Paper No. CB(2)385/02-03(01)

立法會
Legislative Council

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

Background paper prepared by the Legislative Council Secretariat

Purpose

This paper gives a summary of the issues and concerns raised by members of the Panel on Health Services on the following Regulations made under the Chinese Medicine Ordinance (Cap. 549) at its meeting on 25 October 2002 -

(a) Chinese Medicine (Fees) Regulation;
(b) Chinese Medicines Regulation; and
(c) Chinese Medicines Traders (Regulatory) Regulation.

The Regulations

Chinese Medicine (Fees) Regulation

2. 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

3. 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

4. The Chinese Medicines Traders (Regulatory) Regulation provides for the procedures to be adopted by the Regulatory Committee of Chinese Medicines Traders and the Chinese Medicines Board in dealing with complaints or information against licensed Chinese medicines traders under the Chinese Medicine Ordinance (Cap. 549).

Issues and concerns raised by members

Types of medicinal products to be regulated

5. In response to a member's enquiry on the types of medicinal products which would come under the Chinese Medicine Regulation, the Administration clarified that under the Chinese Medicine Ordinance, "proprietary Chinese Medicine" meant, *inter alia*, any proprietary product composed of as active ingredients any Chinese herbal medicines or any materials of herbal, animal or mineral origin customarily used by the Chinese. The Administration further explained that all proprietary Chinese medicines, irrespective of whether they were manufactured in or outside Hong Kong, would need to be individually registered with the Chinese Medicine Council of Hong Kong.

Assessment of the impact of the proposed fees

6. A member asked the Administration whether it had conducted any assessment of the impact of the proposed fees on the Chinese medicine trade and consumers. The Administration responded that it had conducted a regulatory impact assessment of the proposed regulation of Chinese medicines prior to introducing the Chinese Medicine Bill into the Legislative Council in February 1999. The finding showed that consumers would be willing to pay more for Chinese medicines if their safety and quality were ensured as a result of the implementation of regulatory control of Chinese medicine.

Qualified staff for implementation of the regulatory measures

7. Members expressed concern as to whether the Department of Health (DH) had enough qualified staff to implement the new licensing and registration measures. The Administration explained the DH had 10 pharmacists who were knowledgeable in Chinese medicines and had also hired several Chinese medicine experts from the Mainland to help cope with the anticipated workload.

Timeframe for implementation and transitional arrangements

8. In response to members' questions on the timeframe for implementation of the proposed regulatory measures, the Administration informed the Panel that the licensing of traders and manufacturers of Chinese medicines and the registration of proprietary Chinese medicines presently offered for sale in Hong Kong would take two to three years to complete. In the interim period, transitional arrangements would be put in place to minimise disruptions to the Chinese medicine trade.

Relevant papers

9. Members may wish to refer to an extract from the minutes of the meeting of the Panel on 25 October 2002 in **Appendix I** for further details of the discussion on the Regulations.

10. The Administration's papers entitled "Regulatory Control on Chinese Medicines" and "Fees relating licensing of Chinese medicines traders and registration of proprietary Chinese medicines" provided for the Panel meeting on 25 October 2002 (LC Papers Nos. CB(2)1/02-03(01) and CB(2)186/02-03(02) are in **Appendix II**.

Council Business Division 2
Legislative Council Secretariat
18 November 2002

Appendix I

Extract from the draft minutes of special meeting of the Health Services Panel held on 25 October 2002

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I. Regulatory control on Chinese medicines
(LC Paper No. CB(2)1/02-03(01))

At the invitation of the Chairman, Assistant Director of Health (Traditional Chinese Medicine) (ADH(TCM)) briefed members on the salient points of the proposed Chinese Medicine Regulation and the Chinese Medicines Traders (Regulatory) Regulation set out in the above Administration's paper, and that of the proposed fees payable in respect of Chinese medicines traders and registration of proprietary Chinese medicines set out in an additional Administration's paper tabled at the meeting (LC Paper No CB(2)186/02-03(02)).

