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Paper for the Panel on Health Services

Report of the Subcommittee on Issues Relating to the Development of Chinese Medicine

Purpose

This paper reports the deliberations of the Subcommittee on Issues Relating to the Development of Chinese Medicine ("the Subcommittee") formed under the Panel on Health Services ("the Panel").

Background

Regulatory framework of Chinese medicine

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

3. Under CMO, all 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 CMO 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. Besides, 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 CMO to obtain the relevant Chinese medicines traders licence from CMB before commencement of their business.

The Chinese Medicine Development Committee ("CMDC")

4. The Chief Executive ("CE") announced in his 2013 Policy Address the establishment of 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; research and development; and development of the Chinese medicines industry (including Chinese medicines testing). In May 2013, a Chinese Medicine Practice Subcommittee and a Chinese Medicines Industry Subcommittee were formed under CMDC to study the relevant specific areas.

5. As set out in the 2014 Policy Address, the Government has accepted CMDC's recommendation and decided to reserve a site in Tseung Kwan O for setting up a Chinese medicine hospital. On CMDC's recommendation, the Hospital Authority ("HA") has launched the Integrated Chinese-Western Medicine ("ICWM") Pilot Programme for in-patients in public hospitals, so as to gather experiences for the operation and regulation for the future Chinese medicine hospital.

Motion passed by the Panel on 19 May 2014

6. At the Panel meeting on 19 May 2014, members expressed concerns on the development of Chinese medicine services during discussion of "Development of Chinese medicine hospital and ICWM". While members in general welcomed the proposed Chinese medicine hospital, they were disappointed at the lack of a commissioning timetable for the hospital. Concerns were also raised on the non-provision of Chinese medicine services in the public healthcare system; the pay levels of Chinese medicine graduates in Hong Kong; and problems concerning development of the Chinese medicines industry, etc.

7. The Panel passed a motion urging the Government to, among others, expeditiously implement the establishment of a Chinese medicine hospital; incorporate the hospital as well as the 18 Chinese Medicine Centres for Training and Research ("CMCTRs")[1] 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;

[1] CMCTRs operate in a tripartite collaboration model involving HA, non-governmental organizations ("NGOs") and local universities. NGOs are responsible for the day-to-day clinic operation.

and set up a dedicated department to provide assistance to the Chinese medicines industry and to take forward the development of the Chinese medicines industry.

8. To enable more focused discussion, the Panel further agreed at its meeting on 16 June 2014 to appoint a subcommittee to study and review the Government's strategy, policies and initiatives to promote the long-term development of Chinese medicine and make timely recommendations.

The Subcommittee

9. Under the chairmanship of Hon CHAN Han-pan, the Subcommittee has held nine meetings with the Administration. The membership of the Subcommittee is in **Appendix I**. The Subcommittee has also received views from deputations on issues relating to the production, registration and development of pCms. A list of the deputations which have given views to the Subcommittee is in **Appendix II**.

Deliberations of the Subcommittee

10. The deliberations of the Subcommittee cover three major areas as follows -

(a) issues relating to the production, registration and development of pCms;

(b) issues relating to the implementation of the ICWM Pilot Programme; and

(c) issues relating to the continuing education for registered CMPs and professional specialization of CMPs.

Area I : issues relating to the production, registration and development of pCms

Introduction of Good Manufacturing Practice ("GMP") requirements to pCms

Current position

11. At present, the GMP requirement in respect of pCms in Hong Kong is not mandatory. A licensed pCm manufacturer who wishes to be certified as complying with the GMP requirements in the production and quality control of pCms may apply to CMB for a GMP Certificate for Manufacturer. As at December 2015, there were 278 licensed pCm manufacturers in Hong Kong. 14 local pCm manufacturers had been awarded with GMP Certificates.

12. It was announced in the 2010-2011 Policy Address that the Government would actively engage the trade to work out a timetable for mandatory compliance with GMP for the manufacture of pCm, in order to ensure the safety of pCm and enhance its quality, and to align with international trend of GMP development in the production of medicines. In May 2011, CMB recommended to adopt in due course the GMP standard of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") as a licensing requirement for local pCm manufacturers.

Measures to support the trade to implement GMP

13. Some members have expressed grave concern about the difficulties faced by local pCm manufacturers in order to be GMP-compliant, such as financial constraints, lack of technical know-how and expertise, as well as shortage of suitable land space for establishing GMP facilities. These members consider that the pCm manufacturing industry is not yet GMP-ready. They opine that as most local pCm manufacturers are small and medium enterprises ("SMEs"), the adoption of GMP standards should be voluntary rather than a mandatory requirement so as to allow room for the survival of SME pCm manufacturers. Otherwise, they may be squeezed out from the pCm manufacturing industry despite proven efficacy of their ancient traditional formula. The market would then be dominated by large-scale pCm manufacturers that are GMP-capable at the expense of the SME pCm manufacturers.

14. In response to members' serious concern about the trade's view that they have not received adequate support in introducing GMP to the pCm manufacture, the Administration has informed members that the Department of Health ("DH") has conducted a number of GMP briefings, attended meetings with Chinese medicine associations and met different pCm manufacturers. Moreover, DH has invited local and Mainland experts to brief Chinese medicines traders on GMP requirements and relevant training as well as consultancy services, and to share their experience in the implementation of GMP. Besides, DH will meet with manufacturers who are interested in the implementation of GMP and already have 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. However, members in general consider that meetings and briefings alone are of little help.

