File ref: HWF CR 1/1/3911/98 (02) Pt.8

LEGISLATIVE COUNCIL BRIEF

Chinese Medicine Ordinance
(Chapter 549)

CHINESE MEDICINE (FEES) REGULATION

INTRODUCTION

At the meeting of the Executive Council on 22 October 2002, the Council ADVISED and the Acting Chief Executive ORDERED that the Chinese Medicine (Fees) Regulation, at Annex A, should be made.

BACKGROUND AND ARGUMENT

General Background

2. As reported in the brief on the Chinese Medicines Regulation and the Chinese Medicines Traders (Regulatory) Regulation, the Chinese Medicine (Fees) Regulation will need to be made to provide for the fees payable in respect of licensing of Chinese medicines traders and registration of proprietary Chinese medicines and related matters.

The Proposal

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, 70% of the cost of administering the registration system is being recovered initially, rising to full cost recovery in three years.

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. We aim at achieving full cost recovery in three years.

5. As regards registration of proprietary Chinese medicines, we propose a lower cost recovery rate initially in view of the possible financial burden on traders and manufacturers arising from the requirement to seek

registration for each and every proprietary Chinese medicine manufactured and/or sold in Hong Kong.

6. In view of the current economic situation and to alleviate the financial burden on the trade, we propose to set the fees for registration and certification of proprietary Chinese medicines initially at $2,000 for those of multiple active ingredients (item 12b and 13b of the fee schedule at Annex A) and $1,000 for those of single active ingredient (item 12a and 13a), representing cost recovery rates of 25.2% and 27.9% respectively. These 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 lower initial fees will demonstrate Government's commitment to promote the development of Chinese medicine.

7. Cost computation of the fee items is at Annex B. A table setting out the validity period of licences and certificates and the cost recovery rates of the fee items is at Annex C.

THE REGULATION

8. The Regulation sets out the fees payable under the Chinese Medicine Ordinance in relation to licensing of Chinese medicines traders and registration of proprietary Chinese medicines. **Clause 1** provides that this Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice in the Gazette.

9. **Clause 2** provides for the fees payable under the Ordinance.

10. **Clause 3** provides that all fees set out in the Schedule that have been received shall be paid into the general revenue.

IMPLICATIONS OF THE REGULATIONS

Economic, Financial and Civil Service Implications

11. The Regulations have economic, financial and civil service implications as set out at Annex D.

Basic Law, Human Rights, Binding Effects, Productivity, Sustainability Development and Environmental Implications

12. The Regulation is in conformity with the Basic Law, including the provisions concerning human rights. The Regulation will not affect the current binding effect of the Chinese Medicine Ordinance and has no productivity, sustainability development or environmental implications.

PUBLIC CONSULTATION

13. 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 low levels, particularly those relating to the registration of proprietary Chinese medicines, to alleviate their financial burden. The fee levels proposed at paragraph 6 should have addressed these concerns. The Chinese medicine practitioners who normally only prescribe herbal medicine will not be affected. Consultation with the general public is not considered necessary, as they are not likely to be directly affected by the Regulation.

LEGISLATIVE TIMETABLE

14. The Regulation will be gazetted on 1 November 2002 and tabled at the Legislative Council on 6 November 2002.

PUBLICITY

15. We will issue a press release on 1 November 2002 when the Regulation is gazetted. A spokesman will be available to answer media and public enquiries.

ENQUIRIES

16. Any enquiry on this brief can be addressed to Mr Peter Kwok, Assistant Secretary for Health, Welfare and Food at 2973 8117 or by fax at 2840 0467.

Health, Welfare and Food Bureau
November 2002
File Ref : HWF CR 1/1/3911/98 (02) Pt.8

CHINESE MEDICINE (FEES) REGULATION

(Made by the Chief Executive in Council under section 161(1) of the Chinese Medicine Ordinance (Cap. 549))

1. Commencement

This Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice published in the Gazette.

2. Fees

The amounts set out in column 4 of the Schedule are the fees prescribed in relation to the corresponding items specified in column 3 of that Schedule.

3. Disposal of fees received

All fees set out in the Schedule that have been received shall be paid into the general revenue.

