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Panel on Commerce and Industry

Meeting on 21 June 2016

Updated background brief on research and development of Chinese medicines

Purpose

This paper provides updated background information on the research and development ("R&D") of Chinese medicines ("CM"). It also provides a summary of views and concerns on the subject expressed by Members in previous discussions.

Background

2. In his 1998 Policy Address, the Chief Executive ("CE") first set forth his vision of promoting the development of CM in Hong Kong. A statutory body and framework have since been established to accord legal recognition of CM and to regulate the practice, use and trading of CM. With effect from 2004, Chinese medicaments made in Hong Kong enjoy tariff-free access to the Mainland under the Mainland and Hong Kong Closer Economic Partnership Arrangement. According to the Administration, the free trade pact has become a major catalyst in attracting trade and manufacturing investment in CM.

3. To more effectively orchestrate efforts of Government, industry, the academic and R&D sectors in promoting the development of R&D and testing of CM to meet future needs, the Government set up the Committee on Research and Development of Chinese Medicines ("CRDCM") in December 2011 to explore the strategies of promoting R&D and testing of CM in Hong Kong and to join hands with all sectors to promote work in these areas.

The Committee of Research and Development of Chinese Medicines

4. CRDCM is chaired by the Commissioner of Innovation and Technology and comprises representatives from the Government, industry, academic and research sectors. The terms of reference and current membership of CRDCM are in **Appendices I** and **II** respectively.

5. CRDCM has adopted the following board directions to promote the development of the CM sector in Hong Kong:

(a) strengthening the support of R&D of CM;
(b) promoting testing and certification of CM;
(c) facilitating collaboration among stakeholders;
(d) understanding and supporting industry needs; and
(e) promoting the work of CRDCM to the industry and the community.

The Chinese Medicine Development Committee

6. In February 2013, CE announced the setting up of the Chinese Medicine Development Committee ("CMDC") to focus on the study of four major areas of CM, namely personnel training and professional development, development of CM services, R&D, as well as development of the CM industry. CMDC is chaired by the Secretary for Food and Health and comprises representatives of various sectors such as Chinese medicine practice, academia, scientific research and healthcare services, and lay members. CRDCM has been rendering full support to CMDC in promoting overall development of CM in Hong Kong, especially in supporting R&D, testing and certification of CM and technology upgrading of the local CM industry. The terms of reference and current membership of CMDC are in **Appendices III** and **IV** respectively.

7. CE announced in his 2015 Policy Address that the Administration had accepted the recommendation of CMDC to set up a testing centre for CM to be managed by the Department of Health ("DH"). The testing centre will specialise in the scientific research on the testing of CM, with a view to setting reference standards for the safety, quality and testing methods of CM. Apart from continuing to study and formulate more Hong Kong Chinese Materia Medica Standards ("HKCMMS")[1], the testing centre will also embark on

[1] The Hong Kong Chinese Materia Medica Standards ("HKCMMS") project, launched by the Department of Health in 2001, aims to provide applicable and adoptable reference standards for the CM industry, with a view to ensuring the safety and quality of Chinese herbal medicines and public health. Up to June 2015, the research on 236 Chinese herbal medicines commonly used in Hong Kong had been completed, and 7 editions of HKCMMS have been published.

relevant hi-tech research to strengthen the capability for the quality control and identification of CM. A herbarium on CM for international standard will also be set up. Members were briefed by the Administration on the details at the meeting of the Panel on Health Services ("HS Panel") on 19 January 2015. In his 2016 Policy Address, CE announced that the preparatory work for setting up the testing centre had been undertaken and the Administration had reserved a site in Tseung Kwan O to develop a CM hospital.

8. Regarding the development of CM, the Administration also accepted the recommendations of CMDC:

(a) to support the continued implementation of the HKCMMS project to study and formulate standards for more Chinese herbal medicines; and

(b) to launch studies on the standard of CM decoction pieces under the HKCMMS project. During the course of the study, views of the CM industry should be sought.

Good Manufacturing Practice for proprietary Chinese medicines

9. To promote the standardization of the proprietary Chinese medicines ("pCm") manufacturing industry and enhance the standard of the CM trade in line with international trends and requirements for manufacturing of medicinal products to assure the quality and safety of pCm, the Chief Executive announced in the 2010-2011 Policy Address that a timetable for mandatory compliance with the Good Manufacturing Practice ("GMP") for manufacture of pCm would be worked out to safeguard public health and boost the public confidence in using pCm. The Administration undertook to actively engage the industry and conduct consultations to gather views from the CM industry on the timetable and detailed proposal for implementation of mandatory GMP. Up to present, the GMP requirement in respect of pCm in Hong Kong is not yet mandatory. The Administration is still in process of consulting various stakeholders of the pCm sector on the arrangements for the implementation of GMP.

10. According to the Chinese Medicine Ordinance (Cap. 549) ("CMO"), a licensed pCm manufacturer may apply to the Chinese Medicines Board ("CMB") for a Certificate for Manufacturer ("GMP Certificate"), which certifies the manufacturer's compliance with good practices in the manufacture and quality control of pCm. There are currently 278 licensed pCm manufacturers in Hong Kong. Most of them are small and medium enterprises ("SMEs") (i.e. with less than 100 employees). Up to May 2016, 14 local pCm manufacturers have been awarded the GMP Certificate.

