

立法會
Legislative Council

LC Paper No. CB(2)1554/17-18

(These minutes have been
seen by the Administration)

Ref : CB2/BC/6/16

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Minutes of the third meeting
held on Friday, 13 October 2017, at 10:45 am
in Conference Room 3 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
Hon KWOK Wai-keung, JP
Dr Hon Helena WONG Pik-wan
Dr Hon Elizabeth QUAT, BBS, JP
Dr Hon Junius HO Kwan-yiu, JP
Hon SHIU Ka-fai
Dr Hon Pierre CHAN

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

Mr James LAM
Assistant Secretary for Food and Health (Health) 2
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

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

Staff in attendance : Mr Bonny LOO
Assistant Legal Adviser 4

Ms Jasmine TAM
Senior Council Secretary (2) 8

Miss Maggie CHIU
Legislative Assistant (2) 5

Action

I. Meeting with 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), CB(2)2141/16-17(02), CB(2)16/17-18(01) to (02) and CB(3)630/16-17]

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

Admin

2. The Bills Committee requested the Administration to:

- (a) provide a copy each of the four practising guidelines for Chinese medicine traders promulgated by the Chinese Medicine Council of Hong Kong ("CMCHK");
- (b) provide a comparison between (i) the standards formulated by CMCHK and currently used for testing of pesticide residues and heavy metal contents in Chinese herbal medicines sold in Hong Kong and (ii) the reference standards developed under the Hong Kong Chinese Materia Medica Standards project in respect of the maximum permitted limits of pesticide residues and heavy metal contents in Chinese Materia Medica;
- (c) provide a comparison of the standards currently adopted in Hong Kong, the Mainland and other places around the world in respect of the maximum permitted limits of heavy metal

Action

contents in Chinese herbal medicines; and explain why the standards currently used for testing of heavy metal contents in Chinese herbal medicines sold in Hong Kong only covered four heavy metal contents (viz. lead, arsenic, cadmium and mercury);

- (d) provide further information to address the issues raised in paragraph 6 of item 3 and items 5 and 7 of the letter dated 27 September 2017 from Dr Helena WONG (LC Paper No. CB(2)2141/16-07(02)) in relation to the second stage test of the testing of pesticide residues and heavy metal contents in Chinese herbal medicines, the maximum permitted level (total intake) of arsenic and cadmium, and the formulation of standards for maximum permitted limits of sulphur dioxide in Chinese herbal medicines;
- (e) advise whether pharmaceutical manufacturers were permitted to manufacture health food products under the law; and if they were not, whether the Department of Health ("DH") would initiate investigations into suspected cases and take enforcement actions accordingly; and
- (f) advise the staff establishment of the Chinese Medicine Division of DH, which was mainly responsible for regulatory and public health affairs relating to Chinese medicine, and that of the dedicated unit to be set up under the Food and Health Bureau for developing Chinese medicine.

II. Any other business

3. The Chairman said that the next meeting would be scheduled for mid-November 2017, so as to allow time for the Administration to prepare and provide the various information requested by members at this meeting.

(Post-meeting note: With the concurrence of the Chairman, the fourth meeting of the Bills Committee was scheduled for 21 November 2017 at 2:30 pm.)

4. There being no other business, the meeting ended at 12:44 pm.

**Proceedings of the third meeting of
the Bills Committee on Chinese Medicine (Amendment) Bill 2017
held on Friday, 13 October 2017, at 10:45 am
in Conference Room 3 of the Legislative Council Complex**