SCHEDULE [ss. 2 & 3]

FEES

Item	Relevant section of the Ordinance	Description	Amount $
1.	115(3)	Issue of a wholesaler licence in Chinese herbal medicines	1,100
2.	114(3)	Issue of a retailer licence in Chinese herbal medicines	995
3.	135(2)	Issue of a wholesaler licence in proprietary Chinese medicines	1,100
4.	132(2)	Issue of a manufacturer licence in proprietary Chinese medicines	2,890
5.	116(3)	Renewal of a wholesaler licence in Chinese herbal medicines	955

6.	136(3)	Renewal of a wholesaler licence in proprietary Chinese medicines		955
7.	116(3)	Renewal of a retailer licence in Chinese herbal medicines		850
8.	136(3)	Renewal of a manufacturer licence in proprietary Chinese medicines		2,440
9.	117, 127, 137	Issue of a certified copy of a licence or certificate		140
10.	145(1)	Change of the address of the premises specified in a licence		700
11.	133	Issue of a certificate for manufacturer (Good practices in manufacture)		26,650
12.	121(1)	(a)	Application for the registration of a proprietary Chinese medicine with single active ingredient	500
		(b)	Application for the registration of a proprietary Chinese medicine with multiple active ingredients	1,000
13.	121(2)	(a)	Issue of a certificate of registration of a proprietary Chinese medicine with single active ingredient	500
		(b)	Issue of a certificate of registration of a proprietary Chinese medicine with multiple active ingredients	1,000
14.	129(2)	Application for a certificate for clinical trial and medicinal test		2,440
15.	129(3)	Issue of a certificate for clinical trial and medicinal test		79
16.	123(3)	Renewal of the registration and issue of a certificate of registration of a proprietary Chinese medicine		1,170
17.	124(1)	Application for variation of registered particulars of a registered proprietary Chinese medicine		1,790
18.	130(2)	Issue of a certificate of sale of a proprietary Chinese medicine		270

Clerk to the Executive Council

COUNCIL CHAMBER

2002

Explanatory Note

This Regulation provides for the fees payable under the Chinese Medicine Ordinance (Cap. 549) in respect of registration of proprietary Chinese medicines and licensing Chinese medicines traders and connected matters.

COST COMPUTATION

Fees payable under the Chinese Medicine (Fees) Regulation

Cost at 2002-03 Prices
(for processing one application)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12a)	(13a)	(12b)	(13b)	(14)	(15)	(16)	(17)	(18)
	$	$	$	$	$	$	$	$	$	$	$	$		$		$	$	$	$	$
Staff Costs	1,386	1,252	1,386	3,654	1,201	1,201	1,067	3,075	174	888	33,751	3,169		7,022		3,078	100	1,484	2,255	336
Departmental Expenses	85	78	85	214	75	75	67	180	10	50	1,910	187		405		182	6	91	134	26
Accommodation Costs	61	56	61	160	53	53	48	135	8	39	1,474	133		297		129	4	56	97	16
Depreciation	11	9	11	29	9	9	8	25	1	7	280	26		58		25	1	12	18	2
Central Administrative Overhead	29	26	29	75	25	25	22	63	4	18	687	65		144		64	2	31	47	7
Unit Cost at price level 2002-03	**1,572**	**1,421**	**1,572**	**4,132**	**1,363**	**1,363**	**1,212**	**3,478**	**197**	**1,002**	**38,102**	**3,580**		**7,926**		**3,478**	**113**	**1,674**	**2,551**	**387**
Proposed Fee	**1,100**	**995**	**1,100**	**2,890**	**955**	**955**	**850**	**2,440**	**140**	**700**	**26,650**	**500**	**500**	**1,000**	**1,000**	**2,440**	**79**	**1,170**	**1,790**	**270**