Funding and training for technologies related to CM

11. Currently, the CM trade could apply for various funding programmes under the Innovation and Technology Fund ("ITF") as well as the SME Funding Scheme under the Trade and Industry Department to cater for the diversified business needs of enterprises. As of December 2015, ITF has supported over 80 CM-related projects with a total funding of about $200 million since its establishment in 1999. These projects involve R&D of new CM, technologies related to manufacturing, analysis, testing and quality control of CM, pre-clinical and clinical testing of CM, as well as research on integrative Chinese and Western medicines.

Previous Discussions

12. The development of CM in Hong Kong and related issues have been discussed at the meetings of the Panel on Commerce and Industry ("CI Panel") on 19 March 2013 and 17 June 2014, the meeting of the HS Panel on 19 January 2015, as well as the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine under the Panel on Health Services ("the Subcommittee") on 25 November 2014. Major views and concerns expressed by Members are summarized in the ensuing paragraphs.

Measures to support the CM industry for implementing GMP

13. The CI Panel met with the deputations of the pCm industry to receive their views on the difficulties encountered in becoming GMP-compliant at its meeting on 19 March 2013. Members were sympathetic towards pCm manufacturers who faced different challenges, such as financial constraints, lack of technical know-how and expertise, as well as shortage of suitable land space for establishing GMP facilities. At the meeting of the CI Panel on 17 June 2014, some members opined that the adoption of GMP standards should be voluntary rather than a mandatory requirement so as to allow room for the survival of SMEs whose valuable traditional prescriptions with proven efficacy could be preserved. They considered that the pCm manufacturing industry was yet to be GMP-ready and cautioned against a hasty introduction of mandatory compliance.

14. At the meeting of the HS Panel on 19 January 2015, some members expressed grave concern that the Administration would introduce mandatory GMP requirements to pCm after the setting up of the testing centre managed by DH.

15. The Administration responded that there was currently no specific implementation timetable for mandatory GMP requirements to pCm. The

Innovation and Technology Commission ("ITC") and CRDCM would play a supportive role in facilitating the industry to upgrade and meet the various challenges ahead. CMDC would also examine the problems encountered by the industry. The Administration would continue to listen to the views of the industry before deciding on the way forward while providing the necessary support and assistance to pCm manufacturers to move towards GMP-compliant. The Administration also clarified that it had no intention to link the introduction of mandatory GMP requirements to pCm to the setting up of the testing centre.

Promoting testing and certification of CM

16. At the meeting of the CI Panel on 17 June 2014, some members enquired about the Administration's efforts and achievements in promoting the development of testing and certification of CM, and whether the testing laboratories accredited by the Hong Kong Accreditation Service ("HKAS") would perform efficacy testing of CM to ascertain the efficacy of HKCMMS.

17. The Administration advised that the Hong Kong Council for Testing and Certification had been promoting the development of CM testing and certification. The major initiatives in this regard included the introduction of inter-laboratory comparison programmes and new accreditation services for CM testing laboratories based on HKCMMS. The Inter-laboratory comparison exercises had been conducted in 2012 and 2014, with participation of 12 and 15 local laboratories respectively. The participating laboratories could access their CM testing capability by comparing their testing results with other laboratories through the exercises. On accreditation of CM resting laboratories, HKAS under ITC had launched new accreditation services to cover authentication and testing of CM based on HKCMMS since March 2011. As of March 2014, 12 laboratories had been accredited for testing heavy metals, pesticide residues and microbial contents of CM.

Registration of pCm products under the Chinese Medicine Ordinance

18. At the meeting of the CI Panel on 17 June 2014, some members were concerned that, due to the stringent registration requirements of pCm in Hong Kong, as well as the substantial cost and the lengthy process involved in the registration of a new pCm product, pCm manufacturers were reluctant to proceed with the necessary registration prior to ascertaining the market receptiveness of their products. It had impeded the development of new pCm products by local manufacturers, and also frustrated the introduction of new products by overseas manufacturers into the local market, thereby undermining the development of the CM industry. They called upon the Administration to appropriately relax the registration requirements of pCm in Hong Kong and allow the sale of a small quantity of non-registered pCm as tester.

19. In response, the Administration advised that same as the practice adopted in other countries, a medicinal product must be registered locally prior to being sold in the market so as to safeguard public health and ensure safety in using the product. All kinds of pCm must be registered by CMB under CMO before they could be imported, possessed or sold in Hong Kong.

Difficulties encountered by the trade in the registration of pCm

20. At the Subcommittee meeting on 25 November 2014, some members were concerned about the difficulties encountered by the trade in the registration of pCm, such as the high testing costs and long processing time taken by CMB, and the difficulty in identifying laboratories which were accredited by CMB for the testing.

