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Bills Committee on Chinese Medicine Bill

Minutes of meeting
held on Saturday, 26 June 1999 at 2:30 pm
in Conference Room B of the Legislative Council Building

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

Action

		Miss Miranda NG Senior Assistant Law Draftsman, Department of Justice
		Dr LEUNG Ting-hung Assistant Director of Health (Traditional Chinese Medicine)
		Mr CHAN Ling-fung, Frank Scientific Officer, Department of Health
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

I. Meeting with the Administration

Members examined clauses 119 to 159 of the Bill. No comments were made on clauses 119, 124, 126, 127, 128, 129, 130, 131, 133, 134, 135, 136, 137, 138, 140, 141, 143, 146, 148, 152, 153, 155, 156, 157, 158 and 159. Their deliberations on other clauses were given below.

Clause 120 (Application for registration of proprietary Chinese medicines to be made by manufacturers, importers, etc.)

2. Deputy Director of Health (DDH) informed members that the arrangements in clause 120(b) for the importation of proprietary Chinese medicine were similar to those for western medicine.

3. In response to Miss CHOY So-yuk, DDH said that registration was required of proprietary Chinese medicines which were claimed to have a curing effect. In assessing an application for such a registration, regard would be given to the efficacy and safety of the product.

4. In response to Dr LEONG Che-hung, DDH said that besides registration as proprietary Chinese medicine, customs clearance and an import licence were also required of a product before it could be sold to the public.

Action

Clauses 121 and 122

5. In response to Miss CHAN Yuen-han, DDH said that the form, information and materials set out in clause 121(1)(a) would be basically similar to those for western medicine. Information required would include clinical testing results, manufacturing and packaging methods, and Chinese medicine principles behind the curing effect of the product. Laboratory tests might also be carried out on the proprietary Chinese medicine. Clear and detailed requirements would be drawn up, although not in the principal legislation so as to maintain flexibility in implementation.

6. Miss CHAN Yuen-han considered that the requirements for registration of proprietary Chinese medicine should be clearly made known to importers and manufacturers. She added that once the Bill was enacted, extensive and wide publicity, such as through the television, should immediately be launched. DDH responded that while the form of publicity was not yet determined, publicity through television would be one of the options.

7. Senior Assistant Legal Adviser (SALA) conveyed Mrs Selina CHOW's view that in relation to clause 121(1)(b), some deputations had expressed concern about the adequacy of intellectual property protection in respect of Chinese proprietary medicine formulas. Miss CHOY So-yuk shared the same concern. In response, DDH said that although the formulas were not disclosed to the public and other manufacturers, they were disclosed to the Administration in the registration process. He added that it was not unusual to have a number of manufacturers producing proprietary Chinese medicine of the same formula. The difference in efficacy was usually due to differences in the method of manufacture rather than the formulas. Principal Assistant Secretary for Health and Welfare (Medical) 1 (PAS(HW)1) added that the Administration would move a Committee Stage amendment (CSA) to prohibit the disclosure of confidential information obtained officially during the process of application for a licence, a certificate or renewal of the same. She hoped to provide the CSA to members for consideration at the next meeting. SALA said that the Director of Intellectual Property had stated in a previous meeting that it was a requirement under the common law to maintain the confidentiality of information provided in confidence by others. As only civil proceedings could be instituted against the disclosure of such information, the Chinese medicine sector hoped that the confidentiality requirement could be laid down in the Bill.

8. SALA conveyed Mrs Selina CHOW's suggestion that the requirement of "serious danger" be added to clause 121(4) in relation to public interest. Members noted that the Administration had stated at the previous meeting that the imposing of the condition of "serious danger" might give rise to arguments about whether the danger was serious. Members agreed that no change be made to the clause.

9. In response to Miss CHOY So-yuk, DDH said that products such as drink-mix

Action

powders claiming to have a curing effect would have to be registered as proprietary Chinese medicines. In assessing the efficacy of a proprietary Chinese medicine, consideration would be given to whether the composition of the medicine would give the claimed effect under Chinese medicine theories. An analysis of the ingredients would also be made, if necessary.

10. Dr LEONG Che-hung was concerned that in the determination of an application for registration as a proprietary Chinese medicine, there was no examination as to whether the formula belonged to another registered proprietary Chinese medicine. He added that such a problem was also found with western medicine. DDH responded that the Department of Health (DH) was examining the issue with the Intellectual Property Department, with a view to proposing amendments to the Pharmacy and Poisons Ordinance (Cap. 138) (PPO) to address the issue.

