立法會
Legislative Council

Ref : CB2/PS/1/13

LC Paper No. CB(2)646/14-15
(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 Tuesday, 25 November 2014, at 10:45 am
in Conference Room 2A 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 Hon Alice MAK Mei-kuen, JP Dr Hon KWOK Ka-ki Dr Hon Elizabeth QUAT, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP
Member absent	:	Hon CHEUNG Kwok-che
Public Officers attending	:	Items I and II 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 Mr Robert LAW Kwok-wai Senior Pharmacist (Traditional Chinese Medicine) 2 Department of Health Dr Theobald CHAN Sing-kwok Senior Biotechnology Officer 2 Innovation and Technology Commission

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. Registration and testing of proprietary Chinese medicines
[LC Paper Nos. CB(2)322/14-15(01) and (02)]

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

Follow-up actions required of the Administration

2. Members expressed grave concern about the difficulties encountered by the trade in meeting the requirements for registration of proprietary Chinese medicines ("pCms") and urged the Administration to strengthen provision of support and assistance to the trade. The Administration agreed to relay to the Chinese Medicines Board ("CMB") the trade's concerns and strengthen the provision of information to the trade, particularly on the arrangements for review against decisions of CMB in relation to applications for registration, to enhance understanding of the registration requirements and appeal mechanism.

Admin

Admin

3. The Subcommittee requested the Administration to provide supplementary information on the following issues raised by members -

(a) similarities and differences between pCms and pharmaceutical products in terms of registration and testing requirements;

(b) the registration and testing requirements for Chinese medicine products in Hong Kong, Mainland China and Taiwan;

(c) details of the various tests required for registration of pCms in Hong Kong and the costs; and

(d) details of the funding schemes available for application by the Chinese medicine sector.

(*Post-meeting note:* The supplementary information paper (LC Paper No. CB(2)453/14-15(02)) provided by the Administration was issued vide LC Paper No. CB(2)466/14-15 on 15 December 2014.)

Action

II. Introduction of the Good Manufacturing Practice ("GMP") requirement in respect of proprietary Chinese medicines
[LC Paper Nos. CB(2)322/14-15(03) and (04)]

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 provide supplementary information on the following issues raised by members –

(a) arrangements to address the concern expressed by local pCm manufacturers as to whether they could retain their name or trademark on their pCm products under the contract manufacturing services provided by the Hong Kong Institute of Biotechnology; and

(b) the Administration's response to the suggestion of setting up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangement.

(*Post-meeting note*: The supplementary information paper (LC Paper No. CB(2)453/14-15(02)) provided by the Administration was issued vide LC Paper No. CB(2)466/14-15 on 15 December 2014.)

III. Any other business

6. Members agreed that the Subcommittee would receive views from deputations on the registration, testing and development of pCms and the introduction of GMP requirements to pCms at the next meeting to be held on 16 December 2014 at 10:45 am.

(*Post-meeting note*: With the concurrence of the Chairman, the next meeting was held on 16 December 2014 from 10:15 am to 12:15 pm.)

