立法會
Legislative Council

LC Paper No. CB(2)1088/11-12
(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 Monday, 16 January 2012, at 10:45 am
in Conference Room 2A of the Legislative Council Complex

Members present	:	Dr Hon LEUNG Ka-lau (Chairman) Hon CHEUNG Man-kwong 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
Member absent	:	Hon LI Fung-ying, SBS, JP
Public Officers attending	:	Item II 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. Confirmation of minutes
[LC Paper No. CB(2)779/11-12]

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

II. Progress of the implementation of provisions relating to the requirements of label and package inserts of proprietary Chinese medicines
[LC Paper No. CB(2)795/11-12(01)]

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

3. Principal Assistant Secretary for Food & Health (Health)1 ("PAS(H)1") updated members on the implementation progress of the relevant provisions relating to the requirements of label and package insert of proprietary Chinese medicines ("pCms") after their commencement on 1 December 2011.

Non-compliant cases

4. Noting from paragraph 8 of the Administration's paper that 64 non-compliant cases had been found since the commencement of the label and package insert requirements, the Chairman sought information on the number of non-compliant cases which had been rectified, whether the pCms in question had been permitted to be re-sold on the market and the time required for the Department of Health ("DH") to process and approve

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applications for the re-selling of pCms with the rectified label and package insert. He hoped that DH would not take too long to process such applications. Assistant Director of Health (Traditional Chinese Medicine) ("ADH(TCM)") advised that provided the applicants had furnished all the necessary and appropriate documents, DH could complete processing such applications within a week. Up to 13 January 2012, of the 64 non-compliant cases, nine had been rectified by the traders concerned, submitted to DH for approval and subsequently allowed to be put on sale again.

5. Mr Vincent FANG considered that a pCm trader would suffer a significant loss if its pCm was removed from sale immediately after it was found non-compliant. He considered that as DH and the trader concerned might hold different views on whether the label and package insert of the pCm in question was compliant or not, it might be more appropriate for DH to discuss the case with the trader concerned before deciding whether to order immediate removal of the pCm in question from sale.

6. ADH(TCM) advised that the traders had been kept informed of the statutory requirements. Before commencement of the relevant requirements, holders of pCm registrations had also been issued with letters and informed of the label and package insert information of the pCm concerned for verification. Therefore, traders of non-compliant products should not dispute the reasons of non-compliance. The warning letters issued to the traders concerned also set out the problems that needed to be rectified. The 64 non-compliant cases mainly involved pCms already on sale for some time. In general, the implementation of the statutory requirements had been smooth. DH had conducted surveillance on the label and package inserts of pCms based on the detailed information provided by pCm applicants during the registration process, such as major ingredients, dosage and method of usage. The Administration considered it appropriate to order immediate removal of non-compliant pCms from sale, so that the public would not be misled by the incorrect or incomplete information on the label and package inserts of such pCms.

7. In response to the Chairman's enquiry on whether the whole lot of a pCm would be removed from sale if an individual batch of it was found non-compliant, ADH(TCM) advised that only the non-compliant batch of pCms would be removed from sale.

8. Noting from paragraph 7 of the Administration's paper that the Administration would require pCm traders to cease selling non-compliant pCms and issue a warning letter to them, provided that no hazard to public

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health would be caused, Mr WONG Ting-kwong sought clarification on whether this was the Administration's policy towards persons who failed to comply for the first time and whether repeat offenders would be prosecuted. In his view, the risk of repeated offences was high, as the quality of Chinese herbs might be subject to climate or seasonal changes and the functions of the pCms concerned might not meet the health claims stated in their label and package inserts.

9. ADH(TCM) advised that each non-compliant case should be considered on its own facts and merits on a case-by-case basis. If a pCm was found non-compliant for the first time but the offence involved was serious, such as causing hazard to public health, DH would consult the Department of Justice ("DoJ") on whether immediate prosecution should be instituted.

