立法會
Legislative Council

LC Paper No. CB(2)779/11-12
(These minutes have been seen by the Administration)

Ref : CB2/PS/3/10

Panel on Health Services

Subcommittee on Registration of Proprietary Chinese Medicines

Minutes of the meeting
held on Tuesday, 22 November 2011, at 4:30 pm
in Conference Room 2A of the Legislative Council Complex

Members present	:	Dr Hon LEUNG Ka-lau (Chairman) Hon LI Fung-ying, SBS, JP Hon Vincent FANG Kang, SBS, JP Dr Hon Joseph LEE Kok-long, SBS, JP Hon WONG Ting-kwong, BBS, JP Hon CHAN Hak-kan Hon CHEUNG Kwok-che Dr Hon PAN Pey-chyou Hon Alan LEONG Kah-kit, SC
Members absent	:	Hon CHEUNG Man-kwong
Public Officers attending	:	Items III and IV Ms Estrella CHEUNG Principal Assistant Secretary for Food & Health (Health)1 Dr Ronald LAM Assistant Director of Health (Traditional Chinese Medicine)

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		Mr Frank CHAN Chief Pharmacist (Traditional Chinese Medicine)
Clerk in attendance	:	Mr Thomas WONG Chief Council Secretary (2)2
Staff in attendance	:	Miss Jasmine TAM Council Secretary (2) 2
		Miss Emma CHEUNG Legislative Assistant (2)2

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I. Election of Chairman and Deputy Chairman

Members agreed that there was no need to re-elect a Chairman for the 2011-2012 session.

II. Confirmation of minutes

[LC Paper No. CB(2)302/11-12]

2. The minutes of the meeting on 20 July 2011 were confirmed.

III. Meeting with the Administration

[LC Paper No. CB(2)349/11-12(01)]

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

4. Principal Assistant Secretary for Food & Health (Health)1 ("PAS(H)1") updated members on the progress of the commencement of provisions of the Chinese Medicine Ordinance (Cap. 549) ("CMO") related to the mandatory registration of proprietary Chinese medicines ("pCms") and the requirements of label and package insert [LC paper No. CB(2)349/11-12(01)].

Registration of pCms

5. Referring to paragraph 8 of the Administration's paper,

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Dr PAN Pey-chyou and Mr CHEUNG Kwok-che asked why 6 100 out of the 16 990 applications for registration of pCms had been rejected. Assistant Director of Health (Traditional Chinese Medicine) ("ADH(TCM)") advised that of the 6 100 rejected applications, about half were related to the failure of providing the three basic safety test reports of the pCms under application in terms of heavy metals and toxic elements, pesticide residues and microbial limit ("the three basic safety tests"); about 1 600 were withdrawn by the applicants; and around 1 000 more were related to the failure of submission of the required registration documents and/or fulfilling the definition of pCm under section 2 of CMO.

6. Dr PAN Pey-chyou sought information on the reasons for withdrawal of applications for registration of pCms. ADH(TCM) advised that the Administration did not have such information, as the applicants had not been required to provide it.

7. Dr PAN Pey-chyou also pointed out that the pCm trade had repeatedly expressed concern about the low success rate of applications for registration of pCms. He queried whether the definition of pCm and the existing classification categories of pCms were too stringent. PAS(H)1 clarified that if a product did not fulfill the definition of pCm as stipulated in CMO, its registration as pCm under CMO was not required. The product could still be sold in Hong Kong as other products such as a pharmaceutical product or a health product if it fulfilled the relevant requirements.

8. Mr CHEUNG Kwok-che pointed out that the pCm trade had expressed concern about whether it was appropriate for the Chinese Medicine Board ("CMB"), established under the Chinese Medicine Council of Hong Kong, to assess the applications for registration of pCms from the perspective of Western medicine. He asked whether there were traditional Chinese medicine ("TCM") practitioners on CMB and whether CMB had gone through careful deliberation before rejecting any application.

9. ADH(TCM) advised that CMB mainly included representatives of the Chinese medicine trade, TCM practitioners, consumer representatives and public officers from the Government Laboratory and Innovation and Technology Commission. It had often communicated with the pCm trade and the registration applications of pCms would be assessed by professionals from various disciplines such as Chinese medicine practice, Chinese medicines and pharmacognosy, chemistry and so forth. All applications were then submitted to CMB for careful deliberation. CMB

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had informed failed applicants of the reasons for rejecting their applications. Failed applicants could re-apply if they could make up for what they had failed or apply for review of their applications, or they could ask for a meeting to seek clarifications.

Applications for review

10. Referring to Annex II to the Administration's paper, Mr CHAN Hak-kan asked why about half (i.e. 584) of the total number of applications for review (i.e. 1 209) were related to the failure of providing the three basic safety test reports. PAS(H)1 advised that pCm traders were only required to submit such reports for transitional registration of their pCms. The Administration had repeatedly reminded them to provide such reports but did not have detailed information on why some had failed to do so.

