立法會
Legislative Council

LC Paper No. CB(2)1883/16-17(05)

Ref : CB2/BC/6/16

Bills Committee on Chinese Medicine (Amendment) Bill 2017

Background brief prepared by the Legislative Council Secretariat

Purpose

This paper provides background information and summarizes relevant discussions of the Panel on Health Services ("the Panel") on the proposed amendments to the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") and three items of its subsidiary legislation which seek to confer powers on the Director of Health ("Director")[1] to prohibit the sale of Chinese medicines or related products or to recall such products in specified circumstances.

Background

2. The Ordinance, enacted in July 1999, provides a statutory framework for the regulation of the practice, use, trading and manufacturing of Chinese medicines in Hong Kong. The Chinese Medicine Council of Hong Kong ("CMCHK") is established under the Ordinance to develop and implement these regulatory measures. The Chinese Medicines Board ("CMB") is one of the two boards[2] established under CMCHK, as the board responsible for regulatory measures regarding Chinese medicines.

3. Under the Ordinance, all products fall within the definition of proprietary Chinese medicine ("pCm")[3] must be registered before they can be imported,

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1 Under section 2(1) of the Ordinance, "Director" also includes a Deputy Director of Health.

2 The other board is the Chinese Medicine Practitioners Board.

3 Under section 2(1) of the Ordinance, "proprietary Chinese medicine" includes any proprietary product composed of any Chinese herbal medicines or any materials of herbal, animal or mineral origin customarily used by the Chinese, formulated in a finished dose form, and known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any human disease or symptom, or for the regulation of the functional states of the human body.

manufactured or sold in Hong Kong. To get registered in Hong Kong, a pCm must fulfil the registration requirements regarding safety, quality and efficacy as prescribed by CMB. Separately, all Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal medicines[4], or manufacture or wholesale of pCms are required under the Ordinance to obtain the relevant Chinese medicines traders licence from CMB before the commencement of their business.

4. Under the Chinese Medicines Regulation (Cap. 549F), licensed wholesalers of Chinese herbal medicines, licensed manufacturers of pCms and licensed wholesalers of pCms are required to set up and maintain a system of control to enable the rapid and, so far as practicable, complete recall of any Chinese herbal medicine, intermediate product[5] generated or pCm manufactured in the course of manufacture or pCm which has been sold or distributed by the traders concerned in the event that the products are found to be dangerous, injurious to health or unfit for human consumption.

5. The judgment of a judicial review case handed down by the Court of First Instance on 21 May 2015[6] concluded that the Director had no lawful power under the Ordinance to instruct the licensed wholesaler concerned to recall the two suspected unregistered pCms in question on 27 March 2014 and the decision to issue the instruction to recall was ultra vires. Upon a review of the Ordinance and its subsidiary legislation, the Administration has also found that there is currently no provision providing that an unlicensed trader must carry out recall actions regarding pCms or Chinese herbal medicines which may pose threats to public health.

The Chinese Medicine (Amendment) Bill 2017

6. The Administration introduced the Chinese Medicine (Amendment) Bill 2017 into the Legislative Council ("LegCo") on 14 June 2017 to amend the Ordinance and its subsidiary legislation to empower the Director to prohibit the sale of Chinese medicines and other substances or compounds generated in the course of manufacture of pCm or to recall such products in specified circumstances. The key features of the proposed legislative amendments are set out in paragraphs 5 to 10 of the LegCo Brief (File Ref: FHB/H/24/24).

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[4] Under section 2(1) of the Ordinance, "Chinese herbal medicine" means any of the substances specified in Schedule 1 or 2 to the Ordinance.

[5] Under section 2 of the Chinese Medicines Regulation, "intermediate product" means a substance or compound generated in the course of manufacture of a pCm and which is to be used in further preparation or production process of the medicine.

[6] *Man Hing Medical Supplies (International) Ltd v Director of Health* [2015] 3 HKLRD 224

Deliberations of the Panel

7. The Panel was consulted on the legislative proposals on 28 February 2017. The deliberations and concerns of members are summarized in the following paragraphs.

