立法會
Legislative Council

LC Paper No. CB(2)302/11-12
(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 Wednesday, 20 July 2011, at 10:45 am
in Conference Room B of the Legislative Council Building

Members present	:	Dr Hon LEUNG Ka-lau (Chairman) Hon CHEUNG Man-kwong Hon LI Fung-ying, SBS, JP Dr Hon Joseph LEE Kok-long, SBS, JP Hon CHAN Hak-kan Dr Hon PAN Pey-chyou
Members absent	:	Hon CHEUNG Kwok-che Hon Alan LEONG Kah-kit, SC
Public Officers attending	:	Item II Professor Gabriel M LEUNG, JP Secretary for Food and Health (Acting) Dr Ronald LAM Assistant Director of Health (Traditional Chinese Medicine) Mr Frank CHAN Senior Pharmacist (Traditional Chinese Medicine)

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		Miss Janny WUN Secretary of the Chinese Medicine Council
Clerk in attendance	**:**	Mr Thomas WONG Chief Council Secretary (2)2
Staff in attendance	**:**	Ms Alice LEUNG Senior Council Secretary (2) 2 Miss Emma CHEUNG Legislative Assistant (2)2

I. Confirmation of minutes

[LC Paper No. CB(2)2386/10-11]

The minutes of the meeting on 22 June 2011 were confirmed.

II. Meeting with the Administration

[LC Paper Nos. CB(2)2400/10-11(01), CB(2)2159/10-11(01) and CB(2)2346/10-11(01)]

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

3. Members generally considered that the Administration had not sufficiently addressed the concerns raised by the Chinese medicines trade ("the trade") at the meetings of the Panel on Health Services about the implementation of mandatory registration of proprietary Chinese medicines ("pCms").

Requirements for test results on pCms

4. Ms LI Fung-ying expressed concern about the high costs incurred from the requirements for proving the safety, efficacy and quality of pCms and the related complicated registration procedures. These requirements would eventually drive out small and medium-sized pCm traders (including manufacturers) from the market and stifle the development of Chinese medicines in Hong Kong. She called on the Administration to actively consider the trade's strong request for support measures to

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facilitate its compliance with the provisions relating to mandatory registration of pCms.

5. Dr PAN Pey-chyou opined that it was a financial burden for small and medium-sized pCm traders to fulfill the registration requirements for their pCms to pass the three basic safety tests of heavy metals and toxic elements, pesticide residues and microbial limit ("the three basic tests"). Noting that the Hong Kong Jockey Club Institute of Chinese Medicine ("HKJCICM") set up by the Government in partnership with the Hong Kong Jockey Club Charities Trust had supported research on Chinese medicine, including laboratory testing, he asked whether the Administration would discuss with HKJCICM the feasibility of providing laboratory testing services at a lower cost to such pCm traders.

6. Secretary for Food and Health (Acting) ("SFH(Ag)") responded that –

(a) the Administration understood the trade's difficulties in complying with the registration requirements. However, as the Chinese Medicine Ordinance (Cap. 549) ("CMO") had been enacted since 1999, pCm traders had the primary responsibility for ensuring the safety, efficacy and quality of their pCm products;

(b) the manufacturing cost of a pCm was not as huge as that of a western medicine. Fundamentally, when applying to the Chinese Medicine Board for transitional registration of pCm, the trade was only required to have pCms passed the three basic tests to prove their safety. Those traders which could manufacture many kinds of pCms should be big enterprises and able to finance the costs of the three basic tests for each kind of pCm. They had expressed support for the implementation of mandatory registration of pCms and label and package insert requirements. As at end of June 2011, 51 "Certificates of Registration of pCm" had been issued;

(c) the Administration's stance had all along been clear that it would be inappropriate to use public funding to directly subsidize private companies. The foremost difficulty for some pCm traders in complying with the registration requirements was not the cost for conducting the three basic tests, which totalled not more than $10,000, but the submission of documents on the manufacturing process of some pCms, as certain parts of the process, if disclosed,

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might not be acceptable to the public. The Administration would not relax the requirements for the three basic tests but was willing to provide technical support (such as information on laboratory testing) for the trade, especially small and medium-sized manufacturers, to facilitate their compliance with the registration requirements; and

(d) the regulatory experience on the Mainland showed that about one-fourth to one-third of pCm traders were forced to close down after the implementation of the mandatory regulatory regime of pCms. However, the registration requirements for pCms on the Mainland were more stringent than those in Hong Kong because pCm manufacturers on the Mainland had been required to meet the Good Manufacturing Practice. The Administration expected that the negative impact of the mandatory pCm registration system on the survival of the trade in Hong Kong would not be very significant.