Legend

(1) Issue of a wholesaler licence in Chinese herbal medicines
(2) Issue of a retailer licence in Chinese herbal medicines
(3) Issue of a wholesaler licence in proprietary Chinese medicines
(4) Issue of a manufacturer licence in proprietary Chinese medicines
(5) Renewal of a wholesaler licence in Chinese herbal medicines
(6) Renewal of a wholesaler licence in proprietary Chinese medicines
(7) Renewal of a retailer licence in Chinese herbal medicines
(8) Renewal of a manufacturer licence in proprietary Chinese medicines
(9) Issue of a certified copy of a licence or certificate
(10) Change of the address of the premises specified in a licence
(11) Issue of a certificate for manufacturer (Good practices in manufacture)
(12a) Application for the registration of a proprietary Chinese medicine with single active ingredient
(12b) Application for the registration of a proprietary Chinese medicine with multiple active ingredients
(13a) Issue of a certificate of registration of a proprietary Chinese medicine with single active ingredient
(13b) Issue of a certificate of registration of a proprietary Chinese medicine with multiple active ingredients
(14) Application for a certificate for clinical trial and medicinal test
(15) Issue of a certificate for clinical trial and medicinal test
(16) Renewal of the registration and issue of a certificate of registration of a proprietary Chinese medicine
(17) Application for variation of registered particulars of a registered proprietary Chinese medicine
(18) Issue of a certificate of sale of a proprietary Chinese medicine

Footnote : The cost recovery rate is -
70% for items 1 to 11 and 14 to 18
27.9% for items 12a and 13a
25.2% for items 12b and 13b

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

Annex D

Chinese Medicine (Fees) Regulation

Implications of the Proposals

Economic Implications

The regulatory system on Chinese medicines traders and proprietary Chinese medicines will bring benefits in terms of public health protection and safety. The licensing and registration systems will facilitate the development of Hong Kong as an international centre of Chinese medicine. There will be additional cost and compliance work imposed on Chinese medicines traders by the new regulatory framework, but the additional control will facilitate their products to gain international acceptance. Consultation with the traders concerned suggest that the proposed fees should not impose a significant financial burden on Chinese medicines traders.

Financial and Civil Service Implications

The Department of Health will require a complement of 20 staff at an annual cost of about $17.8 million to administer the licensing system of Chinese medicines traders and registration system of proprietary Chinese medicines. The proposed fees will generate revenue of about $9.7 million in the first year of implementation.

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LEGISLATIVE COUNCIL BRIEF

Chinese Medicine Ordinance, Cap. 549

CHINESE MEDICINES REGULATION

CHINESE MEDICINES TRADERS (REGULATORY) REGULATION

INTRODUCTION

On 30 October 2002, the Chinese Medicine Council of Hong Kong ("the Council"), with the approval of the Secretary for Health, Welfare and Food and in exercise of the power under Section 161(5) of the Chinese Medicine Ordinance (Cap. 549), made the Chinese Medicines Regulation, at Annex A, and the Chinese Medicines Traders (Regulatory) Regulation, at Annex B.

BACKGROUND AND ARGUMENT

General Background

2. The Chinese Medicine Ordinance ("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 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 of practising Chinese medicine practitioners under the transitional arrangements provided in the Ordinance. The registration exercise is already at an advanced stage and 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. The Council has finalised the regulatory measures to control the trading and manufacture of Chinese medicines, which include licensing of Chinese medicines traders and registration of proprietary Chinese medicines. 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. To minimise disruptions to the existing Chinese medicine trade, the Ordinance provides some transitional arrangements whereby existing Chinese medicine traders and manufacturers who meet the specified requirements may continue with their business, pending the completion of the licensing and registration procedures. Under the transitional arrangements, where an application for licensing or registration is made within the specified time period, the trader, manufacturer or proprietary Chinese medicine concerned will be deemed to be licensed or registered. The deeming provision will cease to have effect when the application is accepted/refused, or on a date to be appointed by the Secretary for Health, Welfare and Food, whichever is earlier.

6. The following regulations will have to be made to implement the regulatory control of Chinese medicines :-

(a) The Chinese Medicines Regulation, setting out licensing requirements and practising conditions in respect of Chinese medicines traders and registration and labelling requirements for proprietary Chinese medicines;

(b) The Chinese Medicines Traders (Regulatory) Regulation, setting out the disciplinary procedures to be followed in handling complaints against licensed Chinese medicines traders; and

(c) The Chinese Medicine (Fees) Regulation, setting out the level of fees payable for licensing of Chinese medicines traders and registration of proprietary Chinese medicines and related matters.

