中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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10 May 2021

Mr Colin Chui
Clerk to Panel
Panel on Health Services
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Mr Chui,

Legislative Council Panel on Health Services
Follow-up to the meeting on 9 April 2021

During the discussion on the development of the Chinese Medicine Hospital (CMH) and the Government Chinese Medicines Testing Institute (GCMTI) in Tseung Kwan O at the meeting of the Legislative Council Panel on Health Services held on 9 April 2021, Members requested the Government to provide supplementary information. Having consulted the Department of Health (DH) and the Hospital Authority (HA), the requested information is provided as follows –

The HA's Mechanism and Criteria for Procuring Chinese Medicine (CM) Products

2. The HA has been procuring CM products from the market for the use of the 18 Chinese Medicine Clinics cum Training and Research Centres (CMCTRs) in accordance with the established open and transparent procurement mechanism through tendering. All CM products supplied to the HA must meet the local statutory requirements, Good Manufacturing Practices (GMP) standard, and the specifications set out in the tender documents. Certificates issued by the relevant government departments of the place where the manufacturer operates are required for the CM products to certify their compliance with the GMP standard. Qualitative and quantitative tests on the CM

products in respect of identification and safety must be conducted according to available referential standards. Safety tests include those for heavy metals, pesticide residues, microbial limit, aflatoxins and sulphur dioxide residues. Tenderers and their products must meet the legal safety and quality requirements stipulated in the tender documents before the HA would accept their bids and consider their bid prices.

3. In tendering exercises for the supply of CM granules for prescription, the HA, taking into consideration factors such as market supply and clinical service needs, has included both single CM granules and compound CM granules among the tender items. The former is a required supply item whereas the latter is optional. The existing supplier selected under the above-mentioned tendering mechanism has met the requirements specified in the tender. In its successful bid, the supplier has opted to provide single CM granules (required supply item) but not compound granular products (optional supply item). The HA will review tender items of CM products on a regular basis, and will make timely adjustments having regard to the market development and clinical service needs.

4. The HA has all along been guided by the principle of prudent risk management to safeguard the safety of patients and ensure the quality of CM products used by the 18 CMCTRs. Over the years, the HA has set up governance structure and collaboration framework to steer the planning and implementation of the quality assurance measures of CM products, as well as the central procurement and promotion of continuous quality assurance of CM products, so as to dovetail with the evolving regulatory requirements, the quality standards from authoritative literature, and the development of CM drugs industry. For continuous quality assurance, the HA appoints accredited laboratories under the Hong Kong Laboratory Accreditation Scheme and local academic institutions which have participated in drafting the Hong Kong Chinese Materia Medica Standards (HKCMMS) to conduct internal sample checks of CM products, so as to monitor the authenticity and safety of CM products.

GCMTI

(a) The positioning and work of the GCMTI

5. Having considered the recommendation of the Chinese Medicine Development Committee, the Government announced the establishment of a Chinese medicines testing institute to be managed by the DH that would specialise in scientific research on CM drugs with a view to setting reference standards on safety, quality and testing method of CM drugs. Based on this positioning, the missions of the GCMTI are to develop a set of internationally-recognised reference standards for CM drugs and

related products by employing state-of-the-art technology and through scientific research, and to help empower the industry through transfer of technology to strengthen quality control of products, thereby establishing the brand image of Hong Kong in CM drugs and strengthening Hong Kong's position as an international trade centre of CM drugs.

6. The objectives of the GCMTI's work include:

(i) to set up a number of advanced laboratories of internationally-recognised standards to embark on high-tech scientific research and develop testing methods which will be transferred for reference and use of the CM drugs and testing industry;

(ii) to establish a CM drugs herbarium laboratory for the collection of Chinese materia medica (CMM) specimens and corresponding animal/plant voucher specimens and for development of a digitalised CM drugs information platform;

(iii) to set up an international collaboration and training centre (including a training and technology transfer laboratory) for providing training to the CM drugs and testing industry, promoting reference standards of CM drugs, and transferring technical know-how to the testing industry;

(iv) to continue to formulate reference standards for CMM; and

(v) to strengthen international collaboration and to promote harmonisation of reference standards for CM drugs and testing methods.

