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Legislative Council

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LC Paper No. CB(2)1290/14-15
(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 Friday, 13 March 2015, at 10:45 am
in Conference Room 2B of the Legislative Council Complex

Members present	:	Hon CHAN Han-pan, JP (Chairman) Hon Vincent FANG Kang, SBS, JP Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN Hon WONG Ting-kwong, SBS, JP Hon CHEUNG Kwok-che Hon YIU Si-wing Hon Alice MAK Mei-kuen, JP Dr Hon KWOK Ka-ki Dr Hon Elizabeth QUAT, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP
Public Officers attending	:	Items II and III 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 Mr Robert LAW Kwok-wai Senior Pharmacist (Traditional Chinese Medicine) 2 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. Confirmation of minutes of meeting
[LC Paper No. CB(2)1008/14-15]

The minutes of the meeting held on 26 January 2015 were confirmed.

II. Further discussion on the registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice requirements to pCms
[LC Paper Nos. CB(2)983/14-15(01) to (02) 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 Chairman requested the Administration to -

(a) review the adequacy of the existing measures to further support the trade in implementing Good Manufacturing Practice ("GMP"), taking into account the financial strength and expertise of local pCm manufacturers who were mostly small and medium enterprises;

(b) consider setting up an independent non-governmental organization to provide technical support and assistance to pCm manufacturers and traders in fulfilling the GMP requirements for pCm production;

(c) consider setting up a dedicated fund to support the pCm industry and promote the development of Chinese medicine;

(d) relay to the Chinese Medicines Board ("CMB") the suggestion of further extending the deadline (i.e. 30 June 2015) for the

submission of quality specification and stability test reports to CMB by holders of "Notice of confirmation of transitional registration of pCm" (i.e. "HKP");

(e) address the concern expressed by the trade regarding the inadequate number of accredited local and Mainland laboratories for conducting pCm testing; and

(f) promote the mutual recognition of pCm registration and GMP standards between the Mainland and Hong Kong so as to save manufacturers and traders' efforts in meeting different requirements.

Admin Clerk

4. The Subcommittee agreed to conduct a site visit to a local laboratory which provided pCm testing services for the trade in April 2015. The Administration was requested to provide necessary assistance.

(*Post-meeting note*: A visit to Hong Kong Standards and Testing Centre was arranged on 27 April 2015.)

III. Arrangements for migration of pCms from transitional registration to formal registration

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

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

6. Members in general were concerned about the transitional arrangements for pCms for cases of conversion from HKP to the "Certificate of registration of pCm" (i.e. "HKC"). They considered that the Administration should allow manufacturers and traders to sell out their pCms issued with HKP, instead of product recall, when migrating to HKC in order to avoid unnecessary wastage arising from product recall. The Administration undertook to further discuss with the trade to address their concerns regarding the transitional/interfacing matters.