7. The Chinese Medicines Regulation and the Chinese Medicines Traders (Regulatory) Regulation were made by the Council on 30 October 2002.

Details about the Chinese Medicine (Fees) Regulation will be the subject of a separate brief.

THE REGULATIONS

The Chinese Medicines Regulation

8. The Chinese Medicines 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 –

(a) Section 1 provides that the Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice in the Gazette.

(b) Sections 3 to 6 set out the licensing requirements in respect of retailers and wholesalers of Chinese herbal medicines as well as manufacturers and wholesalers of proprietary Chinese medicines.

(c) Sections 7 to 14 set out the duties of licensed retailers and wholesalers of Chinese herbal medicines.

(d) Section 15 prescribes the registration particulars required to be furnished on application for registration of a proprietary Chinese medicine.

(e) Sections 16 to 21 set out the duties of licensed manufacturers and wholesalers of proprietary Chinese medicines.

(f) Sections 22 to 24 prescribe the requirements regarding the labelling of containers and packages of Chinese herbal medicines.

(g) Sections 25 to 26 provide for the requirements in respect of labels on packages of proprietary Chinese medicine to be sold in Hong Kong.

(h) Section 27 prescribes the labelling requirements on packages of proprietary Chinese medicines to be exported.

(i) Section 28 prescribes the requirements for package inserts in packages of proprietary Chinese medicines.

(j) Sections 29 and 30 specify the duration of certain licences and certificates.

(k) Section 31 deals with offences and penalties in respect of contravention of certain provisions of the Regulation.

(l) Sections 33 to 37 provide exemptions for certain proprietary Chinese medicines from sections 119 (proprietary Chinese medicines to be registered), 143 (proprietary Chinese medicines to be labelled) and 144 (package inserts for proprietary Chinese medicines) of the Ordinance.

(m) Sections 38 to 40 and the Schedules prescribe the forms of various certificates and licences.

The Chinese Medicines Traders (Regulatory) Regulation

9. 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 in dealing with complaints or information against licensed Chinese medicines traders under the Chinese Medicine Ordinance (Cap. 549) –

(a) Section 1 provides for the Regulation to commence on a date to be appointed by the Secretary for Health, Welfare and Food by notice in the Gazette.

(b) Sections 3 to 5 provide for the handling of a complaint against or information about a licensed Chinese medicine trader received by the Regulatory Committee

(c) Section 6 provides for the consideration of the complaint or information, and making of recommendations, by the Regulatory Committee.

(d) Sections 7 to 9 provide for the fixing of a date for a meeting of the Board to consider the complaint or information; the consolidation of complaints or information, and the giving of amendment notice of meeting to the trader.

(e) Sections 10 to 13 provide for the procedures of the Board's meeting for considering a complaint or information and informing the trader of the Board's decision.

(f) Section 14 provides that the Board's decision to suspend or revoke a licence shall not take immediate effect so as to allow for an appeal.

(g) Section 15 makes it clear that the Board is not required to inquire into the propriety of a conviction.

IMPLICATIONS OF THE REGULATIONS

Economic, Financial and Civil Service Implications

10. The Regulations have economic, financial and civil service implications as set out at Annex C.

Basic Law, Human Rights, Binding Effects, Productivity Sustainability Development and Environmental Implications

11. The Regulations are is in conformity with the Basic Law, including the provisions concerning human rights. The Regulations will not affect the current binding effect of the Chinese Medicine Ordinance and have no productivity, sustainability development or environmental implications.

PUBLIC CONSULTATION

12. The two Regulations were made by the Chinese Medicine Council of Hong Kong, which consists of members of the Chinese medicine professions, academics and other community leaders. We have also organised open fora for the Chinese medicines trade to consult them on the proposed regulatory measures.

LEGISLATIVE TIMETABLE

13. The Regulations will be gazetted on 1 November 2002 and tabled at the Legislative Council on 6 November 2002.

PUBLICITY

14. We will issue a press release on 1 November 2002 when the Regulations are published in the Gazette.

Enquiries

15. Any enquiries on this brief should be addressed to Mr Peter Kwok, Assistant Secretary for Health, Welfare and Food at 2973 8117 or by fax at 2840 0467.

