立法會
Legislative Council

Ref : CB2/PS/1/13

LC Paper No. CB(2)1008/14-15
(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 Monday, 26 January 2015, at 10:45 am
in Conference Room 1 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 YIU Si-wing Dr Hon KWOK Ka-ki Dr Hon Elizabeth QUAT, JP
Member absent	:	Hon CHEUNG Kwok-che Hon Alice MAK Mei-kuen, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP
Public Officers 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 Dr Alice WONG Yuk-ming Senior Medical & Health Officer (Traditional Chinese Medicine) 1 Department of Health

Attendance by invitation	:	The Hong Kong Society of Chinese Medicines Ltd. Mr TSUI Kam-chuen President Mr NG Wo-mau Chinese Medicine Informatics (HK) Ltd. Mr KWONG Ping-nam Director Luen Yick Pharmaceutical Co. Ltd. Mr CHOW Kam-tim Manager O.K. Pharmaceuticals Factory HK Ms KUNG Ngar-shuen Marketing Director Natural Health Care Development Ltd. Mr LAM Hiu-ban Managing Director Hong Kong SME Development Federation Ltd. Mr Philip WONG Hung Oriental Int'l Health Products Co. Ltd. Miss NG Chak-sze Company Representative HK Chinese Medicine Merchants Association Ltd. Mr CHAN Pak-wai Vice Chief Supervisor Mr YUEN Yee-lum

Mr KO Fei

Mr Victor MA Kee-kin

Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.

Mr Nicholas WONG

Mr Daniel WONG Po-ling

Tam Kam Medicament Manufacturing Factory

Ms LI Tsui-man

H.K. Ophthal Center in Chinese Medicine

Ms LI Kam-fung

Miss FUNG Chuk-fong

Miss Bernice LEUNG Wai-chung

Canhealth Pharmaceutical Limited

Miss LEE On-lan
Production Manager

Hong Kong & Kowloon Chinese Medicine Merchants Association Limited

Mr Jack PANG Cheung-hi
Life President

Hong Kong Chinese Medicine Manufacturers United Association

Mr KONG Chi-hung
Chairman of directors

Ms CHUI Yuk-lung

Hong Kong Chinese Patent Medicine Manufacturers Association

Dr Timothy TAM
Pharmaceutical Consultant

W.S.D. Mty

Mr Edward FUNG
Manager

Democratic Alliance for the Betterment and Progress of Hong Kong

Mr YIP Man-pan
Deputy Spokesperson of Health Services

Hong Kong Institute of Biotechnology Ltd.

Dr Ken S Y YEUNG
General Manager, Biologics and GMP Consultation Department

Singapore Merlion (Int'l) Medicated Oil Manufactory Co. Ltd.

Mr KONG Ka-fung
Co. Representative

Hong Kong Productivity Council

Ms YU Man-ying
Consultant

Hong Kong Wing Hong Pharmaceutical Limited

Mr Jacky WONG Sui-hung
Vice General Manager

Wah Sun Medical Trading Company

Mr Chris CHOW
Manager

Healthy Chinese Medicine Consultation Centre

Miss M Y TSE
Executive Director

Lai's Medicine

Mr Johnny LAI Chik-yeung
Director

Lai Shing Medicine Factory Limited

Mr Danny LAI Chik-wang
Managing Director

Clerk in attendance	:	Ms Joanne MAK Chief Council Secretary (2) 3
Staff in attendance	:	Ms Priscilla LAU Council Secretary (2) 5
		Mr William LEE Legislative Assistant (2) 9

Action

I. Registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice ("GMP") requirements to pCms
[LC Paper Nos. CB(2)453/14-15(02), CB(2)322/14-15(01) to (04)]

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

2. The Subcommittee received views from 33 deputations and noted the submissions provided by two organizations which did not attend the meeting. The Subcommittee noted the following major views expressed by the deputations -