11. Referring to Annex II to the Administration's paper, the Chairman asked about the latest progress of the 612 applications which had applied for review and were being followed up by applicants, CMB or the Chinese Medicine Committee under CMB. ADH(TCM) advised that most of the 612 applications were related to the failure of providing the three basic safety test reports or the required quality specification, method and testing reports, etc. About half of these applications were reinstated after providing the required reports.

Classification categories of pCms

12. The Chairman noted from paragraph 7 of the Administration's paper that of the 16 990 applications for registration of pCms, 9 123 pCms had been granted a transitional registration status and only 134 pCms a formal registration status. He asked whether the 134 pCms were "Established medicines" which referred to, among others, an ancient prescription documented in Chinese medicines bibliography in or before the Qing dynasty or a modified ancient prescription which was based on an ancient prescription with reasonable and rational modifications, or "New medicines" which referred to, among others, a prescription comprising a newly discovered Chinese herb. ADH(TCM) advised that the 134 formally-registered pCms were all "Established medicines", with most of them being ancient prescriptions and some being modified ancient prescriptions.

13. The Chairman pointed out that many pCms had been sold in Hong Kong for decades but pCm traders had preferred to apply for transitional,

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instead of formal, registration of such pCms, as such pCms did not fulfill the standards of "Established medicines" defined by CMB and it was unrealistic for them to fulfill the standards of "New medicines". Under the mandatory registration requirements for pCms, should a pCm be classified by CMB as an "Established medicine", its application for formal registration would only be required to provide test reports on its safety and certain basic documents in respect of its safety, efficacy and quality, and would be exempted from providing various high-cost test reports on its efficacy and quality, as the pCm concerned had been authoritatively documented. On the other hand, should a pCm be classified as a "New medicine", its applications would need to provide test reports on the safety, efficacy and quality of the pCm concerned and the costs incurred would be as huge as those of providing scientific support to a new western medicine.

14. The Chairman further pointed out that the existing classification categories of pCms were not stipulated in CMO but determined by CMB, and therefore any alterations to such categories should not require legislative amendments. He called on the Administration and CMB to review the existing classification categories of pCms and in particular consider pCm traders' suggestion to formulate a new classification category known as "Empirical Formula" to accommodate pCms which might not fulfill the standards of "Established medicines" or "New medicines" but had been sold in Hong Kong for many years and empirically proved safe or harmless for use.

15. PAS(H)1 advised that if a pCm had been sold in Hong Kong for decades, it should be eligible for transitional registration and the trader concerned did not need to fulfill the standards of "Established medicines". It was difficult for CMB to grant a formal registration status to pCms when their safety, efficacy and quality had not been proved. The Administration did not have any plan at the moment to change the arrangement for transitional registration of pCms or prohibit the sale of transitionally-registered pCms.

16. ADH(TCM) also advised that CMB needed to assess the impact of a pCm under application on the health of its users in accordance with objective standards. The assessment of whether a pCm was an "Established medicine" would rely on the standards or evidence set out in the authoritative sources on traditional Chinese medicines. Under the classification category of "Established medicines", there were certain sub-categories, such as modified ancient prescriptions, which should allow sufficient flexibility for CMB to consider whether to grant a registration status to a pCm which did not fulfill the definition of an ancient

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prescription but had long been sold in Hong Kong. Nevertheless, for the "New medicines" category, before being granted a formal registration status, the pCm under application needed to go through vigorous scientific tests in terms of its safety, efficacy and quality.

Support for the pCm trade

17. Ms LI Fung-ying pointed out that many pCm traders, especially those manufacturing many kinds of pCms, had expressed worry about the high costs of providing the required test reports on the safety, efficacy and quality of each kind of pCms under application and the uncertainty over whether their applications for registration of pCms would succeed. She called on the Administration to enhance its support measures to facilitate the trade's compliance with the registration requirements, such as the provision of free laboratory test services for pCms which had not been registered. Dr Pan Pey-chyou shared a similar view and suggested that the Administration might provide financial assistance (such as loans) to the needy pCm traders. He recalled that the Administration had assisted small and medium-sized enterprises in securing loans from lending institutions for meeting business needs to tide over their liquidity problem during the financial crisis in previous years.

18. PAS(H)1 advised that it was incumbent upon the applicants to ensure and prove the safety, efficacy and/or quality of the pCms under application. The Administration was unable to do so for them, as the number of pCms involved would be huge and it was inappropriate to use public funding to directly subsidize individual trades or private companies. To protect public health, the Administration would not relax the registration requirements, such as the provision of reports on the three basic safety tests and acute toxicity tests, but had been providing technical support (such as guidelines on laboratory testing) for the trade.

19. In response to Ms LI Fung-ying's enquiry on whether the Administration had made reference to the implementation experiences of the regulatory regimes for pCms in jurisdictions outside Hong Kong, such as Taiwan and the Mainland, ADH(TCM) advised that the Administration had closely communicated with the relevant authorities in nearby jurisdictions and exchanged views with their experts. The Administration would exercise prudence in making reference to their regulatory regimes, which were different from Hong Kong's. For instance, pCm manufacturers on the Mainland were required to meet the Good Manufacturing Practice, while such a requirement was still non-binding in Hong Kong. In addition, the pCm registered in Hong Kong could not contain any western drug

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ingredients.

