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Panel on Commerce and Industry

Meeting on 17 June 2014

Background brief on research and development of Chinese medicines

Purpose

This paper provides background information on the research and development (R&D) of Chinese medicines (CM), including the development of the proprietary Chinese medicine (pCm) manufacturing industry in Hong Kong. It also provides a summary of views and concerns expressed by Members in previous discussions.

Background

2. In view of its demonstrated efficacy, natural origin and fewer side effects, CM are increasingly accepted as a form of alternative medicine in the western world. With its state-of-the-art research infrastructures and prominence in biomedical research with international recognition, Hong Kong is well-positioned to capitalize on the strategic advantage of its proximity to the rich pool of CM resources in the Mainland,.

The Committee on Research and Development of Chinese Medicines (the Committee)

3. Following a comprehensive review in 2010-2011 on how best to support R&D and testing of CM, the Committee was established to facilitate collection of views from stakeholders and better coordinate the efforts in promoting R&D and testing of CM to meet the future needs of Hong Kong. The Committee, chaired by the Commissioner for Innovation and Technology,

comprises representatives from the Government, industry, academic and research sectors. The terms of reference and membership of the Committee are in Appendices I and II respectively.

4. The Committee has adopted the following broad directions to promote the development of the CM sector in Hong Kong:

- (a) strengthen support for R&D of CM;
- (b) promote testing and certification of CM;
- (c) facilitate collaboration among stakeholders;
- (d) understand and support industry needs; and
- (e) promote the work of the Committee to the industry and the community.

Good Manufacturing Practice (GMP) requirement for pCm manufacturing

5. To promote the standardization of the 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 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.

Previous discussions

6. The development of CM in Hong Kong and related issues have been discussed at various meetings of the Legislative Council and the Panel on Commerce and Industry (the Panel). Major views and concerns expressed by Members are summarized in the ensuing paragraphs.

Membership of the Committee

7. Some Panel members questioned whether the Committee chaired by the Commissioner for Innovation and Technology who might not have sufficient knowledge and experience in CM would contribute to the sustainable long-term development of R&D of CM. These members were of the view that the Committee should be chaired by a representative from the CM industry, and that

its membership should include representatives from the commerce and industry sectors who possessed relevant knowledge and experience to help promote the commercialization of R&D results and manufacturing of pCm.

Overall development of CM in Hong Kong

8. Members were generally dissatisfied with the slow progress in the promotion of CM-related R&D in Hong Kong. Some members were concerned whether Hong Kong's CM development had been hindered by professionals of Western medicine, and called on the Committee to look into ways and means to remove the barriers between Chinese and Western medicine and promote integrative health care. Concern was also raised that the Administration had not given equal treatment to CM and Western medicine despite its claim to promote CM development. These members called on the Administration to take the lead in recognizing the status of CM by including CM in the coverage of civil service medical benefits. On promoting R&D in CM, some members opined that a sound intellectual property protection system should be set up to encourage investment in R&D and in manufacturing pCm.

9. In view that the Mainland and Hong Kong applied different reference standards in respect of the testing of Chinese materia medica and registration of pCm, some members suggested the Administration to consider developing a common standard of CM testing in the two places so as to facilitate the access of Hong Kong-made pCm into the Mainland market.

10. Under the agenda item "Development of Chinese medicine hospital and integrated Chinese-Western medicine", the Panel on Health Services at its meeting on 19 May 2014 passed a motion urging the Administration to, among other things, set up a dedicated department to take forward the development of the CM industry and to assist the CM industry in the process of transformation and promotion.

<u>GMP requirement for pCm manufacturing</u>

11. The Panel met with deputations of the pCm industry to receive views on the difficulties encountered in becoming GMP-compliant at its meeting on 19 March 2013. Members were sympathetic towards pCm manufacturers who faced multiple challenges, such as financial constraints, lack of technical know-how, and shortage of suitable land for setting up GMP facilities. Members considered the CM trade not yet GMP-ready and cautioned against a hasty introduction of mandatory compliance. There were worries that most local pCm manufacturers, being small and medium enterprises (SMEs), would be squeezed out of business should mandatory GMP be implemented, resulting in market domination by large companies that were GMP-capable at the expense of SMEs.

12. The Panel was particularly concerned about the lack of government support to help the local pCm industry become GMP-ready, and called on the Administration to formulate comprehensive policies and workable guidelines in consultation with the industry stakeholders, and to provide the necessary hardware and software support, including direct financial support or tax incentives, support on manpower training and provision of facilities to help local pCm manufacturers overcome the GMP-compliance challenges. On hardware infrastructural support, members requested the Administration to take the lead in revitalizing vacant industrial buildings or consider setting up a CM science and technology park to provide GMP-standard factory premises. Some members expressed reservations about the Administration's proposal to expand the current GMP consultancy services and the contract manufacturing arrangements of GMP service providers, fearing that such a move might result in acquisition and merger of local pCm SMEs by pharmaceutical giants.