Time marker	Speaker	Subject(s)/Discussion	Action required
<i>Agenda item I: Meeting with the Administration</i>			
000638 - 000822	Chairman Admin	Opening remarks	
000823 - 002133	Chairman Dr Helena WONG Admin ALA4	<p>Dr Helena WONG's enquiry and the Administration's reply regarding the licensing requirement for the import of Chinese herbal medicines into Hong Kong.</p> <p>While noting that licensed wholesalers of Chinese herbal medicines were required under the Practising Guidelines for Wholesalers of Chinese Herbal Medicines issued by the Chinese Medicines Board ("CMB") to purchase herbal medicines or processed herbal medicines only from reputable suppliers, Dr Helena WONG expressed concern about how the Administration could ensure that the above requirement, which was not legally binding on the relevant wholesalers, had been complied with. Pointing out that the manufacturing process of those Chinese medicine products supplied to the Hospital Authority must meet the Good Manufacturing Practice ("GMP") standards, Dr WONG considered that it should be made mandatory that licensed wholesalers of Chinese herbal medicines had to purchase herbal medicines or processed herbal medicines from suppliers meeting the GMP requirements.</p> <p>The Administration's advice that licensed wholesalers of Chinese herbal medicines were required under the practising guidelines to keep the relevant purchase records and transaction documents for a period of not less than two years from the date of transaction to enable the tracing of the source of herbal medicines or processed herbal medicines purchased where necessary. The Department of Health ("DH") would conduct inspections on the premises of licensed wholesalers and retailers of Chinese herbal medicines on a regular basis to ensure their compliance with the requirements of the law and the practising guidelines. Contravention of the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") and/or the practising guidelines by Chinese medicines traders might result in prosecution, disciplinary action by the Chinese Medicine Council of Hong Kong ("CMCHK"), and cancellation of licences in serious cases.</p> <p>The Chairman's remark that while the above concern raised by Dr Helena WONG as well as the concerns raised by members and deputations at previous meetings over the definition of proprietary Chinese medicines and the development of Chinese medicine fell outside the scope of the Bill which was spelt out in its long title, the Administration should seek to address such concerns and report relevant issues to the Panel on Health Services ("the Panel").</p> <p>The Legal Adviser to the Bills Committee's advice that Rule 57(4)(a) of the Rules of Procedure ("RoP") provided that an amendment proposed to be moved to a bill must be relevant to the subject matter of the bill and to the subject matter of the clause to</p>	

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		<p>which it related. The Administration appeared to have taken a rather narrow view of the scope of the Bill. It was for the President to rule, after having considered all relevant information including the long title of the Bill and the relevant Legislative Council ("LegCo") Brief, whether a proposed amendment to the Bill complied with RoP 57(4)(a).</p> <p>The Administration's remark that any proposed amendment to the Ordinance would require extensive consultation with and support of the trade before it could be introduced into LegCo for its scrutiny. It would report to the Panel on relevant development in this regard.</p>	
002744 - 003822	Chairman Mr SHIU Ka-fai Admin	<p>Mr SHIU Ka-fai's call for the Administration to address the beauty industry's concern about whether the provision of massage and manipulative therapy services would be considered as "practising Chinese medicine" and hence be subject to regulation under the Ordinance.</p> <p>Mr SHIU Ka-fai's concern and the Administration's response regarding the regulation of health products which were composed mainly of Chinese herbal medicines and mixed with other materials or substances (e.g. vitamins).</p>	
003823 - 004834	Chairman Dr Helena WONG Admin	<p>Dr Helena WONG's views that to avoid enforcement disputes, the Administration should clarify the circumstances under which a Chinese herbal medicine would be regarded as being "dangerous or injurious to health" and warrant the issuance of a Chinese medicine safety order ("CMSO"). It should also impose a licensing condition requiring licensed wholesalers of Chinese herbal medicines to purchase herbal medicines or processed herbal medicines only from suppliers meeting the GMP requirements such that the source of the medicines could be traced.</p> <p>The Administration's response as follows:</p> <ul style="list-style-type: none"> (a) the Director of Health would in future decide on the need to issue CMSOs for Chinese herbal medicines in the light of the existing regulatory standards for routine surveillance if the Bill was passed. The Bill had also 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; and (b) wholesalers and retailers of Chinese herbal medicines were already required under the relevant practising guidelines to ensure that the name and the batch number (provided by the supplier) of herbal medicines or processed herbal medicines acquired were clearly stated on the container or package of the medicines as well as in the relevant purchase invoices to enable the tracing of the source of the medicines where necessary. <p>On Dr Helena WONG's concern about whether the existing regulatory standards for pesticide residues and heavy metal contents in Chinese herbal medicines sold in Hong Kong were on par with relevant international standards, the Administration advised that regulatory bodies around the world had not</p>	