Admin

IV. Any other business

7. There being no other business, the meeting ended at 1:00 pm.

Council Business Division 2
Legislative Council Secretariat
20 April 2015

Annex

Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Friday, 13 March 2015, at 10:45 am in Conference Room 2B of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
Agenda item I - Confirmation of minutes of meeting			
000130 - 000207	Chairman	Confirmation of minutes of Subcommittee meeting held on 26 January 2015	
Agenda item II - Further discussion on the registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice requirements to pCms			
000208 - 000357	Chairman	The Chairman decided that the issue concerning the sale of unregistered pCms as food products raised by Dr KWOK Ka-ki in his letter dated 6 March 2015 would be discussed under agenda item III.	
000358 - 000839	Administration	Briefing by the Administration on its responses to issues raised at the meetings held on 16 December 2014 and 26 January 2015 [LC Paper No. CB(2)983/14-15(01)].	
000840 - 002948	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing pointed out that most local pCm manufacturers faced great difficulties in becoming GMP compliant, and urged the Administration to provide adequate technical and financial support to meet the needs of the industry. He suggested that the Administration might consider introducing less stringent requirements for pCm production instead of adopting the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") GMP standard as a licensing requirement for local pCm manufacturers. The Administration advised that - (a) in the interest of public safety, production of pCms should be enhanced in terms of both manufacturing technology and management to meet the latest pharmaceutical requirements stipulated in GMP; (b) the policy to implement GMP requirements was still at consultation stage and the Administration had yet to fix an implementation schedule; and (c) the Administration supported the trade in implementing GMP through various channels, such as (i) conducting	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		GMP briefings and meeting with manufacturers who were interested in the implementation of GMP by the Department of Health ("DH"); (ii) launching different funding programmes by the Innovation and Technology Fund to support universities, research institutions and companies to conduct applied research projects relating to research and development and testing of Chinese medicines; and (iii) setting up GMP product development and technical support platform for local pCm manufacturers through the GMP contract manufacturing arrangements under the three-year project carried out by the Hong Kong Institute of Biotechnology ("HKIB").	
002949 - 004059	Chairman Mr WONG Ting-kwong Administration	Given that many local pCm manufacturers expressed strong reservations about the implementation of GMP requirements, Mr WONG Ting-kwong considered that the Administration should review the adequacy and effectiveness of its measures to support the industry in moving towards GMP. Consideration should be given to providing tailor-made assistance, such as advice on financing arrangements, for individual pCm manufacturers. Mr WONG believed that once there were cases of relatively small-scale local pCm manufactures succeeding in becoming GMP-compliant, the trade would have greater confidence in the implementation of GMP requirements for pCm production. To ease the concern over the intellectual property problem arising from the GMP contract manufacturing arrangements, Mr WONG suggested that the Administration should demonstrate successful examples by inviting interested pCm manufacturers to participate in the three-year project carried out by HKIB.	
004100 - 005330	Chairman Dr Elizabeth QUAT Administration	Dr Elizabeth QUAT echoed Mr WONG Ting-kwong's views and expressed concern that the prescribed registration requirements for pCm and the GMP requirements recommended for adoption by Hong Kong were different from those of the Mainland and other Asian places. In response, the Administration explained for the recommendation to implement GMP requirements, including the GMP standard of PIC/S. However, it should be noted that the Government had yet to fix an implementation schedule. The Administration advised that there were successful cases of pCm products imported from the Mainland in meeting the prescribed registration requirements and getting registered in Hong Kong.	

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005331 - 010345	Chairman Mr Christopher CHUNG Administration	Considering that the Chinese Pharmacopoeia had already provided national authoritative standards for pCms, Mr Christopher CHUNG questioned the need to develop the Hong Kong Chinese Materia Medica Standards ("HKCMMS"). The Administration advised that - (a) to enhance public health and to facilitate research and trade in Chinese medicines, DH had developed HKCMMS since 2002 to ascertain the authenticity, safety and quality of commonly used Chinese Materia Medica ("CMM") in Hong Kong. HKCMMS set out the names, sources and descriptions of CMM, as well as methods of identification, tests and assays. While the Chinese Pharmacopoeia was a regulatory standard covering different scope and types of CMM, HKCMMS served as reference standards of safety and quality for CMM commonly used in Hong Kong with a diversity of parameters of standard; and (b) HKCMMS received support from the Mainland regulatory authorities and professionals. Both the State Administration of Traditional Chinese Medicine and the China Food and Drug Administration ("CFDA") had offered valuable advice on the development of HKCMMS.	
010346 - 011740	Chairman Administration	The Chairman considered that many local SME pCm manufacturers were in lack of capital and expertise to comply with the GMP standard and HKCMMS which imposed very high standards for pCm manufacture and quality of Chinese herbal medicines respectively. The Chairman raised various issues as set out in paragraph 3 of the minutes for the Administration's consideration. In response to the Chairman's enquiry, the Administration explained that 30 June 2015 was only the deadline for the submission of the necessary test reports. According to the Chinese Medicine Ordinance (Cap. 549), pCms issued with "Notice of confirmation of transitional registration of pCm" (i.e. "HKP") could be sold legally on the market, until they were formally registered and issued with the Certificate of registration of pCm (i.e. "HKC"), or until their registration applications had been refused or until such date to be promulgated by the Secretary for Food and Health in the Gazette, whichever date was the earliest. The Chinese Medicines Board ("CMB") would continue to vet applications for conversion of transitional registration to formal	**Admin to consider the Chairman's concerns** (paragraph 3 of the minutes)

