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Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Background brief prepared by the Legislative Council Secretariat for the meeting on 8 June 2020

Regulatory regime for Chinese herbal medicines and proprietary Chinese medicines and development of the industry

Purpose

This paper provides background information and summarizes the concerns of members of the Panel on Health Services ("the Panel"), the two Subcommittees on Issues Relating to the Development of Chinese Medicine ("the Subcommittee") appointed by the Panel in the Fifth and Sixth Legislative Council ("LegCo") and the Bills Committee on Chinese Medicine (Amendment) Bill 2017 ("the Bills Committee") on the regulatory regime for Chinese herbal medicines and proprietary Chinese medicines ("pCm").

Background

Regulatory framework of Chinese medicine

2. The Chinese Medicine Ordinance (Cap. 549) ("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, among others, develop and implement these regulatory measures. A Chinese Medicine Practitioners Board and a Chinese Medicines Board ("the CM Board") have been set up under the Council to assist it in pursuing its functions.

3. At present, there are 31 types of toxic Chinese herbal medicines and 574 types of commonly used Chinese herbal medicines listed in Schedule 1 and Schedule 2 to the Ordinance respectively.[1] Separately, under the Hong Kong Chinese Materia Medica Standards ("HKCMMS"),[2] the research on 299 Chinese herbal medicines commonly used in Hong Kong has been completed. All Chinese medicines traders who engage in a business of retail and wholesale of these Chinese herbal medicines are required under the Ordinance to obtain relevant licence from the CM Board. In addition, those Chinese herbal medicines specified in Schedule 1 may only be sold or dispensed based on prescription by registered Chinese medicine practitioners. According to the Import and Export Ordinance (Cap. 60), any person who wish to import or export any of the 31 Chinese herbal medicines specified in Schedule 1 and five Chinese herbal medicines specified in Schedule 2 to the Ordinance (namely, Flos Campsis, processed Radix Aconiti, processed Radix Aconiti Kusnezoffii, Radix Clematidis and Radix Gentianae) must first apply for an import or export licence from the Department of Health ("DH"). While no registration system has been established for persons who engage in the dispensing of Chinese herbal medicines in Hong Kong, retailers of Chinese herbal medicines that engaged in the dispensing of Chinese herbal medicines are required under the Ordinance and the Chinese Medicines Regulation (Cap. 549F) to nominate a person responsible for supervision of the work.

4. Under the Ordinance, all products falling within the definition of pCm[3] must be registered with CM Board before they can be imported, manufactured and/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 CM Board. Separately, all Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal medicines, or manufacture or wholesale of pCms are required under the Ordinance to apply to CM Board for a

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

[2] DH launched the HKCMMS project in 2002. An International Advisory Board is established under the project to, among others, give advice on the principles, methodologies, parameters and analytical methods for the development of HKCMMS. To date, nine editions of HKCMMS have been published.

[3] Under section 2(1) of the Ordinance, pCm refers to any proprietary product composed solely of any Chinese herbal medicines and/or any materials of herbal, animal or mineral origin customarily used by the Chinese as active ingredients; formulated in a finished dose form; and known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

relevant Chinese medicines traders licence before the commencement of their business. Manufacturers holding a pCm manufacturer licence may apply to CM Board for a certificate for manufacturer to certify that they follow the requirements of good practices in manufacture and quality control of pCms (i.e. the Good Manufacturing Practice ("GMP") Certificate).

Chinese Medicine Development Committee

5. Established in February 2013, the Chinese Medicine Development Committee ("the CM Development Committee") is chaired by the the Secretary for Food and Health to give recommendations to the Administration concerning the direction and long-term strategy of the future development of Chinese medicine in Hong Kong. The CM Development Committee is tasked to study four key areas, namely the development of Chinese medicine services, personnel training and professional development, research and development and development of the Chinese medicines industry (including Chinese medicines testing). A Chinese Medicine Practice Subcommittee and a Chinese Medicines Industry Subcommittee are formed under the CM Development Committee to study the relevant specific areas.

Chinese Medicine Development Fund

6. The Financial Secretary announced in his 2018-2019 Budget Speech the setting up of the Chinese Medicine Development Fund ("the Fund") of $500 million to provide support in areas such as applied research, Chinese medicine specialization, knowledge exchange and cross-market co-operation. The Fund provides Chinese medicine practitioners and the Chinese medicine drug sector with financial support to jointly promote the development of Chinese medicine and enhance the overall standard of the industry, including nurturing talent for the Chinese medicine industry and the Chinese medicine hospital, promoting Chinese medicine-related studies and scientific research, and providing assistance to local Chinese medicine traders for improving the quality and standards of production and registration of pCm in accordance with statutory requirements. It also enhances public knowledge and understanding of Chinese medicine. The Fund commenced operation in June 2019. The first batch of funding was released in the fourth quarter of 2019.