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		<p>formulated a standardized set of maximum permitted limits of pesticide residues and heavy metals for Chinese herbal medicines. The current standards used by DH for testing of pesticide residues and heavy metal contents in Chinese herbal medicines sold in Hong Kong, which covered 37 pesticide residues and four heavy metal contents and were applicable to all the 605 types of Chinese herbal medicines regulated by the Ordinance, were formulated by CMCHK with reference to other international standards. CMCHK would review the limits and scope of pesticide residues and heavy metal contents in Chinese herbal medicines under the market surveillance system from time to time.</p>	
004835 - 005845	Chairman Mr SHIU Ka-fai Admin	<p>Mr SHIU Ka-fai's reiteration of his concern about the lack of regulation on health products which were composed mainly of Chinese herbal medicines and mixed with other materials or substances; and his view that the Administration's current practice of adopting the results of the second-stage tests (i.e. tests of pesticide residues in the decoctions of Chinese herbal medicines) in assessing whether a Chinese herbal medicine might pose public health risk was appropriate.</p> <p>Mr SHIU Ka-fai's enquiry and the Administration's reply regarding whether a wholesaler of Chinese medicine products to whom a CMSO was addressed 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.</p> <p>In reply to Dr Helena WONG's earlier enquiry about why sulphur dioxide residue was not a regular testing item under DH's market surveillance system for Chinese herbal medicines, the Administration advised that the Hong Kong Chinese Materia Medica Standards ("HKCMMS") Volume 9 to be released in 2018-2019 would include the testing of sulphur dioxide residue. CMB would later consult the industry on the adoption of the testing method for sulphur dioxide residue promulgated by HKCMMS as a routine quality monitoring method of Chinese herbal medicines.</p>	
005846 - 012206	Chairman Dr Helena WONG Admin Mr SHIU Ka-fai	<p>On Dr Helena WONG's view that the results of the first-stage tests (i.e. tests of pesticide residues and heavy metal contents in Chinese medicine decoction pieces), rather than those of the second-stage tests as proposed by the Administration, should be adopted in assessing whether a Chinese herbal medicine might have public health risk and warrant the issuance of a CMSO, the Administration reiterated that the testing of pesticide residues and heavy metal contents in the decoction of Chinese herbal medicines was considered to be a closer simulation of condition during human consumption which was more appropriate for human risk assessment.</p> <p>On Dr Helena WONG's queries about why only 37 pesticide residues and four heavy metal contents were selected for testing under DH's market surveillance system for Chinese herbal medicines and the differences in certain regulatory standards adopted for routine surveillance and the quality reference limits set out under HKCMMS, the Administration explained that CMCHK had selected 37 pesticide residues and four heavy metals for testing the Chinese herbal medicines regulated under the Ordinance after</p>	

