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Legislative Council

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Paper for the House Committee meeting on 13 December 2002

Report of the Subcommittee on Chinese Medicine (Fees) Regulation, Chinese Medicines Regulation and Chinese Medicines Traders (Regulatory) Regulation

Purpose

This paper reports on the deliberations of the Subcommittee on Chinese Medicine (Fees) Regulation, Chinese Medicines Regulation and Chinese Medicines Traders (Regulatory) Regulation.

Background

2. The Chinese Medicine Ordinance (Cap. 549) (the Ordinance) was enacted by the Legislative Council in July 1999 to provide a statutory framework for the regulation of the practice, use, trading and manufacture of Chinese medicine in Hong Kong. The Chinese Medicine Council of Hong Kong (the CMC) was established in September 1999 under the Ordinance to develop and implement regulatory measures.

3. Under the regulatory framework for Chinese medicines, all retailers and wholesalers of Chinese herbal medicines as well as wholesalers and manufacturers of proprietary Chinese medicines will be subject to licensing control to ensure proper storage, handling, dispensing of Chinese herbal medicines as well as the manufacturing of proprietary Chinese medicines. All proprietary Chinese medicines manufactured or offered for sale in Hong Kong will need to be individually registered with the CMC, having regard to the safety, quality and efficacy of the medicines concerned.

The Regulations

Chinese Medicine (Fees) Regulation

4. The Chinese Medicine (Fees) Regulation sets out the proposed fees

payable in respect of licensing of Chinese medicines traders and registration of proprietary Chinese medicines.

Chinese Medicines Regulation

5. The Chinese Medicines Regulation stipulates the licensing requirements and practising conditions of all Chinese medicines traders as well as the registration and labelling requirements for proprietary Chinese medicines.

Chinese Medicines Traders (Regulatory) Regulation

6. The Chinese Medicines Traders (Regulatory) Regulation provides for the procedures to be adopted by the Regulatory Committee of Chinese Medicines Traders (the Regulatory Committee) and the Chinese Medicines Board in dealing with complaints or information against licensed Chinese medicines traders under the Ordinance.

The Subcommittee

7. At the House Committee meeting on 8 November 2002, Members agreed that a Subcommittee should be formed to scrutinise the three Regulations. The membership list of the Subcommittee is in **Appendix I**.

8. Under the chairmanship of Dr Hon LO Wing-lok, the Subcommittee has held four meetings with the Administration and has met with representatives from 16 Chinese medicines associations listed in **Appendix II**.

Deliberations of the Subcommittee

Fees for licensing Chinese medicines traders and registration of proprietary Chinese medicines

Licensing of Chinese medicines traders

9. It is Government policy that fees and charges should in general be set at levels sufficient to recover the full cost of providing the services. In line with the cost recovery rate for Chinese medicine practitioners, the Administration proposes to cover initially 70% of the cost for administering the licensing system for Chinese medicines traders, rising to full cost recovery in three years.

Registration of proprietary Chinese medicines

10. The Administration proposes to set the fees for registration and certification of proprietary Chinese medicines at the following levels initially -

(a) $1,000 for products of single active ingredient, representing cost-recovery rate of 27.9%; and

(b) $2,000 for products of multiple active ingredients, representing cost recovery rate of 25.2%.

11. The above fees are comparable to that for the registration of western medicines (currently at $1,920). The Administration aims at achieving full recovery in five years, to tie in with the expiry date of the registration certificate which is valid for five years. The Administration has pointed out that the low initial fees demonstrate Government's commitment to promote the development of Chinese medicines.

12. Members note that the trade considers that the fees are reasonable and that in setting the fees, the Administration has taken into consideration views and concerns expressed by the trade during the consultation process.

Suitability of premises

13. Members have asked the Administration to clarify one of the licensing requirements, namely, "the premises are in all other aspects suitable" in sections 3(e), 4(d), 5(g) and 6(c) of the Chinese Medicines Regulation.

14. The Administration has pointed out this licensing requirement/practising condition is modelled on section 13(4)(b) of the Pharmacy and Poisons Ordinance (Cap. 138) which regulates western medicine. Its purpose is to ensure that premises of different types of Chinese medicine traders are in all aspects suitable to carry out their respective businesses and that their products would not be adversely affected by the environment within which the premises are located.

15. On being asked by the Subcommittee to give examples to illustrate such a requirement, the Administration has informed members that the following scenarios are within the purview of the "catch-all" provision -

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

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

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

16. Members share the view that such examples should be included in the practising guidelines for Chinese medicines traders to facilitate their compliance with the requirement. The Administration has undertaken to do so.

17. Members have asked the Administration to explain why the licensing requirements and practising conditions are set out in a rather broad manner. The Administration has pointed out that 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 businesses.