Proposal to set up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangements

15. To better support the trade, some members have suggested that the Administration should consider setting up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangements. The

Administration has advised the Subcommittee that the Innovation and Technology Fund ("ITF") and the Hong Kong Jockey Club Charities Trust will jointly support the Hong Kong Institute of Biotechnology ("HKIB") to conduct a three-year project to set up a GMP product development and technical support platform for traditional oral solid pCm products. Upon completion of the project, HKIB's existing pCm GMP production area will be expanded from 2 880 sq ft to 8 500 sq ft; and production lines for two new types of pCm solid dose forms (i.e. pills and granules; the existing two are capsules and powder) will be established, which will enable HKIB to provide GMP contract manufacturing services for the four most common types of pCm solid dose forms in Hong Kong.

16. According to the Administration, the three-year project will also provide internship opportunities for Chinese medicines workers and students (such as students studying relevant professional programmes at the Vocational Training Council) so as to equip them with the necessary skills and practical experience which will be conducive to supporting the upgrading and development of the local Chinese medicines industry.

17. While expressing welcome to the three-year project, some members have stressed that pCm manufacturers are very concerned as to whether they would have to provide their pCm master formula to HKIB under the GMP contract manufacturing arrangements. The trade is also concerned about the possibility that they may have to dismiss their workers after contracting out their pCm manufacturing to HKIB through the new platform, thereby causing layoffs in the industry. The Administration and representatives of the Innovation and Technology Commission ("ITC") have assured members that the provision of any pCm master formula to HKIB under the GMP contract manufacturing arrangements would be subject to contractual agreements between the manufacturer and HKIB. The confidentiality of the pCm master formula would be protected by way of the contractual agreements, which would be legally binding. Representatives of ITC have further advised that pCm manufacturers will not necessarily have to dismiss their workers. According to the Administration, it will consider how to provide further assistance to the trade in the long term based on the experience gathered from the implementation of the three-year project.

18. Some members have questioned whether the adoption of PIC/S GMP standard would suit Hong Kong as most of the pCm manufacturers in Hong Kong are SMEs which experience difficulties in fulfilling the general GMP requirements, not to mention upgrading themselves to meet the high standard of PIC/S when in lack of financial capacity and technical knowhow. The Administration has explained that CMB recommends adopting the GMP standard of PIC/S as a licensing requirement for local pCm manufacturers with a

view to enabling the local pCm industry to keep up with the international standards. In response to members' view that the Administration should not introduce the GMP requirements hastily, the Administration has assured members that the implementation timetable for introducing GMP requirements to pCms is still under consultation and has yet to be fixed. The Administration has undertaken that it would continue to listen to the views of the industry before coming to a view on the implementation schedule.

Registration and testing of pCms

Existing regulatory framework

19. CMO stipulates, among others, that all products falling within the definition of pCms must be registered before they can be imported, manufactured and sold in Hong Kong. CMB started to accept applications for pCm registration on 19 December 2003. To get registered in Hong Kong, a pCm must fulfill the registration requirements regarding safety, quality and efficacy as prescribed by CMB. To guarantee the quality and efficacy of pCms, their safe consumption and public health, CMO requires that starting from 3 December 2010, all products falling within the definition of pCms must be registered before they can be imported, manufactured or sold in Hong Kong.

20. Having taken into account the history and practical circumstances of the sale of pCms in Hong Kong, CMO provides an arrangement of transitional registration. Where a pCm was manufactured, sold, or supplied for sale in Hong Kong on 1 March 1999, the relevant manufacturer, importer or local agent/representative of a manufacturer outside Hong Kong may, in accordance with CMO, apply for transitional registration of the pCm within the designated period (i.e. from 19 December 2003 to 30 June 2004) -

(a) "Notice of confirmation of transitional registration of pCm" (i.e. "HKP") will be issued if the pCm has been assessed by CMB as meeting the registration requirements. To facilitate the processing of transitional registration of pCm to formal registration, the holder of HKP concerned has to submit the necessary documents in respect of safety, quality and efficacy to CMB. "Certificate of registration of pCm" (i.e. "HKC") will be issued if the pCm has been assessed by CMB as meeting the registration requirements;

(b) those applications which are not eligible for transitional registration but have submitted three basic test reports[2] will be issued with

[2] The basic test reports must include three acceptable test reports, i.e. (1) heavy metals and toxic element test report; (2) pesticide residue test report; and (3) microbial limit test report.

"Notice of confirmation of (non-transitional) registration application of pCm" (i.e. "HKNT").

Difficulties encountered by the trade in the registration of pCms

21. The Subcommittee has reflected to the Administration the difficulties encountered by the trade in the testing of safety and quality of pCms. In gist, the Administration has noted that these difficulties include -

(a) testing costs are expensive and the processing time taken by CMB is too long;

(b) it is difficult to identify laboratories which are accredited by CMB for the testing. Laboratories in the Mainland often refuse to conduct testing due to voluminous workload; and

(c) the threshold for the standard of test reports is too high. For example, there are technical difficulties in establishing product specifications, and a long period of time is required to work out suitable testing methods.

