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

Development of the Government Chinese Medicines Testing Institute

Purpose

This paper aims to brief and invite members to provide views on the Government's work and progress in establishing the Government Chinese Medicines Testing Institute (GCMTI).

Background

2. Hong Kong has developed into a mature market for and a trading port of Chinese medicine (CM) drugs leveraging on her unique blend of eastern and western cultures as well as wide acceptance of the use of CM drugs by the public. Local scientific research and testing technologies also help promote the development of CM drug testing in Hong Kong. In 2013, the Government set up the CM Development Committee (CMDC) to provide advice to the Government on the directions and long-term strategies for promoting the development of CM in Hong Kong.

3. Having consulted the CMDC, the Government announced the establishment of a CM drug testing institute development of the GCMTI to be managed by the Department of Health (DH) under the 2015 Policy Address. The GCMTI will specialise in testing of and scientific research on CM drugs with a view to setting reference standards for their safety, quality and testing methods.

Mission of the GCMTI

4. The missions of the GCMTI are to develop internationally-recognised reference standards for CM drugs and related products by employing state-of-the-art technology and engaging in scientific research, to strengthen quality control of CM drugs and their products by the CM drug industry through transfer of testing technology to the industry, to establish the brand image of Hong Kong's CM drugs, as well as to develop Hong Kong into an international hub of testing and quality control of CM drugs. The functions of the GCMTI include:

(i) to embark on high-tech scientific research and develop testing methods which will be transferred to the CM drug industry and the testing industry for their reference and use, as well as to provide training to them with a view to strengthening their capability for CM drug quality control and identification;

(ii) to collect CM drug specimens and specimens of their originating plant/animal species, and establish a digitalised platform for sharing its integrated information with the public, the industry and research institutions;

(iii) to continue formulating reference standards for CM drugs under the Hong Kong Chinese Materia Medica Standards (HKCMMS) project; and

(iv) to promote reference standards and testing methods of CM drugs through organising international exchange events.

5. Through the works stated above, the GCMTI will assist the CM drug industry to strengthen the quality control of their products, and the testing industry to enhance their professional standards and recognition internationally which in turn will facilitate the local CM drug industry to further expand into international markets.

Advisory Body

6. DH set up the GCMTI Advisory Committee (AC) in 2017 with the aim of providing a platform for stakeholders to advise on long-term development strategies, measures and specific research proposals of the GCMTI. The AC is the advisory body to the GCMTI, with members from the CM drug trade, academia, the Government and the International Advisory Board of the HKCMMS project. The Chinese Herbal Medicines Task Force, the Proprietary Chinese Medicines Task Force as well as the Technical Support Group were set up under the AC to respectively undertake focused discussions on specific topics and to provide expert advice on technical aspects of research projects to the AC for consideration.

The temporary GCMTI

7. Prior to the establishment of the GCMTI building, DH has established a temporary testing institute at Hong Kong Science Park in March 2017 in order to embark on the research and promotion work as

soon as possible. The GCMTI at the temporary site has embarked on the following projects, with progress as follows:

(1) Identification of easily confused species of Chinese Materia Medica (CMM) in Hong Kong by macroscopic and microscopic characteristics

- The project aims to identify and differentiate 100 pairs of easily confused species of CMM in phases. By highlighting differences of macroscopic and microscopic features of CMM, and employing simple and practical methods, easily confused species CMM pairs can be compared and differentiated.
- As of March 2020, research results of 50 pairs of easily confused species of CMM have been published at the website of DH's Chinese Medicines Regulatory Office (CMRO).

(2) Collection of specimens for the GCMTI

- Specimens of CMM including those commonly used in Hong Kong, daodi (道地) CMM, CMM of Lingnan (嶺南) origin, etc. and their originating plant specimens will be collected in phases to build up the collection for the GCMTI.

(3) Building of a digitalised platform on CM

- The digitalised platform on CM specimens is preliminarily planned to be composed of 5 databases, respectively comprising information on herbarium specimens, CMM specimens, microscopic slides, chemical information and DNA information. The digitalised images and information of the platform will be made accessible by the public, the CM drug trade, the testing industry and research institutes.
- It will serve as an integrated database, key reference source and platform for relevant stakeholders on research and applications of CM drugs.

(4) Analysis of chemical markers of CMM in medicinal oil for external use

- This research project aims to develop and validate the quantitative and/or qualitative testing method(s) for the determination of chemical markers of CMM as well as chemical constituents commonly found in Chinese medicinal oil for external use so as to provide reference to CM drug traders in setting relevant quality standards.
- The relevant methods have been published at the website of DH's CMRO.