The application process

18. Members have asked the Administration to provide information on the measures that will be taken to facilitate those traders who need to apply for both the retailer licence and the wholesaler licence. The Administration has informed members that the Department of Health and the Chinese Medicines Board will provide one-stop service in respect of the following -

(a) provision of information or document and receipt of application;

(b) site inspection of the premises; and

(c) issuing of licences.

Keeping of transaction records for not less than two years

19. Members have expressed concern as to whether the proposed length of time is adequate. The Administration has explained that it is the minimum requirement for the wholesalers and manufacturers of proprietary Chinese medicines and wholesalers of Chinese herbal medicines to keep their transaction records in their premises for not less than two years. There is a similar requirement for western medicine traders in the Pharmacy and Poisons Regulation.

20. The Administration has also pointed out that 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 (sections 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.

Consideration of complaints by the Regulatory Committee and the Chinese Medicines Board

21. Members are of the view that the references to "statement in mitigation" in sections 5, 6, 7 and 10 of the Chinese Medicines Traders (Regulatory) Regulation may convey a wrong message to the defendant that it would be to his advantage to admit to a complaint or information against him. The Administration has explained that the intention is that a defendant could submit statement in mitigation if he indeed committed the offence. The Administration has also pointed out that the relevant sections, even without the phrases "statement in mitigation", already provide that the defendant may make any explanation or representation to the Regulatory Committee and/or the Chinese Medicines Board in support of his case. Having regard to members' view, the Administration has agreed to move amendments to delete all references to "statement in mitigation" in sections 5, 6, 7 and 10 of the Chinese Medicines Traders (Regulatory) Regulation.

22. Members consider that the defendant should be provided with copies of all papers which have been considered by the Regulatory Committee before the meeting of the Chinese Medicines Board. The Administration has agreed to add a new section 10(2) to the Chinese Medicines Traders (Regulatory) Regulation to provide that copies of all documents, statements and reports to be put before the Board under section 10(1)(f) would be furnished to the defendant before the meeting. However, the Administration has pointed out that the procedures for handling complaints which may result in revocation of a business licence are generally informal. A licensing authority is not normally required to furnish papers considered by it to the defendant, whether under Hong Kong legislation or under comparable legislation of the United Kingdom. The usual safeguards for the defendant are that he will have an opportunity to be heard and will have the right of appeal. These safeguards are already contained in the Regulation.

Appeal mechanism

23. Members note that section 140 of the Ordinance allows the traders to request the Chinese 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 Chinese Medicines Board.

Practising guidelines

24. Four sets of draft practising guidelines have been drawn up by the Chinese Medicines Board for Chinese herbal medicines retailers, Chinese herbal medicines wholesalers, proprietary Chinese medicines manufacturers and proprietary Chinese medicines wholesalers respectively to facilitate their compliance with the regulatory measures.

25. As requested by the Subcommittee, copies of the draft guidelines have been provided for members' information. Members note that the trade is being consulted on the guidelines and on completion of the consultation process, the guidelines will be issued to the traders and manufacturers concerned.

Consultation with the trade

26. Members note that the CMC and the relevant trade associations have been consulted extensively on the proposed licensing fees and their views have been taken into account in setting the fee levels proposed.

27. As regards the other two Regulations, members note that they were made by the CMC, which consists of members of the Chinese medicine profession, academics and other community leaders, and that the Administration has organised over 20 open fora for the Chinese medicines trade to consult them on the proposed regulatory measures.

28. The deputations which attended the second meeting of the Subcommittee have all indicated support of the proposed regulatory measures.

Funding schemes for which the Chinese medicines trade is eligible

29. A number of representatives have asked whether any funding schemes are available to assist them to comply with the regulatory measures. As requested by the Subcommittee, the Administration has provided brief notes on a number of funding schemes administered by the Innovation and Technology Commission and the Department of Trade and Industry for the Subcommittee's information. Copies of the relevant information have been provided to the deputations for their reference.

Proposed amendments

30. In addition to the proposed amendments mentioned in paragraphs 21 and 22 above, the Administration will move a number of minor or textual amendments to the Chinese Medicines Regulation and the Chinese Medicines Traders (Regulatory) Regulation at the Council meeting on 18 December 2002. The Administration's proposed amendments are in **Appendix III**.

Follow-up action by the Administration

31. As reported in paragraph 17 above, the Administration has undertaken to include in the practising guidelines for Chinese medicines traders examples illustrating the application of the licensing/registration condition that "the premises are in all respects suitable" referred to in sections 3(e), 4(d), 5(g) and 6(c) of the

Chinese Medicines Regulation.

Recommendation

32. The Subcommittee recommends support of the Regulations and the amendments to be moved by the Administration.

Advice sought

33. The House Committee is invited to note the Subcommittee's recommendation in paragraph 32 above. Dr Hon LO Wing-lok, Chairman of the Subcommittee, made a verbal report on the Subcommittee's deliberations to the House Committee on 6 December 2002.