21. In response to the concern about the long processing time, the Administration explained that some applicants, during the application process, might 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. CMB might need to take some time for follow-up and require the applicants to submit the supplementary information for verification. As regards the support services for pCm registration and testing, the Administration advised that there were currently nine local laboratories, as well as 17 Mainland laboratories recognized by the China Food and Drug Administration and CMB, providing pCm testing services for the trade. The Administration added that where necessary, it might request the relevant Mainland regulatory authorities to extend the list of recommended laboratories to cover more laboratories qualified for conducting pCm testing.

Council meeting

22. At the Council meeting of 14 October 2015, Hon CHAN Han-pan asked a written question on whether any registration was in place to regulate the sale of health food products whose names and packaging were very similar to those of pCm, as well as whether the authorities would conduct studies and formulate specific legislation and framework to regulate health food products containing CM.

Latest development

23. The Administration will update the Panel on the progress of the R&D development of CM on 21 June 2016.

Relevant papers

24. A list of relevant papers is set out in **Appendix V**.

Council Business Division 1
Legislative Council Secretariat
17 June 2016

Appendix I

Committee of Research and Development of Chinese Medicines

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 organizations outside Hong Kong.

Appendix II

Membership of the Committee on Research and Development of Chinese Medicines

Chairman

Commissioner for Innovation and Technology

Members (in alphabetical order)

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
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

Appendix III

The Chinese Medicines Development Committee

Terms of reference

(a) To examine the current landscape and the needs of the Chinese medicine sector in the areas of personnel training and professional development, Chinese medical services, scientific research and development of the Chinese medicines industry, etc;

(b) To explore the future development directions and goals of the above areas;

(c) To set priorities for the development goals of the above areas;

(d) To recommend feasible strategies and measures for projects for priority development; and

(e) To monitor the implementation of relevant measures.

Appendix IV

Membership of the Chinese Medicines Development Committee

Chairman

Secretary for Food and Health

Members (in alphabetical order)

Prof CHAN Chi-fai, Andrew, SBS, JP
Mr CHAN Yu-ling, Abraham
Mr FAN Chor-ho, Paul, SBS, BBS, JP
Ms FENG Jiu
Mr HUI Sang
Prof KWAN Hoi-shan, BBS, JP
Prof LAO Li-xing
Prof LEUNG Wing-nang, Albert
Mr LI Ying-sang, Tommy, BBS, MH, JP
Prof LU Ai-ping
Mr LUK Shun-hoi
Ms NGAN Man-shan, Teresa
Dr TUNG Yuk, Stewart
Mr WONG Kit
Mr Wong Kong-hui, Kenlay, MH
Dr YIP Wai-chun, Andrew
Dr YU Chau-leung, Edwin
Ms Yu Wun-pan, Grace, MH
Prof Zhao Zhong-zhen, MH
Permanent Secretary for Food and Health (Health)
Commissioner for Innovation and Technology
Director of Health
Chief Executive of the Hospital Authority

Appendix V

Research and development of Chinese medicines
List of relevant papers

Council/ Committee	Date of meeting	Paper
Panel on Commerce and Industry	19 March 2013	Administration's paper on "Good Manufacturing Practice System for proprietary Chinese medicine in Hong Kong " provided by Food and Health Bureau (LC Paper No. CB(1)696/12-13(04)) Administration's paper on "Good Manufacturing Practice for the Chinese medicines sector - possible areas of support to the industry" provided by Innovation and Technology Commission (LC Paper No. CB(1)696/12-13(05)) Updated background brief on "Good Manufacturing Practice requirement in respect of proprietary Chinese medicine in Hong Kong" prepared by the Legislative Council Secretariat (LC Paper No. CB(1)696/12-13(06)) Minutes of meeting (LC Paper No. CB(1)1023/12-13)
Panel on Commerce and Industry	17 June 2014	Administration's paper on "Research and development of Chinese medicines" (LC Paper No. CB(1)1595/13-14(03)) Updated background brief on "Research and development of Chinese medicines" prepared by the Legislative Council Secretariat (LC Paper No. CB(1)1595/13-14(04)) Minutes of meeting (LC Paper No. CB(1)1976/13-14)

Council/ Committee	Date of meeting	Paper
Panel on Health Services	19 January 2015	Administration's paper on "Relevant policy initiatives featuring in the Chief Executive's 2015 Policy Address" (LC Paper No. CB(2)612/14-15(03)) Minutes of meeting (LC Paper No. CB(2)2033/14-15)
Council	14 October 2015	Written question asked by Hon CHAN Han-pan (http://www.info.gov.hk/gia/general/201510/14/P201510140741.htm)
Subcommittee on Issues Relating to the Development of Chinese Medicine	25 November 2014	Administration's paper on "Policy and direction of supporting development of pCms" (LC Paper No. CB(2)441/15-16(01)) Updated background brief on "Development of Chinese Medicine" prepared by the Legislative Council Secretariat (LC Paper No. CB(2)322/14-15(02)) Report of the Subcommittee (issued on 2 February 2016) (LC Paper No. CB(2)802/15-16) Minutes of meeting (LC Paper No. CB(2)646/14-15)