立法會
Legislative Council

LC Paper No. CB(2)499/99-00
(These minutes have been
seen by the Administration)

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Bills Committee on Chinese Medicine Bill

Minutes of meeting
held on Monday, 26 April 1999 at 2:30 pm
in Conference Room A of the Legislative Council Building

Members Present	:	Prof Hon NG Ching-fai (Chairman) Hon David CHU Yu-lin Hon Michael HO Mun-ka Hon LEE Kai-ming, JP Hon LUI Ming-wah, JP Hon Mrs Selina CHOW LIANG Shuk-yee, JP Hon Ronald ARCULLI, JP Hon CHAN Yuen-han Dr Hon LEONG Che-hung, JP Dr Hon Philip WONG Yu-hong Hon YEUNG Yiu-chung Hon Ambrose LAU Hon-chuen, JP Hon SZETO Wah
Members Absent	:	Hon HO Sai-chu, JP Hon Cyd HO Sau-lan Dr Hon TANG Siu-tong, JP Hon CHOY So-yuk Hon LAW Chi-kwong, JP
Public Officers Attending	:	Mr Gregory LEUNG Wing-lup, JP Deputy Secretary for Health and Welfare 1 Miss Eliza YAU Principal Assistant Secretary for Health and Welfare (Medical) 1

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		Miss Miranda NG Senior Assistant Law Draftsman, Department of Justice
		Dr LEUNG Ting-hung Assistant Director of Health (Traditional Chinese Medicine)
Attendance by Invitation	:	Hong Kong Chinese Herbalists Association
		Mr HO Ka-cheong
		The Hong Kong Medicine Dealers' Guild
		Mr Wong Ying-lau
		Mr Wong Kai-cheong
		Hong Kong Chinese Patent Medicine Manufacturers' Association
		Mr CHAN Yin
		Mr WEI Chi-hua
		Mr LUI Wai-keung
		Mr LAU Wing-ki
		Mr LAM Yu-kee
Clerk in Attendance	:	Ms Doris CHAN Chief Assistant Secretary (2) 4
Staff in Attendance	:	Mr LEE Yu-sung Senior Assistant Legal Adviser
		Ms Joanne MAK Senior Assistant Secretary (2) 4

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I. Meeting with deputations

The Chairman welcomed the deputations to the meeting.

Hong Kong Chinese Herbalists Association
(LC Paper No. CB(2)1635/98-99 (01))

2. Mr HO Ka-cheong of the Hong Kong Chinese Herbalists Association outlined the salient points of the Association's submission. He said that the Association supported the Bill and considered that all Chinese medicine practitioners should be required to undertake continuous education in Chinese medicine to keep abreast of its new developments.

The Hong Kong Medicine Dealers' Guild
(LC Paper No. CB(2)1778/98-99 (01))

3. Mr Wong Kai-cheong of the Hong Kong Medicine Dealers' Guild briefed members on the following proposals on behalf of the Guild as set out in its submission -

(a) There should be more representatives from the manufacturing group to sit on the Chinese Medicines Board;

(b) Under the retail licensing requirement (clause 114), there should be at least two instead of one deputy for shops which engaged in both wholesale and retail sale of Chinese medicines in order to meet operational needs. The Guild suggested that there should not be any specific requirements in respect of the qualifications of the person to be responsible for the supervision of the dispensing of Chinese herbal medicines. It took the view that the person should just be one designated by the licence holder of the retail shop concerned;

(c) Under the licensing requirement (clause 132) for manufacturers, the person to be responsible for the supervision of the manufacture of proprietary Chinese medicines should be one who was familiar with the operation of the factory concerned with at least five years' working experience at the factory. In addition, the number of deputy required should be two instead of one;

(d) The meaning of "public interest" in clause 125 leading to "de-registration of proprietary Chinese medicines" should be clarified; and

(e) Clinical trials / medicinal tests mentioned in clause 129 should be required only for the proprietary Chinese medicines containing the scheduled potent Chinese medicines.

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Hong Kong Chinese Patent Medicine Manufacturers' Association
(LC Paper No. CB(2)1778/98-99(02))

4. Mr WEI Chi-hua of the Hong Kong Chinese Patent Medicine Manufacturers' Association made the following suggestions -

(a) There should be more representatives from the manufacturing group to sit on the Chinese Medicines Council (CMC) and the boards and committees established under the CMC;

(b) In respect of clause 132(1)(b)(ii), the number of deputy required should be revised to be " at least one"; and

(c) The Association was concerned as to whether or not all proprietary Chinese medicines would be required to undergo clinical trial / animal tests in the future.

