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The People's Republic of China

*Our ref.:* FH CR 1/3911/12
*Your ref.:* CB2/PS/1/13

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19 October 2015

Ms Joanne MAK
Secretary
Subcommittee on Issues Relating to the Development of Chinese Medicine
Legislative Council Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Ms Mak,

**Panel on Health Services**
**Subcommittee on Issues Relating to**
**the Development of Chinese Medicine**

**Administration's response to issues raised at the meetings on 9 June and 21 July 2015**

At the meetings of the Subcommittee on Issues Relating to the Development of Chinese Medicine ("the Subcommittee") held on 9 June and 21 July 2015, Members requested the Administration to provide supplementary information on issues relating to the development of Chinese medicine practitioners ("CMPs") and Chinese medicines. The supplementary information is set out below.

## I. Arrangements for the Chinese Medicine Practitioners Licensing Examination

2. The Chinese Medicine Council of Hong Kong ("CMC") is an independent statutory organisation established under the Chinese Medicine

Ordinance (Cap 549) ("CMO") to implement regulatory measures for CMPs and Chinese medicines. The Department of Health ("DH") provides professional and administrative support to the CMC to facilitate the latter to formulate and execute various regulatory measures on Chinese medicines. The Chinese Medicine Practitioners Board under the CMC is a statutory regulatory body set up under the CMO to carry out various regulatory measures for CMPs as stipulated in the CMO, which include organising and holding the Chinese Medicine Practitioners Licensing Examination.

3. At the meeting of the Chinese Medicine Practitioners Board held on 13 August 2015, the DH relayed to board members the views of the Subcommittee on assisting graduates of Chinese medicine degree programmes in the Mainland to apply for the Chinese Medicine Practitioners Licensing Examination when they return to Hong Kong. The reply of the Chinese Medicine Practitioners Board is as follows:

(i) According to Section 61(1)(a) of the CMO, an applicant must satisfy the Chinese Medicine Practitioners Board that at the time of the application for taking the Chinese Medicine Practitioners Licensing Examination, he/she has satisfactorily completed the undergraduate programme in Chinese medicine practice or its equivalent which is approved by the Chinese Medicine Practitioners Board. To be eligible to take the licensing examination, an applicant must provide proofs of graduation and relevant degree certificates with the application.

(ii) The Chinese Medicine Practitioners Board currently recognises full-time undergraduate programmes in Chinese medicine with a duration of not less than five years offered by three local universities and 30 Mainland institutions as programmes eligible for taking the licensing examination. An approved programme should basically comprise 10 compulsory subjects on Chinese medicine and Chinese medicine clinical training of not less than 30 weeks. The list of recognised institutions and detailed information of the examination are published in the Candidates' Handbook for the Chinese Medicine Practitioners Licensing Examination and uploaded onto the website of CMC (http://www.cmchk.org.hk).

(iii) The Examination Committee under the Chinese Medicine Practitioners Board is responsible for vetting the applications for the Chinese Medicine Practitioners Licensing Examination. Relevant documentary proofs such as the certificate of degree in Chinese

medicine, graduation certificate, transcripts and internship certificates must be submitted within the specified application period. Applicants who fail to submit the above documentary proofs to the Chinese Medicine Practitioners Board before the deadline will not be allowed to sit for the examination.

(iv) The written part of the Chinese Medicine Practitioners Licensing Examination takes place in June every year. Arrangements for taking the examination will not be made for applicants who fail to submit the relevant information to the Chinese Medicine Practitioners Board before the specified deadline. While the Chinese Medicine Practitioners Board understands that students of different undergraduate degree courses in Chinese medicine in different areas may graduate at different times, the current arrangement has already accommodated, as far as possible, the different graduation time of most students of the recognized institutions. After considering factors such as resources and supporting facilities, the Chinese Medicine Practitioners Board has decided that the practice of holding examination once a year will be maintained for the time being.

## II. Integrated Chinese-Western Medicine Pilot Programme

4. The Subcommittee requested the Administration to provide information on whether tui-na treatment in stroke care and low back pain care will be provided under the Integrated Chinese-Western Medicine ("ICWM") Pilot Programme ("the Pilot Programme").

5. The Pilot Programme aims to: (a) make use of the advantages of ICWM to provide appropriate medical treatment for patients; (b) gather experiences for the development of Chinese medicine in-patient service and the establishment of the Chinese medicine hospital, facilitate the training of Chinese medicine graduates; and (c) explore the development of Chinese medicine specialisation. A dedicated task force was set up by the Hospital Authority ("HA") to design relevant clinical and operational frameworks which steer the current operation of the Pilot Programme.