(5) Establishment of reference DNA sequence library of CMM and employment of DNA method for the analysis of Cervi Cornu Pantotrichum (deer antler velvet, 鹿茸) as a complementary approach

- The project aims to develop DNA barcoding method and establishing a reference DNA sequence library for identification of species origin of CMM.
- The reference DNA sequences for the first three CMM species would be published at the website of the CMRO for reference and use by the industry.
- In addition, another project aims to develop DNA-based identification methods for Cervi Cornu Pantotrichum as a complementary approach to existing methods, thus facilitating the CM trade to identify genuine products, avoid purchasing dubious products and resolve the difficulties the industry faces in identifying authentic products.
- The GCMTI has preliminarily developed a specific polymerase chain reaction (specific-PCR) method for the rapid identification of two genuine species of Cervi Cornu Pantotrichum, i.e. Cervus nippon and Cervus elaphus. Further assessment regarding the suitability of the method is being carried out.

Training

8. The GCMTI has provided training to stakeholders from the CM drug and testing industries based on the results from the aforementioned research projects. As of December 2019, the GCMTI has organised 18 briefing sessions, training workshops and other activities for over 600 participants, including representatives from CM practitioners, the CM drug industry, the testing sector and students from the relevant disciplines. The activities have been effective in promoting the use of macroscopic and microscopic features of CMM to differentiate easily confused species CMM pairs, and the use of validated multi-analytes testing methods for five chemical markers in Chinese medicinal oil for external use. The activities organised have also allowed meaningful exchanges amongst stakeholders on matters relating to CM drugs.

The Permanent GCMTI

9. In order to promote further development of CM drug industry and the testing sector, the Government announced in the 2019 Policy Address the establishment of the permanent GCMTI next to the CM Hospital (i.e. at Pak Shing Kok, Area 78, Tseung Kwan O).

10. The proposed scope of the project comprises various dedicated laboratories, a CM herbarium laboratory, an international collaboration and training centre, a medicinal plant garden, laboratories for the CM Section (CMS) of the Government Laboratory (GL), the macroscopic and microscopic identification laboratory of DH and a laboratory for conducting proficiency test schemes and producing reference materials, etc.

11. The GCMTI will provide facilities for conducting various CM drug and testing related work that would directly benefit the public and various stakeholders, as well as foster the development of CM drugs in the following aspects:

(i) dedicated laboratories would employ multiple techniques in the research work of testing and standard setting of CM drugs to improve the standard of testing and quality of CM drug products in Hong Kong;

(ii) the CM herbarium laboratory would collect and form a repository of a wide variety of CM drugs specimens including species of CM drugs commonly used in Hong Kong as well as herbal medicines that are indigenous to Hong Kong. The GCMTI would also establish a digitalised platform. Coupling of the CM herbarium laboratory and digitalised platform will form a comprehensive database on knowledge, research and application of CM drugs, furnish a wide range of stakeholders with reference materials and provide an exchange platform for the promotion of CM culture;

(iii) the international collaboration and training centre would host conferences, lectures and seminars to promote the transfer of technical know-how of CM drug testing to the CM drug sector, and to enhance the capability of the CM drug sector in respect of quality control of CM drug products;

(iv) the outdoor medicinal plant garden cultivated with various types of medicinal plants that are used in CM would allow visitors to gain knowledge and be inspired to develop interest in CM drugs, while appreciating various medicinal plants in a natural environment; and

(v) the laboratories for CMS of GL, and the macroscopic and microscopic identification laboratory of DH are both dedicated to testing services to support the regulatory work in

respect of CM drugs. Colocation of their offices would enhance synergy, and thus improve enforcement efficiency, thereby safeguarding the safety of CM drug products and public health. GL will also be tasked with providing proficiency test schemes and producing reference materials, and in turn enhance the standard of CM drugs testing laboratories in Hong Kong and promote the development of CM drug testing industry.

12. DH is working with the Architectural Services Department and other relevant departments on the necessary preparation work for the permanent GCMTI. The Government plans to submit the proposal to Sai Kung District Council and the Panel on Health Services of the Legislative Council in the second quarter and fourth quarter of 2020 respectively. Please refer to the **Annex** for the project schedule.

Advice Sought

13. Members are invited to note and provide views on the above.

Food and Health Bureau
Department of Health
June 2020

Annex

Project Schedule of the GCMTI

	Task	Tentative Timeline
(i)	Submit the proposal to Sai Kung District Council	2nd quarter of 2020
(ii)	Submit the proposal to Panel on Health Services of the Legislative Council	4th quarter of 2020
(iii)	Submit the proposal to Public Works Subcommittee of the Legislative Council	1st quarter of 2021
(iv)	Seek funding approval from Finance Committee of the Legislative Council	1st quarter of 2021
(v)	Commence construction works	3rd quarter of 2021
(vi)	Complete construction works	2nd quarter of 2024