Council Business Division 2
Legislative Council Secretariat
12 December 2002

Appendix I

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

Membership List

Chairman	Dr Hon LO Wing-lok
Members	Dr Hon David CHU Yu-lin, JP
	Hon Cyd HO Sau-lan
	Dr Hon LUI Ming-wah, JP
	Hon Mrs Selina CHOW LIANG Shuk-yee, GBS, JP
	Hon CHAN Yuen-han, JP
	Dr Hon LAW Chi-kwong, JP
	Hon Michael MAK Kwok-fung
	Hon LEUNG Fu-wah, MH, JP
	Hon Audrey EU Yuet-mee, SC, JP
	(Total : 10 Members)
Clerk	Ms Doris CHAN
Legal Adviser	Miss Anita HO
Date	19 November 2002

Appendix II

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

List of deputations

- Chinese Medicine Merchants Association Ltd.
- The Hong Kong Medicine Dealers' Guild
- The Hong Kong Society of Chinese Medicines
- Cultural Centre of Chinese Medicine Ltd.
- Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.
- H.K. Chinese Patent Medicine Manufacturers' Association Ltd.
- Hong Kong General Chamber of Pharmacy Ltd.
- Hong Kong Chinese Medicine Employees Association
- Hong Kong Chinese Prepared Medicine Traders Association Limited
- Modernized Chinese Medicine International Association Limited
- The Hong Kong Pharmaceutical Manufacturers Association Ltd.
- International General Chinese Herbalists and Medicine Professional Association Ltd.
- Po Sau Tong Ginseng & Antler Association - Hong Kong Limited
- The Chinese Manufacturers' Association of Hong Kong
- Hong Kong Medicine Workers General Union (Yee-Shing)
- Hong Kong and Kowloon Chinese Medicine Merchants Association Ltd.
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Miss Miranda Ng #69547
1st working draft : 5.12.2002

INTERPRETATION AND GENERAL CLAUSES ORDINANCE

RESOLUTION OF THE LEGISLATIVE COUNCIL

CHINESE MEDICINES REGULATION

Resolution made and passed by the Legislative Council under section 34 of the Interpretation and General Clauses Ordinance (Cap. 1) on December 2002.

RESOLVED that the Chinese Medicines Regulation, published in the Gazette as Legal Notice No. 160 of 2002 and laid on the table of the Legislative Council on 6 November 2002, be amended in the Chinese text –

(a) in section 26(2)(e)(ii), by repealing "生產商" and substituting "製造商";

(b) in section 36, by repealing everything after "114條" and substituting –

"並不適用於符合下述說明的中成藥 –

(a) 由任何註冊中醫或表列中醫在其執業的處所合成或在其監管下合成的，但僅在該中成藥是爲了向一名由他直接治理的病人施用或供應而正在使用的情況下方不適用；或

(b) (i) 由負責人；或

(ii) 在該人的監管下，

於有效零售商牌照所指的處所並按照任何註冊中醫或表列中醫開出的處方個別配製或合成的。".

Clerk to the Legislative Council

December 2002

INTERPRETATION AND GENERAL CLAUSES ORDINANCE

RESOLUTION OF THE LEGISLATIVE COUNCIL

CHINESE MEDICINES TRADERS (REGULATORY) REGULATION

Resolution made and passed by the Legislative Council under section 34 of the Interpretation and General Clauses Ordinance (Cap. 1) on December 2002.

RESOLVED that the Chinese Medicines Traders (Regulatory) Regulation, published in the Gazette as Legal Notice No. 161 of 2002 and laid on the table of the Legislative Council on 6 November 2002, be amended -

(a) in section 5(3)(c)(i), by repealing ", any representations or any statement in mitigation" and substituting "or any representations";

(b) in section 6 –

(i) in subsection (3), by adding ", either of its own motion or at the request of the defendant," after "may";

(ii) in subsection (4)(c), by repealing ", representations or statement in mitigation" and substituting "or representations";

(iii) in subsections (5) and (6), by repealing

", representations and statement in mitigation" and substituting "and representations";

(c) in section 7 -

(i) in subsection (3)(c), by repealing "a summary of";

(ii) in subsection (4)(a), by repealing ", representations or statement in mitigation" and substituting "or representations";

(d) in section 10 -

(i) by renumbering it as section 10(1);

(ii) in subsection (1)(e), by repealing ", representations or statement in mitigation" and substituting "or representations";

(iii) by adding -

"(2) The Board secretary shall furnish to the defendant, before the meeting, copies of all documents, statements and reports to be put before the Board under subsection (1)(f).";

(e) in section 11(1), by adding ", either of its own motion or at the request of the defendant," after "may".

Clerk to the Legislative Council

December 2002