22. In response to the above concerns, the Administration has advised that when processing applications for pCm registration, CMB has been actively communicating with the trade through various channels. In October 2015, the Administration informed the Subcommittee that CMB had, in collaboration with DH, conducted 19 seminars/sharing sessions and 43 briefings since 2011 to explain to trade associations, Chinese medicines traders and laboratories the requirements and technical issues for pCm registration, and to brief the trade on how to assess whether their products fall within the definition of pCm and subject to registration. Representatives of CMB and DH had attended 12 meetings/exhibitions held by the trade to explain the requirements for and implementation of pCm registration in Hong Kong. Through interviews with individual applicants and publication of the Chinese Medicines Traders Newsletter, CMB and DH also explain to the trade and applicants the requirements for pCm registration and testing as well as the latest arrangements for pCm registration.

23. On the support services for pCm registration and testing, the Administration has advised that currently nine local laboratories, as well as 17 Mainland laboratories recognized by the China Food and Drug Administration and CMB, provide pCm testing services for the trade. Where necessary, the Administration may request the relevant Mainland regulatory authorities to extend the list of recommended laboratories to cover more laboratories qualified for conducting pCm testing. To address members' concern about the cost and

time required for pCm testing by local laboratories, the Administration has provided the relevant details in **Appendix III** for members' reference.

24. In response to members' concern about the long processing time, the Administration has explained that some applicants, during the application process, may amend or correct product information (e.g. trade mark, packing specification, information about the manufacturer and the applicant) because of business needs or operational strategies. In this regard, CMB will take some time for follow-up and require the applicants to submit the supplementary information for verification.

Measures to facilitate the trade to migrate their transitional registrations to formal registrations

25. Members have urged the Administration to introduce facilitating measures for the trade to migrate their transitional registrations to formal registrations. The Administration has advised that having assessed the overall situation of the trade, CMB already resolved in June 2013 to extend the deadline for submitting the product specification and general stability test reports by HKP holders from 30 June 2013 to 30 June 2015. If their quality specification and stability test reports could not be submitted before 30 June 2015, they could still be sold legally in the market until they are formally registered and issued with HKC, or until their registration applications have been refused, or until such a date to be promulgated by SFH in the Gazette, whichever date is the earliest.

26. After the deadline of 30 June 2015, the Subcommittee has continued to hold meetings to monitor closely the registration situation. Members have noted that as at 3 July 2015, CMB had issued 503 HKC. There were still 8 537 pCm products issued with HKP, of which over 89% of the HKP holders concerned had submitted the product quality or stability test reports, whereas 11% of them had not. Members have urged the Administration to provide assistance to the HKP holders concerned as far as possible to help them resolve difficulties in fulfilling the registration requirements. Some members consider that some of these HKP holders are just unwilling to disclose the master formula of their pCm products, and have suggested that a new category which does not require the provision of the master formula (as long as the pCm products concerned have proven safety and efficacy) should be created. Some members have proposed to "freeze" the HKP status of pCms which are unable to fulfil the registration requirements for the time being and allow the HKP holders concerned to resume their application for formal registration at any time during the frozen period. This would obviate the need for the pCm manufacturer concerned to apply afresh for formal registration when he/she is financially or technically in a better position to fulfill the registration requirements.

27. The Administration has further advised that the "Established medicines category" in the existing pCm registration system is provided for the registration of those pCms which is an ancient prescription, a modified ancient prescription or a pharmacopoeia prescription (which has been set out in the Pharmacopoeia of the People's Republic of China). In accordance with CMO, pCm manufacturers or traders have to disclose the master formulae of their pCm concerned in the registration. A mechanism is already in place to protect the confidentiality of these master formularies of pCms. The Administration will explain the relevant mechanism to the trade to address their concern.

28. The Administration has also explained that under the existing legislation and regulatory framework, there is no provision which allows "freezing" the HKP status of pCms which fail to comply with the requirements on safety, quality and efficacy. For a pCm issued with HKP, if its HKC application is rejected by CMB, the HKP concerned will be invalidated and the pCm will no longer be allowed for sale in the market. This is in line with the principle of ensuring the efficacy of pCms and their safe use by the public. CMO does not empower CMB to allow such pCms to "freeze" their HKP status.

29. The Subcommittee has noted that as at mid-November 2015, a total of about 18 000 applications for pCm registration were received, of which about 14 110 also applied for transitional registration. After assessment by CMB, 8 052 pCm products were issued with HKP, 559 with HKC and 399 with HKNT. The total number of applications for formal registration of pCm which have been rejected was 361, among which 249 products have not been circulating on the market prior to this date. The remaining 112 products have already been removed from the market.

Transitional arrangements for holders of HKP issued with HKC

30. The Subcommittee has urged the Administration to address concern that for cases of conversion from HKP to HKC, the time allowed to the manufacturers concerned for replacing labels and package inserts (i.e. six months) is inadequate. Some members have requested that apart from giving more time, the Administration should allow greater flexibility for manufacturers and traders to sell out their pCms issued with HKP, instead of requiring them to conduct product recall when such pCms are still not yet sold out by the deadline. These members consider that this would avoid causing confusion to consumers and unnecessary wastage.

31. Having considered members' views, CMB has decided that for cases of conversion from HKP to HKC, the deadline for replacing labels and package

inserts is to be extended from six months to 12 months. Individual product holders may apply to CMB for further extension if they have such a need. The Administration has advised that the extension[3] should allow product holders sufficient time to deal with the transitional/interfacing matters.