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

Council Business Division 2
Legislative Council Secretariat
14 January 2015

Annex

Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Tuesday, 25 November 2014, at 10:45 am in Conference Room 2A of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
Agenda item I - Registration and testing of proprietary Chinese medicines ("pCms")			
000302 - 000934	Chairman Administration	Opening remarks Briefing by the Administration	
000935 - 001817	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing enquired about the progress of pCm registration, reasons for refusal, the appeal channel and the number of laboratories for pCm testing. The Administration advised that - (a) So far, about 5 000 applications for pCm registration had been refused mainly due to (i) failure to furnish sufficient information to support that the relevant pCms were manufactured, sold or supplied for sale in Hong Kong on 1 March 1999 in order to apply for transitional registration; (ii) failure to provide product specifications, method of analysis and test reports; (iii) failure to meet the safety requirements in terms of heavy metals and toxic elements, pesticide residue and/or microbial limit; and/or (iv) failure to satisfy the approving authority that the principle of formulating a prescription of the product complied with the Chinese medicine theories; (b) according to section 140 of the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance"), any person aggrieved by the decision of the Chinese Medicines Committee regarding pCm registration might request the Chinese Medicines Board ("CMB") to review the decision. In reviewing a decision, CMB might invite the applicant to make representations in writing or in person; (c) there were about 20 laboratories qualified for conducting pCm testing including those in the Mainland recognized by China Food and Drug Administration ("CFDA") (former called the State Food and Drug Administration) and CMB. If necessary, CMB might request the regulatory authorities in the Mainland to expand the list of recommended laboratories in order to increase the number of laboratories qualified for conducting pCm testing.	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
001818 - 002846	Chairman Prof Joseph LEE Administration	Prof Joseph LEE said that the trade had the impression that it was more difficult for pCms to meet the relevant registration requirements than pharmaceutical products. He asked about the differences between the two kinds of products in terms of registration and testing requirements. The Administration advised that - (a) both pharmaceutical products and pCms were required to satisfy the criteria of safety, quality and efficacy, and must be registered with the relevant statutory regulatory bodies before they could be sold in Hong Kong. On the whole, regulatory requirements for pCms in Hong Kong were similar to those of the Mainland and Taiwan; and (b) the various tests for registration of pCms must meet the requirements set out in the relevant handbook and technical guidelines formulated by CMB. Both the Chinese Medicines Committee and CMB comprised representatives from the trade and Chinese medicine practitioners. Besides, the Panel for Registration of pCms was tasked to provide professional advice on the professional and technical aspects in processing the applications for pCms registration. The panel consisted of professionals from various sectors such as Chinese medicine practice, Chinese medicines and chemical analysis.	**Admin** (paragraph 3(a) of the minutes)
002847 - 004409	Chairman Mr YIU Si-wing Administration Prof Joseph LEE	In response to Mr YIU Si-wing's enquiry about the testing and documents in support of the safety, quality and efficacy as required by CMB, the Administration advised that different registration groups of pCm had different registration requirements and hence required different documents which included, among others, (a) safety test reports in terms of heavy metals and toxic elements, pesticide residues and microbial limit; (b) product specification (covering "description", "identification", "assay" and "inspection") of pCm together with the method of analysis; and (c) the interpretation and principle of formulating the prescription, with an analysis based on the theory of Chinese medicine. The Chairman requested the Administration to provide supplementary information in this regard.	**Admin** (paragraph 3(b) of the minutes)
004410 - 004644	Chairman Administration	The Chairman pointed out that certain traditional pCms bearing the same name (e.g. 保嬰丹) but produced by different manufacturers might vary in their formulae. He enquired about the assessment criteria for determining which of the pCms concerned fulfilled the registration requirements, and the basis for accepting any deviation from pharmacopoeial standards. The Administration advised that in vetting an application for registration of traditional pCm, the Chinese Medicines Committee and the Panel for Registration of pCms would consider whether the	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		prescription of pCm under application was an ancient prescription, or a modified ancient prescription or a pharmacopoeial prescription (which had been documented in the Pharmacopoeia) for registration under the "Established medicines category". For the modified ancient presciption, appropriate adjustments were allowed to the prescription provided that the applicant was able to explain to the satisfaction of the approving authority that the adjustments were based on the theory of Chinese medicine. Otherwise, the pCm under application should be made under the "New Medicines category".	
004645 - 011851	Chairman Dr Elizabeth QUAT Administration Mr YIU Si-wing	Dr Elizabeth QUAT pointed out that the trade had complained about the expensive testing cost, lack of laboratories to conduct pCm testing and long processing time. The Administration advised that - (a) there were currently a total of around 20 local ISO 17025 accredited laboratories and municipal Institutes for Drug Control in the Mainland which were recognized by both CMB and CFDA to provide pCm testing service; (b) in some cases, applicants needed to provide supplementary information and documents in connection with their applications for registration of pCms and this might entail longer processing time. The Administration agreed to provide details of the price and time required for various tests required for registration of pCms in Hong Kong. In general, it took around two months to prepare a product safety report, and much more time for preparing a stability test report to establish the stability and shelf life of a product; and (c) Department of Health ("DH") had been holding regular briefing sessions for the trade on the registration requirements of pCm and for exchange of views on technical issues for establishment of quality specifications. The relevant information had been uploaded onto the website of the Chinese Medicine Council of Hong Kong. DH was willing to meet with applicants who had encountered difficulties in the testing of pCm or whose application was unsuccessful, and give advice where necessary. Dr Elizabeth QUAT suggested that the Administration should encourage the universities to provide training courses on manufacturing of pCm and to offer technical assistance to the trade. She also suggested that the Administration should strengthen the relevant guidelines on registration of pCms for reference by the trade. The Administration advised that the Chinese University of Hong Kong had offered courses on the manufacture and testing of pCms for the trade and laboratory personnel.	**Admin** (paragraph 3(c) of the minutes)