Health, Welfare and Food Bureau
November 2002
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CHINESE MEDICINES REGULATION

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CHINESE MEDICINES REGULATION

(Made by the Chinese Medicine Council of Hong Kong under section 161(5) of the Chinese Medicine Ordinance (Cap. 549) with the approval of the Secretary for Health, Welfare and Food)

PART 1

PRELIMINARY

1. Commencement

This Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice published in the Gazette.

2. Interpretation

In this Regulation, unless the context otherwise requires -

"batch number" (批次編號) means a series of numbers, letters or other symbols, or a series consisting of a combination of numbers, letters and other symbols, used -

(a) in the case of a Chinese herbal medicine supplied to a wholesale dealer in Chinese herbal medicines, for the purpose of identifying when and by whom the medicine is supplied to the dealer; or

(b) in the case of a proprietary Chinese medicine, for the purpose of identifying when and by whom the medicine is produced;

"excipient" (賦形劑), in relation to a proprietary Chinese medicine, means a substance or compound that is used or intended to be used in the preparation or production of the medicine but which is not an active ingredient of the medicine;

"expiry date" (失效日期), in relation to a proprietary Chinese medicine, means the expiry date of the medicine as determined by the manufacturer who

produces the medicine, being the date after which the medicine should not be administered;

"ingredient" (成分), in relation to a proprietary Chinese medicine, means -

(a) its active ingredient; or

(b) its excipient;

"intermediate product" (中間產品) means a substance or compound generated in the course of manufacture of a proprietary Chinese medicine and which is to be used in further preparation or production process of the medicine;

"manufacturing process" (製造程序), in relation to a proprietary Chinese medicine, means the preparation, production, packing or repacking process of the medicine;

"packing material" (包裝物料), in relation to a proprietary Chinese medicine, means a material used for packing or repacking the medicine;

"responsible person" (負責人) -

(a) in relation to the dispensing of Chinese herbal medicines, means a person responsible for the supervision of the dispensing or his deputies -

(i) as nominated in an application for a retailer licence under section 114(2)(b) of the Ordinance; or

(ii) as notified to the Medicines Board under section 145(2) of the Ordinance;

(b) in relation to the manufacture of proprietary Chinese medicines, means a person responsible for the supervision of the manufacture or his deputies -

(i) as nominated in an application for a manufacturer licence under section 132(1)(b) of the Ordinance; or

(ii) as notified to the Medicines Board under section 145(2) of the Ordinance;

"Schedule 1 medicine" (附表 1 藥材) means a Chinese herbal medicine specified in Schedule 1 of the Ordinance;

"Schedule 2 medicine" (附表 2 藥材) means a Chinese herbal medicine specified in Schedule 2 of the Ordinance;

"Vocational Training Council" (職業訓練局) means the Vocational Training Council established under section 4 of the Vocational Training Council Ordinance (Cap. 1130).

PART 2

LICENSING REQUIREMENTS IN RESPECT OF APPLICATIONS FOR RETAILER, WHOLESALER AND MANUFACTURER LICENCES

3. Licensing requirements in respect of applications made under section 114 of the Ordinance

For the purposes of section 114(3) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a retailer licence -

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so

that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material;

(d) where Chinese herbal medicines are to be dispensed in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for dispensing the medicines are provided in the premises;

(e) the premises are in all other respects suitable for carrying on a business in the retail of Chinese herbal medicines; and

(f) each responsible person nominated in the application complies with the minimum requirements regarding knowledge and experience as set out in section 1 of Schedule 1.

4. Licensing requirements in respect of applications made under section 115 of the Ordinance

For the purposes of section 115(3) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a wholesaler licence in Chinese herbal medicines -

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so

that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material; and

(d) the premises are in all other respects suitable for carrying on a business in the wholesale of Chinese herbal medicines.

