

26 November 2002

Clerk to Subcommittee
(Attn.: Ms Doris Chan)
Subcommittee on Chinese Medicine (Fees) Regulation
Chinese Medicines Regulation and
Chinese Medicines Traders (Regulatory) Regulation
Legislative Council
Legislative Council Building
8 Jackson Road
Central
Hong Kong

Dear Ms Chan,

**Subcommittee on Chinese Medicines (Fees) Regulation,
Chinese Medicines Regulation and
Chinese Medicines Traders (Regulatory) Regulation)**

Thank you for your letter of 21 November 2002 enclosing a list of issues raised by Members at the Subcommittee meeting held on 19 November 2002. Our comments/responses are as follows:

- (a) As agreed at the meeting on 19 November 2002, we shall respond to the points raised in the submission from the Chinese Medicines Merchants Association Ltd. at the coming meeting.
- (b) The draft practising guidelines for Chinese medicine traders are

enclosed for Members' information/reference.

(c)&(d) The purpose of the licensing requirement/practising condition, namely, "the premises are in all other aspects suitable" is to ensure that premises of different types of Chinese medicine traders are in all aspects suitable to carry out their respective business and that their products would not be adversely affected by the environment within which the premises are located. This is modeled on section 13 (4)(b) of the Pharmacy and Poisons Ordinance (Cap 138) which regulates western medicine.

The following scenarios are within the purview of the above "catch-all" provision:

(i) the premises of certain traders should not be located in residential buildings which may cause nuisance to residents;

(ii) manufacturers should not be located adjacent to or near source of severe pollution as this may lead to contamination of their products; and

(iii) the trader's facilities or equipment installed should be supported by special construction facilities.

(e) The scale of operation and scope of business of Chinese medicine traders vary significantly from small herbal shops to manufacturers which are of standards comparable to Good Manufacturing Practice. It is therefore impractical to set out exhaustively all the licensing requirements and practising conditions in rigid terms. The rationale of the present version is to provide flexibility to facilitate the traders to carry out their business.

(f) We are consulting the Medicines Board of the Chinese Medicine Council of Hong Kong and shall brief Members at the next meeting,

(g) Section 140 of the Chinese Medicine Ordinance allows the traders to request the Medicines Board to review any decision of the Chinese Medicines Committee and the Chinese Medicines Traders Committee. Section 141 of the Ordinance provides for appeal to

the Court of First Instance against the decision of the Medicines Board.

(h) To facilitate those traders who need to apply for both retailer licence and wholesaler licence for Chinese herbal medicines, the Department of Health and the Medicines Board will provide one-stop service in respect of the following:

- (i) provision of information or document and receipt of application;
- (ii) site inspection of the premises; and
- (iii) issuing of licences.

(i) It is the minimum requirement for the wholesaler and manufacturer of proprietary Chinese medicines and wholesaler of Chinese herbal medicines to keep their transaction records in their premises for not less than 2 years. There is similar requirement for western medicine traders in the Pharmacy and Poisons Regulation (regulation 28 (2) read with regulation 39 (d) and regulation 35 read with regulation 39 (e)). Apart from the keeping of transaction records, the Chinese Medicines Regulation requires the traders to set up and maintain a system of control for a rapid and complete recall of medicines sold or distributed (section 11 (i), 16 (q) and 20 (g)). In this connection, the traders are required to keep relevant transaction records up to and until the products are sold or distributed. This requirement is stipulated in the practising guidelines for traders.

2. The attendance list of the Administration for the meeting on 28 November 2002 is at the Annex for your information and necessary action.

Yours sincerely,

(Peter Kwok)

for Secretary for Health, Welfare and Food

c.c. Director of Health (Attn.: Dr T H Leung)

Department of Justice (Attn.: Miss Miranda Ng, Miss Betty Cheung,
Ms Stella Chan)