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
011852 - 012737	Chairman Administration	Pointing out that less than 3% of the pCms issued with "Notice of confirmation of transitional registration of pCm" (i.e. "HKP") had been issued with "Certificate of registration of pCm" (i.e. "HKC"), the Chairman expressed concern about the difficulties encountered by the trade in meeting the registration requirements and the need for the Administration to strengthen assistance for the trade in resolving the difficulties. He requested the Administration to provide details of the funding schemes available for application by the trade to facilitate their development. The Administration agreed to liaise with CMB on the trade's concerns and strengthen the provision of information to the trade, particularly on the arrangements for review against decisions of CMB in relation to applications for registration.	**Admin** (paragraphs 2 and 3(d) of the minutes)
Agenda item II - Introduction of the Good Manufacturing Practice ("GMP") requirement in respect of proprietary Chinese medicines			
012738 - 013244	Chairman Administration	Briefing by the Administration	
013245 - 014119	Chairman Mr YIU Si-wing Administration	Mr YIU Si-wing considered that as the pCm industry was not yet GMP-ready, the Administration should encourage local pCm manufacturers to comply with GMP requirements, rather than implementing the mandatory compliance with GMP. He also suggested implementing "quality trademark" for local pCm manufacturers in order to promote their traditional pCms with proven efficacy. The Administration advised that the introduction of pCm registration and GMP requirements in pCm manufacturing were two main approaches to enhance the standard of pCms in respect of safety, quality and efficacy, thereby promoting local pCms in overseas market. There was currently no timetable for mandatory compliance with GMP for the manufacture of pCms. CMB and DH would maintain close communication with the trade on the timetable and specific arrangements in the implementation of GMP.	
014120 - 015807	Chairman Mr Vincent FANG Administration Mr YIU Si-wing	Mr Vincent FANG said that while he was pleased to note that a three-year project would be launched to set up a GMP product development and technical support platform for traditional oral solid pCm products, pCm manufacturers were very concerned as to whether they would have to provide their pCm master formula to the Hong Kong Institute of Biotechnology ("HKIB") under the GMP contract manufacturing arrangements and the intellectual property problems thus arising. Representative of the Innovation and Technology Commission ("ITC") briefed members on the purpose of the three-year project planned to be launched as detailed in paragraphs 9 and 10 of the	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		Administration's paper (LC Paper No. CB(2)322/14-15(03)), and explained that the provision of any pCm master formula to HKIB under the GMP contract manufacturing arrangements would be subject to the contractual agreements between the manufacturer and HKIB, which would be legally binding. Mr FANG further asked whether the pCm manufacturers participating in the three-year project might have to dismiss their workers after contracting out their pCm manufacturing to HKIB by making use of the aforementioned new platform. Representative of ITC advised that it was not necessarily the case as the manufacturers might consider only to seek technical support for GMP implementation rather than contract manufacturing from the new platform. Mr FANG asked whether the Administration would consider setting up GMP factory premises that could be provided for use by pCm manufacturers under leasing arrangement. Representative of ITC advised that the Hong Kong Science and Technology Parks Corporation was reviewing the land use in the industrial estates and, upon completion of the review, it would explore how to enhance support to the pCm industry. Mr FANG requested the Administration to consider the suggestion. Mr YIU Si-wing asked about the response of the trade to the above three-year project. The Administration advised that the project was supported by the Committee on Research and Development of Chinese Medicines under ITC, which comprised representatives from the Chinese medicines industry including pCm manfacturers and traders. It was generally considered that the new platform would provide better support to the trade, as GMP contract manufacturing services would be an option for local manufacturers in the manufacture of the four most common types of pCm solid formulations in Hong Kong.	**Admin** (paragraph 5(b) of the minutes)
015808 - 020432	Chairman Administration	Extension of meeting Noting that PIC/S GMP standard was widely adopted by the pharmaceutical manufacturing industry worldwide, the Chairman considered that, as most of the 279 pCm manufacturers in Hong Kong licensed in accordance with the Ordinance were small and medium enterprises, they lacked financial capacity and technical knowhow to upgrade themselves to meet the GMP standard of PIC/S. The Administration advised that CMB had recommended to adopt the GMP standard of PIC/S as a licensing requirement for local pCm manufacturers with a view to enabling the local pCm industry to keep up with the international standards.	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		In response to the Chairman's enquiry as to whether pCm manufacturers could still keep their name or trademark on the pCm products under the contract manufacturing services provided by HKIB, the Administration agreed to provide detailed information on the issue.	**Admin** (paragraph 5(a) of the minutes)
020433 - 021630	Chairman Mr Vincent FANG Administration Dr KWOK Ka-ki Mr YIU Si-wing	Dr KWOK Ka-ki expressed concern about the progress of the implementation of GMP compliance. The Administration advised that at present, 12 local licensed pCm manufacturers had been awarded with GMP Certificates. While there was no timetable for implementation of mandatory GMP compliance, CMB would take into account the views of pCm manufacturers and difficulties faced by the industry in determining the timetable.	
Agenda item III – Any other business			
021631 - 021651	Chairman	Arrangement and date of next meeting	

Council Business Division 2
Legislative Council Secretariat
14 January 2015