# 立法會 Legislative Council

Ref: CB2/PS/1/13 <u>LC Paper No. CB(2)2013/14-15</u>

(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, 14 April 2015, at 4:45 pm in Conference Room 2B of the Legislative Council Complex

Members : Hon CHAN Han-pan, JP (Chairman)
present Hon Vincent FANG Kang, SBS, JP

Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN

Hon YIU Si-wing Dr Hon KWOK Ka-ki

**Members**: Hon WONG Ting-kwong, SBS, JP

**absent** Hon CHEUNG Kwok-che

Hon Alice MAK Mei-kuen, JP Dr Hon Elizabeth QUAT, JP

Hon Christopher CHUNG Shu-kun, BBS, MH, JP

**Public Officers:** <u>Items I and II</u>

attending

Professor Sophia CHAN Siu-chee, JP Under Secretary for Food and Health

Miss Janice TSE Siu-wa, JP

Deputy Secretary for Food and Health (Health) 1

Food and Health Bureau

Dr Ronald LAM Man-kin

Assistant Director (Traditional Chinese Medicine)

Department of Health

Ms Polly CHAN Bo-fong

Senior Pharmacist (Traditional Chinese Medicine) 3

Department of Health

Chinese Medicine Development Committee Non-official Members

Mr Tommy LI Ying-sang, BBS, MH, JP

Professor Zhao Zhong-zhen, MH

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. Development of proprietary Chinese medicines ("pCms")

[LC Paper Nos. CB(2)1221/14-15(01) and (02)]

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

Follow-up actions required of the Administration

Admin

- 2. The Chairman requested the Administration to consider -
  - (a) setting up a dedicated fund to support the pCm industry and promote the development of Chinese medicine;
  - (b) reviewing the Chinese Medicine Ordinance (Cap. 549) so as to facilitate the development of Chinese medicine in Hong Kong;
  - (c) enhancing support for the Chinese medicine industry to enable the industry to expand to the Mainland market; and
  - (d) how to cope with the trade's need in developing the Hong Kong Chinese Materia Medica Standards ("HKCMMS").

Admin

3. In response, <u>the Administration</u> said that it would relay to the Chinese Medicine Development Committee the Chairman's concerns and suggestions.

Admin

- 4. <u>The Subcommittee</u> requested the Administration to provide the following supplementary information -
  - (a) amount of funding provided by the Innovation and Technology Commission on the research and development of Chinese medicines since 1999;
  - (b) a brief account of how HKCMMS were applied in the use of Chinese medicine and pCm production;
  - (c) a list of Chinese medicines for which HKCMMS would be checked against by the Hospital Authority;
  - (d) the expenditure involved for developing HKCMMS; and
  - (e) the timetable, budget as well as the participating government departments and institutions for developing the testing centre for Chinese medicines and the herbarium of Chinese medicines as announced in the 2015 Policy Address.
- II. Further discussion on the registration of pCms and the arrangements for migration of pCms from transitional registration to formal registration

[LC Paper Nos. CB(2)983/14-15(01) and (03)]

5. <u>The Subcommittee</u> deliberated (index of proceedings attached at **Annex**).

## Follow-up actions required of the Administration

6. The Subcommittee was concerned about the extension of deadline for submitting the product specification and general stability test reports by holders of Notice of confirmation of transitional registration of pCm (i.e. "HKP"). While members stressed the need for the Administration to provide support to the pCm industry in meeting the registration requirements, some members considered that the Administration should not defer again the deadline for submission of test reports (i.e. 30 June 2015) for the formal registration of their pCm products. The Administration undertook to relay members' views and concerns to the Chinese Medicines Board.

Admin

Admin

7. <u>The Chairman</u> was concerned about the transitional arrangements for conversion from HKP to the "Certificate of registration of pCm" (i.e. "HKC"). To avoid product recall and market chaos, the Chairman suggested that the Chinese Medicine Ordinance should be reviewed to allow the co-existence of HKP and HKC of the same pCm in the market.

Admin

8. At the request of the Subcommittee, <u>the Administration</u> would provide an updated figure of pCm products which had been issued with HKP but their quality specification and stability test reports were still pending.

