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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 17 December 2018

Chinese Medicine Development Fund

Purpose

This paper provides background information and summarizes the concerns of members of the Panel on Health Services ("the Panel") and the Subcommittee on Issues Relating to the Development of Chinese Medicine ("the Subcommittee") appointed by the Panel in the Fifth Legislative Council ("LegCo") on the Chinese Medicine Development Fund and relevant issues relating to the development of the Chinese medicine industry.

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. Based on the principle of professional self-regulation, the Chinese Medicine Council of Hong Kong ("the CM Council") has been 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. Under the Ordinance, any person who wishes to be registered as registered Chinese medicine practitioner ("CMP") should undertake and pass the Licensing Examination. To be eligible to undertake the Licensing Examination,

a person should satisfy the Chinese Medicine Practitioners Board that he or she has satisfactorily completed such undergraduate degree course of training in Chinese medicine practice or its equivalent as is approved by the Chinese Medicine Practitioners Board. Transitional arrangements for those CMPs who were practising Chinese medicine on 3 January 2000 to continue their practice as listed CMPs are provided for under the Ordinance. 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. Separately, all proprietary Chinese medicines ("pCm") must be registered by the CM Board before they can be imported, manufactured or sold in Hong Kong. The relevant provisions under the Ordinance concerning mandatory registration of pCm and requirements on labelling and package insert for pCm have come into effect since 3 December 2010 and 1 December 2011 respectively. To further ensure the safety of pCm and to keep up with the international trends of developing Good Manufacturing Practice ("GMP") for medicines, it was announced in the 2010-2011 Policy Address that a timetable for mandatory compliance with GMP for manufacture of pCm would be worked out. In May 2011, the CM Board recommended the adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme GMP standard as a licensing requirement for local manufacturers in pCm. All Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal medicines, or manufacture or wholesale of pCm are also required under the Ordinance to obtain the relevant Chinese medicines traders licence from the CM Board before the commencement of their business.

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 ("SFH") to give recommendations to the Government 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 of $500 million to provide support in areas such as applied research, Chinese medicine specialization, knowledge exchange and cross-market co-operation, and help local Chinese medicines traders with the production and registration of pCm. According to the Administration, the Fund will commence operation in the first half of 2019.

Deliberations of the Panel and the Subcommittee

7. Issues relating to the development of the Chinese medicine industry on those areas covered by the CM Development Fund were discussed by the Panel at a number of meetings and by the Subcommittee. The deliberations and concerns of members are summarized in the following paragraphs.

Development of practice specialization and specialist registration

8. Noting that there was currently neither specialist training nor specialist qualification accreditation system for CMPs in Hong Kong, some members considered that there was a need to establish a statutory specialist registration system for CMPs and credential the specialist qualification. It was suggested that specialties of Internal Medicine and Gynaecology could be introduced as the first step.

9. According to the Administration, the Chinese Medicine Practice Sub-committee under the CM Development Committee had started discussing the development of Chinese medicine specialization to, among others, tie in with the development of the first Chinese medicine hospital, and would make recommendations to the Administration in due course. The implementation of the Integrated Chinese-Western Medicine Pilot Programme for defined disease areas at selected public hospitals would help explore the development of Chinese medicine specialization. This apart, the Chinese medicine industry and the Schools of Chinese Medicine of the three local universities the Hong Kong had jointly establish the Chinese Medicine Specialty Development Working Group in July 2014 to promote the development of Chinese medicine specialization. Three sub-groups were set up under the Working Group, namely Acupuncture Sub-group, Chinese Medicine Orthopaedics and

Traumatology Sub-group, and Internal Medicine Sub-group, to examine the specialty training content and assessment criteria according to their ambits.

Good Manufacturing Practice requirements for proprietary Chinese medicines

10. 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.