2. Ms LI Fung-ying asked the following questions -

(a) Whether products, such as diet pills and health food, composed of Chinese herbal medicines, and their traders and manufacturers would come under the proposed Chinese Medicine Regulation and Chinese Medicines Traders (Regulatory) Regulation;

(b) Whether proprietary Chinese medicines manufactured outside Hong Kong and offered for sale in Hong Kong would be governed by the two proposed Regulations mentioned in (a) above; and

(c) Whether the Administration had conducted any assessment of the impact of the proposed fees payable in respect of licensing of Chinese medicine traders and registration of proprietary Chinese medicines on the trade, in particular, the possibility of the trade transferring the increased costs to consumers.

3 ADH(TCM) replied in the positive to Ms LI's first question, as under the Chinese Medicine Ordinance, "proprietary Chinese medicine" meant, inter alia, any proprietary product composed of as active ingredients any Chinese herbal medicines or any other materials of herbal, animal or mineral origin customarily used by the Chinese.

4. ADH(TCM) also replied in the positive to Ms LI's second question, as all proprietary Chinese medicines, irrespective of whether they were manufactured outside or in Hong Kong, would need to be individually registered with the Chinese Medicine Council of Hong Kong (CMC) under the proposed Chinese Medicine Regulation.

5. As to Ms LI's last question, Deputy Director of Health (DDH) said that the Administration had conducted a regulatory impact assessment of the proposed regulation of Chinese medicines prior to introducing the Chinese Medicine Bill into the Legislative Council (LegCo) in February 1999. The findings showed, amongst others, that consumers would be willing to pay more for Chinese medicines if their safety and quality were ensured as a result of the implementation of regulatory control on Chinese medicines.

6. Mr Michael MAK enquired whether the Department of Health (DH) had adequate staff with the requisite knowledge and experience to carry out inspections of retailers of Chinese medicines.

7. DDH assured members that DH had adequate suitably trained staff to carry out inspections of retailers of Chinese medicines. In order to pave way for the regulation of Chinese medicines, DH had been providing Chinese medicine training for some of its doctors and pharmacists since 1995. For instance, some of the staff concerned had been sent to Beijing to learn about the Mainland practice in the regulation of Chinese medicines, and many DH pharmacists were currently pursuing a degree course in Chinese medicine pharmacy and some of them would be graduating soon. DDH further said out that the labelling requirements of Chinese medicines under the proposed Chinese Medicine Regulation should further help DH staff to carry out their inspections of retailers of Chinese medicines. DH had enlisted the assistance of Mainland experts in drawing up the aforesaid labelling requirements.

8. Mr MAK further asked the following questions -

(a) What action would DH take to tackle of problem of retailers selling Chinese medicines which they concocted themselves but sold under the names of registered Chinese medicines; and

(b) What was the number of retailers of Chinese herbal medicines in Hong Kong.

Mr MAK also requested the Administration to provide a paper to the Panel on how DH would carry out its enforcement work on regulatory control on Chinese

medicines after the relevant Regulations had come into operation.

9. DDH responded that counterfeit drugs were a worldwide problem and DH would shortly discuss with the trade on how to address the problem of counterfeit Chinese medicines. As regards Mr MAK's second question, DDH said that the number of retailers of Chinese herbal medicines in Hong Kong was about 1 400. He assured members that DH had adequate qualified staff to carry out the enforcement work. DDH further said that the implementational details on the regulatory measures to control the trading and manufacture of Chinese medicines were being drawn up, and DH would be happy to brief members in this regard when such details were finalised and put into practice.

10. Having regard to the Administration's intention to introduce the two Regulations on regulatory control of Chinese medicines and the Regulation on the fees into LegCo later this year, Miss CHAN Yuen-han enquired when the Administration planned to bring these three Regulations into operation. Referring to paragraph 6(h) of the Administration's paper (LC Paper No. CB(2)1/02-03(01)) which set out the types of medicine which could be exempted from certain provisions of the Chinese Medicine Ordinance (Cap. 549), Miss CHAN enquired whether such exemptions would also apply to powdered medicines processed from Chinese herbal medicines.

11. DDH responded that in view of the large number of existing traders and manufacturers of Chinese medicines, the regulatory control of Chinese medicines would be implemented by phases from 2003 so as to give sufficient time to the affected parties to make the necessary changes for meeting the licensing requirements. As to Miss CHAN's second question, DDH said that as granules processed from individual Chinese herbs used for filling prescriptions were not classified as proprietary Chinese medicines, they would not be subject to registration with CMC. However, DH would draw up guidelines to regulate their application.