### III. Any other business

- 9. Members noted that the next meeting would be held on 4 May 2015 at 10:45 am. The Chairman would further discuss with the Administration on the agenda items for the next meeting.
- 10. There being no other business, the meeting ended at 7:10 pm.

Council Business Division 2
<u>Legislative Council Secretariat</u>
13 August 2015

# Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Tuesday, 14 April 2015, at 4:45 pm in Conference Room 2B of the Legislative Council Complex

Time	Speaker(s)	Subject(s) / Discussion	Action	
marker	 	iotary Chinoso modicinos ("nCms")	required	
Agenuu ne	Agenda item I - Development of proprietary Chinese medicines ("pCms")			
001437 -	Chairman	Opening remarks		
002333	Administration			
		Briefing by the Administration		
002334 - 004020	Chairman Prof ZHAO Zhong-zhen	Considering that the Pharmacopoeia of the People's Republic of China ("the Chinese Pharmacopoeia") had already provided		
		authoritative and comprehensive standards for Chinese medicines, the Chairman sought Prof ZHAO Zhong-zhen's view on the need to develop the Hong Kong Chinese Materia		
		Medica Standards ("HKCMMS").		
		Prof ZHAO Zhong-zhen advised that -		
		(a) the Chinese Pharmacopoeia was a regulatory standard mandatory for Chinese Materia Medica ("CMM"), Chinese medicines decoction pieces and pCms. HKCMMS covered reference standards for 200 CMM which were commonly used, of international importance and with good economic values. As opposed to the Chinese Pharmacopoeia, HKCMMS provided more detailed reference standards of safety and quality of CMM peculiar to the practical circumstances in Hong Kong, such as contents of heavy metals, pesticide residues and aflatoxin;		
		(b) the principle, methodologies, parameters and analytical methods of HKCMMS were developed under the guidance of the International Advisory Board consisting of local, Mainland and overseas renowned experts. HKCMMS, which were bilingual, had gained international recognition as a reputable reference; and		
		(c) HKCMMS would include, on the recommendation of the Chinese Medicine Development Committee, Chinese medicines decoction pieces in the scope of research.		
004021 -	Chairman	The Administration briefed members on the application of	_	
005021	Administration	HKCMMS as detailed in paragraphs 14 and 15 of the		