10. In response to Mr Vincent FANG's enquiry on whether pCms manufactured before the commencement of the label and package insert requirements could continue to be sold on the market if they were replaced with the rectified label and package insert, PAS(H)1 answered in the affirmative.

Liability for non-compliance

11. In response to the enquiry of Mr WONG Ting-kwong and Dr Joseph LEE on the liability of the holder of the pCm registration certificate, retailers, wholesalers and importers if the pCm they sold, distributed or imported was found non-compliant, ADH(TCM) advised that the warning letter was issued to the registration certificate holder, who had to be informed of the label and package insert in question. However, as the entire supply chain of a pCm was complicated and involved various parties, whether persons other than the registration certificate holder would be held liable for non-compliance would depend on investigation findings and the advice of DoJ.

12. Mr WONG Ting-kwong expressed concern that retailers might be supplied with counterfeit pCms and put them on sale unknowingly. Mr WONG and Mr Vincent FANG considered that the retailers concerned should not be held liable for the sale of such pCms if they could produce the documentary proof that such pCms had been provided by their suppliers. The Administration should make reference to the similar arrangements for the sale of food and copyrighted products.

13. PAS(H)1 advised that any person who sold counterfeit pCms might

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commit other offences in addition to violation of label and package insert requirements. DH would carefully examine the liability of various parties involved in a non-compliant case and DoJ's advice would be sought if necessary. ADH(TCM) advised that the relevant provisions relating to the label and package insert requirements did not contain any immunity provision. He reiterated that whether a retailer or wholesaler had liability would depend on the facts and merits of a non-compliant case. The guidelines issued by the Chinese Medicines Board under the Chinese Medicine Council of Hong Kong ("CMC") established under the Chinese Medicine Ordinance (Cap. 549) ("CMO") on labels and package inserts of pCms had emphasized that retailers and wholesalers should procure pCms from reputable and reliable suppliers.

14. Dr Joseph LEE sought clarification on whether retailers and wholesalers were obliged to check whether a pCm was in compliance with the label and package insert requirements before putting the pCm concerned on sale. ADH(TCM) advised that the relevant provisions stipulated that no person might sell, or had in his possession for the purpose of selling, any pCm unless the package of the pCm was labelled in the prescribed manner and with a package insert which complied with the prescribed requirements. DH had conducted briefings for various Chinese medicine trade associations to explain the label and package insert requirements. Relevant information leaflets had been distributed to their members. Retailers and wholesalers had been advised to check the basic information on a pCm with their suppliers before putting it on sale. They had also been informed that detailed information on each pCm under registration application was available at CMC's website.

15. Mr Vincent FANG considered that given the large number of pCms, it was impractical for retailers and wholesalers to check the label and package insert of each pCm against its registration information at CMC's website before putting it on sale. ADH(TCM) advised that in addition to checking the information on pCms, retailers and wholesalers could also obtain a documentary proof from their suppliers that the label and package inserts of the pCms provided by them were in compliance with the statutory requirements. The information of registered pCms on CMC's website could serve as a supplementary source of information for reference by retailers and wholesalers.

16. Mr WONG Ting-kwong, Dr Joseph LEE, Mr Vincent FANG and the Chairman called on the Administration to maintain close communication with the pCm trade on the liability that might be borne by various parties in the sale of non-compliant pCms and consider stipulating

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such liability in the relevant guidelines clearly. The Chairman also called on the Administration to consider providing immunity in relation to the unknowing sale of non-compliant pCms.

Progress of registration of pCms

17. The Chairman sought information on the latest number of pCms which had been granted a formal registration status and the number of registration applications under the "New medicines" category which were being processed. ADH(TCM) advised that up to mid-January 2012, a total of 188 pCms had been granted a formal registration status, and around 10 more applications for registration under the "New medicines" category were being processed.