The recall order

8. Members generally expressed support for the legislative proposal to strengthen the control of the sale of Chinese medicines by conferring statutory power on the Director to order any person to recall from the market any Chinese herbal medicines or pCms which might pose threats to public health so as to fill the lacuna in the Ordinance. Question was raised about the grounds for making a recall order.

9. The Administration advised that under the legislative proposal, the Director would order any person (regardless of whether the person was a licensed trader under the Ordinance or not) who had supplied Chinese herbal medicines, pCms and/or intermediate products to recall the products concerned from the market and to withdraw the same from being supplied should the Director had reasonable cause to believe, at the time of making the recall decision, that such products were dangerous or injurious to health, or unfit for use by human being; or the order was necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; or the products were being sold or distributed in contravention of the Ordinance, such as Chinese herbal medicines 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.

10. Some members shared the various concerns raised by the Chinese medicine traders over the operational issues of the recall order. They called on the Administration to fully communicate with the trade. At the meeting, the Panel passed a motion urging the Administration to take into account the concerns of the trade in drafting the legislative proposal. In particular, the Director should provide sufficient time for the trade to recall the products concerned; specify clearly what constituted a recall, to the extent reasonably possible, of those products already supplied; and lower the maximum penalty for non-compliance, which was proposed to be a fine at level 6 (i.e. $100,000) and imprisonment for two years, to an appropriate level.

11. According to the Administration, there was no significant difference between the recall action in future and the existing recall system set up and maintained by the trade. The Department of Health ("DH") had conducted a meeting with 16 Chinese medicines traders associations and six briefing sessions for individual licensed Chinese medicines traders in January 2017 to facilitate the trade to better understand the legislative proposal. A seven-week public consultation on the legislative proposal was conducted from January to February 2017. The public and the trade supported the proposal.

12. The Administration further advised that each recall action was considered as an independent exercise. When issuing a recall order, DH would ensure adequate communication with the Chinese medicine trader concerned. In deciding the appropriate manner of recall, there were a number of factors to be considered, including the nature of the problem and sales networks, as well as the level of health risk posed by the problematic products. The proposed maximum penalty for non-compliance was the same as the existing maximum penalties for not complying with other regulations for Chinese medicines under the Ordinance. To ensure the fair and just handling of all case, an appeal mechanism would be put in place such that a person bound by a recall order could appeal against the decision of the Director.

Testing of Chinese herbal medicines

13. Some members considered it necessary for the Administration to strengthen the existing mechanism in monitoring the quality and safety of Chinese medicines available in the market. There was a view that the Administration should increase the number of samples of Chinese herbal medicines drawn from the market for testing of pesticide residues and heavy metals contents in tandem with the conferring of power upon the Director for making a recall order under the Ordinance. The Administration advised that since February 2017, DH had increased the targeted number of market surveillance samples of Chinese herbal medicines, at both wholesale and retail levels, from 30 to 45 per month, with a view to covering all Chinese herbal medicines currently available for sale in local market within a year.

Scope of the legislative exercise

14. There was a view that the Administration should take the opportunity of this legislative exercise to introduce a new category in the existing pCm registration system to cover pCms being an established medicine with proven safety and quality; to allow applicants for formal registration of pCm to change those active ingredients in the master formula that were banned or no longer available; to provide a longer transitional period for pCms being approved to

migrate from transitional registration to formal registration; and to regulate those products not consisted solely of Chinese medicine materials and were currently regarded as "health food products". Members were assured that DH would continue to address the above concerns of the trade as and when appropriate.

Relevant papers

15. A list of the relevant papers on the LegCo website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
14 July 2017

Appendix

Relevant papers on the Chinese Medicine (Amendment) Bill 2017

Committee	Date of meeting	Paper
Panel on Health Services	28.2.2017 (Item V)	Agenda CB(2)1056/16-17(01) CB(2)1297/16-17(01)

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