Policies of supporting the development of pCms

The Hong Kong Chinese Materia Medica Standards Project

32. Members have expressed high expectations of the development of Chinese medicine in Hong Kong and urged the Administration to formulate policies and active measures to promote the development of pCms. The Administration has advised that to safeguard public health and promote the development of Chinese medicine, the Government is committed to developing comprehensive reference standards for some commonly used Chinese herbal medicines. To this end, DH launched the Hong Kong Chinese Materia Medica Standards ("HKCMMS") project in 2001. According to the Administration, the HKCMMS project aims to provide applicable and adoptable reference standards for the Chinese medicines industry, with a view to ensuring the safety and quality of Chinese herbal medicines and public health. In addition, the formulation of HKCMMS allows Hong Kong to align with international standards, facilitates trading of Chinese herbal medicines and enhances the quality of the raw materials for manufacturing pCms, thereby creating more business opportunities. So far, the research on 236 Chinese herbal medicines commonly used in Hong Kong has been completed, and seven editions of HKCMMS have been published. In future, HKCMMS will be targeted at developing standards for about 30 Chinese herbal medicines each year and will include, as recommended by CMDC, the study of Chinese medicines decoction pieces. However, some members have doubted the value of HKCMMS as they consider that most of the pCms manufacturers are following the standards set out in the Pharmacopoeia of the People's Republic of China, which gives a more comprehensive coverage of Chinese medicines. In addition, Hong Kong is indeed not the place of origin of Chinese herbal medicines.

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[3] Details of the relevant arrangements are as follows –

(a) A product holder who is granted HKC status will receive from CMB a notification letter with a return slip. He must complete the return slip and indicate in it a preferred effective date for HKC of his product, which should be within 12 months after he is notified of the granting of HKC status. Product holders issued with HKC must ensure that starting from the effective date, the particulars of the pCm for sale on the market are identical with the registered particulars of that pCm.

(b) If a product holder fails to complete the replacement of old packaging label and insert for his product before the effective date, he must apply to CMB for extending the deadline. CMB will consider such applications on a case-by-case basis. The extended period approved by CMB will not be longer than 12 months.

Proposal of setting up a dedicated fund for development of Chinese medicine

33. Some members have criticized that the Chinese medicines industry cannot benefit from HKCMMS, which in their view are actually not widely applied by the industry. Besides, the Government has not provided the trade with more effective assistance over the years. In their opinion, a more effective way of support is to set up a dedicated fund for the development of Chinese medicine. The Administration has advised that further support measures can be mapped out after the existing measures have been tried out. In addition, ITF has launched different funding programmes to support universities, research institutions and companies to conduct applied research projects relating to development and testing of Chinese medicines. For example, the General Support Programme (GSP) under ITF provides support to various projects (including technical training) which would help promote the development of Chinese medicine.

Testing centre for Chinese medicines

34. The Administration has advised that apart from continuing to study and formulate more HKCMMS, the Government has also accepted the recommendation of CMDC to set up a testing centre for Chinese medicines to be managed by DH. The testing centre will specialize in the testing of and scientific research on Chinese medicines, with a view to setting reference standards for the safety, quality and testing methods of Chinese medicines. The testing centre will also embark on relevant hi-tech research to strengthen the capability for the quality control and identification of Chinese medicines. A herbarium on Chinese medicines of international standard will be set up. According to the Administration, through various platforms and close collaboration with the relevant international and Mainland organizations, the testing centre will help promote HKCMMS and the reference standards for testing Chinese medicines as authoritative international benchmarks to pave the way for the internationalization of Hong Kong's Chinese medicines industry. DH has started the preparatory work for setting up the testing centre. Some members have suggested that the testing centre should prepare reference materials for the testing of Chinese medicines.

35. Some members have suggested that an intermediary organization or a dedicated department should be set up to provide technical support and funding assistance specifically to pCm manufacturers in respect of testing, registration and GMP implementation matters. These members have stressed that the Government support is vital to enabling the trade to succeed in upgrading and further development. The Administration has advised that there are a number of NGOs also providing technical support for pCm manufacturers. For instance, the Hong Kong Baptist University and the Hong Kong University of Science and Technology have each set up a research laboratory to provide the trade with

technical support for Chinese medicine testing. HKIB also provides the trade with various consultancy services, including those on pCm product registration. Moreover, the trade may apply for funding under various funding schemes and the SME Funding Schemes administered respectively by ITF and the Trade and Industry Department.

36. Members have, however, pointed out that ITF is to cater for research and development projects, not specifically for the Chinese medicine sector. Members in general consider that support provided by the Government for the development of the Chinese medicines industry is far from adequate, despite the popularity of Hong Kong's pCms among Mainland consumers. Members have urged the Administration to allocate adequate funding and resources to enhance the development of the Chinese medicines industry and expand its market. Some members have cautioned that some pCm manufacturers may move out from Hong Kong to neighbouring places (e.g. Macao) where the supply of land and government funding support are more abundant for better development. These members have urged the Administration to regard the Chinese medicines industry in Hong Kong as a Chinese cultural industry and promote its development.