(a) many deputations considered that once mandatory compliance with GMP standard was implemented, the survival of local pCm manufacturers would be threatened as they were mostly small and

medium enterprises ("SMEs") and lacked capital and expertise to build and operate GMP facilities. Moreover, they did not see the need for the introduction of mandatory GMP requirements as local pCm manufacturers mainly targeted the local and the Asian markets rather than the world market. These deputations considered that the adoption of GMP standards should be a voluntary requirement only, so that pCm manufacturers would be free to choose whether or not to apply for GMP certificates, depending on their financial strength, production scale and market positioning. Some deputations expressed the view that measures should be introduced to preserve the traditional pCms and their unique traditional way of production;

(b) there was a strong call for the Administration to provide more support and assistance to the pCm industry. Consideration should be given to setting up GMP factory premises for pCm manufacturers under leasing arrangement. Besides, more GMP training and technical consultation services should be provided to the industry. In addition, the Administration should engage stakeholders in the pCm industry to draw up detailed guidelines on GMP requirements before their implementation;

(c) a number of deputations expressed grave concern about the difficulties faced by pCm manufacturers in applying for registration of their pCm products, which included expensive testing cost, lack of clear guidelines on product specification and inadequate laboratory test services. There was a suggestion of setting up a non-governmental organization to provide assistance to pCms manufacturers in respect of testing and registration matters;

(d) some deputations expressed concern that some pCm products which failed to be registered under the existing regulatory framework were available for sale in the market as health food products with nutrition labels;

(e) some deputations considered it necessary to review the existing classification categories of pCms. Consideration should be given to introducing a new classification category, such as "Empirical formula", to accommodate those pCms which might not fulfill the standards of "Established medicines" but had been sold in Hong Kong for many years and empirically proven safe or harmless for use;

(f) there was concern as to whether those pCms which were issued with "Notice of confirmation of transitional registration of pCm" ("HKP") could continue to be sold if their quality test reports could not be provided by the deadline of 30 June 2015;

(g) apart from giving more time (instead of six months), the Administration should also allow greater flexibility for manufacturers and traders to sell out their pCms issued with HKP, instead of product recall when migrating to "Certificates of registration of a pCm" ("HKC") in order to avoid market chaos and unnecessary wastage ;

(h) there was a view that guidelines on the application and renewal of Chinese medicines trader licences were not clear enough. It was also suggested that the validity of trader licences should be extended from two to three or five years;

(i) there was a view that it was difficult for wholesalers of Chinese herbal medicines to meet the requirement of maintaining complete transaction record; and

(j) some deputations considered that the existing regulatory framework of Chinese medicine was not conducive to the development of Chinese medicine. In their view, there was a need to review the Chinese Medicine Ordinance (Cap. 549) ("CMO"). Furthermore, the Administration should consider setting up a dedicated fund to support the pCm industry and promote the development of Chinese medicine.

3. In response, the Administration made the following initial response -

(a) the purpose of introducing GMP requirements to pCms was to promote the standardization and quality control of pCm manufacturing, and to align with the trends of GMP development in the production of medicines. The Chinese Medicines Board ("CMB") and the Department of Health ("DH") regularly organized briefing sessions for the trade to enhance their understanding of the requirements in respect of pCm registration, testing and GMP implementation;

(b) it should be noted that GMP requirements for pCm manufacturing were being implemented in some places including the Mainland, Taiwan, Singapore, etc. To assist local pCm manufacturers to

become GMP compliant, the Hong Kong Institute of Biotechnology had received funding from the Government to carry out a three-year project to set up a GMP product development, technical support and training platform for the pCm industry. The Administration would actively engage the trade to work out a timetable for mandatory compliance with GMP for pCm manufacturing whenever appropriate;

(c) to comply with CMO and to avoid causing confusion to customers, pCm manufacturers and traders were required to replace new labels and package inserts for pCms issued with HKP when application for HKC had been approved for these pCms. According to CMB, the relevant registration holders could apply for an extension of the six-month grace period if more time was needed for the labelling replacement work;