11. The Administration advised that the Department of Health would meet with manufacturers who were interested in the implementation of GMP and already had preliminary proposals on the design of their factory premises, and explain to them the current requirements of GMP guidelines in order to assist them to implement GMP. It should be noted that with funding support from the Innovation and Technology Fund and the Hong Kong Jockey Club Charities Trust, the Hong Kong Institute of Biotechnology would conduct a three-year project set up a GMP product development and technical support platform for traditional oral solid pCm products. Upon completion of the project, the Institute would be able to provide GMP contract manufacturing services for the four most common types of pCm solid dose forms in Hong Kong. On some members' concern about the provision of the pCm master formula to the Institute under the above arrangement, the Administration assured members that the confidentiality of the pCm master formula would be protected under the legally binding contractual agreements.

Registration of proprietary Chinese medicines

12. Members noted that under the transitional registration arrangement were provided for pCm which were manufactured, sold, or supplied for sale in Hong Kong on 1 March 1999, under which a Notice 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 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.

13. The Administration advised that there were a number of local laboratories and Mainland laboratories which were recognized by the China Food and Drug Administration and the CM Board to provide pCm testing services for the trade. Where necessary, the Administration would request the Mainland regulatory authorities to expand the list of recommended laboratories to cover more laboratories qualified for conducting pCm testing. It should be noted that the Hong Kong Baptist University and the Hong Kong University of Science and Technology had each set up a research laboratory to provide the trade with technical support for Chinese medicines testing. Given that many applicants for formal pCm registration had difficulties to provide the required documents on quality specifications, a pilot programme had been implemented to provide consultancy services to the trade to facilitate the formal registration applications of 10 pCm. The Administration would map out the way forward in this regard having regard to the experience gained from the pilot programme.

System enhancement

14. Members noted that licensed wholesalers and retailers of Chinese herbal medicines, as well as licensed wholesalers and manufacturers of pCm were required under the relevant practising guidelines to keep the transaction documents for a period of not less than two years from the date of transaction to enable the tracing of the source and distribution channels of the Chinese herbal medicines, pCm or ingredients, as the case might be, suspected to have problems where necessary. Separately, Chinese medicine information had been included in the sharable scope in the Stage Two development of the Electronic Health Record Sharing System. Taking into account that information technology was not extensively used in the Chinese medicine sector to support their operation and many of their records were in paper form, members considered that the Administration should provide both financial and technical support to improve the warehouse management and logistics tracking of Chinese medicines traders,

as well as the clinical management systems of the private Chinese medicine clinics.

Setting up a dedicated fund for development of Chinese medicine

15. Members had long considered that the Administration had not provided the Chinese medicine trade with adequate support and assistance. The Panel passed a motion at its meeting on 19 May 2014 urging the Administration to, among others, set up a dedicated department to provide assistance to the Chinese medicine industry and to take forward the development of the Chinese medicine industry.

16. Members were subsequently advised in February 2018 on the plan of the Administration to provide funding support to further promote and drive the development of Chinese medicine. The Administration would work out the funding details in consultation with the CM Development Committee and the Chinese medicine industry. Members called on the Administration to provide adequate financial assistance and technical support to local pCm manufacturers to meet the GMP requirements, pCm traders to fulfill the requirements in formal registration of their pCm products, as well as the wholesalers and retailers of Chinese herbal medicines to improve the warehouse management.

Relevant papers

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

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Appendix

Relevant papers on the Chinese Medicine Development Fund

Committee	Date of meeting	Paper
Panel on Health Services	21.1.2013 (Item IV)	Agenda Minutes
	18.3.2013 (Item IV)	Agenda Minutes
	20.1.2014 (Item III)	Agenda Minutes
	19.5.2014 (Item IV)	Agenda Minutes
	19.1.2015 (Item III)	Agenda Minutes
Subcommittee on Issues Relating to the Development of the Chinese Medicine	2.2.2016 *	Report
Panel on Health Services	26.1.2017 (Item I)	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

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