Request for review of CMO

37. Apart from enhancing support and assistance for the development of the industry, some members have called for review of CMO which, in their opinion, is not conducive to the development of the industry and may even deter pCm manufacturers, thus affecting the development of Chinese medicine. These members have expressed concern about the low success rate of applications for formal registration of pCms and consider it unsatisfactory for CMO to impose rigidly the same stringent registration/testing requirements on various kinds of pCms. They have queried, for example, the need to impose the same stringent requirements on a pCm which is only for external application as those imposed on an oral pCm. These members have also proposed that the Administration should explore introducing more classification categories of pCms (with different levels of registration and testing requirements) to accommodate pCms which may not fulfill the standards of "Established Medicines" but have been sold in Hong Kong for years and proven to be safe or harmless for use. Some members consider that the Administration's requirement to apply the standards of western medicines to Chinese medicines does not go well with the theories of traditional Chinese compound prescriptions and the actual situation.

38. The Administration has explained that to ensure the safe use of medicines by the public, CMO stipulates that all pCms must meet the requirements regarding safety, quality and efficacy prescribed by CMB before they can be

formally registered in Hong Kong. The Administration has stressed that the pCm registration system has given priority to public interests and the safety and efficacy of medicine.

Area II: issues relating to the implementation of the ICWM Pilot Programme

The ICWM Pilot Programme

39. Members welcome the Government's decision to set up a Chinese medicine hospital announced in the 2014 Policy Address. They consider that the development of a Chinese medicine hospital to provide Chinese medicine in-patient services will help enhance the professional training and standards of CMPs in Hong Kong. The Subcommittee has noted that before the establishment of the Chinese medicine hospital, the Administration will carry out specific research projects, such as the introduction of in-patient services in public hospitals under the ICWM Pilot Programme so as to gather experience of the operation of ICWM and Chinese medicine in-patient service which shall form the basis for formulating the mode of operation of the future Chinese medicine hospital.

40. The Administration has explained that the ICWM Pilot Programme aims to make use of the advantages of ICWM to provide appropriate medical treatment for patients; gather experiences for the development of Chinese medicine in-patient services and the establishment of the Chinese medicine hospital; facilitate the training of Chinese medicine graduates; and explore the development of Chinese medicine specialization. Phase I of the ICWM Pilot Programme, launched on 22 September 2014, provides ICWM treatment for HA in-patients of three disease areas, namely stroke care, acute low back pain care and cancer palliative care at Tung Wah Hospital, Pamela Youde Nethersole Eastern Hospital and Tuen Mun Hospital respectively. In-patients of HA who have voluntarily joined the ICWM Pilot Programme will have to pay a daily service fee of HK$200 (excluding fee and charges for HA hospital services) consecutively from the first day of receiving the ICWM treatments until discharge or upon exiting the ICWM Pilot Programme. The daily service fee includes all consultation, decoction, acupuncture, etc, provided within the day. When the participating patients have been discharged from the hospital, they will have to pay the relevant CMCTR HK$120 for each out-patient Chinese medicine visit under the ICWM Pilot Programme.

41. The Subcommittee has noted that as at 30 April 2015, a total of 114 patients had joined the ICWM Pilot Programme. A mechanism has also been established in the hospitals to facilitate the conduct of ward rounds and case

discussions on a regular basis, with a view to fostering clinical exchanges and mutual learning among Chinese and Western medicine healthcare professionals. Besides, HA will develop advanced Chinese medicine training courses for nurses, pharmacists, medical staff and allied health professionals.

42. While expressing support for the ICWM Pilot Programme, some members have requested the Administration to explore expanding the service scope and the scale of the Pilot Programme. They also consider that the number of participating hospitals should be increased so as to benefit more patients. Some members have further suggested providing tui-na treatment in stroke care and low back pain care under the ICWM Pilot Programme.

43. The Administration has explained that subject to the smooth operation of the Phase I of the ICWM Pilot Programme, HA plans to launch the Phase II at other four public hospitals for the same three disease areas[4]. Thereafter, the evaluation reports which assess the effectiveness of the Pilot Programme at two different stages should be completed in the second quarter of 2015 and the second quarter of 2016 respectively. HA will brief CMDC and its Chinese Medicine Practice Subcommittee in due course on the progress and outcome of the ICWM Pilot Progamme.

44. The Administration has also considered members' suggestion of providing tui-na treatment under the ICWM Pilot Programme. It has informed the Subcommittee that HA has agreed to consider, on the basis of scientific evidence, the introduction of cupping, tui-na treatment and prescription for Chinese medicines, in order to meet the clinical needs arising from the course of acupuncture.

45. To make use of the advantages of ICWM to provide appropriate medical treatment for patients, some members have suggested that CMPs should be allowed to make use of x-ray examinations and diagnostic imaging services in their practice after receiving the necessary professional training and obtaining the qualifications. Consideration may also be given to amending the relevant legislation to relax certain restriction imposed on the practice of CMPs. The Administration has subsequently informed members that the CMPs Board under CMC has noted the views of the Subcommittee about strengthening training relating to Western medicine in the Chinese medicine programme and the need for review of the restriction imposed on the practice of CMPs.

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[4] The Phase II of the ICWM Pilot Programme was launched on 21 December 2015 and has expanded to other four public hospitals (namely the Prince of Wales Hospital, Shatin Hospital, Kwong Wah Hospital and Princess Margaret Hospital) to provide in-patients of the same three selected disease areas with ICWM treatment.

Area III: issues relating to the continuing education for registered CMPs and professional specialization of CMPs

46. At present, there is neither specialist training nor specialist qualification accreditation system for CMPs in Hong Kong. To promote the development of Chinese medicine in Hong Kong, the Subcommittee considers it necessary for the Administration to enhance the professional development and recognition of CMPs. The Subcommittee has exchanged views with the Administration and HA on issues such as the continuing education arrangement and remuneration package for CMPs as well as the latest development in promoting Chinese medicine specialization in Hong Kong.