(d) in some applications for pCm registration, the applicants were required to provide supplementary information with respect to the up-to-date findings on safety and quality of Chinese medicines, such as hazardous effects of particular ingredients. As a result, the processing of relevant applications took more time. If applicants required more time to provide testing reports, CMB could exercise discretion and accommodate such requests;

(e) the Government had all along attached great importance to the development of Chinese medicine industry in Hong Kong. The Chief Executive announced in his 2013 Policy Address the establishment of a Chinese Medicine Development Committee ("CMDC") to give recommendations to the Government concerning the direction and long-term strategy of the future development of Chinese medicine in Hong Kong. Established in February 2013 and chaired by the Secretary for Food and Health, CMDC was tasked to study relevant key areas. In the 2015 Policy Address, it was further announced that the Government had accepted the CMDC's recommendation to set up a testing centre for Chinese medicines managed by DH. The testing centre would specialize in scientific research on Chinese medicines, with a view to setting reference standards on safety, quality and testing methods of Chinese medicines; and

(f) the concerns on pCm registration and GMP implementation raised by deputations were well noted by the Administration and would be reflected to CMDC and CMB whenever appropriate.

Follow-up actions required of the Administration

Admin 4. The Administration was requested to provide written response to various concerns raised by the deputations at this and the last meetings, and to the following issues raised by members -

(a) the total number of applications for pCms registration received by the CMB, of which how many had been rejected and reasons;

(b) the number of pCm brands that had disappeared from the market due to unsuccessful application for registration; and

(c) response to some deputations' view that it was not necessary to implement GMP requirements to pCms in Hong Kong, as most local pCm manufacturers were SMEs targeting mainly local and Asian markets.

Date of next meeting

5. Members noted that at the request of the Administration and with the concurrence of the Chairman, the next meeting would be held on 13 March 2015 at 10:45 am to further discuss the registration, testing and development of pCms and the introduction of GMP requirements to pCms.

6. The Chairman suggested and members agreed to add arrangements for migration of pCms from HKP to HKC to the Subcommittee's list of issues to be discussed.

(*Post meeting note*: At the instruction of the Chairman, the above subject was included in the agenda of the meeting on 13 March 2015 at 10:45 am.)