12. The Chairman asked the following questions -

(a) How long it would take for all proprietary Chinese medicines to be registered with CMC; and

(b) Whether Hong Kong had enough qualified people to implement the regulatory measures to control the trading and manufacture of Chinese medicines.

13. ADH(TCM) said that in view of the large number of proprietary Chinese medicines presently offered for sale in Hong Kong, DH envisaged that it would

take two to three years for all these medicines to be registered with CMC. To minimise disruptions to the existing Chinese medicine trade, some transitional arrangements would be put in place whereby Chinese medicine traders and manufacturers might continue their business, pending the completion of the licensing and registration procedures. Under the transitional arrangements, where an application for licensing was made by an existing trader or manufacturer, or where an application for registration of a proprietary Chinese medicine was made by the manufacturer or importer concerned, within a time period to be determined by CMC, the trader, manufacturer or proprietary Chinese medicine concerned would be deemed to be licensed or registered until the application was accepted or refused. New proprietary Chinese medicines would, however, be required to be registered with CMC first before they could be offered for sale in Hong Kong. ADH(TCM) assured members that although the whole licensing scheme of traders and manufacturers of Chinese medicines and the registration of proprietary Chinese medicines would take two to three years to complete, the safety of the public would be safeguarded by existing legislation such as the Public Health and Municipal Services Ordinance (Cap. 132). Furthermore, over the past few years, DH had already sampled over 2 000 proprietary Chinese medicines each year to ensure that they were fit for human consumption.

14. Regarding the Chairman's second question, ADH(TCM) said that DH had enough qualified staff to implement the regulatory measures on control of Chinese medicines. At present, DH had 10 pharmacists well versed in Chinese medicines. In addition, DH had hired several Mainland experts in Chinese medicine to render support to DH in implementing the new licensing and registration measures. This workforce would be further strengthened upon the obtaining of degree qualification in Chinese medicine pharmacy by several DH staff in the coming months. ADH(TCM) further said that there should be no shortage of manpower to cope with the regulatory measures on control of Chinese medicines, as a significant number of local graduates in Chinese medicine pharmacy would be coming on stream in the next few years.

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Appendix II

For discussion
on 25 October 2002

Paper No. CB(2)1/02-03(01)

Legislative Council Panel on Health Services
Meeting on 25 October 2002

Regulatory Control on Chinese Medicines

Purpose

The purpose of this paper is to seek Members' views on the regulatory framework for Chinese medicines proposed by the Chinese Medicine Council of Hong Kong.

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 medicines in Hong Kong. The Chinese Medicine Council of Hong Kong ("the Council") was established in September 1999 under the Ordinance to develop and implement these regulatory measures.

3. With the making of the relevant subsidiary legislation in May 2000, the Council commenced in August 2000 the registration exercise for practising Chinese medicine practitioners under the transitional arrangements provided in the Ordinance. The names of listed Chinese medicine practitioners were announced in December 2001. The first batch of registered Chinese medicine practitioners will be announced shortly.

4. Under the regulatory framework, 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 and dispensing of Chinese herbal medicines as well as manufacturing of proprietary Chinese medicines. Moreover, all proprietary Chinese medicines manufactured or offered for sale in Hong Kong will need to be individually registered with the Council, having regard to the safety, quality and efficacy of the medicines concerned.

5. The Council has finalised the regulatory measures to control the trading and manufacture of Chinese medicines, which will be presented in the form of two regulations to be tabled at the Legislative Council. The provisions of the two draft regulations are summarised below for Members' consideration.

(A) The Chinese Medicine Regulation

6. The Chinese Medicine Regulation sets out the licensing requirements and practising conditions of all Chinese medicines traders as well as the registration and labeling requirements for proprietary Chinese medicines. The more significant provisions of the Regulation include -

(a) **<u>Licensing Requirements of Chinese Medicines Traders</u>** –

(i) Retailers and wholesalers of Chinese herbal medicines have to ensure suitable storage area and facilities are available for the retail and wholesale of Chinese herbal medicines and that Schedule 1[note1] medicines are stored effectively separated from

[note1] 31 potent Chinese herbal medicines listed in Schedule 1 of the Chinese Medicine Ordinance.

