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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14 February 2018

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 22 January 2018, 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 at the Bills Committee meeting on 22 January 2018.

(a) Composition and functions of the Chinese Medicines Board

2. The Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (the Council) was established under section 12 of the Chinese Medicine Ordinance (Cap. 549) (CMO). Its composition and functions are set out in section 14 and Schedule 3 of the CMO as follows:

Composition of the CMB –

(i) The Director of Health (Chairman);
(ii) Two public officers;
(iii) Five persons from the trade of Chinese medicines, 2 of whom shall be members of the Council;
(iv) Two Chinese medicine practitioners;
(v) One person from an educational or scientific research institution in Hong Kong; and
(vi) Three lay persons

Functions of the CMB –

(i) to implement the policy and activities as determined by the Council, and to provide guidance to its committees;
(ii) to make recommendations and reports to the Council regarding its activities or the implementation of policies;
(iii) to approve or reject applications for registration of proprietary Chinese medicines (pCms), variation of registered particulars of pCms and to make decision to de-register pCms;
(iv) to approve or reject applications for licences and renewal of licences in respect of Chinese medicines traders, to determine licensing requirements and to make exemptions as provided for under the CMO;
(v) to advise the Council on any amendments to Schedules 1 and 2 of the CMO;
(vi) to inquire into the conduct of licensed traders of Chinese medicines and to determine the action to be taken against a licensed trader;
(vii) to issue relevant certificates under the CMO;
(viii) to implement the transitional arrangements for licensing of traders of Chinese medicines and registration of pCms;
(ix) to handle reviews against decisions of the committees as provided for under the CMO; and
(x) to carry out any other functions assigned to it under the CMO or delegated

to it by the Council.

3. According to the Chinese Medicines Regulation (Cap. 549F), wholesalers of Chinese herbal medicines (Chms) or pCms, and manufacturers of pCms, are required to set up and maintain a system of complaint and recall of Chinese medicinal products. This is to enable the rapid and, as far as practicable, complete recall of any medicinal products sold, or distributed, which may later be found to be dangerous or injurious to health, or unsuitable for human consumption. To assist the Chinese medicines traders in setting up an effective system of recall, the CMB developed the "Guidelines on Recall of Chinese Medicinal Products".

4. In response to the request of the Chairman of the Bills Committee on Chinese Medicine (Amendment) Bill 2017 at the meeting on 17 September 2017 and the enquiry from member Dr Hon Helena Wong Pik-wan to the Chairman dated 11 September 2017, the Food and Health Bureau has provided response together with the above-mentioned recall guidelines on 22 September 2017

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

5. 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.

6. Licensed 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 Department of Health (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 practising guidelines.

7. The DH draws samples of around 45 Chms every month from the market for testing, which the regular testing items include pesticides residues, heavy metals content and morphological identification, in order to monitor the quality and safety of the Chm regulated under the CMO. After conducting risk assessment, the DH randomly draws different Chms totaling 45 samples for testing every month and deploy its staff to purchase from different licensed Chinese medicines traders and manufacturers. The market monitoring system covers the whole territory of Hong Kong and inspects licensed Chinese medicines traders and manufacturers selling Chms on a random basis. The DH also conducts targeted testings in response to information collected from other channels, including adverse drug reaction reporting system, public complaints and referrals from other government departments.

8. From 1 January 2016 to 31 December 2017, no licensed Chinese medicines trader was found to have violated the provision in the practising guidelines as mentioned in paragraph 5 above.

(c) Regulation and enforcement of the sale of herbal teas in Chinese herbal tea shops

9. By the end of December 2017, there were 398 valid Chinese Herb Tea Permits issued by the Food and Environmental Hygiene Department (FEHD). Premises covered by Chinese Herb Tea Permits are subject to regular bimonthly inspections. To ensure that the formulae of these herb teas are safe for human consumption, the FEHD will send the formulary and dosage of each ingredient in the formulary of each type of Chinese herb teas sold on the premises to the Director of Health for vetting. The Centre for Food Safety had taken eight samples in permitted premises for selling Chinese herb teas in 2017 for testing of plasticisers, pathogens, etc. As all test results of the samples were satisfactory, no prosecution action was needed.