6. To ensure the safe operation of "evidence-based practice", the HA implements a series of clinical management measures. According to the clinical plan of the HA, the criteria for selecting the disease areas include: (a) the disease areas where the treatment of Chinese medicine or the synergy

effect generated by treatment of ICWM are effective with the support of scientific proof; (b) the disease areas that a certain number of patients is anticipated; and (c) the diseases that the inclusion and exclusion criteria can be clearly defined. The clinical plan has clearly set out the inclusion and exclusion criteria, the indications of Chinese and Western medicine treatments, etc. The clinical protocol of each disease area is based on scientific evidence and jointly developed by a working group comprising experts in Chinese medicine and Western medicine. It includes clinical guidelines for integrating Chinese medicine with Western medicine, inclusion and exclusion criteria, clinical outcome indicators and clinical risk management. To meet clinical needs, other treatments may also be considered on the basis of scientific evidence. For example, in response to the clinical needs which may arise from the course of acupuncture, the HA is considering the introduction of cupping, tui-na treatment and prescription for Chinese medicines. The Chinese Medicine Practitioners Board under the CMC noted the views of the Subcommittee about strengthening the training relating to Western medicine in the Chinese medicine programme and review of the restriction imposed on the practice of CMPs.

## III. Work Progress of the Chinese Medicine Development Committee

7. The Chief Executive set up the Chinese Medicine Development Committee ("CMDC") in February 2013 to focus on the study of four major areas of Chinese medicine, namely the development of Chinese medicine services, personnel training and professional development, research and development, as well as development of the Chinese medicines industry (including the testing of Chinese medicines). The Chinese Medicine Practice Sub-committee and the Chinese Medicines Industry Sub-committee were formed under the CMDC to focus deliberation on respective areas. After two years of discussions and studies, the CMDC has made specific recommendations, among others, on the development of the Chinese medicine hospital, ICWM, Chinese Materia Medica Standards and the testing of Chinese medicines. The Government has accepted the recommendations and is implementing them in phases, of which the details are provided in the following paragraphs. The CMDC will continue to conduct discussions and studies on other aspects of Chinese medicine and make recommendations to the Government when appropriate.

8. As for Chinese medicine practice, the development of Chinese medicine service, personnel training and professional development are complementary to one another. In this regard, the Chief Executive announced

in the 2014 Policy Address that the Government had accepted the CMDC's recommendation and reserved a site in Tseung Kwan O for the development of a Chinese medicine hospital. Apart from providing in-patient service for the public, the Chinese medicine hospital can provide facilities to support teaching, clinical practice and scientific research of the local tertiary institutions, including the Schools of Chinese Medicine of the three universities. The Chinese medicine hospital will serve as an important platform for personnel training and professional development of CMPs, and help strengthen and enhance the quality of professional training for CMPs, as well as scientific research of Chinese medicine in Hong Kong.

9. The Government also agreed with the CMDC's recommendation to carry out some practical study projects before the establishment of the Chinese medicine hospital with a view to gathering experience in the ICWM and the operation of Chinese medicine in-patient service. To this end, the Government has commissioned the HA to implement the Pilot Programme. After fully consulting the CMDC, the HA already launched phase I of the Pilot Programme in September 2014 in three public hospitals to provide in-patients of three disease areas (namely stroke care, acute low back pain care and cancer palliative care) with ICWM treatment during in-patient stay and follow-up Chinese medicine out-patient service. In view of the generally smooth operation of phase I of the Pilot Programme, the HA intends to launch phase II by the end of 2015 and extend the Pilot Programme to cover a total of seven public hospitals (including the three existing participating public hospitals). The results of the Pilot Programme and the experience gained will serve as an important reference for the Government and the CMDC in considering the mode of operation of the Chinese medicine hospital, and in studying the future personnel training needs for CMPs. In the meantime, the Chinese Medicine Practice Sub-committee under the CMDC has started the discussion on how the training of CMPs and healthcare personnel could cater the needs of the future development of Chinese medicine in-patient service and ICWM.

10. While studying the mode of operation of the Chinese medicine hospital, the Chinese Medicine Practice Sub-committee has started preliminary discussion on the development of specialties for Chinese medicine practice. The sub-committee 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 academia. In recent years, the CMP sector and academia have also started the discussion on specialty development of Chinese medicine practice. The Chinese Medicine Practice Sub-committee

will maintain communication with the CMPs, academia and other relevant sectors to study the feasibility of specialty development of Chinese medicine practice.