Schedule 2[note2] medicines or materials. Moreover, where Chinese herbal medicines are to be dispensed, the retailer should ensure that the business premises have adequate space and suitable facilities for the dispensing and he must nominate a person with the required knowledge and experience to be responsible for the supervision of the dispensing.

(ii) Manufacturers and wholesalers of proprietary Chinese medicines shall ensure that the sanitary and hygiene conditions of the premises are suitable for the manufacture and wholesale of proprietary Chinese medicines and that suitable storage area and facilities are available. In addition, manufacturers should ensure that Schedule 1 medicines are stored effectively separated from Schedule 2 medicines or materials. Moreover, a manufacturer must nominate a person with the required knowledge and experience to be responsible for the supervision of the manufacture of proprietary Chinese medicines.

(b) **Duties of licensed retailers and wholesalers of Chinese herbal medicines** – In addition to the licensing requirements which an applicant has to satisfy the Medicines Board when lodging an application for a licence, retailers and wholesalers of Chinese herbal medicines have to comply with the following duties: -

(i) Retailers or wholesalers of Chinese herbal medicines have to ensure that their business premises are maintained in sanitary

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[note2] 574 Chinese herbal medicines commonly used in Hong Kong listed in Schedule 2 of the Chinese Medicine Ordinance.

condition and that adequate space and suitable facilities are available for storing Chinese herbal medicines. In addition, each type of Chinese herbal medicines should be stored in a separate labeled container.

(ii) A retailer has to keep invoice or other documents evidencing business transactions for not less than 2 years from the date of transaction, containing relevant details such as the date of the transaction and the name and quantity of the medicine acquired or received. Retailers who dispense Schedule 1 medicines have to ensure that dispensation of such medicine is in accordance with a prescription given by a registered Chinese medicine practitioners and that records of transaction with relevant details such as the name and address of the registered Chinese medicine practitioner are kept for not less than 2 years from the date of the transaction.

(iii) Where processing of Chinese herbal medicines is conducted, a wholesaler has to ensure adequate equipment and facilities are available for the processing. In addition, he should ensure that relevant particulars of each processing such as the name and quantity of the medicine or mixture used in the processing and the name of the person who supervises the processing are recorded and that such record are kept for not less than 2 years from the completion date of processing.

(iv) A wholesaler of Chinese herbal medicines is required to set up a system of control for the complete recall of any Chinese herbal medicines sold or distributed by him should it be

considered necessary. He is also required to keep transaction records in respect of Chinese herbal medicines for not less than 2 years from the date of transaction.

(v) A wholesaler of Schedule 1 medicines is permitted to sell or distribute any such medicines only to the authorized persons which include registered Chinese medicine practitioners and other licensed retailers and wholesalers of Schedule 1 medicines.

(c) **Duties of licensed manufacturers of proprietary Chinese medicines** - In addition to the licensing requirements, manufacturers of proprietary Chinese medicines have to observe the following duties -

(i) A manufacturer should ensure that the humidity, lighting, temperature and ventilation of his business premises are suitable for the storage of materials and intermediate products generated and medicines manufactured, as well as for the manufacturing processes conducted.

(ii) He should take adequate steps to prevent contamination of any ingredient, intermediate product generated or medicines manufactured during the manufacturing process.

(iii) He should put in place a system of control for the complete recall for all intermediate products generated or proprietary Chinese medicine manufactured in the course of manufacture sold or distributed by him should it be considered necessary.

(iv) A manufacturer has to keep a control sample of each batch of intermediate product generated and proprietary Chinese medicine manufactured by him from the date of generation or manufacture for not less than 2 years from the date of last transaction or expiry date of the batch of product/medicine.

(v) A manufacturer shall ensure that manufacturing and transaction records relating to each manufacturing process, sale or distribution of proprietary Chinese medicines are kept for not less than 2 years from the expiry date of the medicines.

(d) **Registration of proprietary Chinese medicine** - All proprietary Chinese medicines manufactured or offered for sale in Hong Kong will need to be individually registered with the Council, having regard to the safety, quality and efficacy of the medicines concerned. The following particulars are required to be registered for a proprietary Chinese medicine –

(i) its Chinese and English name;
(ii) its dose form;
(iii) the name and quantity of each of its active ingredient:
(iv) the name and quantity of each of its excipient (if any);
(v) its specification;
(vi) its indication (if any);
(vii) its dosage and method of usage;
(viii) each of its labels to be attached or printed on its package;
(ix) the package insert to be supplied for its sale inside Hong Kong;

(x) each of the package inserts to be supplied for its sales outside Hong Kong (if any) ;

(xi) the name and address of each of its manufacturers; and

(xii) its function or pharmacological action.

