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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 25 November 2014

Development of Chinese Medicine

Purpose

This paper provides background information on the development of Chinese medicine and summarizes the concerns of the members of the Panel on Health Services ("the Panel") on issues relating to the subject.

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 ("CMCHK") 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 ("CMB") have been set up under CMCHK to assist it in pursuing its functions.

3. Under the Ordinance, all Chinese medicine practitioners ("CMPs") should be registered before they can practise Chinese medicine in Hong Kong. The Ordinance also stipulates that all proprietary Chinese medicines ("pCms") must be registered by CMB before they can be imported, manufactured or sold in Hong Kong. The relevant provisions under the Ordinance concerning mandatory registration of pCms and requirements on labelling and package insert for pCms

have come into effect since 3 December 2010 and 1 December 2011 respectively. All Chinese medicines traders who engage in a business of retail and wholesale of Chinese herbal medicines, or manufacture or wholesale of pCms are also required under the Ordinance to obtain the relevant Chinese medicines traders licence from CMB before the commencement of their business.

4. 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, CMB recommended the adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") GMP standard as a licensing requirement for local manufacturers in pCm, and implementation of PIC/S GMP standard in four years.

Provision of public Chinese medicine outpatient services

5. To promote the development of "evidence-based" Chinese medicine and provide training placements for local Chinese medicine degree programme graduates, the Administration has established 18 public Chinese Medicine Centres for Training and Research ("CMCTR") (or commonly known as "Chinese medicine clinics"). Each CMCTR operates on a tripartite collaboration model involving the Hospital Authority ("HA"), a non-governmental organization ("NGO") and a local university, with the NGOs as the operators.

Standards and testing of Chinese medicines

6. To safeguard public health and facilitate research and trade in Chinese medicines, the Department of Health ("DH") has been developing the Hong Kong Chinese Materia Medica Standards ("HKCMMS") since 2002 to ascertain the authenticity, safety and quality of commonly used Chinese Materia Medica. Six editions of HKCMMS covering standards for a total of 200 Chinese Materia Medica have been published.

7. On the research and development ("R&D") of Chinese medicines, the Innovation and Technology Fund has been providing funding support to universities, R&D institutions and companies to conduct, among others, applied research projects relating to R&D and testing of Chinese medicines. A Committee on Research and Development of Chinese Medicines was set up in December 2011 to explore strategies to promote R&D and testing of Chinese medicines in Hong Kong.

Training and professional development of CMPs

8. Three local universities (i.e. The University of Hong Kong, The Chinese University of Hong Kong and the Hong Kong Baptist University) currently offer six-year full-time University Grants Committee ("UGC")-funded undergraduate degree programmes in Chinese medicine which have an annual intake of about 90 students. Graduates of these programmes are eligible for the CMP Licensing Examination to qualify as registered CMPs. At present, NGOs operating CMCTRs are required to employ at least 12 junior CMPs or CMP trainees and provide training for them.

9. A Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development was established by the Administration in January 2012 to conduct a strategic review on healthcare manpower planning and professional development. The review covers 13 healthcare professions including CMPs who are subject to statutory regulation.

The Chinese Medicine Development Committee

10. The Chief Executive announced in his 2013 Policy Address the establishment of a Chinese Medicine Development Committee ("CMDC") to give recommendations to the Government concerning the direction and long-term strategy of the future development of Chinese medicine in Hong Kong. Established in February 2013 and chaired by the Secretary for Food and Health ("SFH"), CMDC is tasked to study four key areas, namely the development of Chinese medicine services; personnel training and professional development; R&D; and development of the Chinese medicines industry (including Chinese medicines testing). A Chinese Medicine Practice Sub-committee and a Chinese Medicines Industry Sub-committee were formed under CMDC in May 2013 to study the relevant specific areas.

Deliberations of the Panel

11. The Panel discussed issues relating to the development of Chinese medicine at a number of meetings. The deliberations and concerns of members are summarized below.

