

Ref : CB2/SS/1/03

LC Paper No. CB(2) 869/03-04 (These minutes have been seen by the Administration)

Subcommittee on Commencement Notices under the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese Medicines Regulation

Minutes of meeting held on Tuesday, 2 December 2003 at 1 pm in Conference Room A of the Legislative Council Building

Members : present		Hon Cyd HO Sau-lan (Chairman) Hon Margaret NG Hon Mrs Selina CHOW LIANG Shuk-yee, GBS, JP Hon LEUNG Yiu-chung Hon Ambrose LAU Hon-chuen, GBS, JP Hon LI Fung-ying, JP Dr Hon LO Wing-lok, JP	
Members : Absent		Hon Michael MAK Kwok-fung Hon Audrey EU Yuet-mee, SC, JP	
Public officers : attending		Mr Thomas YIU Deputy Secretary for Health, Welfare and Food	
		Miss Angela LUK Principal Assistant Secretary for Health, Welfare and Food	
		Dr T H LEUNG Deputy Director of Health	
		Dr Constance CHAN Assistant Director of Health	
		Ms Pamela LI Acting Senior Pharmacist (Traditional Chinese Medicine) Department of Health	

		Mr Freely CHENG Assistant Secretary for Health, Welfare and Food Miss Miranda NG Senior Assistant Law Draftsman Department of Justice
Clerk in attendance	:	Mrs Constance LI Chief Assistant Secretary (2)5
Staff in : attendance		Miss Monna LAI Assistant Legal Adviser 7
		Miss Lolita SHEK Senior Assistant Secretary (2)7

Action

I Meeting with the Administration

[LC Paper Nos. CB(2) 458/03-04(04) & (05), CB(2) 513/03-04(01), and CB(2) 536/03-04(01) to (03)]

The Subcommittee deliberated (Index of proceedings attached at Annex).

2. The Administration briefed members on its response to issues and concerns raised at previous meetings [LC Paper No. CB(2) 458/03-04(04)], and the further information requested by members at the meeting on 10 November 2003 [LC Paper No. CB(2) 458/03-04(05)].

3. <u>The Administration</u> informed members that after listening to the deputations' views at the Subcommittee meeting on 28 November 2003, the Administration had held a further meeting with the trade to discuss their concerns. Twelve deputations that had given views to the Subcommittee attended that meeting and supported that the registration system for proprietary Chinese medicines (PCMs) should commence on 19 December 2003 to safeguard public health. The Application Handbook for Registration of Proprietary Chinese Medicines had also been agreed to by the trade.

4. <u>The Chairman, Miss Margaret NG and Mr LEUNG Yiu-chung</u> maintained the view that the registration system for PCMs should only commence after the following concerns had been fully addressed -

(a) the representativeness of members appointed to the Chinese Medicine Council and its Boards and Committees, and the system on avoidance of conflict of interest in the assessment of applications for registrations;

- (b) the objectivity and transparency of the system to assess applications for registration of PCMs;
- (c) the availability of an independent appeal channel for applicants who were aggrieved with the decision of the Chinese Medicine Council on their appeals against the decision(s) of the Boards/Committees, without having to appeal to the court;
- (d) the need for the trade's concerns about the implementation details to be fully reflected to the Administration and the Chinese Medicines Board; and
- (e) the availability of sufficient laboratory support and the final version of the Application Handbook for Registration of Proprietary Chinese Medicines to the trade.
- 5. <u>Mrs Selina CHOW</u> pointed out that -
 - (a) the composition of the Chinese Medicine Council and its Boards and Committees reflected the outcome of deliberations of the Legislative Council (LegCo) and the demand from the Chinese medicines trade for due representation in these bodies. The representativeness of these trade members was widely recognised by the trade, and they represented the interests of their organisations and the trade and not their personal interests;
 - (b) laboratory support in the Mainland was necessary to facilitate early implementation of the PCM registration to safeguard public health; and
 - (c) the Administration had addressed the concerns of the trade which had re-affirmed its support of the commencement of the registration of PCMs on 19 December 2003.

6. <u>Mr Ambrose LAU and Dr LO Wing-lok</u> said that they supported the commencement of the registration of PCMs on 19 December 2003 in order to safeguard public health.