(e) <u>Labelling of Containers by wholesalers</u> - Under the Ordinance, a wholesaler in Chinese herbal medicines shall attach or print on each container of Chinese herbal medicine a label in a conspicuous position, or cause a label to be so attached or printed.

(i) A label on a container in which Schedule 1 Chinese herbal medicines are stored shall include the following-

(a) the name, at least in Chinese, of the medicine;

(b) the name of the wholesaler;

(c) the batch number of the medicine;

(d) a warning containing the Chinese text: "毒性中藥" or "毒性中葯"; and

(e) a warning containing the English text: "Toxic Chinese Medicine" (if appropriate).

(ii) A label attached to a container in which Schedule 2 medicines are stored shall -

(a) include the name, at least in Chinese, of the medicine; and

(b) has the name of the medicine being clearly and distinctly set out.

(f) <u>Labelling of package of proprietary Chinese medicines</u>

(i) The package of proprietary Chinese medicines for the purpose of sale must be labeled. A label on a package of proprietary Chinese medicine shall include at least in Chinese the following particulars –

(a) the name of the medicine;
(b) the name of main active ingredients;
(c) the name of the country or territory in which the medicine is produced;
(d) the registration number of the medicine;
(e) the name of the holder of the certificate of registration of the medicine;
(f) its packing specification;
(g) its dosage and method of usage;
(h) its expiry date; and
(i) its batch number.

(ii) Some Chinese medicine practitioners may commission a licensed manufacturer to manufacture Chinese medicines for a patient or a number of patients under his direct care. For medicines so manufactured for internal application or both internal and external application of a patient under the direct care of the Chinese medicine practitioner, the label should include at least in Chinese the following information:

(a) the name and address of the Chinese medicine practitioner;
(b) the name and address of the manufacturer who manufactures the medicine;
(c) the date on which it is produced;

(d) the name and quantity of each ingredient listed in the prescription;

(e) a statement containing the following text-

(A) “須按照中醫指示使用” or

(B) “須按照中医指示使用”;

(f) a statement containing the English text: “To be used only in accordance with the instructions of a Chinese medicines practitioner” (if appropriate);

(g) a statement containing the following Chinese text –

(A) “只供中醫施用於或供應予獲開給本成藥的處方，並且是由他直接治理的病人” or

(B) “只供中医施用于或供应予获开給本成葯的处方，并且是由他直接治理的病人”;

(h) a statement containing the English text: “To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to the patient to whom the prescription of this medicine is given and who is under his direct care” (if appropriate);

(i) its packing specification;

(j) its dose form;

(k) its expiry date; and

(l) its batch number.

(iii) For medicines manufactured for <u>external</u> application of a patient or a number of patients under the direct care of the Chinese medicine practitioners, the label has to include at least in Chinese the following information –

(a) the name and address of the Chinese medicine practitioner;

(b) the name and address of the manufacturer who manufactures the medicine;

(c) the date on which it is produced;

(d) the name and quantity of each ingredient listed in the prescription;

(e) a statement containing the following text-

(A) “須按照中醫指示使用” or

(B) “須按照中医指示使用”.

(f) a statement containing the English text: “To be used only in accordance with the instructions of a Chinese medicines practitioner” (if appropriate);

(g) a statement containing the following Chinese text –

(A) “只供中醫施用於或供應予由他直接治理的病人” or

(B) “只供中医施用于或供应予由他直接治理的病人”;

(h) a statement containing the English text: “To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to a patient or patients under his direct care” (if appropriate);

(i) a statement containing the Chinese text: “只供外用”;

(j) a statement containing the English text: “For external application only” (if appropriate);

(k) its packing specification;

(l) its dose from;

(m) its expiry date; and

(n) its batch number.

(iv) An exporter of proprietary Chinese medicine manufactured in Hong Kong shall ensure that a label on the outermost package of the medicine likely to be sold or distributed to an ultimate user of the medicine shall include the following particulars:

(a) the name of the medicine;
(b) the name of the holder of the certificate of registration of the medicine; and
(c) the registration number of the medicine.