Development of Chinese medicine

12. Concern was raised about the timeframe for CMDC to complete its study on the policies and measures to further the development of Chinese medicine. Some members considered that the Administration should first clearly define the position of Chinese medicine in primary, secondary and tertiary care in the

healthcare system to facilitate the study of CMDC. There was a view that Chinese medicine should be classified as a supplementary treatment in the public healthcare system so that, where appropriate, doctors could make referral for patients to receive the treatment. Members also called on the Administration to ensure that the development directions would be formulated from the perspective of Chinese medicine, rather than a Western medicine perspective. Question was raised about the appropriateness to adopt the evidence-based medicine approach for the development of Chinese medicine in Hong Kong.

13. The Administration agreed with the need to map out the positioning of Chinese medicine in the healthcare system. Given that the healthcare system was currently Western medicine-based and there was a need to promote integrated Chinese and Western medical services, the Administration would engage the Western and Chinese sectors to examine the direction for developing Chinese medicine in Hong Kong. Its initial thought was that Chinese medicine would be regarded as one of the components, instead of a supplementary treatment, in future hospital services involving close collaboration with Western medicine in both clinical and non-clinical settings. The Administration further explained that the evidence-based approach in Chinese medicine, which had been broadly accepted, served to ensure the consistency in ingredients, and the availability of scientific evidence on the safety and efficacy of Chinese medicines.

Establishment of a Chinese medicine hospital

14. Members had long called for the establishment of a Chinese medicine hospital in Hong Kong. In their view, the establishment of a Chinese medicine hospital to provide inpatient services for members of the pubic and training grounds for local Chinese medicine graduates was crucial to foster the development of Chinese medicine in tertiary care in Hong Kong.

15. At the Panel meeting on 20 January 2014 to receive a briefing from SFH on the 2014 Policy Address in relation to health matters, members were advised that the Government had accepted CMDC's recommendation and reserved a site in Tseung Kwan O, which was originally earmarked for private hospital development, for setting up a self-financing Chinese medicine hospital to be operated in the mode of integrated Chinese-Western medicine ("ICWM"). The hospital would provide 400 beds as well as facilities to support teaching, clinical practice and scientific research of the Schools of Chinese Medicine under the three local universities, and help strengthen and enhance the quality of the professional training of Chinese medicine practitioners and the scientific research of Chinese medicine in Hong Kong. While generally welcoming the proposal to set up a Chinese medicine hospital, members were gravely concerned about the mode of operation and scope of services of the hospital.

16. The Administration advised that given the developments in medical services and the fact that the local healthcare system was based on Western medicine, it would not be feasible to set up a Chinese medicine hospital to provide only Chinese medicine services without resorting to western medical equipments and treatment for some acute cases and complex illnesses. In this regard, a Chinese medicine-led hospital integrating Chinese and Western medicine approaches was considered the most feasible mode of operation of the Chinese medicine hospital under the existing legal and administrative frameworks. The Administration also advised that as recommended by CMDC, some practical research projects, such as the ICWM pilot project, would be carried out before the establishment of the hospital in order to gather experience in the operation and regulation of ICWM and Chinese medicine inpatient services. These might serve as the basis for formulating the regulation for and the mode of operation of the proposed Chinese medicine hospital.

17. Questions were raised as to whether the service scope of the proposed Chinese medicine hospital would be confined to the three disease areas under the study of the ICWM pilot project, namely stroke rehabilitation, low back pain and palliative care for cancer, and whether CMPs or medical doctors would assume a leading role in the provision of treatment to patients admitted to the hospital if it was to be operated on an ICWM model. Some members cast doubt as to whether there could be candid collaboration between Chinese and Western medical personnel in the provision of clinical services to patients given the lack of mutual understanding between the two professions and the absence of Chinese medicine experts in the Government and HA to provide a balanced view in policy formulation.

18. The Administration advised that CMDC, which mainly comprised representatives from the Chinese medicine practice, the Chinese medicine trade and academia, would continue to hold discussions to map out the detailed mode of operation of the Chinese medicine hospital, including its scope of services and the roles of Chinese and Western medical personnel in the provision of treatment and care to patients, and make recommendations to the Government. Reference would also be made to the clinical and operational frameworks of the ICWM pilot project under which clinical protocols of the three disease areas under study would be jointly developed by a working group comprising experts in Chinese medicine and Western medicine to provide clinical guidelines for integrating Chinese medicine with Western medicine, inclusion and exclusion criteria, clinical outcome indicators and clinical risk management. A set of operational guidelines setting out the roles and responsibilities of the Chinese and Western medical personnel, workflow of transfer, discharge and follow-up treatment of patients would also be developed under the ICWM pilot project.