5. Referring to clause 132(1), Mr WONG and Mr WEI requested the Administration to clarify whether the person to be responsible for supervising the manufacture of proprietary Chinese medicines had to be someone who must be stationed at the factory.

6. Mrs Selina CHOW said that she had heard feedback from the Chinese medicines traders that the Administration had not consulted them on the Bill adequately. She invited the deputations to elaborate their concerns about the proposed registration requirement under clause 129 on the conduct of clinical trials or medicinal tests for proprietary Chinese medicines and their views on the possible impact brought on the trade by this requirement. In response, Mr WEI Chi-hua pointed out that there would be practical difficulties to conduct such tests for lack of supporting facilities. In fact, it was not known which hospitals in Hong Kong could be engaged to conduct such clinical trials or animal tests if they were so required. The sector was also concerned about the costs involved for conducting these tests.

7. Mr Wong Kai-cheong suggested that proprietary Chinese medicines manufactured based on traditional formulae should not be required to undergo clinical trials to prove their safety and efficacy, as the Compentium of Materia Medica had already set out in detail the curative effects of individual items of Chinese herbal medicines. He highlighted that even overseas countries importing proprietary Chinese medicines from Hong Kong had never required the local manufacturers to conduct clinical trials for their medicines. Instead, the importers only requested the manufacturers concerned to guarantee and take full responsibility for the quality and safety of their medicines. Mr WEI Chi-hua supplemented that countries like Malaysia, Thailand and Singapore did not require Hong Kong manufacturers to conduct clinical trials for their proprietary Chinese medicines before exporting the

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medicines to them.

8. However, Dr LUI Ming-wah took the view that as the Compentium of Materia Medica had been written hundreds years ago, it could not be solely relied upon to determine the medicinal nature of Chinese herbal medicines. He considered that in order to promote Chinese medicines in the international market, clinical trials for Chinese medicines were necessary as they were more scientific ways to demonstrate the efficacy and safety of the medicines.

Response of the Administration

Consultation with the sector

9. In response to members' requests at the last meeting for information on the consultation conducted by the Administration with the Chinese medicines traders, Assistant Director of Health (Traditional Chinese Medicine) (AD(TCM) said that an information paper had been provided on the subject (LC Paper No. CB(2)1778/98-99 (05)). Referring to the paper, AD(TCM) pointed out that the Administration had taken the following steps to consult the sector -

(a) In November 1997, the Health and Welfare Bureau (HWB) had issued the "Consultation Document on the Development of Traditional Chinese Medicine in the Hong Kong Special Administrative Region" to invite the public and the sector to express their views on the proposed regulatory framework. About 50 submissions had been received at the end of the consultation period;

(b) Briefings had been held for District Boards and meetings/visits had been made to Chinese medicine traders and manufacturers during the consultation period;

(c) From March to September 1998, meetings had been held with more than 10 associations of Chinese medicines traders and manufacturers. In May 1998, the HWB had conducted two briefing sessions attended by representatives from 46 organizations of Chinese medicine practitioners and Chinese medicine traders and manufacturers. From March to December 1998, 14 visits had been made to individual traders and manufacturers by the Department of Health (DH); and

(d) In January 1999, the DH had conducted another briefing session for 46 organizations of Chinese medicine practitioners and Chinese medicine traders and manufacturers. Representatives from the Hong Kong Medicine Dealers' Guild and the Hong Kong Chinese Patent Medicine Manufacturers' Association were amongst those invited to attend the briefings and meetings held with the HWB and DH in February 1998

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and in May 1998 respectively.

Clause 129 - Clinical trials and medicinal tests

10. In response to general concerns about clause 129, Deputy Secretary for Health and Welfare 1 (DS(HW)1) explained that in determining an application of a proprietary Chinese medicine for registration, the Medicines Board would consider, as required by clause 122, the safety, efficacy and quality of the proprietary Chinese medicine concerned. He stressed that there were no plans at the moment to make it a mandatory requirement for all these applications for registration to be supported with results of clinical trials conducted for the medicines concerned. However, the Medicines Board might upon application, issue a certificate for a clinical trial and medicinal test to be conducted if they were deemed required. The purpose of clause 129 was therefore only to facilitate the conduct of such a clinical trial or medicinal test for any proprietary Chinese medicine. He agreed with Dr LUI Ming-wah that in order to promote Chinese medicines in the world market, it was necessary to conduct clinical trials for them.

11. Dr LEONG Che-hung also took the view that it was important to conduct scientific research for Chinese medicines in order to promote them in the world market. He noted that at present the Chinese University of Hong Kong, the University of Hong Kong and some hospitals had been conducting clinical trials for western medicines applying for registration. He considered that the same requirements should be imposed on proprietary Chinese medicines.