Requirements of label and package insert

20. The Chairman noted that under the Chinese Medicine Regulation, a pCm manufactured outside Hong Kong and re-exported through Hong Kong did not need a label setting out the required particulars on the outermost package of the pCm, while a pCm manufactured in Hong Kong for the purpose of exporting needed to have such a label. He queried why pCms manufactured in Hong Kong were subject to differential treatment, which had been providing convenience to pCm manufacturers outside Hong Kong but discouraging the manufacturing of pCms in Hong Kong. Mr WONG Ting-kwong added that the Administration had told the pCm trade that the differential treatment was intended to protect the reputation of pCm manufacturers in Hong Kong.

21. ADH(TCM) advised that a pCm manufactured outside and re-exported through Hong Kong did not need the required label as it was not sold in Hong Kong and had been subjected to the registration requirements, and monitoring of the drug regulatory authority, of the country of origin.

22. Noting from paragraph 16 of the Administration's paper that the Administration would review the implementation of the label and package insert requirements one year after their commencement on 1 December 2011, Ms LI Fung-ying suggested and members agreed that the review should be conducted three months instead of one year after the commencement of such requirements to facilitate early detection and rectification of problems arising from their implementation.

IV. Any other business

Next meeting and follow-up action

23. Members agreed that -

(a) the next meeting be held on Monday, 16 January 2012, at 10:45 am, to monitor the implementation progress of the label and package insert requirements;

(b) should the implementation of the requirements for mandatory registration of pCms and their label and package insert be

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smooth, the Subcommittee would conclude its work after the next meeting; and

(c) the Administration should report to the Panel on Health Services on the implementation progress of the aforesaid requirements at regular intervals after the conclusion of the Subcommittee's work.

24. There being no other business, the meeting ended at 5:49 pm.

Council Business Division 2
Legislative Council Secretariat
10 January 2012

Annex

Proceedings of the meeting of the Subcommittee on Registration of Proprietary Chinese Medicines on Tuesday, 22 November 2011, at 4:30 pm in Conference Room 2A of the Legislative Council Complex

Time marker	Speaker	Subject	Action required
000301 - 000338	Chairman Mr CHEUNG Kwok-che	Members' agreement that there was no need to re-elect a Chairman for the 2011-2012 session.	
000339 - 000403	Chairman	Confirmation of minutes [LC Paper No.: CB(2)302/11-12]	
000404 - 000947	Chairman Admin	The Administration's briefing on the latest progress of the registration of proprietary Chinese medicines ("pCms") and the preparation for the implementation of provisions relating to the requirements of label and package insert of pCms [LC Paper No. CB(2)349/11-12(01)].	
000948 - 001829	Chairman Admin Mr WONG Ting-kwong	The Chairman's concern about the differential requirements of label and package insert imposed on pCms manufactured in Hong Kong for the purpose of exporting and those manufactured outside, and re-exported through, Hong Kong.	
001830 - 002240	Chairman Mr CHAN Hak-kan Admin	Mr CHAN Hak-kan's concern about the progress of processing applications which had been rejected for registration of pCms but had applied for review and the reasons for applicants' failure to provide the three basic safety test reports on pCms under application.	
002241 - 002507	Chairman Admin	The Administration's advice on the latest progress of the 612 applications which had applied for review and were being followed up by applicants, the Chinese Medicine Board ("CMB") or the Chinese Medicine Committee under CMB.	
002508 - 002940	Chairman Admin	The Administration's response to the Chairman's view on the existing classification categories of pCms.	
002941 - 003755	Chairman Dr PAN Pey-chyou Admin	Dr PAN Pey-chyou's concern about the low success rate of applications for registration of pCms and the availability of assistance to rejected applicants.	

Time marker	Speaker	Subject	Action required
003756 - 005025	Chairman Mr CHEUNG Kwok-che Admin	The Administration's response to Mr CHEUNG Kwok-che's concern about the representation of traditional Chinese medicine practitioners on CMB, process of assessing the applications for registration of pCms and reasons for rejection.	
005026 - 010522	Chairman Ms LI Fung-ying Admin Dr PAN Pey-chyou	Concern of Ms LI Fung-ying and Dr PAN Pey-chyou about the availability of support for pCm traders in complying with the requirements for the registration of pCms. The Administration's response to Ms LI Fung-ying's suggestion to make reference to the implementation experiences of the regulatory regimes for pCms in jurisdictions outside Hong Kong.	
010523 - 011145	Chairman Admin	The Chairman's concern about the stringent requirements for registration of pCms classified by CMB as "New medicines" and problems relating to the existing classification categories of pCms.	
011146 - 011600	Chairman Mr CHEUNG Kwok-che Ms LI Fung-ying Mr Vincent FANG Kang	Date of next meeting and follow-up action	

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