Deliberations of the Panel, the Subcommittee and the Bills Committee

7. Issues relating to the regulatory regime for Chinese herbal medicines and pCm were discussed by the Panel at a number of meetings, and by the

Subcommittee and the Bills Committee. The deliberations and concerns of members are summarized in the following paragraphs.

Regulatory standards for Chinese herbal medicines available in the market

8. Members noted that under DH's market surveillance system to monitor the quality and safety of the 605 types of Chinese herbal medicines regulated under the Ordinance, around 45 samples of these Chinese herbal medicines were collected every month from the market for testing. Items subjected to regular testing include 37 pesticide residues (including 20 organochlorine pesticides and 17 organophosphorus pesticides), four heavy metals contents (namely lead, arsenic, cadmium and mercury) and morphological identification. Separately, targeted tests were conducted on samples of Chinese herbal medicines obtained from other channels which include adverse drug reaction reporting system, public complaints and referrals from other government departments. Tests for targeted items might involve morphological identification, physiochemical testing and testing for adulteration with Western drug ingredients. Some members considered that DH should strengthen its market surveillance system such that sub-standard Chinese herbal medicines in the market could be identified and recalled in a timely manner to safeguard public health.

9. The Administration advised that the number of samples of Chinese herbal medicines taken by DH for regular testing has increased from about 30 to 45 per month starting from February 2017. In the first half of 2017, DH had collected a total of 289 samples of Chinese herbal medicines, of which 64.8% was taken from retailers of Chinese herbal medicines, 18.5% from wholesalers of Chinese herbal medicines and 16.7% from other channels (such as patients of Chinese herbal medicines poisoning and Chinese medicine clinics), for testing.

10. On members' concern about the difference in certain regulatory standards for routine surveillance of Chinese herbal medicines and the quality reference limits set out under HKCMMS, the Administration advised that the regulatory bodies around the world had not formulated a standardized set of maximum permitted limits of pesticide residues and heavy metals for Chinese herbal medicines. 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 were set as reference standards on the quality of individual 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 were formulated by CMCHK with reference to other international standards, including those of the World Health Organization and those set by different countries or regions on herbs or raw

materials of natural plant preparations. CMCHK had selected these 37 pesticide residues and four heavy metals for testing the Chinese herbal medicines regulated under the Ordinance after considering their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally.

11. Members noted that the testing of Chinese herbal medicines is carried out by the Government Laboratory, aiming to see if pesticide residues and heavy metal contents exist in the decoctions of the Chinese herbal medicines. In the first stage of the two-stage tests conducted by the Government Laboratory, preliminary tests were conducted on the Chinese herbal medicine samples in their raw state. If the test results were found in compliance with the limits set by CM Board, no further testing would be conducted, otherwise the second stage tests would be conducted to see if pesticide residues and heavy metal contents existed in the decoctions of the Chinese herbal medicines concerned (not applicable if the Chinese herbal medicines concerned "could be directly taken after being grounded into powder", a condition as mentioned in Part 1 of the Pharmacopoeia of the People's Republic of China 2015). Some members were of the view that results of the first-stage test, rather than that of the second-stage test should be adopted in assessing whether a Chinese herbal medicine might have public health risk as not all Chinese herbal medicines were to be taken in the form of decoctions.

12. The Administration advised that the testing of pesticide residues in the decoction of Chinese herbal medicines is considered to be a closer simulation of condition during human consumption which is more appropriate for human risk assessment. It should be noted that results of the second-stage tests so far had proved that pesticide residues and heavy metal contents in all samples of Chinese herbal medicines concerned did not exceed the maximum residue limits set by the CM Board.

Good Manufacturing Practice requirements for proprietary Chinese medicines

13. Members noted that the Administration had yet mapped out the timetable for requiring mandatory compliance with GMP for the manufacture of pCm. Some members expressed grave concern about the various difficulties faced by local manufacturers, who were mostly small-and-medium enterprises, in order to be GMP-compliant. These included lack of technical know-how and expertise, high cost associated with procuring the relevant equipment and setting up the GMP facilities. They considered that the Administration should provide assistance to pCm manufacturers in this regard. There was a further view that the Administration should set up GMP-compliant factory premises for use by pCm manufacturers under leasing arrangements.

14. The Administration advised that the introduction of GMP to pCm manufacturing aimed to foster the standardization and quality control of pCm manufacturing and to keep up with international trends of developing GMP for medicinal products. Under the Enterprise Support Programme of the Fund, manufacturers of pCms were provided, among others, technical and hardware support to assist them in conforming with the GMP standard.