19. On members' concern about the timetable for the setting up of the proposed Chinese medicine hospital, the Administration advised that it would take into account the recommendations of CMDC in taking forward the proposal. As regards the ICWM pilot project which would shed light on the development of Chinese medicine inpatient services and the establishment of the Chinese medicine hospital, the plan of HA was to conduct an interim review and a final review in the third quarter of 2015 and the third quarter of 2016 respectively. HA would brief CMDC and its Chinese Medicine Practice Sub-committee on the progress of the Project. According to the Administration, subject to the completion of the works procedures, the construction of the proposed Chinese medicine hospital was expected to be completed in four to five years' time.

Regulatory regime for the Chinese medicine hospital

20. Noting that the proposed Chinese medicine hospital would not be run by HA but by an operating body on a self-financing basis, members were concerned about the regulatory regime for monitoring the operation of the hospital, including the level of charges so that its services would not become unaffordable to the less privileged. They were particularly concerned that the high capital cost for the building and maintenance of the hospital building by the NGO concerned would be levied upon patients who would have to pay high clinical fees for their visits while CMPs employed by the hospital would be given low pay. There was also a view that the support to be provided by the hospital in the areas of teaching, clinical internships and scientific research would be limited if the three local universities offering UGC-funded full-time degree programmes in Chinese medicine would have no involvement in the operation of the hospital.

21. According to the Administration, same as those private hospitals providing Western medical services, DH would monitor compliance of the Chinese medicine hospital with the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165). The Administration had established a Steering Committee on Review of the Regulation of Private Healthcare Facilities in October 2012 to conduct a review on the regulatory regime for private healthcare facilities with a view to strengthening the regulatory standards. The review would cover, among others, the regulatory approach for private healthcare facilities providing Chinese medicine inpatient services. The Administration would consult the public on the various regulatory proposals put forward by the Steering Committee and prepare for the necessary legislative procedures in accordance with the results of the consultation. The Administration considered it more flexible for a NGO experienced in providing Chinese medicine services to operate the Chinese medicine hospital on self-financing basis at the initial stage of its operation.

Implementation of ICWM in public hospitals

22. Members were concerned about the present collaboration between Chinese and Western medical services for patients receiving treatment in public hospitals. The Administration advised that there had been increasing interface between Chinese and Western medicine services in public hospitals in recent years. More than 20 public hospitals had provided Chinese and Western medicine shared care services covering pain management, rehabilitation treatment of stroke/diseases of the nervous system, cancer treatment, palliative care, treatment of diabetes mellitus, dysthymia, gynaecology, orthopedics and traumatology, osteopathy, as well as treatment of ear, nose and throat diseases.

23. Question was raised on why stroke rehabilitation, low back pain and palliative care for cancer were selected as the disease areas of the ICWM pilot project. The Administration advised that the three disease areas were selected because the treatment of Chinese medicine or the synergy effect generated by treatment of ICWM for these areas was effective with the support of scientific proof. This apart, a certain number of patients were anticipated for these disease areas. The inclusion and exclusion criteria of the three disease areas could also be clearly defined.

Services provided by CMCTRs

24. There were views that the Administration should include the services provided by CMCTRs as part of the standard services of HA. It was suggested that CMCTRs should be run by the Government to demonstrate its commitment to the development of Chinese medicine in Hong Kong. Consideration should also be given to including the services provided by CMCTRs in the scope of medical and dental benefits for civil service eligible persons ("CSEPs").

25. The Administration explained that a tripartite collaboration model was adopted for the operation of CMCTRs, under which the NGOs concerned were responsible for the day-to-day operation of CMCTRs. As such, the services of CMCTRs did not form part of the standard services of HA, and fell outside the scope of civil service medical benefits under prevailing policy. The Administration stressed that while CMDC would explore the positioning of Chinese medicine in the public healthcare system, the discussions on the development of Chinese medicine and the provision of Chinese medicine services as part of the medical benefit for CSEPs should be handled separately. The Civil Service Bureau would keep in view any significant changes to the nature and mode of service delivery of CMCTRs in future that would warrant a review of their implications on the scope of civil service medical benefits.