Continuing education for CMPs

47. According to CMO, registered CMPs must fulfil the requirements of continuing education in Chinese medicine ("CME") as prescribed by the CMPs Board of CMC before they can renew their practising certificates. On 28 February 2005, the CMPs Board formally implemented CME system for registered CMPs, and shortlisted the accredited CME Administrators and CME Programme Providers under the CME system.

48. According to the Administration, the practising certificates of registered CMPs should normally be renewed every three years. Registered CMPs must fulfill CME requirements as prescribed by the CMPs Board before they can renew their practising certificates. Therefore, the CME cycle for each registered CMP, which commences on the effective date of his/her practicing certificate and ends on the expiry date, will normally last for three years. Registered CMPs are required to participate in CME activities and attain a minimum of 60 CME points during the three-year cycle.

49. Some members have expressed concern about the measures in place to enhance CMPs' clinical professional standard. The Administration has advised that HA has set up junior and senior scholarship scheme to encourage serving CMPs to attend courses offered by various training bodies in the Mainland. From 2009 to 2015, there were a total of 81 and 25 CMPs participating in the junior and senior scholarship scheme respectively; and received training at various Chinese medicine institutions in Beijing, Shanghai, Tianjin and Guangzhou.

Remuneration package for CMPs in Hong Kong

50. Some members have called on the Administration to consider introducing a qualification framework and an official pay scale for CMPs to enhance their professional development and give them clear progression pathways and a better prospect. These members have further suggested that a Chinese medicine clinic

with ICWM should be set up and run by the Government, so as to gain more experience of the ICWM approach and prepare for the establishment of a Chinese medicine hospital. Besides, this Chinese medicine clinic should be used to provide a basis for the establishment of a formal pay structure for CMPs.

51. The Administration and HA have advised that the Chinese Medicine Practice Subcommittee under CMDC focuses on the deliberation on, among others, the personnel training and professional development of CMPs. Besides, the Government has established 18 CMCTRs, one in each of the 18 districts, to promote the development of "evidence-based" Chinese medicine and provide training placements for graduates of local undergraduate programmes of Chinese medicine. Each CMCTR is required to employ at least 12 junior CMPs or CMP trainees and provide them with training[5]. Fresh graduates of local Chinese medicine undergraduate programmes will be engaged as junior CMPs in the first year, and as CMP trainees in the second and third years. The 18 CMCTRs provide a total of 216 training places. As at June 2015, the 18 CMCTRs employed a total of 361 CMPs, including 211 junior CMPs/CMP trainees. CMPs working at CMCTRs are employees of the NGO operators. The governing board of each CMCTR comprises representatives from HA, NGOs and local universities to oversee the management and operation of CMCTRs, as well as to keep in view the remuneration package for CMPs. Currently, the salary of CMPs working at CMCTRs ranges from $19,000 to $70,000. According to the Administration, the annual subsidy to the NGOs concerned had been increased in April 2013 to enhance, among others, the remuneration package for CMPs.

Professional specialization of CMPs

52. Some members have suggested that Chinese medicine specialties should be created and the relevant specialist qualification accreditation system should be established. In this connection, an examination system should be put in place. These members have further suggested introducing the specialties of Internal Medicine and Gynaecology for CMPs as the first step.

53. The Administration has advised that the Chinese Medicine Practice Subcommittee has started discussing the development of Chinese medicine specialization. The Chinese Medicine Practice Subcommittee has made reference to the specialist training and registration system of medical practitioners in Hong Kong as well as the current situation of specialty development of Chinese medicine practice in other areas, and taken heed of the concerns and views expressed by representatives of the sector and academics.

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[5] Details of the training programmes of continuing education in Chinese medicine developed by HA for CMPs working at CMCTRs are set out in LC Paper No. CB(2) 628/15-16(01).

54. According to the Administration, the CMP sector and academics in recent years have also started discussion on the development of Chinese medicine specialization. Over the past few years, the Schools of Chinese Medicine of local universities organized forums to explore the development directions of specialization, raise industry awareness and stimulate discussion about whether a specialist training or specialist qualification accreditation system for CMPs should be established in Hong Kong. In July 2014, the Hong Kong Chinese Medicine Specialty Development Working Group ("Working Group") was jointly established by the industry and the Schools of Chinese Medicine of three universities to consolidate the Chinese medicine industry and academia 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. The Chinese Medicine Practice Subcommittee will continue to study the development of Chinese medicine specialization and maintain communication with CMPs, academics and other relevant sectors, and will make recommendations to the Government in due course.