12. Dr LUI Ming-wah took the view that it was impractical to require all the existing proprietary Chinese medicines to undergo clinical trials in view of the large number of medicines involved. He considered that clinical trials however should be conducted at least for new brands of proprietary Chinese medicines introduced to Hong Kong, and for those existing ones whose manufacturers desired to conduct the clinical trials for their medicines for the purpose of raising their reputations. He noted that there were four well established Chinese medicine universities on the Mainland from which advice could be sought as to how to conduct such clinical trials for proprietary Chinese medicines.

13. Mrs Selina CHOW expressed reservations about the need to conduct clinical trials for proprietary Chinese medicines if they were prepared based on traditional formulae. Moreover, she drew members' attention to the point made by the deputations that the overseas importers had not imposed such a requirement on the local manufactured proprietary Chinese medicines. She considered that the Administration should consider the practical difficulties faced by the sector and the economic impact that would be brought on the trade before making any decision.

14. AD(TCM) reiterated the Administration’s policy and clarified that it had no

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intention at this stage to make it a mandatory requirement for the manufacturers to conduct clinical trials for the existing proprietary Chinese medicines nor for new ones when applying for registration. He said that clinical trials might be required for a new proprietary Chinese medicine which was prepared based on a new formula and when that the Medicines Board, based on the information presented to it, had doubt about the safety of the medicine in question.

15. Mr WONG Kai-cheong took the view that so long as a new proprietary Chinese medicine did not contain any potent Chinese medicines as ingredients, it did not necessarily have to undergo a clinical trial. In response to Dr LUI Ming-wah's comments, he considered that there should not be any worry about changes in the nature of Chinese herbal medicines since they were being consumed by people everyday and had proved to be effective in curing diseases. He stressed that it would be hindering the development of Chinese medicine in Hong Kong should the Government require manufacturers to conduct clinical trials for all proprietary Chinese medicines.

16. Dr LUI Ming-wah was of the view that manufacturers should be encouraged to conduct clinical trials for their proprietary Chinese medicines be they new or not. He suggested that the Government could encourage them to do so by giving them credits for the good quality of their medicines if it was so proved by clinical trials. This would help boost the reputation of the medicines concerned. Dr LEONG Che-hung pointed out that on the Mainland clinical trials were conducted for proprietary Chinese medicines (such as one for drug rehabilitation) even though they did not contain potent Chinese medicines. He considered that clinical trials were necessary to prove the efficacy of the medicines and to promote them to customers.

17. Mr Ambrose LAU was concerned about the cost for conducting clinical trials. In response, DS(HW)1 said that the Administration well understood the concerns of the sector and assured that the Bill, as it stood, did not propose to make it a mandatory requirement for all proprietary Chinese medicines to have clinical trials conducted in order to get registered. He pointed out that it would however damage the reputation of the sector if it was laid down explicitly in the Bill that all the new proprietary Chinese medicines did not have to undergo clinical trials in applying for registration.

18. Mrs Selina CHOW referred to clause 129(4) and asked under what circumstances that the Medicines Board would refuse an application for registration on the grounds of public interest. In reply, DS(HW)1 said that the Medicines Board would do so if it found that, having regard to the information provided by the applicant in accordance with clause 129(2), the proprietary Chinese medicines in question were not suitable for consumption. He reiterated that the Medicines Board would basically consider the three factors relevant to determination of application for registration as stipulated under clause 122. He shared the views of some members that it would be difficult to prove the efficacy of a particular proprietary Chinese medicine. Therefore, the Medicines Board might take into account the following factors in

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considering the efficacy of a particular proprietary Chinese medicine -

(a) how long the medicine had been launched into the market;

(b) the track record of the product such as whether there had been any complaints lodged about its efficacy; and

(c) the formula based on which the medicine was manufactured. It would be examined based on the theories of traditional Chinese medicine.

19. Senior Assistant Legal Adviser (SALA) pointed out that there were no provisions in the Bill specifying whether or not the information to be provided under clause 129 should include the results of clinical trials. Rather, he considered that clause 129 was an enabling provision for the Medicines Board to require applicants to provide any information as the Board might specify. AD(TCM) reiterated that there were no provisions in the Bill specifying that the conduct of clinical trials was a must for proving the efficacy of any proprietary Chinese medicine. Moreover, he pointed out that there was a consensus reached by the Administration and the sector that the existing proprietary Chinese medicines should not be required at this stage to undergo clinical trials.