11. On the development of Chinese medicines, the CMDC, after detailed discussions, has recommended the Government to continue with the Hong Kong Chinese Materia Medica Standards ("HKCMMS") project to study and formulate reference standards for more Chinese Materia Medica ("CMM"), and include a study on the reference standards for Chinese medicines decoction pieces under the HKCMMS project. The Government has accepted the CMDC's recommendations. Seven editions of HKCMMS, covering the studies and reference standards for a total of 236 CMM, have been published by the DH so far, and the study on another 60 CMM is underway. Having consulted experts in scientific research, the DH is also actively working on the details of the pilot study on the reference standards for Chinese medicines decoction pieces.

12. Moreover, the Government stated in the 2013 Policy Address that Hong Kong enjoys a clear advantage and has good development potential in the testing and certification industry, which has built a good foundation based on a robust accreditation system, high professional standards and an excellent reputation. Chinese medicines industry is one of the selected industries with potential demand for testing and certification services. Having examined the current Chinese medicine testing services in Hong Kong, the CMDC agreed that Chinese medicine testing would help ensure the quality and safety of products and strengthen consumer confidence, and that the development of Chinese medicine testing standards and related business could also help develop Hong Kong as an international Chinese medicine testing and certification hub. After thorough deliberation, the CMDC suggested that the Government should seize the advantage and set up a testing centre for Chinese medicines specialising in the testing of and scientific research on Chinese medicines, with a view to establishing reference standards and testing methods for Chinese medicines and promoting them as authoritative international benchmarks. This would enhance the testing standards in Hong Kong, thereby improving the quality of Chinese medicines and paving the way for internationalisation of the Chinese medicines industry. The CMDC also considered that the role of the Government should be to formulate policies, set directions and provide appropriate legal framework. Hence the testing centre should be responsible for establishing rigorous reference standards and testing methods for Chinese medicines while the testing services should be provided by the practitioners / organisations of the industry to facilitate the development of the testing industry in Hong Kong.

13. The Government accepted the recommendations of the CMDC and announced in the 2015 Policy Address that it will plan and develop a testing centre for Chinese medicines to be managed by the DH. The testing centre will specialise 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. Apart from continuing to study and formulate more HKCMMS, the testing centre will also embark on relevant hi-tech research with a view to strengthening the capability for the quality control and identification of Chinese medicines. A herbarium on Chinese medicines of international standard will be set up. Through various platforms and close collaboration with the relevant international and Mainland organisations, the testing centre will promote the HKCMMS and the reference standards for Chinese medicines testing as authoritative international benchmarks to pave the way for the internationalisation of Hong Kong's Chinese medicines industry. The DH is now actively carrying out the preparation work for the establishment of the testing centre and will update the CMDC on the progress when appropriate.

## IV. The registration of proprietary Chinese medicines

14. The Chinese Medicines Board ("CMB") under the CMC is a statutory regulatory body established under the CMO. It is responsible for executing and implementing various regulatory measures for Chinese medicines stipulated in the CMO, and formulating policies on the registration of proprietary Chinese medicines ("pCms") taking into account the current situation of the pCm industry in Hong Kong.

15. Taking into account the history and practical circumstances of the sale of pCms in Hong Kong, the CMO provides an arrangement of transitional registration. Where a pCm was manufactured, sold or supplied for sale in Hong Kong on 1 March 1999, its manufacturer or wholesaler may, in accordance with the CMO, apply for transitional registration of the pCm within the specified period. A notice of confirmation of transitional registration of pCm ("HKP") will be issued if the pCm has been assessed by the CMB and confirmed as eligible for transitional registration. To facilitate the processing of transitional registration of pCms to formal registration by the CMB, holders of HKP issued under the CMO are required to submit, according to the registration groups chosen, the necessary documents in respect of safety, quality and efficacy to the CMB. A certificate of registration of pCm ("HKC") will be issued if the pCm has been assessed by the CMB and confirmed as meeting the registration requirements.