7. The DH set up the GCMTI Advisory Committee (AC) in 2017 to advise the Government on long-term development strategies, measures and specific research proposals in respect of the GCMTI. Members of the AC include representatives from the CM drugs trade, CM practice, academia and the Government, as well as international experts of the HKCMMS project. Having considered the views of the AC, as well as those of the CM drugs and testing industries, the DH has worked out the proposed design of the GCMTI project so as to meet the needs of the industry and facilitate the achievement of the GCMTI's missions with a view to fostering the development of CM drugs testing.

8. In recent years, the Government has actively fostered exchanges and cooperation with relevant Mainland organisations in respect of CM drugs testing and research on reference standards. Various cooperation agreements in this regard have been signed. The Mainland has long been supportive to the development of CM drugs in Hong Kong, including offering technical support to the GCMTI, thereby laying a good foundation for the establishment and long-term development of the GCMTI.

9. There will be various facilities relating to CM drugs testing in the GCMTI. Upon completion, the GCMTI will benefit the public and stakeholders, and foster the development of CM drugs in various respects.

(b) Details of the medicinal plant garden

10. The medicinal plant garden of the GCMTI and the adjoining garden of the CMH will be located in between the two buildings. Having considered the views of stakeholders, the medicinal plant garden comprises medicinal and ornamental plants and will be open to the general public, CM practitioners, the CM drugs industry and students. Guided tours will also be available.

11. The medicinal plant garden will be the first of its scale in Hong Kong featuring predominantly medicinal plants of Lingnan (嶺南) characteristics, which will showcase various plants that are used for treatment under CM theory. It also serves to support the GCMTI's research work through "clarifying the source and identity of genuine CM drugs" by facilitating collection and identification of CM specimens, as well as showcasing the entire chain of traditional CM drugs from original plants to proprietary Chinese medicines. Furthermore, the medicinal plant garden will help promote CM drugs education, facilitate training for talents in CM drugs to dovetail with the development of the CMH, and promote CM drugs knowledge to the public and students through guided tours. The planting cost involved in the entire GCMTI works project amounts to about $5.4 million, including a sub-item of $1.8 million relevant to the planting of medicinal plants in the medicinal plant garden. The medicinal plant garden and CM drugs herbarium laboratory are complementary in nature. They are of significant value to scientific research in respect of tracing the source of CM drugs through scientific methods.

(c) Details of CM drugs herbarium and digitalised CM drugs information platform

12. Most CM drugs are derived from plants. The presence of multiple species and easily confused species due to various factors directly affects the quality of CM

drugs. Therefore, the collection of different CM drugs and traditional medicinal plant specimens is important to support accurate species identification.

13. The Food and Health Bureau and the National Medical Products Administration (NMPA) signed the Cooperation Agreement on Construction, Research and Management of Chinese Medicines Herbarium in 2019. The NMPA has been supportive to the establishment of the CM drugs herbarium laboratory by the Government. Apart from contributing various sets of precious CM specimens, the NMPA provides technical support to the GCMTI in respect of, inter alia, collecting and managing CM specimens.

14. The CM drugs herbarium laboratory will collect, classify and display various types of CM drugs specimens. In collecting CM drugs specimens of a wide variety, corresponding source plants and specimens of decoction pieces, etc. will also be collected. After assembling various specimens, the CM drugs herbarium laboratory will digitalise physical specimens in phases for display to the general public through the digitalised platform, and compile data based on microscopic, chemical and DNA analysis of physical CM drugs specimens. Stakeholders from the CM drugs industry, testing industry, research sector and academia can make use of the resources from the CM drugs herbarium laboratory and the digitalised platform as an important basis for the testing and identification of CM drugs, through which the scientific research of CM drugs will be supported. The CM drugs herbarium laboratory will be beneficial to the relevant industries in the following ways –