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		Administration's paper (LC Paper No. CB(2)1221/14-15(01)). The Chairman was of the view that HKCMMS had not been widely applied and the Chinese medicine industry had not benefited much from the development of HKCMMS.	•
005022 - 011349	Chairman Prof Joseph LEE Administration Mr Tommy LI	Noting that HKCMMS provided comprehensive reference standards for 200 commonly used CMM, Prof Joseph LEE asked whether HKCMMS would be adopted as a local regulatory standard for CMM. The Administration advised that HKCMMS provided reference standards for the Chinese medicine industry with a view to ensuring the safety and quality of CMM. The formulation of HKCMMS aimed at, among others, serving as an international standard in the control and management of Chinese herbal medicines. Currently, the application of HKCMMS by the industry was only voluntary. In the long term, the Administration would make use of HKCMMS to exercise more effective control on Chinese herbal medicines.	
		Mr Tommy LI held the view that the formulation of HKCMMS was conducive to promoting the development of Chinese medicine as well as the testing and certification of Chinese medicines in Hong Kong. On the other hand, HKCMMS could also facilitate the pCm manufacturers or traders to set up product specification for their pCm products.  The Administration would provide information on the	Admin (paragraph 4(b) of the
011350 - 012439	Chairman Mr YIU Si-wing Administration	application of HKCMMS.  On Mr YIU Si-wing's concern about the total allocation to support the research and development of Chinese medicines and develop the testing centre for Chinese medicines and a herbarium of Chinese medicines, the Administration undertook to provide relevant information.	minutes)  Admin (paragraph 4(a), (d) and (e) of the minutes)
012440 - 013849	Chairman Prof ZHAO Zhong-zhen Mr YIU Si-wing Mr Tommy LI Administration	Mr Tommy LI pointed out that the herbarium was part of the testing centre for Chinese medicines. In his view, the establishment of the testing centre would provide support to the Chinese medicine industry in respect of training, technical support as well as testing and certification of Chinese medicines.	
		The Administration advised on how the setting up of the testing centre would help promote the development of Chinese medicine as detailed in the paragraph 24 and 25 of the Administration's paper (LC Paper No. CB(2)1221/14-15(01)).	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
013850 - 015121	Chairman Administration Mr Tommy LI	Summing up, the Chairman raised various issues for the Administration's consideration. The Administration undertook to relay members' views and concerns to the Chinese Medicine Development Committee.	Admin (paragraph 2 of the minutes)
		Mr Tommy LI welcomed the Chairman's notion of promoting the development of Chinese medicine industry. He further advised that a survey would be conducted to gauge the trade's views on the support they needed.	
_	em II - Further discussion on the contraction of the contraction to formal regions.	on the registration of pCms and the arrangements for migration stration	of pCms from
015122 - 015801	Chairman Administration	The Chairman expressed concern about the deadline of 30 June 2015 for submitting the product specification and general stability test reports by holders of Notice of confirmation of transitional registration of pCm (i.e. "HKP").	
		The Administration advised that -	
		(a) taking into account the practical circumstances of the trade, the Chinese Medicines Board ("CMB") had made the decision to extend the deadline for submitting the test reports which was originally set on 30 June 2009 to 30 June 2013, and further extend it to 30 June 2015. CMB had also adjusted the processing arrangements in May 2014 in order to expedite the processing of transitional registration of pCm to formal registration;	
		(b) individual HKP holders who had difficulties in submitting the test reports could apply for extending the deadline with CMB if they could provide reasonable justifications; and	
		(c) CMB would discuss issues relating to the registration of pCm issued with HKP at its meeting in May 2015.	
015802 - 020431	Chairman Dr KWOK Ka-ki Administration	Dr KWOK Ka-ki noted with concern about difficulties encountered by the trade in registration of pCm. He also stressed the need to ensure the safety of pCm products.	
		The Administration advised that -	
		(a) pCm products issued with HKP had fulfilled the transitional registration requirements prescribed by CMB. The Department of Health also conducted market surveillance to ensure the safety of pCm products; and	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		(b) 30 June 2015 was the deadline for pCm manufacturers and traders to submit the necessary test reports on pCm stability and quality specifications. The transitional registration of pCm would remain valid until the pCm concerned was formally registered, or until the application for its registration was refused, or until such date to be promulgated by the Secretary for Food and Health in the Gazette, whichever date was the earliest.	
020432 - 021309	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing considered that as the deadline had been extended twice, a final deadline should be set for the submission of test reports. He also expressed concern about the difficulties faced by HKP holders in meeting the formal registration requirements.	
		The Chairman remarked that some pCm manufacturers and traders had difficulties in submitting test reports due to inadequate laboratory support and the introduction of additional registration requirements.	
		The Administration advised that CMB would take into account the practical circumstances of the trade and the number of applications carrying HKP status with outstanding test reports in deciding whether further extension of the deadline would be required. The expiry date of transitional registration was to be proposed by CMB.	
		The Administration agreed to provide information in relation to pCm registration.	Admin (para. 8 of the minutes)
021310 - 022539	Chairman Administration Mr Tommy LI	Pointing out that there were over 8 000 pCm products issued with HKP, the Chairman considered that pCm manufacturers and traders should be given more time to sell out their pCms in migrating to "Certificates of registration of a pCm" (i.e. "HKC"). He further requested the Administration to consider reviewing the Ordinance to allow the co-existence of HKP and HKC of the same pCm in the market.	Admin (para. 7 of the minutes)
		The Chairman sought Mr Tommy LI's view on the migration arrangement. Mr LI said that as the trade's representative, he welcomed any measures to allow more flexibility for manufacturers and traders in the migration of their pCm products from HKP to HKC.	
		The Administration briefed members on the transitional arrangements for holders of HKP issued with HKC and advised that these holders should have sufficient time to sell out their pCms issued with HKP. The transitional arrangements were in fact generally accepted by the trade.	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required	
		As stipulated by the Ordinance and to avoid causing confusion to customers, HKP and HKC could not co-exist for the same pCm.		
Agenda ite	Agenda item III – Any other business			
022540 - 022614	Chairman	Items for discussion at the next meeting		

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13 August 2015