11. Miss CHAN Yuen-han enquired whether the assessment of an application for registration in clause 122(1)(b) would be based on requirements meeting the standards of the Good Manufacturing Practice (GMP) on the manufacture of medicine. She also enquired about the time-table for a full implementation of GMP standards in Hong Kong. DDH said that while Hong Kong was moving towards such a direction, a phased approach would be preferred. The Administration had examined the issue and found it difficult to draw up a time-table at this stage. He considered that the time-table should be drawn up by the Chinese Medicines Board (Medicines Board). Compliance with GMP standards could be laid down as a licensing requirement.

12. Dr LEONG Che-hung considered that the Administration should expedite the matter and stress the importance of implementing GMP standards to the proprietary Chinese medicine industry. He added that the efficacy referred to in clause 122(1)(c) would be very difficult to determine. In this connection, he said that there was no mention in the Bill of advertising by Chinese medicine practitioners (CMPs). SALA added that Mrs Selina CHOW had also asked him to seek clarification on how the efficacy was to be determined.

13. DDH agreed with Dr LEONG's view that there should not be delay in the implementation of GMP standards in Hong Kong. He considered that there should be a proper balance so that manufacturers would not be forced to close down as a result of the implementation. DH was currently recruiting CMPs to help the department to better understand the various issues. Some pharmacists had been sent to study Chinese medicine courses so as to facilitate their understanding of the protocol of Chinese herbal medicine. The efficacy of medicines would be determined having regard to -

(a) theories stated in ancient publications on Chinese herbal medicine;

(b) guiding principles under Chinese medicine; and

Action

(c) results of clinical trials.

DDH added that the issue of advertising by CMPs could be dealt with in the code of practice, as was the case for medical practitioners. As regards regulation of the advertisements of proprietary Chinese medicine, PAS(HW)1 said that proprietary Chinese medicines were already regulated by the Undesirable Medical Advertisements Ordinance (Cap. 231) (UMAO). Consequential amendments would be introduced to provide explicitly that Chinese herbal medicines and proprietary Chinese medicines would be regulated by UMAO.

14. SALA conveyed Mrs Selina CHOW's question on how the "conditions as imposed by the Medicines Board" in clause 122(4)(b)(ii) were to be determined. In response, DDH said that the provision sought to deal with the possibility of proprietary Chinese medicine developing to a stage where the poison content of some products reached a level necessitating restrictions to be imposed. Mr HO Sai-chu suggested that the word "reasonable" might be added before "conditions" in clause 122(4)(b)(ii). In this connection, SALA said that it was a requirement under the law that any conditions imposed by an administrative body in discharging its duties must be reasonable. He said that similar provisions on western medicine were also found in PPO. Mr LEE Kai-ming asked whether the conditions would be made as subsidiary legislation. DDH responded that as the conditions would vary according to the circumstances, it might not be practicable to lay down the restrictions in the legislation. The regulation of western medicine was also not made through subsidiary legislation, but through licensing requirements.

15. In response to Dr LEONG Che-hung, SALD explained that clause 122(2) provided that the application for registration of a proprietary Chinese medicine would not be refused on the ground that it was not as efficacious as another product. Clause 122(3) provided that due regard should be given to the safety of a proprietary Chinese medicine. DDH added that similar provisions also applied to western medicine.

Clause 123 (Duration and renewal of registration)

16. SALA conveyed Mrs Selina CHOW's suggestion that similar to clause 121(4), the requirement of "serious danger" should be added to clause 123(3)(b). Members agreed that in line with the decision in respect of clause 121(4), no change should be made to the clause.

Clause 125 (De-registration of proprietary Chinese medicines)

17. In response to Dr LEONG Che-hung, DDH said that besides the tests carried out on a product when application for registration was made, random tests on registered proprietary Chinese medicines were also carried out by DH. He added that in assessing the safety of a product, examination would be made on the formula,

Action

whether the ingredients contained western medicine, the existence of heavy metals, and whether the product contained pesticide. All new proprietary Chinese medicines would be subject to such tests. DH would collaborate with the World Health Organization (WHO) to hold a meeting to discuss the monitoring mechanism and testing of Chinese herbal medicine.

18. Dr LEONG Che-hung enquired whether there would be adequate laboratories and personnel in Hong Kong to carry out medicinal tests on all proprietary Chinese medicines. He also enquired about the expected completion time for the testing of all proprietary Chinese medicines, and whether the Administration would provide subsidy in respect of the testing costs.