II. Any other business

7. There being no other business, the meeting ended at 1:30 pm.

Council Business Division 2
Legislative Council Secretariat
10 March 2015

Annex

Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Monday, 26 January 2015, at 10:45 am in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
Agenda item I - Registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice ("GMP") requirements to pCms			
000310 - 000537	Chairman	Opening remarks	
000538 - 000913	Chairman The Hong Kong Society of Chinese Medicines Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(01)]	
000914 - 001307	Chairman Mr NG Wo-mau	Presentation of views [LC Paper No. CB(2)748/14-15(02)]	
001308 - 001657	Chairman Chinese Medicine Informatics (HK) Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(03)]	
001658 - 002004	Chairman Luen Yick Pharmaceutical Co. Ltd.	Presentation of views	
002005 - 002323	Chairman O.K. Pharmaceuticals Factory HK	Presentation of views [LC Paper No. CB(2)632/14-15(01)]	
002324 - 002728	Chairman Natural Health Care Development Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(04)]	
002729 - 003032	Chairman Hong Kong SME Development Federation Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(05)]	
003033 - 003320	Chairman Oriental Int'l Health Products Co. Ltd.	Presentation of views	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
003321 - 003722	Chairman HK Chinese Medicine Merchants Association Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(06)]	
003723 - 004014	Chairman Mr YUEN Yee-lum	Presentation of views [LC Paper No. CB(2)698/14-15(02)]	
004015 - 004251	Chairman Mr KO Fei	Presentation of views	
004252 - 004610	Chairman Mr Victor MA Kee-kin	Presentation of views [LC Paper No. CB(2)748/14-15(07)]	
004611 - 004821	Chairman Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.	Presentation of views [LC Paper No. CB(2)632/14-15(02)]	
004822 - 005147	Chairman Mr Daniel WONG Po-ling	Presentation of views	
005148 - 005534	Chairman Tam Kam Medicament Manufacturing Factory	Presentation of views [LC Paper No. CB(2)748/14-15(08)]	
005535 - 005912	Chairman H.K. Ophthal Center in Chinese Medicine	Presentation of views [LC Paper No. CB(2)698/14-15(03)]	
005913 - 010223	Chairman Miss FUNG Chuk-fong	Presentation of views [LC Paper No. CB(2)748/14-15(09)]	
010224 - 010558	Chairman Miss Bernice LEUNG Wai-chung	Presentation of views [LC Paper No. CB(2)748/14-15(10)]	
010559 - 010934	Chairman Canhealth Pharmaceutical Limited	Presentation of views [LC Paper No. CB(2)748/14-15(11)]	
010935 - 011354	Chairman Hong Kong & Kowloon Chinese Medicine Merchants Association Limited	Presentation of views	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
011355 - 011633	Chairman Hong Kong Chinese Medicine Manufacturers United Association	Presentation of views [LC Paper No. CB(2)698/14-15(04)]	
011634 - 011945	Chairman Ms CHUI Yuk-lung	Presentation of views [LC Paper No. CB(2)748/14-15(12)]	
011946 - 012302	Chairman Hong Kong Chinese Patent Medicine Manufacturers Association	Presentation of views [LC Paper No. CB(2)632/14-15(03)]	
012303 - 012643	Chairman W.S.D. Mty	Presentation of views [LC Paper No. CB(2)748/14-15(13)]	
012644 - 012941	Chairman Democratic Alliance for the Betterment and Progress of Hong Kong	Presentation of views	
012942 - 013305	Chairman Hong Kong Institute of Biotechnology Ltd.	Presentation of views [LC Paper No. CB(2)698/14-15(05)]	
013306 - 013620	Chairman Singapore Merlion (Int'l) Medicated Oil Manufactory Co. Ltd.	Presentation of views [LC Paper No. CB(2)748/14-15(14)]	
013621 - 013927	Chairman Hong Kong Productivity Council	Presentation of views	
013928 - 014153	Chairman Hong Kong Wing Hong Pharmaceutical Limited	Presentation of views	
014154 - 014449	Chairman Wah Sun Medical Trading Company	Presentation of views	

014450 - 014654	Chairman Healthy Chinese Medicine Consultation Centre	Presentation of views [LC Paper No. CB(2)698/14-15(06)]	
014655 - 015010	Chairman Lai's Medicine	Presentation of views [LC Paper No. CB(2)698/14-15(07)]	
015011 - 015332	Chairman Lai Shing Medicine Factory Limited	Presentation of views [LC Paper No. CB(2)698/14-15(08)]	
015333 - 020812	Chairman Administration	Administration's initial responses to the views and concerns expressed by the deputations	
020813 - 021530	Chairman Prof Joseph LEE Administration	Sharing the deputations' concerns over pCm registration, Prof Joseph LEE called on the Administration to strengthen communication with the trade on the arrangements for migration of pCms from transitional registration to formal registration. Prof LEE further enquired about various issues and the Chairman requested the Administration to provide a written response to Prof LEE's enquiries.	**Admin to provide written response** (paragraph 4 of the minutes)
021531 - 022136	Chairman Mr Vincent FANG Administration	Mr Vincent FANG considered that the stringent registration requirements had led to a decrease in the number of pCm manufacturers, and the proposed implementation of mandatory compliance with GMP for pCm manufacture was detrimental to the pCm industry in Hong Kong. There was also insufficient government assistance for the trade in complying with the registration requirements. The Administration advised that the introduction of GMP requirements to pCms aimed to further ensure the safety of pCm and to keep up with the trends of developing GMP for medicines. As regards the decrease in number of pCm manufacturers after implementation of the Chinese Medicine Ordinance (Cap. 549) ("CMO"), the main reasons were that they failed to comply with the licensing requirements such as hygienic conditions, were unable to provide sufficient supporting documents, or withdrew voluntarily for non-transitional licence, etc. Mr FANG also expressed concern that under the GMP contract manufacturing arrangements, pCm manufacturers had to provide their pCm master formula to the Hong Kong Institute of Biotechnology and that they might have to dismiss their workers. Moreover, the production output provided by the contract manufacturing service might be far more than the actual demand of the manufacturers.	