Recommendations

55. As summarized below, the Subcommittee recommends that the Administration should -

(a) formulate comprehensive policies and provide necessary hardware and software support, including manpower training and provision of facilities, to help local pCm manufacturers overcome the GMP-compliance challenges. Reference may be made to the relevant experience of the Mainland and Singapore;

(b) set up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangements for their pCm production in compliance with GMP requirements;

(c) set up an intermediary organization or a dedicated department to provide technical support and funding assistance specifically to pCm manufacturers in respect of testing, registration and GMP implementation matters;

(d) explore introducing more classification categories of pCms (with different levels of registration and testing requirements) to accommodate pCms which may not fulfill the standards of "Established Medicines" but have been sold in Hong Kong for years and proven to be safe or harmless for use;

(e) consider setting up a dedicated fund to support the upgrading and development of the local Chinese medicines industry;

(f) discuss with the industry their needs and reach consensus with them on the support and assistance that the Administration should provide (including a timetable for providing the support and assistance);

(g) consider amending CMO;

(h) explore expanding the scope of disease areas under the ICWM Pilot Programme;

(i) strengthen the training relating to the Western medicine in the Chinese medicine programme so as to facilitate ICWM;

(j) consider some members' view that a qualification framework and an official pay scale for CMPs should be established to enhance their professional development and give CMPs clear progression pathways and a better prospect;

(k) consider some members' suggestion that a Chinese medicine clinic with ICWM should be set up and run by the Government, so as to gain more experience of the ICWM approach and prepare for the establishment of the future Chinese medicine hospital; and

(l) consider some members' suggestion of creating Chinese medicine specialties and establishing the relevant specialist qualification accreditation system. The Administration may introduce the specialties of Internal Medicine and Gynaecology for CMPs as the first step.

Advice sought

56. The Panel is requested to note the deliberations of the Subcommittee and consider its recommendations in paragraph 55 above.

Council Business Division 2
Legislative Council Secretariat
2 February 2016

Appendix I

Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Membership list

Chairman	Hon CHAN Han-pan, JP
Members	Hon Vincent FANG Kang, SBS, JP Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN Hon WONG Ting-kwong, SBS, JP Hon CHEUNG Kwok-che (up to 26 October 2015) Hon YIU Si-wing, BBS Hon Alice MAK Mei-kuen, BBS, JP Dr Hon KWOK Ka-ki (up to 16 October 2015) Dr Hon Elizabeth QUAT, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP Total : 8 Members
Clerk	Ms Joanne MAK
Legal Adviser	Ms Wendy KAN
Date	15 December 2015

附錄 II
Appendix II

衞生事務委員會
Panel on Health Services

中醫藥發展事宜小組委員會
Subcommittee on Issues Relating to the Development of Chinese Medicine

曾向小組委員會表達意見的團體/個別人士名單
List of organizations/individuals which/who have submitted views to the Subcommittee

	名稱	**Name**
1.	中成藥製造商關注 GMP 小組	Chinese Medicine Manufacturers' Group
2.	天利藥業國際有限公司	Tin Lee Medicine International Limited
3.	世聯中醫藥現代化協會	Worldwide Chinese Medicine Modernization Alliance
4.	仙然康寶發展有限公司	Natural Health Care Development Ltd.
5.	民主建港協進聯盟	Democratic Alliance for the Betterment and Progress of Hong Kong
6.	永安葯業公司	Wing On Medicine Co.
7.	自由黨關注批發零售小組	Concern Group on Wholesale and Retail, Liberal Party
8.	吳和謀先生	Mr NG Wo-mau
9.	李帝發先生	Mr LI Tei-fat
10.	良偉有限公司	Lanway Ltd.
11.	旺高國際發展有限公司	旺高國際發展有限公司
12.	東方國際保健品有限公司	Oriental Int'l Health Products Co. Ltd.
* 13.	保和堂製藥有限公司	Po Wo Tong Pharmaceutical Ltd.
14.	信健有限公司	Smart Planning Ltd.
15.	恒大貿易公司分行	Hang Tai Trading Co. (Branch)
16.	星加坡魚尾獅(國際)藥油廠	Singapore Merlion (Int'l) Medicated Oil Manufactory Co. Ltd.
17.	香港中小企促進聯會	Hong Kong SME Development Federation Ltd.

*	18. 香港中成藥商會	Hong Kong Chinese Prepared Medicine Traders Association Limited
	19. 香港中成藥製造商聯合協會	Hong Kong Chinese Medicine Manufacturers United Association
	20. 香港中華製藥總商會	Hong Kong Chinese Patent Medicine Manufacturers Association
	21. 香港中醫眼科中心	H.K. Ophthal Center in Chinese Medicine
	22. 香港中醫藥信息有限公司	Chinese Medicine Informatics (HK) Ltd.
	23. 香港中醫藥業聯合會有限公司	The Hong Kong Federation of Chinese Medicine Sector Limited
	24. 香港中藥業協會	Hong Kong Chinese Medicine Industry Association
	25. 香港中藥學會有限公司	The Hong Kong Society of Chinese Medicines Ltd.
	26. 香港中藥聯商會有限公司	HK Chinese Medicine Merchants Association Ltd.
	27. 香港永康製藥有限公司	Hong Kong Wing Hong Pharmaceutical Limited
	28. 香港生物科技研究院有限公司	Hong Kong Institute of Biotechnology Ltd.
	29. 香港生產力促進局	Hong Kong Productivity Council
*	30. 香港前線中醫聯盟	Union of Frontline Chinese Medicine Practitioners (Hong Kong)
	31. 香港南北藥材行以義堂商會有限公司	Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.
	32. 香港馬世良堂製藥有限公司	H.K. Ma Sai Leung Tong Med. Mfy. Ltd.
	33. 香港參茸藥材寶壽堂商會有限公司	Po Sau Tong Ginseng & Antler Association Hong Kong Limited
	34. 香港通用檢測認證有限公司	SGS Hong Kong Limited
	35. 香港新中醫學院	Hong Kong Sun Chung Medical Centre University
	36. 香港榮燊製藥廠	W.S.D. Mty
	37. 香港製藥商會	HK Pharmaceutical Manufactureres Association