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		<p>considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally. The focus of the regulatory standards under DH's market surveillance system was on ensuring public safety to prevent causing injuries to health after use, whereas the HKCMMS standards (which currently covered 275 types of commonly used Chinese herbal medicines in Hong Kong) were set as reference standards on the quality of individual Chinese herbal medicines.</p> <p>Mr SHIU Ka-fai reiterated that as most Chinese herbal medicines were taken in the form of decoction, he considered it appropriate to adopt the results of the second-stage tests in assessing whether a Chinese herbal medicine might pose public health risk.</p> <p>Requests of Dr Helena WONG and the Chairman for the Administration to provide (a) a copy each of the four practising guidelines for Chinese medicine traders promulgated by CMCHK; and (b) a comparison between (i) the standards formulated by CMCHK and currently used for testing of pesticide residues and heavy metal contents in Chinese herbal medicines sold in Hong Kong and (ii) the reference standards developed under HKCMMS project in respect of the maximum permitted limits of pesticide residues and heavy metal contents in Chinese Materia Medica.</p>	Admin
012207 - 013126	Chairman Dr Helena WONG Admin	<p>In reply to Dr Helena WONG's enquiry about why only lead, arsenic, cadmium and mercury were selected for testing under DH's market surveillance system for Chinese herbal medicines, the Administration advised that countries around the world had not yet come up with a standardized set of limits for heavy metal contents in traditional Chinese herbal medicines. CMCHK had formulated, with reference to other relevant international standards, the regulatory limits of four heavy metals which were known to be more toxic to human beings.</p> <p>The Chairman remarked that the Administration could further discuss the above matter with Dr Helena WONG after the meeting.</p>	
013127 - 013524	Chairman Dr Junius HO Admin	<p>Dr Junius HO's expression of support for the legislative proposals.</p> <p>Dr Junius HO's enquiry and the Administration's reply regarding whether decoctions of Chinese herbal medicines were covered by the definition of "intermediate product" under the Bill.</p>	
013525 - 015157	Chairman Dr Helena WONG Admin Mr CHAN Han-pan	<p>Dr Helena WONG's remark that the current regulatory standards for heavy metal contents in Chinese herbal medicines seemed to be less stringent than those applicable to food; and her enquiry about whether the Administration would, in tandem with its proposal to update the standards of maximum permitted concentrations of metallic contaminants in food, review and update the limits and scope of permitted heavy metal contents in Chinese herbal medicines to enhance the protection of public health.</p> <p>Mr CHAN Han-pan's view that as Chinese herbal medicines were different from food in various ways, it was not appropriate to apply directly the regulatory standards for the latter to the former.</p>	

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		<p>The Administration's response that Chinese herbal medicines should be treated differently from food as the use of the former and their medication were based on personal physical conditions and medical needs, and Chinese herbal medicines were normally not taken daily like food. To safeguard public health, CMB would review the regulatory standards for heavy metal contents in Chinese herbal medicines from time to time.</p> <p>Dr Helena WONG's request for the Administration to provide in writing (a) a comparison of the standards currently adopted in Hong Kong, the Mainland and other places around the world in respect of the maximum permitted limits of heavy metal contents in Chinese herbal medicines; and (b) the reasons why the standards currently used for testing of heavy metal contents in Chinese herbal medicines sold in Hong Kong only covered four heavy metal contents (viz. lead, arsenic, cadmium and mercury).</p>	Admin
015158 - 015720	Chairman Admin	The Chairman's remark that the Administration should address Dr Helena WONG's concerns over the regulation of pesticide residues and heavy metal contents in Chinese herbal medicines, enhance its communication with the Chinese medicine industry to understand the stakeholders' views on the Ordinance and the development of Chinese medicine, and take heed of the call of members and the trade for an overall review of the Ordinance.	
015721 - 020211	Chairman Mr CHAN Han-pan Mr SHIU Ka-fai Dr Helena WONG	<p>Mr CHAN Han-pan's requests for the Administration to advise in writing (a) whether pharmaceutical manufacturers were permitted to manufacture health food products under the law; and if they were not, whether DH would initiate investigations into suspected cases and take enforcement actions accordingly; and (b) the staff establishment of the Chinese Medicine Division of DH, which was mainly responsible for regulatory and public health affairs relating to Chinese medicine, and that of the dedicated unit to be set up under the Food and Health Bureau for developing Chinese medicine.</p> <p>Mr SHIU Ka-fai's remark that the Administration should gauge extensively views of the trade on regulation of Chinese medicine.</p> <p>Dr Helena WONG's request for the Administration to provide further information to address the issues raised in paragraph 6 of item 3 and items 5 and 7 of her letter dated 27 September 2017 (LC Paper No. CB(2)2141/16-07(02)) in relation to the second-stage test of the testing of pesticide residues and heavy metal contents in Chinese herbal medicines, the maximum permitted level (total intake) of arsenic and cadmium, and the formulation of standards for maximum permitted limits of sulphur dioxide in Chinese herbal medicines.</p>	Admin Admin
<i>Agenda item II: Any other business</i>			
020212 - 020306	Chairman	Date of next meeting	