(v) Package of proprietary Chinese medicines in special/small size on sale in Hong Kong, not being the outermost package to be sold or distributed to an ultimate user of the medicine has the following labeling requirements :-

(a) if the medicine is in the form of a strip pack, blister pack or similar article, the label should include, at least in Chinese, the following particulars :

- the name of the medicine;
- the name of the holder of the certificate of registration of the medicine;
- its expiry date;
- its packing specification; and
- its batch number;

(b) if the medicine is in the form of an ampoule, vial or similar receptacle with not more than 10 ml capacity or equivalent; or contains a single dose in the form of a pill, the label of the medicine should include, at least in Chinese, the name of the medicine.

(g) **Requirements for Package Inserts** - A package insert of a proprietary Chinese medicine on sale in Hong Kong shall include, at least in Chinese, the following particulars –

(a) the name of the medicine;
(b) the name of main active ingredients and their respective quantities;
(c) the name of the holder of the certificate of registration of the medicine;
(d) its dosage and method of usage;
(e) its functions or pharmacological action;
(f) its indications (if any);
(g) its contra-indications (if any);
(h) its side-effects (if any);
(i) its toxic effects (if any);
(j) the precautions to be taken regarding its use (if any);
(k) its storage instructions; and
(l) its packing specification.

(h) **Exemptions** – The Regulation provides for exemptions from certain provisions of the Ordinance to cater for the need of the Chinese medicine trade and profession. The main exemptions include -

(i) Sections 119 (proprietary Chinese medicines to be registered) and 144 (package inserts for proprietary Chinese medicines) shall not apply if the medicine is

- for internal application or both internal and external application, and the medicine is to be administered or supplied to the patient to whom the prescription is given and who is under the direct care of the Chinese medicine practitioner; or
- for external application only, and the medicine is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner; and
- the Medicines Board has received from the manufacturer, at least 1 working day before the day on which the manufacturing process of the medicine begins, a written notification being accompanied by an undertaking.

(ii) Sections 143 (proprietary Chinese medicines to be labeled) and 144 (package inserts for proprietary Chinese medicines) shall not apply if the medicine is

- compounded by or under the supervision of a registered or listed Chinese medicine practitioner at his premises for the use of a patient under his direct care ; or
- compounded by or under the supervision of a responsible person at the premises of a licensed retailer in accordance with a prescription given by a registered or listed Chinese medicine practitioner.

(B)The Chinese Medicines Traders (Regulatory) Regulation

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

(i) Upon receipt of complaint or information against a Chinese medicine trader, the Secretary to the Medicines Board shall submit the complaint or information to the Regulatory Committee for investigation and consideration.

(ii) The Regulatory Committee chairman may invite the complainant to provide further clarification or evidence to support his complaint and seek legal advice or any other assistance as appropriate.

(iii) The Regulatory Committee chairman, shall, after consideration of further clarification, evidence and legal advice or assistance, fix a date for the Committee to consider the complaint or information.

(iv) The Regulatory Committee chairman shall then inform the defendant about the date of the meeting and the complaint or information received and invite him to submit representation or explanation or any statement in mitigation before the meeting.

If the defendant considers necessary, he may attend the Committee meeting to make oral representation.

(v) The Committee meeting for consideration of a complaint shall be held in private. After consideration of the case and written and oral representation and explanation submitted by the defendant, the Committee shall submit its recommendation to the Medicines Board on whether it should exercise its power under section 139 (powers to suspend or revoke licences) or the case is found to be groundless and should not be further pursued.

(vi) Prior to the meeting of the Medicines Board to consider the recommendation of the Regulatory Committee, which should be held in private, the defendant may submit any explanation, representations or statement in mitigation in advance and attend the meeting to make oral representation.

(vii) If the Board decides to suspend or revoke a licence, such decision shall not take immediate effect to allow time for the concerned trader to lodge an appeal to the Court of First Instance whose decision is final.

Consultation with the trade

8. We have organised over 20 open fora to consult the Chinese medicines traders on the proposed regulatory measures in the past year. Views of concerned parties have been taken into account in finalising the draft Regulations.