5. Licensing requirements in respect of applications made under section 132 of the Ordinance

For the purposes of section 132(2) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a manufacturer licence -

(a) the premises to which the application relates are in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are to be stored in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material;

(d) fittings and equipment suitable for use in the manufacturing process specified in the application are provided in the premises;

(e) where intermediate products generated or proprietary Chinese medicines manufactured in the course of manufacture, or both, are to be stored in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the products or medicines, or both, as the case may be, are provided in the premises;

(f) the humidity, lighting, temperature and ventilation of the part of the premises provided for -

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines,

are suitable for their respective purposes;

(g) the premises are in all other respects suitable for carrying on a business in the manufacture of proprietary Chinese medicines; and

(h) each responsible person nominated in the application complies with the minimum requirements regarding knowledge and experience as set out in section 2 of Schedule 1.

6. Licensing requirements in respect of applications made under section 135 of the Ordinance

For the purposes of section 135(2) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a wholesaler licence in proprietary Chinese medicines -

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing proprietary Chinese medicines are provided in the premises; and

(c) the premises are in all other respects suitable for carrying on a business in the wholesale of proprietary Chinese medicines.

PART 3

DUTIES OF HOLDERS OF RETAILER LICENCES

7. General duties of holders of retailer licences

A holder of a retailer licence shall ensure that -

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) the facilities for storing Chinese herbal medicines are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) where Chinese herbal medicines are dispensed in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for dispensing the medicines are provided in the premises;

(f) the facilities (if any) for dispensing Chinese herbal medicines are maintained in good condition;

(g) each type of Chinese herbal medicine stored in the premises is stored in a separate container;

(h) each container referred to in paragraph (g) -

(i) has the name of the medicine stored in it being printed or affixed in a conspicuous position;

(ii) has the name of the medicine stored in it being clearly and distinctly set out and not in any way obscured or obliterated; and

(iii) is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicine stored in it;

(i) no Chinese herbal medicine in his possession is dispensed to any person otherwise than under the supervision of a responsible person;

(j) he does not -

(i) sell by retail;

(ii) dispense to another person; or

(iii) possess for the purpose of retail,

any Chinese herbal medicine other than those acquired or received by him from a holder of a wholesaler licence in Chinese herbal medicines; and

(k) where a prescription given by a registered or listed Chinese medicine practitioner is presented for dispensing any Chinese herbal medicine, the prescription is, as soon as is reasonably practicable after the dispensation is completed, returned to the person by whom it is presented with the following particulars added on it -

(i) the date of the dispensation; and

(ii) the name, address and telephone number of the licence holder.

8. Other duties of holders of retailer licences - keeping of records

(1) A holder of a retailer licence shall ensure that every transaction whereby a Chinese herbal medicine is acquired or received by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction -

(a) the date of the transaction;

(b) the name and quantity of the medicine acquired or received;

(c) the name, address and telephone number of the person who sells or distributes the medicine to him; and

(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

9. Additional duties of holders of retailer licences in respect of Schedule 1 medicines

(1) A holder of a retailer licence in respect of Schedule 1 medicines shall ensure that the following particulars in respect of each dispensation of a Schedule 1 medicine conducted in accordance with a prescription given by a registered Chinese medicine practitioner under section 109(1) of the Ordinance are recorded -

(a) the name and quantity of the medicine dispensed;

(b) the name and address of the registered Chinese medicine practitioner who gives the prescription;

(c) the name and, if known by the responsible person who supervises the dispensation, the address and telephone number of the person to whom the prescription is given;

(d) the date of the dispensation; and

(e) the name of the responsible person referred to in paragraph (c).

(2) The licence holder shall also ensure that -

(a) the particulars mentioned in subsection (1) are recorded as soon as is reasonably practicable after the dispensation;

(b) the responsible person referred to in subsection (1)(c) has affixed his signature in the record prepared pursuant to subsection (1); and

(c) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the dispensation.

10. Additional duties of holders of retailer licences in respect of Schedule 2 medicines

A holder of a retailer licence in respect of Schedule 2 medicines shall ensure that where a prescription given by a registered or listed Chinese medicine practitioner is presented for dispensing any Schedule 2 medicine, the medicine is dispensed in accordance with the prescription.

