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Legislative Council

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LC Paper No. CB(2)1345/15-16
(These minutes have been seen by the Administration)

Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Minutes of the meeting
held on Tuesday, 15 December 2015, at 5:00 pm
in Conference Room 3 of the Legislative Council Complex

Members present	:	Hon CHAN Han-pan, JP (Chairman) Hon Vincent FANG Kang, SBS, JP Hon YIU Si-wing, BBS Hon Alice MAK Mei-kuen, BBS, JP Dr Hon Elizabeth QUAT, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP
Members absent	:	Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN Hon WONG Ting-kwong, SBS, JP
Public Officers attending	:	Items II and III Professor Sophia CHAN Siu-chee, JP Acting Secretary for Food and Health Miss Janice TSE Siu-wa, JP Deputy Secretary for Food and Health (Health) 1 Dr Ronald LAM Man-kin Assistant Director (Traditional Chinese Medicine) Department of Health Dr Edwin TSUI Lok-kin Principal Medical and Health Officer (Traditional Chinese Medicine) Department of Health

Clerk in attendance	:	Ms Joanne MAK Chief Council Secretary (2) 3
Staff in attendance	:	Ms Priscilla LAU Council Secretary (2) 5 Mrs Fonny TSANG Legislative Assistant (2) 3

Action

I. Election of Chairman (if required)

1. Members agreed that election of Chairman for the Subcommittee in the 2015-2016 session was not necessary.

II. Policy and direction of supporting development of proprietary Chinese medicines ("pCms")

[LC Paper Nos. CB(2)441/15-16(01) and CB(2)322/14-15(02)]

2. The Subcommittee deliberated (index of proceedings attached at **Annex**).

Follow-up actions required of the Administration

Admin 3. The Subcommittee requested the Administration to:

(a) enhance communication with the pCm industry and introduce concrete measures for pCm manufacturers to support their compliance with the Good Manufacturing Practice ("GMP") requirements. Reference should be made to the experience of the Mainland China, Taiwan and Singapore in their GMP implementation;

(b) set up an independent body with dedicated funding and manpower to provide technical support and consultation service to pCm manufacturers and traders in respect of pCm registration and GMP implementation;

(c) set up and provide GMP factory premises for use by pCm manufacturers under leasing arrangement; and

(d) set up a one-billion-dollar dedicated fund to support the pCm industry and promote the development of Chinese medicine.

Action

III. Further discussion on the arrangements for the formal registration of pCms

[LC Paper Nos. CB(2)441/15-16(02) and (03)]

4. The Subcommittee deliberated (index of proceedings attached at **Annex**).

Follow-up actions required of the Administration

Admin 5. The Subcommittee requested the Administration to review the existing registration framework for pCms and explore introducing more classification categories to accommodate pCms which might not fulfill the standards of "Established Medicines" but had been sold in Hong Kong for years and proven to be safe or harmless for use.

IV. Any other business

6. There being no other business, the meeting ended at 6:24 pm.

Council Business Division 2
Legislative Council Secretariat
20 April 2016

Annex

Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Tuesday, 15 December 2015, at 5:00 pm in Conference Room 3 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
Agenda item I - Election of Chairman (if required)			
000030 - 000104	Chairman Mr YIU Si-wing Miss Alice MAK	Election of Chairman (if necessary)	
000105 - 000134	Chairman	Subcommittee's extension of work period	
Agenda item II - Policy and direction of supporting development of proprietary Chinese medicines ("pCms")			
000135 - 001040	Chairman Administration	Opening remarks Briefing by the Administration	
001041 - 002745	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing relayed the pCm industry's strong reservations about the introduction of the Good Manufacturing Practice ("GMP") requirements. He considered that as many pCm manufacturers, especially those small and medium enterprises ("SMEs"), lacked the financial strength and expertise to become GMP-ready, the Administration should further discuss with the industry, so as to reach a consensus on how to implement GMP in pCm manufacture. Mr YIU also called on the Administration to introduce feasible and concrete support measures for pCm manufacturers and make reference to the experience of the Mainland China, Taiwan and Singapore in the adoption of GMP requirements. The Administration advised that: (a) the Government was still in the process of consulting various stakeholders of the pCm sector on how to implement GMP. The Administration reiterated that there was no timetable for implementing GMP, and the Administration would take into account the views of the industry and their actual circumstances in drawing up a timetable to progressively implement GMP requirements; (b) the Department of Health ("DH") had organized regular briefings and consultation sessions on GMP	**Admin** (para. 3(a) of the minutes)