(i) CM drugs industry: the collection in the CM drugs herbarium laboratory and digitalised platform can provide the industry with comprehensive and professional information related to CM drugs identification. This will help enhance the capability of the industry to identify and procure quality CM drugs, thereby boosting Hong Kong's reputation as an international CM centre and build up consumer's confidence in using CM drugs;

(ii) Testing industry: The physical specimens used in formulating CM drugs reference standards can support the industry's CM drugs testing work and facilitate seamless transfer of testing methods and standards, with a view to promoting the development of CM drugs testing and certification, as well as maintaining the industry's competiveness among regional and international counterparts; and

(iii) Academia: The physical CM drugs specimens authenticated by experts can be used by the academia for research purpose, and to pass on CM drugs knowledge to younger generations. Besides, they can also help solve the difficulties in identification and origin traceability of CM drugs that may be encountered in the course of scientific research on CM drugs, thereby enhancing the standard of scientific research.

(d) Benefits for the industry

15. Apart from the aforementioned facilities, the setup of the GCMTI will benefit the industry as elaborated below –

(i) The GCMTI will use various dedicated laboratories, including a chemistry laboratory, DNA laboratory, a macroscopic identification laboratory and a microscopic identification laboratory, to embark on high-tech scientific research of testing and standard setting of CM drugs for raising the standard of testing of CM drugs products in Hong Kong. The GCMTI's research outcomes will directly benefit CM drugs traders by providing solutions to their technical difficulties (e.g. methodology examination and identification of CMM) and differentiation of genuine products from fake ones, thereby raising the quality of CM drugs products. As CM and CM drugs are closely related, CM drugs products of higher quality would be conducive to enhance the public's confidence in using CM services. The GCMTI's research projects will benefit the CM and CM drugs sectors as well as the general public. The GCMTI will continue to strengthen communication with academia and stakeholders (in particular the CM drugs trade) in identifying their practical difficulties and formulating appropriate research projects in search for feasible solutions;

(ii) The GCMTI aspires to assist the industry in enhancing CM drugs and testing capabilities of their staff. With the proposed international collaboration and training centre, the GCMTI will be able to organise meetings, seminars, training and educational activities for the CM drugs trade and CM testing industry, as well as to transfer the knowledge of reference standards of CM drugs, and technical know-how of CM drugs testing to the CM drugs and testing industries. The international collaboration and training centre will be used in future to host international conferences and meetings relating to CM drugs with a view to maintaining close liaison with related Mainland and international institutions. The GCMTI will cooperate with relevant overseas

institutions through various international traditional CM drugs platforms including International Regulatory Cooperation for Herbal Medicines of the World Health Organisation and Western Pacific Regional Forum for the Harmonization of Herbal Medicines. In future, CM practitioners and persons engaged in CM drugs trade can participate in training and exchanges through suitable venues and platforms provided by the international collaboration and training centre for enhancing their professional capabilities;

(iii) The Chinese Medicines Section of the Government Laboratory (GL), which is mainly responsible for providing analytical and advisory services to support the DH in its enforcement work, will be relocated to the GCMTI premises. It will also develop new chemical analysis methods to meet the service needs of the DH from time to time. Furthermore, the GL will also set up a new section to promote chemical metrology by organising proficiency testing programmes and developing reference materials on CM drugs to assist testing laboratories in respect of validating analytical methods, establishing traceability of measurement results, ensuring the reliability and accuracy of measurement data, and thereby improving the quality and safety of CM drugs. The new section is to be established in the GCMTI premises to facilitate centralised use of resources and testing technologies for jointly promoting the development of both the CM drugs industry and the testing and certification industry in Hong Kong; and

