For discussion on
21 June 2016

Legislative Council
Panel on Commerce and Industry

Research and Development of Chinese Medicines

PURPOSE

This paper updates Members on the progress of effort made in promoting research and development ("R&D") of Chinese medicines ("CM").

BACKGROUND

2. The Government is committed to promoting the development of CM in Hong Kong. R&D of CM is one of the key areas that the Government is keen to develop. The Committee on Research and Development of Chinese Medicines ("the Committee") was established in December 2011 to facilitate collection of views and better coordinate efforts in promoting R&D and testing of CM. The current membership and terms of reference of the Committee are at ***Annex***. The work done in respect of R&D and testing of CM in the past 24 months are reported below.

ITF SUPPORT OF R&D OF CM

3. The Innovation and Technology Fund ("ITF") administered by Innovation and Technology Commission ("ITC") supports CM applied research. From January 2014 to April 2016, a total of 24 CM-related projects were approved under the ITF with a total funding of about $47.8 million. The supported ITF projects cover a wide array of R&D disciplines, including research on CM-based drugs and formulations for the treatment of Alzheimer's disease, vascular dementia, stroke, depression, cancer and metabolic syndrome; developing herbal-based products for skin care and post-menopausal bone

protection; R&D on Chinese materia medica ("CMM") standards and standardisation of nomenclature; methodologies for processing, testing and quality control of CM; and developing new CM formulation methods, etc. About half of these projects involved collaboration between a university research team and a company, and require the industry partner to contribute matching fund of at least 50% of the total project cost. This is encouraging as it demonstrates that the local CM industry is increasingly committed to leverage the knowledge and resources of local universities to help develop new products or upgrade their technologies.

4. To encourage local researchers and the industry to utilise the ITF for R&D of CM, ITC has organised two workshops and sharing sessions to introduce the ITF and its assessment framework to CM researchers. About 100 representatives from local universities and CM companies attended. ITC will continue to organise similar activities to help stakeholders of the CM sector to better understand the ITF support programmes.

UNDERSTANDING AND SUPPORTING INDUSTRY NEEDS

Testing of CM

5. Testing is important to the successful development of CM products and is an essential measure for CM companies to fulfill the regulatory requirements for product registration, as well as safeguard the safety and quality of CM products. In support of the Government's effort to promote the Hong Kong CMM Standards, and also to enhance the technical capability of local testing laboratories, the Hong Kong Council for Testing and Certification ("HKCTC") organised the second inter-laboratory comparison exercise on chemical testing for 12 CM during 2014–15 to enable participating laboratories to assess their technical capability by comparing testing results with other participants. The third exercise covering five CM started in late April 2016 and will be completed around September/October 2016. The HKCTC also arranged a part-time training course from April to June 2016 on authentication of CM for practitioners.

6. With the endorsement of the HKCTC, the ITF provided funding support of about $2.16 million in 2015 to the Hong Kong Polytechnic University, in collaboration with five other local universities and three private testing laboratories, to develop a classification scheme for chemical testing of 19 CMMs.

7. Besides ITF support, the SME Development Fund ("SDF") administered by the Trade and Industry Department also provided funding of about $1.24 million in 2015 to support a CM trade association to conduct an 18-month project titled, "An awareness programme to strengthen the proprietary Chinese medicines industry on product quality and safety testing". The project included lectures and 30 training classes on testing technologies for proprietary Chinese medicines ("pCm") registration for the CM and testing industries.

Good Manufacturing Practice ("GMP") in respect of pCm

8. The Government has been promoting the implementation of GMP in respect of pCm as a means to ensure the quality and safety of pCm and to keep up with international trends of developing GMP for medicines.

CM GMP training

9. To help local pCm manufacturers to prepare for the future implementation of GMP, the ITF approved funding of about $2.1 million in June 2013 to support a project conducted by the Hong Kong Institute of Biotechnology ("HKIB") to provide basic GMP training, GMP facility visits, surveys and company interviews to local manufacturers free of charge. The project was completed in 2014. Representatives from about 90 local licensed pCm manufacturers participated in the training programme and most of the participants considered the programme very useful for helping them understand GMP requirements.