PART 4

DUTIES OF HOLDERS OF WHOLESALER LICENCES IN CHINESE HERBAL MEDICINES

11. General duties of holders of wholesaler licences in Chinese herbal medicines

A holder of a wholesaler licence in Chinese herbal medicines shall ensure that -

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) the facilities for storing Chinese herbal medicines are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) each type of Chinese herbal medicine stored in the premises is stored in a separate container;

(f) each container referred to in paragraph (e) is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the Chinese herbal medicine stored in it;

(g) where any Chinese herbal medicine or mixture of Chinese herbal medicines is processed in the premises -

(i) equipment and facilities suitable for processing are provided in the premises;

(ii) the equipment and facilities for processing are maintained in good condition;

(iii) the processed medicine or mixture is examined by the licence holder to ensure its quality before it is offered for sale or supplied to or used by any other person;

(iv) the following particulars in relation to each processing are recorded -

(A) the name and quantity of each type of material (including the Chinese herbal medicine or mixture of Chinese herbal medicines to be processed) used in the processing;

(B) the name and quantity of the processed medicine or mixture;

(C) the name or a description of the processing method;

(D) the date of the completion of the processing;

(E) the result of the examination referred to in subparagraph (iii); and

(F) the name of the person who supervises the processing;

(v) the particulars mentioned in subparagraph (iv) are recorded within 72 hours after the completion of the processing; and

(vi) the record prepared pursuant to subparagraph (iv) is retained in the premises to which the licence

relates for a period of not less than 2 years from the date of the completion of the processing.

(h) no Chinese herbal medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(i) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any Chinese herbal medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

12. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 1 medicines - selling restrictions

A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines may sell or distribute a Schedule 1 medicine only to the following categories of persons or entities -

(a) a holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines;

(b) a holder of a retailer licence in respect of Schedule 1 medicines;

(c) a holder of a manufacturer licence;

(d) a registered Chinese medicine practitioner;

(e) a person or an institution exempted under section 158(1) of the Ordinance requiring the medicine for the purpose of education or scientific research;

(f) a Government department or public officer requiring the medicine for the purpose of public service;

(g) a purchaser outside Hong Kong;

(h) a hospital or clinic managed or controlled by the Hospital Authority established under section 3(1) of the Hospital Authority Ordinance (Cap. 113); or

(i) a hospital within the meaning of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165).

13. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 1 medicines - keeping of records

(1) A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines shall ensure that the following particulars in respect of every transaction whereby a Schedule 1 medicine is acquired, received, sold or distributed by him are recorded -

(a) the date of the transaction;

(b) the nature of the transaction;

(c) the name and quantity of the medicine acquired, received, sold or distributed, as the case may be;

(d) the name, address and telephone number of -

(i) the person who sells or distributes the medicine to him; or

(ii) the person to whom he sells or distributes the medicine,

as the case may be;

(e) the reference number of the invoice or other document evidencing the transaction; and

(f) the balance of the medicine remaining in his possession after the completion of the transaction.

(2) The licence holder shall ensure that -

(a) the particulars mentioned in subsection (1) are recorded within 72 hours after the completion of the transaction; and

(b) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

(3) The licence holder shall also ensure that -

(a) every transaction mentioned in subsection (1) is evidenced by an invoice or other document which contains the particulars mentioned in subsection (1)(a) to (e); and

(b) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

14. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 2 medicines - keeping of records

(1) A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 2 medicines shall ensure that every transaction whereby a Schedule 2 medicine is acquired, received, sold or distributed by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction -

(a) the date of the transaction;

(b) the name and quantity of the medicine acquired, received, sold or distributed, as the case may be;

(c) the name, address and telephone number of -

(i) the person who sells or distributes the medicine to him; or

(ii) the person to whom he sells or distributes the medicine,

as the case may be; and

(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

PART 5

REGISTRATION OF PROPRIETARY CHINESE MEDICINES

15. Particulars to be registered for proprietary Chinese medicines

For the purposes of section 121(1)(b) of the Ordinance, the following particulars are required to be registered for a proprietary Chinese medicine -

(a) its Chinese and English name;

(b) its dose form;

(c) the name and quantity of each of its active ingredient;

(d) the name and quantity of each of its excipient (if any);

(e) its specification;

(f) its indication (if any);

(g) its dosage and method of usage;

(h) each of its labels to be attached or printed on its package;

(i) the package insert to be supplied for its sales inside Hong Kong;

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

(k) the name and address of each of its manufacturer; and

(l) its function or pharmacological action.