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		registration. Test reports that were submitted after 30 June 2015 would be subject to further assessment of CMB. The Administration also advised that CMB had provided information on the local and Mainland laboratories providing pCm testing service to pCm manufacturers since the commencement of registration regime. At present, there were nine local laboratories and 17 municipal Institutes for Drug Control in China that were recommended by the CFDA and recognised by CMB to provide pCm testing service. DH could request the regulatory authorities in the Mainland to include more laboratories qualified for conducting pCm testing.	
011741 - 013459	Chairman Mr Vincent FANG Administration	Mr Vincent FANG cited an example of a local manufacturer being unable to provide the required test reports to CMB before the deadline due to the long time taken for compiling such test reports. He expressed concern that the existing 26 accredited laboratories had reached their full capacity, and urged the Administration to estimate the time required for the 26 laboratories to finish conducting pCm testing for the 8 600 products issued with HKP. The Administration advised that for cases of conversion from HKP to HKC, any applicant who was unable to submit the required test reports by the deadline could apply to CMB for extension of the deadline. CMB could exercise discretion in giving approval to such applications if adequate justifications were provided.	
013500 - 014546	Chairman Miss Alice MAK Administration	To facilitate pCm registration, Miss Alice MAK considered that CMB should strengthen communication with pCm manufacturers and traders and provide clear guidelines to them. Miss MAK also expressed concern about the difficulties faced by manufacturers of traditional pCm in applying for registration due to technical problems involved in meeting requirements regarding the safety and quality of their products. She was concerned that these pCm products might be available for sale in the market as health food products. The Administration advised that all products falling within the definition of pCms were subject to the regulation of the Chinese Medicine Ordinance. Health food were also required to comply with other ordinances, such as the Undesirable Medical Advertisements Ordinance (Cap. 231) and Food and Drugs (Composition and Labelling) Regulations (Cap. 132W). A market surveillance on health food was put in place and samples were collected from the market for testing on a regular basis.	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
014547 - 014821	Chairman	Arrangement of visit to local laboratory which provided pCm testing services for the trade.	**Admin/Clerk** (paragraph 4 of the minutes)
Agenda item III - Arrangements for migration of pCms from transitional registration to formal registration			
014822 - 021325	Chairman Administration Dr Elizabeth QUAT	The Chairman expressed concern about the transitional arrangements for pCms issued with HKP when migrating to HKC, especially the impact on the production of pCms. The Administration elaborated that to facilitate the trade to sell out pCms issued with HKP and to avoid causing confusion to customers, pCm manufacturers and traders were given 12 months to receive HKC and replace their HKP concomitantly. The Chairman and Dr Elizabeth QUAT considered that the Administration should allow greater flexibility for manufacturers and traders to sell out their pCms issued with HKP, instead of product recall, when migrating to HKC in order to avoid market chaos and unnecessary wastage. The Administration considered that HKP holders were given sufficient time to complete the replacement of old packaging label and insert for their pCm products. If more time was needed, HKP holders might apply to CMB for further extension. The extended period approved by CMB would not be longer than 12 months. The Administration reiterated that it was a legal requirement that HKP and HKC could not co-exist for the same pCm. The Administration welcomed the trade to propose better transitional/interfacing arrangements without violation of the law.	
Agenda item IV – Any other business			
021326 – 021354	Chairman	Item for discussion at the next meeting	

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