38. 香港濟眾堂中藥廠有限公司	Hong Kong Chi Chun Tang Herbal Factory Limited
39. 香港藥行商會	Hong Kong Medicine Dealers' Guild
40. 徐玉龍女士	Ms CHUI Yuk-lung
41. 悅泰醫藥科技(國際)有限公司	Medic-Pharm Technology (Int'l) Ltd.
42. 粉嶺德昌參茸葯行	Tak Cheong Ginseng Co.
43. 馬基乾先生	Mr Victor MA Kee-kin
44. 高非先生	Mr KO Fei
45. 康溢醫藥有限公司	Canhealth Pharmaceutical Limited
46. 強身保健文化協進會	Health Potential Culture Association
47. 梁慧中小姐	Miss Bernice LEUNG Wai-chung
48. 惠輝貿易公司	Wai Fai Trading Co.
49. 港九中華藥業商會有限公司	Hong Kong & Kowloon Chinese Medicine Merchants Association Limited
50. 翔集堂藥業公司	Nobility Herb & Medicine Company
51. 華燊醫藥貿易公司	Wah Sun Medical Trading Company
52. 馮淑芳小姐	Miss FUNG Chuk-fong
53. 黃保寧先生	Mr Daniel WONG Po-ling
54. 愛群製藥廠	O.K. Pharmaceuticals Factory HK
55. 慈恩堂中藥有限公司	Tsz Yan Tong Chinese Med. Manufacturing Co.
56. 新興製藥廠	新興製藥廠
57. 源汝霖先生	Mr YUEN Yee-lum
58. 溫山南先生	Mr WAN Shan-nam
59. 養身堂中醫藥顧問中心	Healthy Chinese Medicine Consultation Centre
60. 黎氏藥業	Lai's Medicine
61. 黎昇中藥廠有限公司	Lai Shing Medicine Factory Limited
62. 聯益藥業有限公司	Luen Yick Pharmaceutical Co. Ltd.

63. 鴻輝公司	Hung Fai Company
64. 羅偉強先生	Mr LAW Wai-keung
65. 譚金製藥廠	Tam Kam Medicament Manufacturing Factory
66. 關東百源堂	Kwan Tung Pak Yuen Tong

* 只提交意見書
provided submissions only

附錄 III
Appendix III

（只備中文本）
(Chinese version only)

本地化驗所中成藥測試服務收費及測試所需時間參考

測試項目	市場測試費用*	測試所需時間
安全性資料		
重金屬及有毒元素含量	共$3,000 - $5,000	約 1 個月
農藥殘留量		
微生物限度		
急性毒性試驗（適用於口服中成藥）	$8,500-$20,000	6-9 個月
急性毒性及局部毒性試驗（適用於外用中成藥）	$30,000-$100,000	9-12 個月
局部毒性試驗（適用於黏膜用藥）	$10,000-$30,000	6-9 個月
長期毒性試驗（適用於「非固有藥類別-保健品」及「新藥類別」）	$200,000 或以上	18-24 個月
品質性資料		
甲：品質標準、化驗方法及化驗報告		
制定中成藥品質標準（如需要）	開發含量測定及鑒別項目收費： $50,000-&70,000	3-6 個月
製成品品質化驗：	$4000 - $10,000 收費按測試項目的數量調整	約 3 個月
乙：穩定性試驗		
一般穩定性試驗[1] (3 批樣品)	按品質標準化驗的收費 x 化驗次數	按產品有效期調整 以有效期為 3 年計算:

[1] 任何於中成藥註冊法例生效前(即於 2003 年 12 月 19 日前)，已在香港銷售或製造的中成藥，該中成藥的一般穩定性資料，其申請人可於該中成藥註冊續期時提交最少一批產品的檢驗報告及已開展其他批號測試的證明予中藥組;其餘批次產品的檢驗報告，則必須於該中成藥註冊再續期時提交。至於三批產品的加速穩定性試驗報告或常温穩定性試驗報告，其申請人須於該中成藥註冊續期時提交。
於過渡性註冊申請截止日前(即於 2004 年 6 月 30 日或之前)，已在香港銷售或製造的中成藥，若銷售年期已多於 2 年，該中成藥只須提交一般穩定性資料；若銷售年期不足 2 年，則須額外提交加速穩定性試驗報告。

測試項目	市場測試費用*	測試所需時間
	以有效期為 3 年（於 0 年及 3 年進行試驗）計算： $25,000-$60,000	需約 39 個月
加速穩定性試驗[2] (3 批樣品)	$48,000-$120,000	約 6 個月
常溫穩定性試驗[3] (3 批樣品)	以有效期為 3 年計算： $150,000-$330,000	按產品有效期調整 以有效期為 3 年計算： 需約 39 個月

備註：

* 資料來源自本地化驗所經由電話查詢提供。

[2] 於在中成藥註冊法例生效後（即於 2003 年 12 月 19 日及以後）至過渡性註冊申請截止日前（即 2004 年 6 月 30 日或以前），才在香港銷售或製造的中成藥，申請人須於申請註冊時立即提交三批產品的加速穩定性試驗結果、留樣觀察的方案、最少一批產品出廠時（0 年）的原始檢驗結果及已開展其他批號測試的證明予中藥組。

[3] 如已提交常溫穩定性試驗報告,可毋須提交加速穩定性試驗報告及一般穩定性資料。