Control over Chinese medicines

26. There were doubts on whether mandatory GMP requirement should be introduced for the manufacturing of pCm as the number of local pCm manufacturers remained small. Those small and medium enterprises of the pCm manufacturing sector also lacked the financial strength and expertise to build and operate GMP facilities. According to the Administration, the purpose of introducing GMP to pCm manufacturing was to promote the standardization and quality control of pCm manufacturing, and to keep up with international trends of developing GMP for medicinal products. The Administration stressed that while it could consider providing pCm manufacturers with hardware infrastructural support, the pCm manufacturers also had to take steps to invest and modernize their operation.

27. Members were also concerned about the impact of the mandatory registration of pCm on the trade. In particular, they considered the existing definition and classification categories of pCm too stringent and the costs of complying with the provisions related to the mandatory registration of pCm too high to be affordable by the small and medium-sized pCm traders. They urged the Administration to enhance its support measures to facilitate the trade's compliance with the registration requirements; and maintain close communication with the trade on the liability that might be borne by various parties for the sale of non-compliant pCm and clearly stipulate such liability in the relevant guidelines issued by CMB. There were views that consideration should be given to confining the definition of "possession of pCm" under section 119 of the Ordinance to possession of pCm for the purpose of sale; and formulate a new classification category, such as "Empirical formula", to accommodate pCm which might not fulfil the standards of "Established medicines" or "New medicines" but had been sold in Hong Kong for many years and empirically proved safe or harmless for use.

Standards and testing of Chinese medicines

28. Concern was raised about the reference standard adopted by DH in developing HKCMMS for the commonly used Chinese herbs in Hong Kong as many ingredients of local pCm were Chinese herbs imported from the Mainland. The Administration advised that it had maintained close collaboration with the relevant authorities in the Mainland in establishing the safety and quality standards for Chinese herbs. Meanwhile, the Government had accepted CMDC's recommendation which supported the continuation of the HKCMMS project to formulate standards for more Chinese herbal medicines; and the consideration of including study on the standard setting for Chinese medicines decoction pieces under the HKCMMS project, so that HKCMMS could be more widely adopted. DH was now consulting experts in scientific research to actively explore the feasibility of implementing the recommendations.

29. On whether more funding would be provided to support research in Chinese medicines, the Administration advised that research in Chinese medicines was mainly carried out in local universities through funding support from the Research Grant Council of UGC. Upon the announcement of the disbandment of the Hong Kong Jockey Club Institute of Chinese Medicine in 2011, the Hong Kong Jockey Club Charities Trust had agreed to use the remaining $400 million funding to support NGOs to carry out worthwhile Chinese medicines projects in Hong Kong. The Innovation and Technology Fund would also fund applied R&D projects of various technology areas, including Chinese medicine.

Training of Chinese medicine personnel

30. Members were concerned about the employment opportunities of, and the remuneration for, graduates of local full-time Chinese medicine undergraduate degree programmes. There were views that the Administration should formulate a remuneration structure for the Chinese medical grades in the public sector. According to the Administration, there should be no great difficulty for these graduates to obtain employment after graduation, as CMCTRs, the Chinese Medicine Division of DH, and the Chinese medicine clinics run by the private sector and NGOs presently provided a number of job opportunities for these graduates which numbered about 70 each year. Fresh graduates of these programmes who chose to apply to work and receive training at CMCTRs would be employed as junior CMPs in the first year and as CMP trainees in the second and third years. As at January 2014, a total of 224 graduates of these programmes were employed by CMCTRs.

31. Members noted that while transitional arrangements were provided under the registration system of CMPs to enable persons already practising Chinese medicine on 3 January 2000 to become listed CMPs, it was the long-term objective of the Administration that all practising CMPs in Hong Kong would become registered CMPs. There was a view that the Administration should offer courses to the listed CMPs to help them to prepare for the CMP Licensing Examination. The Administration advised that relevant courses were currently provided by the profession for preparing listed CMPs for the CMP Licensing Examination. The Chinese Medicine Practice Sub-committee under CMDC had also started studying the enhancement of personnel training and professional development for CMPs.