10. Separately, SDF approved about $2.6 million funding to support CM trade associations to conduct two projects titled, "To enable the local traditional Chinese medicine manufacturers in meeting GMP requirements with training and awareness programs and the support of electronic technology in production monitoring" and "To strengthen the local traditional Chinese medicine manufacturers in meeting the latest GMP requirements and application

with training and awareness program", respectively. These two projects included seminars and 70 training courses on various aspects of GMP.

CM GMP contract manufacturing and technical support

11. At the C&I Panel meeting on 17th June 2014, the Panel supported a three-year project proposal submitted by HKIB to seek joint funding support from the ITF and The Hong Kong Jockey Club Charities Trust to set up a GMP product development and technical support platform for traditional pCm products in oral solid dose forms. It is expected that upon completion of the project, HKIB's existing pCm GMP production area will be expanded from 2,880ft^2 to 8,500ft^2; and production lines for two new types of pCm solid formulations[1] will be established, enabling HKIB to provide GMP contract manufacturing services for the four most common types of pCm solid formulations for local CM companies, particularly the small and medium size enterprises that are not yet ready to implement pCm GMP in their own manufacturing facilities. Furthermore, HKIB's existing GMP consultancy services will be expanded through this project and internship opportunities for CM workers and students will also be provided to equip them with the necessary skills and practical experience to support the upgrading and development of the local CM industry.

12. This three-year project officially commenced in August 2015 and is currently making a smooth progress.

13. The Committee was aware of the industry's concern about the ownership of the product registration for those pCm products that were produced by contract manufacturing. According to the advice from the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong ("CMCHK"), for registered HKP[2] or HKC[3] products that are produced by contract manufacturing of a local GMP-compliant manufacturer, the registration holders can still keep the product's registration under their names provided that they have retained certain part of the manufacturing process, such as packaging, within their own facilities. For HKC products, if the registration holders opt to outsource the entire manufacturing process to a local GMP-compliant manufacturer, they can still keep the product's registration

[1] The new types of formulations are pills and granules, whereas the existing two are capsules and powder.
[2] HKP refers to pCm that has fulfilled the statutory requirements of transitional registration of pCm.
[3] HKC refers to pCm that has fulfilled the statutory registration requirements of pCm.

under their names provided that they are the wholesaler of the product. We believe that the above clarification can address the concerns of pCm manufacturers.

PLATFORM FOR EXCHANGING VIEWS AND FACILITATING COLLABORATION AMONG STAKEHOLDERS

Providing advice and supporting the development of a CM certification scheme

14. With the ITF funding, the Hong Kong Productivity Council ("HKPC") completed the development of a product certification scheme for CM. In October 2015, a CM company participated in this scheme was awarded the certificate by a certification body for two batches of CM. The HKCTC supports this project and is working with the HKPC and the trade in promoting and fine-tuning the scheme in order to enhance its adoption.

Discussion on clinical trials of CM

15. Clinical trials on CM are important for translating laboratory R&D outcomes into clinical applications and commercialisation of new CM products. In this connection, representatives from the Department of Health ("DH") have participated in Committee discussions on the current regulatory requirements for pCm clinical trials, particularly relating to the procedures and requirements for applying for Certificate for Clinical Trial and Medicinal Test from the CMB under the CMCHK. The Committee has also noted that the CMB adopts a risk-based approach, in which exemption of certain application documents can be considered based on the risk level of the investigational product.

Seminar on R&D of CM

16. To promote R&D of CM and facilitate collaboration among stakeholders, the Committee, in conjunction with the DH, Hospital Authority ("HA") and HKCTC, has been organising an annual seminar since 2012.

17. Apart from R&D of CM, other topics relevant to the development of CM and business interest of the local CM industry were also included in the

seminars, including technology trends in manufacturing; government policies, product registration and regulations; standardisation and modernisation of CM; testing and certification; drug-herb interaction; clinical trials; integrated Chinese-Western medicine; and clinical research and practices for the treatment of stroke, respiratory and gastrointestinal diseases from the Western and Chinese medicine perspectives.

18. The seminar has been well received by stakeholders in the Western and Chinese medicine sectors and attracted over 500 participants in the last three years. Building on the success, the Committee plans to organise the seminar again this September to make good use of this platform to promote collaboration and knowledge sharing among stakeholders.