19. In response, Assistant Director of Health (Traditional Chinese Medicine) ADH(TCM) said that the Administration had already started testing all new proprietary Chinese medicines since the previous year. The Government Laboratory had strengthened its manpower to cope with the increased workload. He envisaged that two to three years would be needed for testing of all existing proprietary Chinese medicine. No charge was levied for such testing.

20. In response to Miss CHOY So-yuk's question on the verification of whether a proprietary Chinese medicine contained wild (野生) or cultivated (種植) herbs, DDH said that the Administration would liaise with WHO on the determination of standards and testing methods for Chinese herbal medicine. In this connection, SALA said that the claiming of cultivated (種植) herbs as wild (野生) would constitute fraudulence under the Theft (Amendments) Bill 1998, which was under scrutiny by the Legislative Council.

21. Members noted that persons selling de-registered proprietary Chinese medicines would be subject to penalties under the legislation.

Clause 132 (Licensing of manufacturers)

22. Members noted that the Administration would move a Committee Stage amendment in respect of the number of deputies in clause 132(1)(b)(ii).

(As the Chairman had to leave to attend to some urgent business, Mr HO Sai-chu took the chair for the ensuing part of the meeting.)

Clause 139 (Powers to suspend, revoke, etc. licences)

23. Members noted that the Regulatory Committee referred to in the clause was a standing committee with functions similar to those of the disciplinary committee for medical practitioners and that under the PPO.

Clause 142 (Chinese herbal medicines to be labelled)

Action

24. In response to Miss CHOY So-yuk, PAS(HW)1 said that requirements in respect of the size and contents of labels for Chinese herbal medicines would be made as subsidiary legislation. The provision was not applicable to the retail of Chinese herbal medicine.

Clause 144 (Package inserts for proprietary Chinese medicines)

25. Members noted that detailed requirements on the package inserts for proprietary Chinese medicines would be made as subsidiary legislation.

Clause 145 (Change of address of premises, etc)

26. In response to Mr HO Sai-chu, Acting Chairman, DDH said that inspections to the premises of manufacturers would be made by inspectors of DH.

Clause 147 (Power of entry and search in relation to domestic premises)

27. Members noted that domestic premises of CMPs where no medicine was dispensed would not be subject to the provision.

28. PAS(HW)1 informed members that the Department of Justice had proposed the addition of a definition for "domestic premises". The Administration would move a CSA to clause 2 in this respect.

Clause 149 (Protection of public officers)

29. SALA asked whether the protection under the clause would, as in the case of the Consumer Council or the Airport Authority, cover members of the Chinese Medicine Council (CMC), its board and committees. He added that public officers might not need such protection, as any legal challenged against the act of such persons would usually be made to the Government as the employer. DDH said that similar provisions also applied in relation to regulation of other medical professions. PAS(HW)1 added that the protection was mainly related to legal liability arising from the actions of public officers. Nevertheless, the Administration would look into the issue.

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Clause 150 (Liability for acts of servants)

30. PAS(HW)1 informed members that the Administration would move a CSA to improve the clarity of the clause.

Clause 151 (Commencement of proceedings)

31. SALA said that the provision for legal proceedings to commence within 12

Action

months after the date of commission of the offence might give rise to problems, as it might not be possible to take legal action against an offence discovered more than 12 months after commission. He suggested that the "date of commission" be amend to "date of discovery". In response, SALD said that there might be technical difficulties with the proposed amendment. ADH(TCM) added that similar provisions, which had been enforced for many years without much problems, was also found in PPO in respect of western medicine.

32. Members agreed that no amendment should be made to the clause.

Clause 154 (Commencement of proceedings)

33. In response to Mr HO Sai-chu, Acting Chairman, PAS(HW)1 said that a fine at level 6 would be equivalent to $100,000.

Other issues

34. In response to Dr LEONG Che-hung, PAS(HW)1 said that requirements on the sale of medicines specified in Schedule 1 would be made as subsidiary legislation.

35. ADH(TCM) informed members that the Administration would introduce some CSAs relating to the technical aspects of Schedules 1 and 2.

II. Date of next meeting

36. Members noted that the next meeting would be held on 28 June 1999 immediately after the special meeting of the House Committee. They agreed that further meetings of the committee be scheduled for 30 June 1999 at 8:00 am and 1 July 1999 at 9:00 am.

37. The meeting ended at 4:35 pm.

Legislative Council Secretariat
21 December 1999