022137 - 023049	Chairman Dr Elizabeth QUAT Administration Mr WONG Ting-kwong	Dr Elizabeth QUAT expressed grave concern about the difficulties faced by pCm manufacturers in complying with the registration and GMP requirements. She urged the Administration to formulate a comprehensive policy to support the traditional pCm industry and preserve traditional pCms. Mr WONG Ting-kwong held the view that the Administration should take into account the principle of Chinese medicine and past practice of the trade, rather than from the perspective of Western medicine, in formulating the regulatory framework for pCms. Given that most local pCm manufacturers were small and medium enterprises, Mr WONG Ting-kwong concurred with the deputations' view that pCm manufacturers should be allowed to choose whether or not they would comply with GMP requirements based on their financial capacity, production scale and target markets. The Administration stressed that the GMP requirements in respect of pCms in Hong Kong was currently not mandatory. It would engage with the trade to work out a timetable for mandatory compliance with GMP for the manufacture of pCms.	
023050 - 023855	Chairman Administration	Referring to the questionnaire survey on the development of Chinese medicine conducted by The Hong Kong Society of Chinese Medicines Ltd., the Chairman considered that the Chinese Medicine Development Committee should maintain closer communication with the trade to gauge their views in formulating a regulatory framework for Chinese medicine. He also expressed concern that certain established medicines might not be allowed under the present regulatory system of pCms to continue with their established traditional ways of manufacturing. The Chairman enquired about the Administration's response to - (a) the suggestion of setting up a dedicated fund to support the pCm industry and promote the development of Chinese medicines; (b) concern about the arrangements for applications for "Certificates of registration of a pCm" ("HKC") of those pCms which had been issued with “Notice of confirmation of transitional registration of pCm" ("HKP") but unable to meet the deadline of 30 June 2015 to submit the test reports on quality;	

		(c) the suggestion of allowing more flexibility and time for manufacturers and traders to sell their pCms issued with HKP when migrating to "HKC"; and (d) the need to step up regulatory control of unregistered pCm products which were available for sale in the market as health food products with nutrition labels; and the timetable for review of CMO. The Administration advised that - (a) manufacturers or traders could write to the Chinese Medicines Board ("CMB") to request for extending the six-month period for handling pCms issued with HKP for which formal registration had been approved with HKC issued. The Administration would also relay to CMB the trade's views and concerns (especially their difficulties encountered in the application process) on the migration of pCms from HKP to HKC; (b) it was illegal to sell products presented as "health food" but fell within the legal definition of pCms without pCms registration. "Health food" which could not be classified as pCm is under the regulation of respective laws relating to food safety or public health of Hong Kong, including the Public Health and Municipal Services Ordinance (Cap. 132), the Undesirable Medical Advertisements Ordinance (Cap. 231) and so forth; and (c) the requests for reviewing CMO and setting up a dedicated fund to support the development of Chinese medicine were noted and would be considered whenever appropriate.	
Agenda item II – Any other business			
023856 - 024210	Chairman	Date and discussion items of next meeting List of issues for discussion by the Subcommittee Closing remarks	**Admin to provide written response to deputations' concerns** (paragraph 4 of the minutes)

Council Business Division 2
Legislative Council Secretariat
10 March 2015