7. Noting from the Administration that about 5 900 applications for registration of pCms had been rejected due to failure to furnish sufficient information and about 1 180 of the rejected cases had applied for review, Mr CHEUNG Man-kwong sought information on a breakdown of such rejected cases, such as the number of cases relating to failure to submit the three basic test reports and those relating to failure to provide information on the manufacturing process, to facilitate members' consideration of whether a special treatment could be provided to such cases.

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8. SFH(Ag) responded that the cost of the three basic tests should be affordable to small pCm traders. The Department of Health ("DH") had all along provided assistance to traders which had difficulty in submitting documents on the manufacturing process of pCms. The Administration noted a few cases in which local traders manufactured pCms in partnership with manufacturers on the Mainland but were unable to access the prescription and therefore could not provide sufficient information for registration of the pCms concerned in Hong Kong. As these cases might involve business disputes, the Administration would not intervene.

9. Noting that some ancient manufacturing methods of pCms might not be acceptable to people nowadays, Dr PAN Pey-chyou suggested that the Administration might consider requesting the trade/Chinese medicine practitioners ("CMPs") to submit the relevant documents to the Chinese Medicine Council of Hong Kong ("CMC") for record only without disclosure to the public.

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Classification of pCms and transparency of the registration system

10. The Chairman pointed out that the trade considered it necessary to test the safety of pCms and had been willing to comply with the requirements for the three basic tests. The trade's major difficulty was to prove the efficacy of pCms. Should a pCm be classified as an "Established medicine" (such as an ancient prescription documented in Chinese medicines bibliography in or before the Qing dynasty), its trader would be exempted from proving its efficacy, as it had been authoritatively documented. On the other hand, should a pCm be classified as a "New medicine", its trader would need to prove the efficacy of the pCm concerned and the cost incurred would be far higher than that of proving its safety. CMO did not set out the criteria for classifying various kinds of pCms. It instead empowered the Chinese Medicines Board ("CMB") under CMC to determine whether a pCm should be classified as an "Established medicine" or a "New medicine".

11. Noting from the Administration that the 51 "Certificates of Registration of pCm" were all issued to pCms formulated according to ancient prescriptions (which fell under the "Established medicines" category), the Chairman pointed out that the trade had expressed concern about the lack of transparency and objectivity in assessing and determining whether a pCm was formulated according to an ancient prescription. The trade was worried that while certain pCms had been sold on the market for dozens of years, regarded by their manufacturers as ancient prescriptions and registered under the transitional registration system, their applications for formal registration might be rejected by CMB on the grounds that such pCms were not ancient prescriptions and their safety, efficacy and quality should be supported by scientific proof. The trade also raised concern about whether the members of CMB, who were all appointed by the Government, could reflect the trade's views comprehensively and the impact of mandatory registration of pCms on the trade.

12. Ms LI Fung-ying and Mr CHEUNG Man-kwong also opined that CMB should enhance its transparency, such as disclosing in detail the conditions under which a pCm was classified.

13. SFH(Ag) responded that –

(a) CMB determined the classification of a pCm based on the information from the applicant. It was an independent statutory body and was not under the influence of DH's

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Chinese Medicine Division, which was responsible for providing administrative support for CMB, among others, and implementing the regulatory measures;

(b) the Administration did not have any plan to change the arrangement for transitional registration of pCms or disallow the sale of transitionally-registered pCms on the market after a specified date. Irrespective of whether pCms were transitionally or formally registered, they could continue to be sold in Hong Kong; and

(c) the Administration had attached importance to the transparency of the registration system of pCms. To assist the trade in applying for registration of pCms, CMB had issued a code of practice including information on the conditions under which a pCm would be classified. He undertook to provide a copy of the code of practice for members' reference.

Admin

14. Noting from the Administration that of the 1 180 rejected cases which had applied for review under section 140 of CMO, 1 030 had been considered by CMB, Dr Joseph LEE sought information on (a) the major points of contention raised by the aforesaid 1 180 cases; (b) the outcomes of the aforesaid 1030 cases; and (c) the major points of contention raised by the remaining rejected cases which had applied for review but had not been considered.