III. Any other business

Conclusion of the Subcommittee's work

18. Members agreed that –

(a) the Subcommittee should conclude its work and a report on its deliberations would be prepared and circulated to members for comments before its submission to the Panel on Health Services ("the Panel") for consideration at its regular meeting scheduled for 13 February 2012; and

(b) the Administration should report to the Panel on the implementation progress of the requirements for mandatory registration of pCms and their label and package inserts at regular intervals after the conclusion of the Subcommittee's work.

19. There being no other business, the meeting ended at 11:46 am.

Council Business Division 2
Legislative Council Secretariat
15 February 2012

Annex

Proceedings of the meeting of the Subcommittee on Registration of Proprietary Chinese Medicines on Monday, 16 January 2012, at 10:45 am in Conference Room 2A of the Legislative Council Complex

Time marker	Speaker	Subject	Action required
000121 - 000154	Chairman	Confirmation of minutes [LC Paper No.: CB(2)779/11-12]	
000155 - 000557	Chairman Admin	The Administration's briefing on the implementation progress of the relevant provisions relating to the requirements of label and package insert of proprietary Chinese medicines ("pCms") after their commencement on 1 December 2011 [LC Paper No. CB(2)795/11-12(01)].	
000558 - 001021	Chairman Admin	The Administration's information on the number of non-compliant cases which had been rectified, whether the pCms concerned had been permitted to be re-sold on the market and the time required for the Department of Health ("DH") to process and approve applications for the re-selling of pCms with the rectified label and package insert.	
001022 - 001450	Chairman Mr Vincent FANG Admin	Mr Vincent FANG's concern about the immediate removal of pCms from sale after they were found non-compliant.	
001451 - 002423	Chairman Mr WONG Ting-kwong Admin	Mr WONG Ting-kwong's concern about – (a) the Administration's policy towards persons who failed to comply with the label and package insert requirements for the first time and repeat offenders; (b) the liability of the holder of the pCm registration certificate, retailers, wholesalers and importers if the pCm they sold, distributed or imported was found non-compliant; and (c) the liability of retailers who were supplied with counterfeit pCms and put them on sale unknowingly.	

Time marker	Speaker	Subject	Action required
002424 - 003445	Chairman Dr Joesph LEE Admin	Dr Joseph LEE's concern about the obligation of retailers to check and ensure the compliance of a pCm with the label and package insert requirements before they put the pCm concerned on sale.	
003446 - 004921	Chairman Mr WONG Ting-kwong Mr Vincent FANG Admin	Views of Mr WONG Ting-kwong and Mr Vincent FANG that retailers should not be held liable for the unknowing sale of non-compliant pCms if they could produce documentary proof that such pCms had been provided by their suppliers. The Chairman's suggestion to provide an immunity provision in the Chinese Medicine Ordinance (Cap. 549) in relation to the unknowing sale of non-compliant pCms.	
004922 - 005500	Chairman Mr Vincent FANG Admin	The Administration's response to Mr Vincent FANG's concern about – (a) whether pCms manufactured before the commencement of the label and package insert requirements could continue to be sold on the market if they were replaced with the rectified label and package insert; and (b) whether DH would exercise flexibility in handling non-compliant cases which caused no hazard to public health.	
005501 - 005908	Chairman Mr WONG Ting-kwong Admin	Mr WONG Ting-kwong's view on granting immunity to retailers from the liability for unknowing sale of non-complaint pCms if they could produce documentary proof that such pCms had been provided by their suppliers.	
005909 - 005937	Chairman Admin	The Administration's response to the Chairman's concern about whether the whole lot of a pCm would be required to be removed from sale if an individual batch of it was found non-compliant with the label and package insert requirements.	
005938 - 010036	Chairman Admin	The Administration's information on the latest number of pCms which had been granted a formal registration status and the number of applications under the "New medicine" category which were being processed.	

010037 - 010231	Chairman Mr Vincent FANG	Members' agreement that the Subcommittee should conclude its work and a report would be prepared and circulated to members for comments before its submission to the Panel on Health Services for consideration at its regular meeting scheduled for 13 February 2012.	

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