Registration of proprietary Chinese medicines

15. Members noted the transitional registration arrangement provided for pCm which were manufactured, sold, or supplied for sale in Hong Kong on 1 March 1999, under which Notices of confirmation of transitional registration of pCm (i.e. "HKP") were issued for those transitional registration applications supported by three acceptable basic test (i.e. heavy metals and toxic element, pesticide residues and microbial limit) reports and which met the transitional registration requirements. Holders of HKP had to submit the necessary documents in respect of safety, quality and efficacy to the CM Board in order to obtain formal registration. Some members were concerned about the various difficulties encountered by the trade in the testing of safety and quality of pCm, which included high testing costs, high testing standards and difficulty in identifying accredited laboratories for the testing. This had resulted in thousands of pCm in the market being issued with HKP. These members urged the Administration to enhance its support to facilitate the trade in migrating the transitional registrations to formal registrations. There was a suggestion of introducing more classification categories of pCm with different levels of safety and quality testing requirements, so as to accommodate those pCm with HKP which had been sold in Hong Kong for years and empirically proved safe or harmless in use.

16. The Administration advised that DH had introduced a series of measures to expedite the transition of the pCm concerned from transitional registration to formal registration, including providing consultancy service for technical support, adjusting the technical requirements and increasing the number of laboratories offering testing service to assist the trade to complete the reports and furnish other information required. Subsidy would be provided under the Fund to facilitate the registration of pCm. It should be noted pCm issued with HKP currently being sold in the market were safe to use by members of the public as safety test reports were submitted for all these products. The Administration would consider setting a target timeframe for the traders concerned to complete the formal registration process.

Amendment to the definition of proprietary Chinese medicines in the Ordinance

17. Members were concerned about the public health risk that might arise from the various orally consumed products composing mainly of Chinese herbal medicines but added other materials or substances (e.g. vitamins) as active ingredients being sold in the market and bottled drinks containing Chinese herbal medicines, such as Spica Prunellae bottled drinks or herbal teas claiming to have heat-clearing effect. Members noted that these products are currently not regulated under the Ordinance. Noting that the Administration was exploring amendments to the definition of pCm in the Ordinance to enhance the regulation against certain orally consumed products containing both Chinese medicines and non-Chinese medicines as active ingredients in the market, they urged the Administration to step up its work in this regard.

18. According to the Administration, the CM Board under CMCHK had set up a working group in May 2017 comprising Chinese medicine experts and representatives from the Chinese medicine industry and the Government Laboratory to formulate the amendment proposal and provide professional advice in this regard. Thereafter, DH had conducted more than 10 consultation sessions with the trade and other relevant stakeholders from March to August 2018. A total of about 300 submissions were received. The trade generally supported the amendment proposal recommended by the working group. CMCHK and the CM Development Committee had respectively endorsed the recommendation of the CM Board to widen the definition of pCm to the effect that a product, formulated in finished dose form, composed of or claimed to be composed of any of Chinese medicine drug which had significant medicinal properties or side-effects, or the public generally would not use it as food, would be regarded as pCm. In addition, a product, formulated in finished dose form, presented as a traditional Chinese medicine preparation would also be regarded as pCm regardless of its composition. The Administration's plan was to consult the Panel on the amendment proposal in the 2020-2021 legislative session.

Relevant papers

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

Council Business Division 2
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Appendix

Relevant papers on regulatory regime for Chinese herbal medicines and proprietary Chinese medicines and development of the industry

Committee	Date of meeting	Paper
Panel on Health Services	21.1.2013 (Item IV)	Agenda Minutes
	18.3.2013 (Item IV)	Agenda Minutes
	16.12.2013 (Item V)	Agenda Minutes CB(2)1007/13-14(01)
	20.1.2014 (Item III)	Agenda Minutes
	19.5.2014 (Item IV)	Agenda Minutes
	19.1.2015 (Item III)	Agenda Minutes
	26.1.2017 (Item I)	Agenda Minutes
	28.2.2017 (Item V)	Agenda Minutes
	16.10.2017 (Item IV)	Agenda Minutes
	12.2.2018 (Item VI)	Agenda Minutes CB(2)1060/17-18(01)
	15.10.2018 (Item III)	Agenda Minutes

Committee	Date of meeting	Paper
	17.12.2018 (Item III)	Agenda Minutes
	21.10.2019 (Item I)	Agenda Minutes
Subcommittee on Issues Relating to the Development of the Chinese Medicine	2.2.2016 *	Report
Report of the Bills Committee on Chinese Medicine (Amendment) Bill 2017	7.3.2018 *	Report
Subcommittee on Issues Relating to the Development of the Chinese Medicine	20.1.2020 (Item I)	Agenda CB(2)773/19-20(02)

* Issue date

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