Admin

Proof of pCms' origin of country

15. Dr PAN Pey-chyou and Ms LI Fung-ying noted that if a pCm was not manufactured in Hong Kong, the applicant applying for registration of the pCm would be required to submit a certified true copy of (a) the production permit or the manufacturer's licence of the pCm's manufacturer, and (b) the free sale certificate or certificate of registration of the pCm, issued by the drug regulatory authority of the country of origin. They expressed concern that as some pCm traders and CMP might only involve in the procurement of pCms, they might not be able to provide such documentary proof. SFH(Ag) advised that pCm traders had the corporate responsibility to provide documents on the country of origin of the pCms imported by them to facilitate CMC to trace their source for the protection of public health.

16. The Chairman expressed concern about the high costs borne by pCm traders if they needed to provide the country of origin of each kind of

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pCm imported by them. SFH(Ag) advised that as small and medium-sized pCm traders generally did not import many kinds of pCms, the cost of meeting the relevant requirements should be affordable.

Transitional registration of pCms

17. Members generally opined that the existing transitional registration arrangement for pCms should remain unchanged for a certain period, as its early withdrawal would not be conducive to the development of the trade. SFH(Ag) responded in the affirmative.

18. Dr PAN Pey-chyou asked whether the transitional registration status of a pCm would remain valid if the application for its formal registration was rejected. SFH(Ag) responded in the negative. Dr Joseph LEE and Mr CHEUNG Man-kwong shared SFH(Ag)'s view. Mr CHEUNG Man-kwong further considered that should a pCm with a formal registration status fail to fulfil the registration requirements, it should not be allowed to apply for transitional registration.

19. Mr CHEUNG Man-kwong called on the Administration to ensure that the reasons for rejecting the applications should be provided to the applicants, and an independent appeal mechanism should be put in place to handle appeals by failed applicants. SFH(Ag) responded in the affirmative and shared Mr CHEUNG Man-kwong's view that there should be clear standards for the safety of pCms, including requirements for the basic tests of their safety, information on their manufacturing process and exemption criteria.

20. Dr PAN Pey-chyou asked whether a transitionally-registered pCm could continue to be sold if its efficacy was not scientifically proven but it had been proved harmless for use. SFH(Ag) advised that only applications for formal registration of pCms had to include product safety, efficacy and quality documents. The Bills Committee scrutinizing the Chinese Medicine Bill had discussed this issue and considered that if the efficacy of a pCm could not be proved and the pCm was harmless, they should be treated as health products and could be sold on the market as long as they did not make any health claims. Dr Joseph LEE opined that pCm traders should not apply for formal registration of pCms if their efficacy had not been proved.

21. Mr CHEUNG Man-kwong called on the Administration to balance the development of the trade and the protection of public health, and continue to exercise vigilance in monitoring the sale of pCms (especially

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those popularly sold).

Exemptions from registration

22. Members shared concerns about the enforcement of section 119 of CMO under which no person should sell, import or possess any pCm unless the pCm was registered under section 121 of CMO. The Chairman and Dr Joseph LEE sought clarification on whether a CMP would commit an offence if he supplied or administered a non-registered pCm to his patients. Dr Joseph LEE also sought information on the enforcement of mandatory registration of pCms and the Administration's measures to help the trade familiarize with the registration requirements and exemptions.

23. Assistant Director of Health (Traditional Chinese Medicine) advised that the Administration had all along communicated with CMPs on pCms exempted from registration and respected CMPs' professional judgments about the administration of medicines to their patients. Under section 158(6) of CMO, an exemption from registration was given to a pCm compounded by or under the supervision of a registered or listed CMP at the premises where the CMP practised if and only if the pCm was used for the purpose of administering or supplying to a patient under his direct care. He elaborated that a CMP would not commit an offence if he imported Chinese herbs or Chinese medicine granules/compounds, used them to formulate a pCm and administered and supplied it to his patients, as the pCm concerned was exempted from registration. However, a CMP would commit an offence if he imported a pCm which was not registered in Hong Kong from other places for sale. The Administration had organized briefing seminars for, and issued letters to, trade associations and stakeholders on statutory registration requirements and exemptions. Enforcement action would be taken against CMPs who had administered unqualified pCms to patients.

Possession of unregistered pCms

24. The Chairman raised concern that members of the public might easily or inadvertently contravene section 119 of CMO under which no person shall possess, among others, any pCm that had not been registered in Hong Kong. SFH(Ag) advised that CMO did not empower DH's Chinese Medicine Division to enter a private flat to search unregistered pCms. CMO had already been implemented for quite some time and did not cause public nuisance. The Administration had not seen any serious problems with the enforcement of the provision against the possession of unregistered pCms.