- 7. <u>The Administration gave the following response to issues raised by members -</u>
 - (a) the composition of the Chinese Medicine Council and its Boards and Committees was stipulated in the Chinese Medicine Ordinance. Their structure and composition were in line with the principle of selfregulation by the trade and fully reflected the outcome of LegCo deliberations leading to the enactment of the Ordinance. The composition of the Chinese Medicines Board was well balanced, and the

Director of Health being a public officer and also the Board Chairman would attend meetings of LegCo Committee(s) to answer Members' questions on the registration of PCMs where necessary;

- (b) registered PCMs were subject to regulation under the Chinese Medicine Ordinance and health claims would be regulated through the Undesirable Medical Advertisements Ordinance; and
- (c) the final version of the Application Handbook for Registration of Proprietary Chinese Medicines would be ready for distribution when the registration of PCMs commenced on 19 December 2003.
- Admin 8. <u>The Subcommittee</u> requested the Administration to provide further information on the following -
 - (a) the qualifications (i.e. academic/professional qualifications and public service records) of members of the Chinese Medicine Council and its Boards and Committees, and the representativeness of the organisations to which these members belonged;
 - (b) the system for review of the performance of these members;
 - (c) the system for declaration of interests by these members, if any, and measures to prevent conflict of interest of these members;
 - (d) regulatory system of western medicines/pharmaceutical products;
 - (e) a list of the experts in Chinese medicines from whom the Chinese Medicines Board would seek advice in assessing the applications for registration of proprietary Chinese medicines, and the criteria for selecting these experts; and
 - (f) the final version of the Application Handbook for Registration of Proprietary Chinese Medicines.
- Admin 9. <u>The Administration</u> was also requested to provide a written response to the concerns raised by members at this meeting and at the meeting on 10 November 2003.

II. Any other business

10. <u>Members</u> agreed to hold the next meeting on Friday, 5 December 2003 immediately after the House Committee meeting to discuss outstanding issues with the Administration.

11. There being no other business, the meeting ended at 3 pm.

Council Business Division 2 Legislative Council Secretariat 5 January 2004

Subcommittee on Commencement Notices under the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese Medicines Regulation

Meeting on Tuesday, 2 December 2003 at 1 pm in Conference Room A of the Legislative Council Building

Time marker	Speaker	Subject	Action Required	
0001-0357	Chairman	Papers to be discussed at the meeting		
0358-2213	Administration Chairman	Introduction of the papers provided by the Administration [LC Paper Nos. CB(2) 458/03- 04(04)&(05), and CB(2)536/03- 04(03)] Meeting between the		
		Administration and the trade on 1 December 2003		
2214-4605	Miss Margaret NG Administration Chairman Mrs Selina CHOW	Appointment of members to the Chinese Medicine Council and its Boards/Committees and their representativeness		
		System on avoidance of conflict of interest in the assessment of applications for registration of Proprietary Chinese Medicines (PCMs)		
4606-5238	Ms LI Fung-ying Administration Chairman	Laboratory support for the trade		
5239-5736	Ms LI Fung-ying Administration Chairman	Concerns expressed by the trade about the implementation of the registration system for PCMs		
5737-011014	Mr LEUNG Yiu-chung Administration	Objectivity and transparency of the system to assess applications for registration of PCMs		

011015-013244	Chairman Miss Margaret NG	Availability of an independent appeal channel for applicants who were aggrieved with the decision of the Chinese Medicine Council on their appeals against the decision(s) of the Boards/Committees, without having to appeal to the court Availability of sufficient laboratory support for the trade Objectivity and transparency of the system to assess applications	
	Administration Mrs Selina CHOW	for registration of PCMs Laboratory support for the trade	information
013245-013910	Mr Ambrose LAU Dr LO Wing-lok Administration	Implementation of the registration for PCMs on 19 December 2003 as scheduled	
013911-014558	Miss Margaret NG Administration	Qualifications of members of the Chinese Medicine Council and its Boards/Committees List of experts in Chinese medicines from whom advice would be sought in the vetting of applications for registration of PCMs	additional information
014559-015648	Chairman Administration Mr LEUNG Yiu-chung Miss Margaret NG	Consultation with the trade on the implementation details of the registration system for PCMs Final version of the Application Handbook for registration of Proprietary Chinese Medicines	the Handbook and a response to the concerns raised by
015649-015908	Chairman	Date of next meeting	

Council Business Division 2 Legislative Council Secretariat 5 January 2004