16. The CMB understands that the trade needs time for adaptation in order to comply with the pCm registration requirements and preparation of the test reports required for registration. The CMB has all along adopted a phased approach in processing pCm registration applications. The CMB first published the Application Handbook for Registration of Proprietary Chinese Medicines in December 2003. It sets out the documents required to be submitted for pCm registration and the deadline for submission. Under the original arrangement, HKP holders were required to submit the product quality and stability test reports by 30 June 2009. However, having regard to the request of the trade for a longer testing period due to the difficulties encountered in establishing pCm quality specifications and conducting stability tests, the CMB extended the deadline twice. It announced the extension of submission deadline from 30 June 2009 to 30 June 2013, and then further extended the deadline to 30 June 2015. In other words, the trade has been given more than ten years to prepare the reports required for formal registration. The Government has implemented transitional measures for the registration system for pCms, taking into account the history and practical circumstances of the sale of pCms in Hong Kong, so as to provide the trade with sufficient time to prepare for registration.

17. The CMB has agreed earlier that reminder letters will be issued to those HKP holders who have not submitted the test reports by the deadline of 30 June 2015, providing another period of three months for submitting the reports. The holders concerned should submit all the test reports required within three months as stipulated in the reminder letters. If they cannot do so, they should provide sufficient reasons for consideration by the CMB. Otherwise, the CMB may consider rejecting the applications concerned.

18. On the other hand, to address the difficulties encountered by the trade in the registration of pCms, such as expensive testing costs and difficulties in establishing product specifications, the Innovation and Technology Fund and the Trade and Industry Department have implemented various funding schemes and the SME funding schemes respectively for application by the trade. These funding schemes are industry-neutral and enterprises / organisations meeting the requirements, including those from Chinese medicine sector, are eligible to apply.

19. In Hong Kong, pCms have been widely used. To ensure the safe use of medicines by the public, the CMO stipulates that all pCms must meet the requirements regarding safety, quality and efficacy prescribed by the CMB before they can be formally registered in Hong Kong. The pCm registration system has given priority to patients' interests and medicine safety and

efficacy. Moreover, we have also made reference to the practices adopted in the neighbouring areas. We have noted that, to protect medication safety of consumers, applicants in the Mainland China and Taiwan are also required to submit information to the authorities concerned for registration to substantiate that their Chinese medicine products are in compliance with the requirements on safety, quality and efficacy.

20. In addition, under the existing legislation and regulatory framework, there is no provision which allows "freezing" the HKP status of the pCms which fail to comply with the requirements on safety, quality and efficacy. On the contrary, according to the CMO, when a HKC application is being processed by the CMB, the HKP concerned shall continue in effect and the pCm concerned shall continue to be permitted for sale, until (i) the issue of a HKC; (ii) the refusal of the HKC application; or (iii) such date as may be specified and promulgated by the Secretary for Food and Health by notice published in the Gazette, whichever is the earliest. In other words, for a pCm issued with HKP, if its HKC application is rejected by the CMB, the HKP concerned will be invalidated and the pCm will no longer be allowed for sale in the market. This is absolutely in line with the principle of ensuring the efficacy of pCms and their safe use by the public. The CMO does not empower the CMB to allow such pCms to "freeze" their HKP status.

21. When processing applications for pCm registration, the CMB has also been actively communicating with the trade through different channels. For example, it has, in collaboration with the DH, conducted 19 seminars / sharing sessions and 43 briefings since 2011 to explain to the 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 the CMB and DH have attended 12 meetings / exhibitions held by trade associations and the trade to brief the requirements for and implementation of pCm registration in Hong Kong. The CMB and DH have also explained to the trade and applicants the requirements for pCm registration and testing as well as the latest arrangements for pCm registration through interviews with individual applicants and publication of Chinese Medicines Traders Newsletter.

22. The Government will ensure the smooth migration of pCms from HKP to HKC, and at the same time strive to ensure the safety, quality and efficacy of pCms available in the local market. The aim is to enhance public confidence in using pCms, which is crucial to foster the development of Chinese medicine.

## V. Supplementary Information on Chinese Medicine Centres for Training and Research ("CMCTRs")

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

24. Each CMCTR is required to employ at least 12 junior CMPs or CMP trainees. 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, 18 CMCTRs employed a total of 361 CMPs, including 211 junior CMPs / CMP trainees. The CMPs working at the CMCTRs are employees of the NGO operators; their employment terms and remuneration packages are determined by the NGOs.

25. Besides, the CMCTRs invite Chinese medicine experts to deliver talks in Hong Kong from time to time to enhance the professional knowledge of the CMPs. The CMTCRs also arrange training placements for the CMPs in Chinese medicine hospitals in the Mainland.

Yours sincerely,

(Miss Fiona CHAU
for Secretary for Food and Health