20. Quoting the example of a proprietary Chinese medicine which was claimed to be able to cure serious illnesses like Hepatitis B or cancer, Dr LEONG Che-hung asked whether or not the Medicines Board would consider the following factors in deciding whether to approve the application of this medicine for registration -

(a) whether the medicine contained the ingredients as listed on its label;

(b) whether the medicine was safe for consumption;

(c) whether it contained any western medicines; and

(d) the efficacy of the medicine.

21. Mr WEI Chi-hua pointed out that there should be no worry about those proprietary Chinese medicines which were manufactured based on the "old formulae", as the "Pharmacopoeia of the People's Republic of China" had recorded their safety and efficacy. On the other hand, he considered that the presence of any toxic substances could simply be checked by laboratory tests. Mr WONG Kai-cheong agreed that for those proprietary Chinese medicines which were claimed to be able to cure serious diseases like cancer and Hepatitis B, their manufacturers should either have to produce data to prove their efficacy or, alternatively, conduct clinical trials for the medicines. He further suggested that the Bill could list these kinds of serious illnesses which at present could not be cured by western medicines. However,

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members in general considered that the suggested list would in no way be exhaustive. Mr WEI Chi-hua said that any proprietary Chinese medicines claiming to be able to cure cancer or Hepatitis B were departing from the fundamental theories of Chinese medicine. He agreed that in these cases, the medicines in question should be required to demonstrate their efficacy by some methods. Dr LEONG urged the Administration to take measures to control these kinds of proprietary Chinese medicines. He also requested the Administration to pay special attention to ensuring the safety of proprietary Chinese medicines.

22. In response to Dr LUI Ming-wah's enquiry, DS(HW)1 said the Bill proposed that a proprietary Chinese medicine which had been sold in Hong Kong on 1 March 1999 would be considered as an "existing" medicine and would be subject to the transitional registration arrangements set out under clause 128. As for those which had not been imported to Hong Kong yet for sale on or before 1 March 1999, DS(HW)1 said that the Medicines Board might require the manufacturer to provide documentary proofs to show how long the medicine had been put on sale and the manufacturer probably would be required to demonstrate to the Medicines Board that the formula of the medicine was in compliance with the theories of Chinese medicine and it should have the efficacy as claimed.

23. Mrs Selina CHOW was concerned about the large spectrum of proprietary Chinese medicines, some of which might be more appropriate to be classified as health food. She questioned whether these health food items would be subject to the same registration requirements as proposed in the Bill. Mrs Selina CHOW considered that much uncertainty still remained regarding the proposed registration requirements for proprietary Chinese medicines. For example, it was not known what specific registration requirements might be laid down by the future Medicines Board in relation to the determination of efficacy of a proprietary Chinese medicine. She requested the Administration to provide more details in the principal legislation on this point or, alternatively, to make an undertaking on the approach that would be adopted by the Medicines Board in considering the factor of efficacy. In response, DS(HW)1 pointed out that clause 114 had already provided for an appeal channel for applicants to lodge any complaints against the decisions made by the Medicines Board. He also reminded members that the tabling of the relevant subsidiary legislation would be a further opportunity for members and the public to examine and discuss the detailed arrangements. Referring to clause 122(1)(c), Mrs Selina CHOW suggested that the Administration should list the consideration factors relevant to the determination of efficacy of a proprietary Chinese medicine for the purpose of registration.

24. In response to the suggestions and concerns raised by the deputations in their submissions, DS(HW)1 made the following points -

(a) The Administration would review the drafting aspect of clause 114 to take into account the actual operational needs at the premises to which the application related;

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(b) Under clause 132(1), the "person to be responsible for supervising the manufacture of proprietary Chinese medicines" would be required to be stationed at the factory concerned during its daily operation;

(c) The required qualifications of the "person responsible for the supervision" under clauses 114 and 132 would be considered under the relevant subsidiary legislation;

(d) The five representatives from the Chinese medicine sector to sit on the Medicines Board would include representatives from all trades within the sector including the manufacturing group; and

(e) The established measures in place for intellectual property protection could be applied to protect proprietary Chinese medicine formulae.

25. Referring to sub-paragraph (e) above, Mr WONG Kai-cheong questioned the scope of protection and asked whether it was the name or the formula of the medicine concerned that was protected. Mrs Selina CHOW considered that the Administration should address the concerns of sector about what would be required to be disclosed in applying for the intellectual property right. Due to shortage of time, the Chairman said that the subject would be further discussed at future meetings and suggested the deputations to provide more views on this matter to the Bills Committee.

II. Date of next meeting

26. Members agreed that the next meeting would be held on 5 May 1999 at 8:30 am.

27. The meeting ended at 4:40 pm.

Legislative Council Secretariat
30 November 1999