(iv) The GCMTI will continue to take forward the HKCMMS project. The HKCMMS project has been launched since 2002, with reference standards for 330 CMM developed. The IAB for the HKCMMS which consists of herbal research experts of herbal medicines from a number of countries, as well as representatives of different pharmacopoeial and regulatory authorities, including experts and institutional representatives from the Mainland, Europe, and the United States. They unanimously support the work of the HKCMMS. At present, the National Institutes for Food and Drug Control under the NMPA is taking part in the research work of HKCMMS. Other partners include the Chinese Pharmacopoeia Commission of the People's Republic of China, the National Administration of Traditional Chinese Medicine and the GL. With their support, the HKCMMS have become well-recognised reference standards in the field of CM drugs testing and certification. A number of Hong Kong GMP certified manufacturers of proprietary Chinese medicines and the HA have adopted reference standards of HKCMMS in the procurement of CM drugs and quality control. The

research work of HKCMMS is of great significance to the standardisation and internationalisation of CM drugs, and can help to promote Hong Kong as an international centre for testing and certification of CM drugs.

(e) Issues raised by the Subcommittee on Issues Relating to the Development of Chinese Medicine

16. As regards the issues relating to the GCMTI previously raised by the Subcommittee on Issues Relating to the Development of Chinese Medicine under the Panel on Health Services as set out in paragraphs 31-35 of the Legislative Council Paper No. CB(4)707/20-21(06), the DH attaches great importance to Members' views and submitted them to the AC in November 2020 for discussion. After thorough review and discussion, the AC unanimously expressed support the work and outputs of temporary testing institute over the past three years, and agreed that various sectors including the CM drugs industry, testing industry and the academia had been benefitted. Views of the AC have been incorporated into paragraphs 10 to 15 above.

17. In summary, the AC supports the establishment of the permanent GCMTI premises and related facilities, including the medicinal plant garden, CM drugs herbarium laboratory (and its digitalised CM drugs information platform), and the international collaboration and training centre. Formulation of research projects will be submitted to the AC and its task forces for deliberation and endorsement, with a view to ensuring that various stakeholders have expressed their views and the projects can meet practical needs of the trade.

18. The GCMTI has all along maintained close partnership with local universities in respect of scientific research work. The DH will continue to communicate with the academia and other stakeholders for strengthening cooperation. In taking forward the establishment of GCMTI, the DH will take into consideration views of the Members and stakeholders, and submit to the AC for deliberation in a timely manner.

(f) Other supplementary information

19. Furthermore, the GCMTI will strive to collaborate with the CMH and the Mainland counterparts with a view to providing further values –

(i) The GCMTI will collaborate with the CMH to provide integrated training and technology transfer events on CM drugs and CM for different stakeholders

(such as CM practitioners, representatives of trade of CM drug and testing industries, and undergraduates and post-graduates of related subjects). Subject to needs of the CMH, the GCMTI will tailor make training courses for the former's staff, students of related subject and members of public on CM drugs to strengthen quality control of CM drugs and promote safe use of drugs by the public.

The future CMH will engage in research of CM drugs including evaluation of CM in clinical setting, while the GCMTI specialises in testing and research of CM drugs, using advanced technology to develop reference standards. The GCMTI will actively collaborate with the CMH in research of CM drugs, with a view to capitalising their respective strengths of specialised fields to further develop CM;

(ii) With a view to facilitating the development of evidence-based Chinese medicine (EBCM), the GCMTI, adjoining the CMH, will provide help desk supporting services on clinical trial of proprietary Chinese medicines, to offer advice on clinical trial design, applications for related certificates and other regulatory issues (such as importing investigational proprietary Chinese medicines) to researchers or research institutes interested in clinical trials, with an aim to advance the standards of clinical trial, and work synergistically with the CMH, thereby further strengthening the important role of GCMTI in driving CM development; and

(iii) In addition, the GCMTI will pool together resources and further the collaborations in CM in Guangdong-Hong Kong-Macao Greater Bay Area by working with Mainland research institutes to formulate internationally recognised standards in CM products, fostering standardisation and internationalisation of CM. Leveraging on this platform, the GCMTI will facilitate the promotion of CM culture and trade to the world.

Yours sincerely,

(Dominic Ho)
for Secretary for Food and Health

c.c. Director of Health (Attn.: Dr Christine Wong)
Chief Executive, Hospital Authority (Attn.: Ms Dorothy Lam)