, she urged the Administration to update the Panel on the regulation of Chinese herbal medicines, intermediate products and pCms in due course.</p>	Admin
015600 - 015853	Chairman Dr Helena WONG Admin	Way forward and legislative timetable	
<i>Agenda item III: Any other business</i>			
015854 - 015858	Chairman	Closing remarks	