13. Some members also questioned whether the adoption of the Pharmaceutical Inspection Inspection Convention and Pharmaceutical Co-operation Scheme (PIC/S) GMP standard would suit Hong Kong as most pCm SMEs were only targeting the Greater China and Asian markets rather than the world market. These members considered that GMP requirements should not be made mandatory and different pCm manufacturers should be free to choose whether or not to apply for GMP certificates, depending on their financial capacity, business model, and target markets. Some members shared the view of some deputations that the Administration should facilitate the local pCm industry in developing Hong Kong's own production-management model with unique traditional Chinese characteristics, leveraging on the opportunities presented by the Greater China and Asian markets.

Council questions

14. At the Council meetings on 22 February, 13 June and 24 October 2012, Members raised questions, among other things, relating to the Administration's plan and overall strategy on development of the pCm manufacturing industry as well as assistance to SME pCm manufacturers in terms of manpower resources, research and technology, funding, land and infrastructural support. Question on whether the Administration would consider offering special tax concessions to SME pCm manufacturers to allay their financial burden in various aspects such as testing, R&D was also raised.

Latest position

15. The Administration will update the Panel on the progress of efforts in promoting R&D of CM on 17 June 2014.

Relevant papers

16. A list of relevant papers is in **Appendix III**.

Council Business Division 1 Legislative Council Secretariat 12 June 2014

Committee on 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 research and development (R&D) of Chinese medicines (CM) in Hong Kong;
- (b) To formulate the broad direction in promoting R&D of CM in Hong Kong, to identify key areas of work, monitor progress and recommend areas of improvement where necessary; and
- (c) To facilitate sharing of R&D outcome and other collaboration among parties concerned to create synergy in R&D of CM and to promote collaboration with organizations outside Hong Kong.

Appendix II

Membership of the Committee on Research and Development of Chinese Medicines

Chairperson

Commissioner for Innovation and Technology

Members (in alphabetical order)

Mr. AU Wai-hung, Anthony, BBS Dr. CHAN Leung-cho Mrs. CHENG CHO Chi-on, Mariana, BBS, JP Dr. CHENG Heung-kwan, Celine Mrs. CHIN Hang-yin, Alice Prof. IP Yuk-yu, Nancy, MH Prof. LAO Li-xing Prof. LEUNG Ping-chung, SBS, JP Mr. LI Ying-sang, Tommy, BBS, MH, JP Prof. LIU Liang Prof. LU Ai-ping 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 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

Research and development of Chinese medicines

List of relevant papers

Date of meeting	Meeting	Minutes/Paper	LC Paper No.
17/1/2012	Panel on Commerce and Industry	Administration's paper	CB(1)829/11-12(03) http://www.legco.gov.hk/yr11-12/engli sh/panels/ci/papers/ci0117cb1-829-3-e. pdf
		Background brief	CB(1)829/11-12(04) http://www.legco.gov.hk/yr11-12/engli sh/panels/ci/papers/ci0117cb1-829-4-e. pdf
		Minutes of meeting	CB(1)1296/11-12 http://www.legco.gov.hk/yr11-12/engli sh/panels/ci/minutes/ci20120117.pdf
22/2/2012	Council meeting	Question No. 14 raised by Dr Hon LAM Tai-fai	Hansard (Page 6083-6092) http://www.legco.gov.hk/yr11-12/engli sh/counmtg/hansard/cm0222-translate- e.pdf
13/6/2012	Council meeting	Question No. 7 raised by Hon Vincent FANG Kang	Hansard (Page 14958-14964) http://www.legco.gov.hk/yr11-12/engli sh/counmtg/hansard/cm0613-translate- e.pdf
24/10/2012	Council meeting	Question No. 6 raised by Dr Hon CHIANG Lai-wan	Hansard (Page 587-597) http://legco.gov.hk/yr12-13/english/cou nmtg/hansard/cm1024-translate-e.pdf

Date of meeting	Meeting	Minutes/Paper	LC Paper No.
18/12/2012	Panel on Commerce and Industry	Administration's paper	CB(1)299/12-13(03) http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/papers/ci1218cb1-299-3-e. pdf
		Background brief	CB(1)299/12-13(04)
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/papers/ci1218cb1-299-4-e. pdf
		Minutes of meeting	CB(1)532/12-13
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/minutes/ci20121218.pdf
19/3/2013	Panel on Commerce and Industry	Administration's papers	CB(1)696/12-13(04)
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/papers/ci0319cb1-696-4-e. pdf
			CB(1)696/12-13(05)
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/papers/ci0319cb1-696-5-e. pdf
		Background brief	CB(1)696/12-13(06)
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/papers/ci0319cb1-696-6-e. pdf
		Minutes of meeting	CB(1)1023/12-13
			http://www.legco.gov.hk/yr12-13/engli sh/panels/ci/minutes/ci20130319.pdf