32. Question was raised about the rationale for requiring the listed CMPs to possess knowledge outside their main streams of practice, such as Gynaecology of Chinese medicine, in order to pass the Licensing Examination. According to the Administration, the Preparatory Committee on Chinese Medicine had broadly consulted the profession on the registration system of CMPs prior to the enactment of the Ordinance. It was widely agreed by the profession that

registered CMPs should master the fundamental and clinical skills of Chinese medicine practice instead of setting up separate registrations for different specialties. Hence, the CMP Licensing Examination was developed to provide a comprehensive professional assessment of the candidates' knowledge of Chinese medicine which included, among others, the basic and clinical subjects of general practice in Chinese medicine.

Motion passed by the Panel

33. At the meeting on 19 May 2014, the Panel passed a motion urging the Administration to expeditiously implement the establishment of a Chinese medicine hospital; incorporate 18 CMCTRs and the Chinese medicine hospital into the public healthcare system to provide them with recurrent funding; formulate a remuneration structure for the Chinese medical grades in the public sector and improve the remuneration packages of graduates of Chinese medicine and pharmacy in Chinese medicine programme; and set up a dedicated department to provide assistance to the Chinese medicines industry in the process of transformation and promotion, and to take forward the development of the Chinese medicines industry.

Recent developments

34. HA launched the "ICWM Pilot Programme" on 22 September 2014 to explore feasibility and gain experience via small-scale pilots in order to explore the development of an ICWM model. Phase One of the Pilot Programme covers stroke care at Tung Wah Hospital, cancer palliative care at Tuen Mun Hospital and acute low back pain care at Pamela Youde Nethersole Eastern Hospital. Eligible inpatient will be invited to enroll into the Pilot Programme on a voluntary basis to receive ICWM care. CMPs from collaborating CMCTRs will provide daily Chinese medicine consultation to the enrolled patients at designated hospital wards, and Chinese medicines and/or acupuncture treatment will be provided according to clinical assessment and the individual clinical protocol. The Pilot Programme will not interfere with the current Western medicine treatment and discharge plan of the enrolled patient. Enrolled patients will be charged by the CMCTR concerned, in addition to the prevailing HA fees and charges, at a fixed lump sum of HK$200 for Chinese medicine care on a daily basis. After discharge, western medicine outpatients will be followed up in day hospital and/or specialist outpatient department of HA, whereas that for Chinese medicine care will be carried out at designated CMCTRs for a maximum of six months, depending on individual protocol.

Relevant papers

35. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

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Legislative Council Secretariat
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Appendix

Relevant papers on the development of Chinese medicine

Committee	Date of meeting	Paper
Panel on Health Services	13.11.2000 (Item IV)	Agenda Minutes
Panel on Health Services	10.2.2003 (Items IV and V)	Agenda Minutes CB(2)1267/02-03(01)
Panel on Health Services	8.12.2003 (Item IV)	Agenda Minutes CB(2)945/03-04(01)
Panel on Health Services	13.6.2005 (Item VI)	Agenda Minutes
Panel on Health Services	14.11.2005 (Item VI)	Agenda Minutes
Panel on Health Services	14.5.2007 (Items IV and V)	Agenda Minutes CB(2)2534/06-07(01)
Panel on Health Services	17.10.2008 (Item I)	Agenda Minutes
Panel on Health Services	16.10.2009 (Item I)	Agenda Minutes
Panel on Health Services	15.10.2010 (Item I)	Agenda Minutes
Panel on Health Services	20.10.2011 (Item I)	Agenda Minutes

Committee	Date of meeting	Paper
Subcommittee on Registration of Proprietary Chinese Medicines	--	Report
Panel on Health Services	11.6.2012 (Item III)	Agenda Minutes CB(2)55/12-13(01)
Panel on Health Services	21.1.2013 (Item IV)	Agenda Minutes
Panel on Health Services	18.3.2013 (Item IV)	Agenda Minutes
Panel on Health Services	20.1.2014 (Item III)	Agenda Minutes
Panel on Health Services	17.3.2014 (Item IV)	Agenda Minutes
Panel on Health Services	19.5.2014 (Item IV)	Agenda Minutes

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