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		requirements for pCm manufacturers. The Chinese Medicine Development Committee and the Committee on Research and Development of Chinese Medicines would continue to listen to the views of the pCm sector on the development of the pCm industry; and (c) to support the trade in implementing GMP, the Innovation and Technology Fund ("ITF") under the Innovation and Technology Commission and the Hong Kong Jockey Club Charities Trust had jointly supported the Hong Kong Institute of Biotechnology ("HKIB") to conduct a three-year project to set up a GMP product development and technical support platform for certain forms of pCm. The Chairman said that the pCm sector was concerned about the scope of services which was limited to four common types of pCm solid formulations and the disclosure of master formula under the GMP contract manufacturing.	
002746 - 004424	Chairman Dr Elizabeth QUAT Administration	Dr Elizabeth QUAT expressed concern that the local pCm manufacturers, especially those SMEs, had met great difficulties in complying with the registration and GMP implementation. She urged the Administration to set up an independent body with dedicated funding and manpower to provide technical support as well as consultation service to pCm manufacturers and traders. The Administration responded that the GMP product development and technical support platform set up by HKIB provided support to the local Chinese medicines industry to comply with GMP requirements. In addition, several funding schemes, such as ITF, were available for application by Chinese medicines manufacturers, related research and development companies, universities and other institutions. The Chairman was of the view that the Government should set up a one-billion-dollar dedicated fund to support the pCm industry and promote the development of Chinese medicine. The Administration undertook to relay members' suggestion to the Chinese Medicine Development Committee for consideration.	**Admin** (para. 3(b) of the minutes) **Admin** (para. 3(d) of the minutes)
004425- 005517	Chairman Mr Vincent FANG Administration	Mr Vincent FANG held a strong view that the implementation of GMP in pCm manufacture would threaten the survival of SME pCm manufacturers. To enhance their capability to meet the mandatory GMP requirements, he urged the Government to provide GMP factory premises for use by pCm manufacturers under leasing arrangement.	**Admin** (para. 3(c) of the minutes)

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		As regards the GMP contract manufacturing arrangements, Mr Vincent FANG cast doubt on its effectiveness as pCm manufacturers were unwilling to provide their pCm master formula to HKIB. Besides, participating pCm manufacturers might have to dismiss their workers after contracting out their pCm manufacturing to HKIB. The Administration stressed that there was no timetable for mandatory compliance with GMP for the manufacture of pCms. The GMP contract manufacturing arrangements provided by HKIB was introduced on a pilot basis to test the acceptance of the pCm industry and gather experience on how to take forward GMP implementation. Other support measures for the industry included conducting GMP briefings and meeting with pCm manufacturers by DH, and the Government had put in place several funding schemes for application by Chinese medicine manufacturers, related research and development companies, universities and other institutions.	
005518 - 010316	Chairman Administration	The Chairman considered that the pCm industry was in need of the Government's technical and training support in moving towards GMP. He reiterated the need for setting up a $1 billion fund to support the pCm industry and promote the development of Chinese medicine. The Administration responded that it would continue to gauge the views of the pCm sector, and explore other initiatives which could facilitate further development of the local Chinese medicines industry.	**Admin** (para. 3(d) of the minutes)
010317 - 010741	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing reiterated that the Administration should maintain a close communication with the pCm sector to work out a timetable for the implementation of GMP in pCm manufacture, and introduce measures to meet the needs of the industry.	
Agenda item III - Further discussion on the arrangements for the formal registration of pCms			
010742 - 012207	Chairman Administration	The Chairman considered that the registration requirements, especially those in respect of efficacy, were too stringent. In his view, the Administration should review the existing pCm registration framework. The Chairman expressed concern that those pCms which failed to meet the registration requirements might be made available for sale in the market as health food products. The Administration briefed members on the progress in pCm registration as detailed in paragraph 5 of the Administration's	**Admin** (para. 5 of the minutes)

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		paper. For those pCms rejected for registration, DH had already put in place market surveillance to ensure that such pCms would no longer be available in the market. As regards pCm registration, the Administration explained that to ensure the safe use of medicines by the public, all pCms should meet the requirements regarding safety, quality and efficacy prescribed in the Chinese Medicine Ordinance (Cap. 549).	

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