PROMOTING THE WORK OF THE COMMITTEE TO THE INDUSTRY AND THE COMMUNITY

Publicity and promotional work

19. To further promote the capabilities and R&D achievements of local universities and R&D institutions, information on CM development is published in the print media from time to time. Topics included CM-related seminars; HA's work on measures to ensure safety and quality of CM; HKIB's technical support to industry on CM manufacturing; various universities' R&D on new CM formulations, CMM standardisation; support for clinical research of CM, as well as CM analysis and testing, etc.

The InnoCarnival

20. The InnoCarnival is an annual event organised by the ITC at the Hong Kong Science Park ("Science Park") with the objective of enhancing public awareness of the importance of innovation and technology to the future development of Hong Kong. At the InnoCarnival 2015, over 70 programme partners including universities, R&D centres, professional bodies, government departments, technology enterprises and youth organisations showcased their innovations and research achievements. With the ITF support, the School of Chinese Medicine of Hong Kong Baptist University also showcased the valuable knowledge and wisdom of traditional Chinese medicine through exhibitions and activities.

RELATED DEVELOPMENTS

21. DH is working on the expansion of the Hong Kong CMM Standards and the setting up of a Testing Centre for CM ("CMTC"). Both initiatives would help to promote the CMM Standards and set authoritative reference quality standards for CM, thereby facilitating the internationalisation of Hong Kong's CM industry and enhancing Hong Kong as an international hub for CM testing. Before the establishment of the CMTC at a permanent site, DH will be supported by the Hong Kong Science and Technology Parks Corporation to set up a temporary CMTC at the Science Park, which is scheduled to commence operation in phases from 2017 onwards.

22. Apart from the work on R&D and testing of CM, the Government also set up the Chinese Medicine Development Committee ("CMDC"), chaired by the Secretary for Food and Health, in February 2013 to advise on the direction and long-term strategy of the future development of Chinese medicine in Hong Kong. The Committee on Research and Development of Chinese Medicines has been providing full support to the CMDC since its establishment. Looking forward, we will continue to render assistance and collaborate with the CMDC and its Chinese Medicines Industry Subcommittee, as well as the Food and Health Bureau/DH in promoting the development of CM in Hong Kong.

ADVICE SOUGHT

23. Members are invited to note the content of the paper.

Innovation and Technology Bureau
Innovation and Technology Commission
June 2016

Annex

COMMITTEE ON RESEARCH AND DEVELOPMENT OF CHINESE MEDICINES

Membership List
(As at 13th June 2016)

Chairperson

Commissioner for Innovation and Technology

Members (in alphabetical order)

Ad personam

Mr. AU Wai-hung, Anthony, BBS
Prof. CHAN Sun-chi, Albert, JP
Mrs. CHENG CHO Chi-on, Mariana, BBS, JP
Dr. CHENG Heung-kwan, Celine
Prof. IP Yuk-yu, Nancy, MH, JP
Prof. LAO Li-xing
Prof. LEUNG Ping-chung, SBS, JP
Mr. LI Ying-sang, Tommy, BBS, MH, JP
Prof. LU Ai-ping
Dr. OR Ka-hang, Kevin
Ms. TANG Mui-fun, Karen
Mr. TSANG Chiu-hing
Mr. WONG Kong-hui, Kenlay, MH
Prof. WONG Ngar-kok, James, MH
Ms. WONG Suet-ying, Alice
Prof. ZUO Zhong, Joan

Ex-officio

Director of Health or representative
Representative of the Hospital Authority
Representative of the Hong Kong Council for Testing and Certification
Representative of the Hong Kong Science and Technology Parks Corporation
Representative of The Hong Kong Jockey Club

Terms of Reference

(a) To act as a platform to gauge views from various stakeholders, including Government, public bodies, industry and the academia on the research and development of Chinese medicines in Hong Kong;

(b) To formulate the broad direction in promoting research and development of Chinese medicines in Hong Kong, to identify key areas of work, monitor progress and recommend areas of improvement where necessary; and

(c) To facilitate sharing of research and development outcome and other collaboration among parties concerned to create synergy in research and development of Chinese medicines and to promote collaboration with organisations outside Hong Kong.