Advice sought

9. Members are invited to comment on the proposed arrangements in paragraphs 6 to 7. Subject to Members' views, the two Regulations will be made by the Chinese Medicine Council of Hong Kong and introduced into the Legislative Council later this year and the proposed regulatory control on Chinese medicine will be implemented by phases from 2003.

Health, Welfare and Food Bureau
October 2002

Paper No. CB(2)186/02-03(02)

For discussion
on 25 October 2002

Legislative Council Panel on Health Services
Meeting on 25 October 2002

Fees relating to Licensing of Chinese medicines traders and Registration of proprietary Chinese medicines

Purpose

This paper sets out the proposed fees payable in respect of licensing of Chinese medicines traders and registration of proprietary Chinese medicines.

Background

2. As reported in an earlier paper, subsidiary legislation for the regulation of Chinese medicines will be tabled at the Legislative Council later this year. It is necessary to establish the levels for various fee items to recover the cost of administering the regulatory system.

3. 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 the case of Chinese medicine practitioners, the initial fees have been set at 70% of the cost of administering the registration system. We expect to recover the full cost in three years.

Licensing of Chinese medicine traders

4. In line with the cost recovery rate for Chinese medicine practitioners, we propose to recover 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

5. We understand that many traders are concerned about the possible financial burden arising from the requirement to seek registration for each and

every proprietary Chinese medicine manufactured and/or sold in Hong Kong. While product registration is a necessary step in the regulatory system, we will try our best to minimize disruption to the trade. We therefore propose 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%.

The above fees are comparable to that for the registration of western medicines (currently at $1,920). We aim at achieving full cost recovery in five years, to tie in with the expiry date of the registration certificate (which is valid for five years). The low initial fees demonstrate Government's commitment to promote the development of Chinese medicine. A table setting out the proposed fees and duration of various licences and certificates is at the Annex.

Consultation with the trade

6. The Chinese Medicine Council of Hong Kong and the relevant Chinese medicines trade associations have been consulted. They generally support the proposal to regulate Chinese medicines, but would like the Government to set the licensing fees at partial cost recovery levels, particularly those relating to the registration of proprietary Chinese medicines. The fee levels proposed at paragraphs 4 and 5 should have addressed these concerns.

Way forward

7. Members are invited to comment on the proposed fees. Subsidiary legislation on the fees will be tabled at the Legislative Council together with the other two regulations on regulatory control of Chinese medicines.

Health, Welfare and Food Bureau
October 2002

Annex

Licensing of Chinese Medicines Traders & Registration of Proprietary Chinese Medicines - Proposed Levels of Fees and Validity period of Licences and Certificates

Licence/Certificate	Validity period of licence/ Year	Proposed fee ($)	Cost Recovery %
Licensing of Chinese Medicine Traders			
Licence for a wholesale dealer in Chinese herbal medicines	2	1,100	70
Licence for a retailer in Chinese herbal medicines	2	995	70
Licence for a wholesale dealer in proprietary Chinese medicines	2	1,100	70
Licence for a manufacturer in proprietary Chinese medicines	2	2,890	70
Renewal of a wholesale dealer licence in Chinese herbal medicines	2	955	70
Renewal of a wholesale dealer licence in proprietary Chinese medicines	2	955	70
Renewal of a retailer licence in Chinese herbal medicines	2	850	70
Renewal of a manufacturer licence in proprietary Chinese medicines	2	2,440	70
Certified copy of a licence or certificate		140	70
Change of the address of the premises specified in a licence		700	70
Certificate for manufacturer (GMP)	2	26,650	70
Registration of Proprietary Chinese Medicines			
Application for registration of a proprietary Chinese medicine with single active ingredient		500	27.9
Issue of a certificate of registration of a proprietary Chinese medicine with single active ingredient	5	500	27.9
		1,000	
Application for registration of a proprietary Chinese medicine with multiple active ingredients		1,000	25.2
Issue of a certificate of registration of a proprietary Chinese medicine with multiple active ingredients	5	1,000	25.2
		2,000	
Application for a certificate for clinical trial and medicinal test		2,440	70
Certificate for clinical trial and medicinal test		79	70
		2,519	
Renewal of a certificate of registration of a proprietary Chinese medicine	5	1,170	70
Variation of registered particulars of a registered proprietary Chinese medicine		1,790	70
Certificate of sale of a proprietary Chinese medicine		270	70