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25. Dr Joseph LEE considered the provisions of CMO in relation to the possession of unregistered pCms acceptable, as they did not confer power on the Administration to enter and inspect private homes and clearly stated that members of the public should not purchase and possess pCms that had not been registered in Hong Kong. Mr CHEUNG Man-kwong was of the view that in enforcing the law, the Administration should have regard to the nature and severity of the violation of the law.

26. Members in general concurred with the Chairman's view that to prevent the public from inadvertently violating the law by purchasing unregistered pCms, the definition of "possession of pCms" should be confined to possession of pCms for the purpose of sale.

III. Any other business

Next meeting

27. Members agreed that the Subcommittee would hold its next meeting in the 2011-2012 session. The Clerk would liaise with the Administration and consult the Chairman on the date for the next meeting.

28. There being no other business, the meeting ended at 12:35 pm.

Council Business Division 2
Legislative Council Secretariat
14 November 2011

Annex

Proceedings of the meeting of the Subcommittee on Registration of Proprietary Chinese Medicines on Wednesday, 20 July 2011, at 10:45 am in Conference Room B of the Legislative Council Building

Time marker	Speaker	Subject	Action required
000000 -	Chairman	Confirmation of minutes [LC Paper No.: CB(2)2386/10-11]	
000225 - 000641	Chairman Admin	Briefing on the progress of the registration of Proprietary Chinese Medicines ("pCms") and the Administration's publicity programmes in preparation for the commencement of the provisions related to the requirements of label and package insert [LC Paper No.: CB(2)2400/10-11(01)].	
000642 - 001457	Chairman Ms LI Fung-ying Admin	Ms LI Fung-ying's concern about the trade's difficulties in complying with the requirements for the registration of pCms and monopolization of the market by large pCm manufacturers.	
001458 - 002437	Chairman Admin	The Chairman's concern about the criteria for classifying a pCm as an "Established medicine" or a "New medicine".	
002438 - 003439	Chairman Mr PAN pey-chyou Admin	The Administration's view on using public funds to directly subsidize pCm traders and the cost for conducting the three basic safety tests for pCms.	
003440 - 004516	Chairman Mr CHEUNG Man-kwong Admin	Mr CHEUNG Man-kwong's request for the Administration to provide a breakdown of the rejected applications for registration of pCms, such as the number of cases relating to failure to submit the three basic safety test reports and those relating to failure to provide information on the manufacturing process.	Admin to provide the requested information (paragraph 7 of the minutes)
004517 - 005621	Chairman Dr Joseph LEE Admin	The Administration's undertaking to provide a written response to Dr Joseph LEE's request for information on the rejected applications for registration of pCms stated in paragraph 8 of the Administration's paper. The Administration's advice on exemptions given to pCms administered or supplied by Chinese Medicines Practitioners ("CMPs") to their patients.	Admin to provide the requested information (paragraph 14 of the minutes)

Time marker	Speaker	Subject	Action required
005622 - 010403	Chairman Ms LI Fung-ying Admin	Ms LI Fung-ying's concern about the difficulties of Chinese medicine traders in providing information on the origin of country of pCms or Chinese herbal medicines imported/procured by them.	
010404 - 011314	Chairman Admin	The Administration's response to the Chairman's concern about the transitional registration of pCms and pCms with the "Certificate of Registration of pCm".	
011315 - 012852	Chairman Mr PAN pey-chyou Admin Dr Joseph LEE	The Administration's response to the views of Dr PAN pey-chyou and Dr Joseph LEE on the transitional registration status of pCms.	
012853 - 013823	Chairman Mr CHEUNG Man-kwong Ms LI Fung-ying Admin	Views of Mr CHEUNG Man-kwong and Ms LI Fung-ying on various aspects of the implementation of mandatory registration of pCms, including the safety of pCms, transparency and fairness of the registration system, transitional registration arrangement for pCms and market surveillance of their sale. The Administration's undertaking to provide a copy of the code of practice on the requirements for registration of pCms.	Admin's undertaking to provide the requested document (paragraph 13(c) of the minutes)
013824 - 014919	Chairman Admin Dr Joseph LEE Mr CHEUNG Man-kwong	Members' view on issues relating to the definition of "possession of pCms" under the Chinese Medicine Ordinance (Cap. 549)	
014920 - 014959	Chairman	Date of next meeting	

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