PART 6

DUTIES OF HOLDERS OF MANUFACTURER LICENCES

16. General duties of holders of manufacturer licences

A holder of a manufacturer licence shall ensure that -

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are stored in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) the facilities (if any) for storing ingredients or packing materials, or both, as the case may be, are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) fittings and equipment suitable for use in the manufacturing process specified in the licence are provided in the premises;

(f) the fittings and equipment used in the manufacturing process are maintained in good condition;

(g) where intermediate products generated or proprietary Chinese medicines manufactured in the course of manufacture, or both, are stored in the premises -

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the products or medicines, or both, as the case may be, are provided in the premises;

(h) the facilities (if any) for storing intermediate products or proprietary Chinese medicines, or both, are maintained in good condition;

(i) the humidity, lighting, temperature and ventilation of the part of the premises provided for -

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines,

are suitable for their respective purposes;

(j) where any ingredient is used in the manufacturing process, the ingredient is examined by a responsible person before it is used to ensure its identity and quality;

(k) no manufacturing process is carried out in the premises otherwise than under the supervision of a responsible person;

(l) adequate steps have been taken to prevent contamination of any ingredient or packing material used, any

intermediate product generated or any proprietary Chinese medicine manufactured in the course of manufacture;

(m) each batch of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture, or both, is examined by a responsible person before it is sold or distributed by the holder of the licence to ensure its quality;

(n) no proprietary Chinese medicine that he manufactures is sold or distributed by him after its expiry date;

(o) each container or package of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the products or medicines, as the case may be;

(p) no intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the product or medicine, as the case may be;

(q) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture which has been sold or distributed in the event of the product or medicine, as the case may be, being found to be dangerous, injurious to health or unfit for human consumption;

(r) a control sample of each batch of intermediate product (if any) generated in the course of manufacture which has been sold is retained, under suitable conditions of storage, in the premises from the date on which the batch of product is generated until the expiry of 2 years from the date of the last transaction in the batch of product; and

(s) a control sample of each batch of proprietary Chinese medicine (if any) manufactured in the course of manufacture is retained, under suitable conditions of storage, in the premises from the date of the manufacture until the expiry of 2 years from the expiry date of the batch of medicine.

17. Other duties of holders of manufacturer licences - keeping of documents relating to acquisition of ingredients

(1) A holder of a manufacturer licence shall ensure that every transaction whereby a batch of ingredient is acquired or received by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction -

(a) the date of the transaction;

(b) the name and quantity of the batch of ingredient acquired or received by him;

(c) the name, address and telephone number of the person who sells or distributes the batch of ingredient to him; and

(d) the reference number of the invoice or other document.

(3) Subject to subsections (4) and (5), the licence holder shall also ensure that the invoice or other document evidencing the transaction is retained

in the premises to which the licence relates from the date of the transaction until the expiry of 2 years -

(a) in the case where a batch of intermediate product is generated from the batch of ingredient, from the date of generation of the batch of product; or

(b) in the case where a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, from the expiry date of the batch of medicine.

(4) Where 2 or more batches of intermediate product or proprietary Chinese medicine are generated or manufactured, as the case may be, from the batch of ingredient and they have different dates of generation or expiry dates, as the case may be, the invoice or other document shall be retained until the expiry of 2 years from the latest of such dates of generation or expiry dates, as the case may be.

(5) Where a batch of intermediate product is generated and a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, the invoice or other document shall be retained until the expiry of 2 years from the latter of the dates referred to in subsection (3)(a) or (b).

18. Other duties of holders of manufacturer licences - keeping of manufacturing records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of each manufacturing process of a proprietary Chinese medicine carried out by him are recorded -

(a) the name of the intermediate product generated or proprietary Chinese medicine manufactured from the manufacturing process, or both, as the case may be;

(b) the quantity of the batch of product or medicine, or both, as the case may be;

(c) the expiry date and batch number of the batch of medicine (applicable only where a proprietary Chinese medicine is manufactured from the manufacturing process);

(d) the name and quantity of each ingredient or packing material used in the manufacturing process;

(e) a description of each manufacturing method used; and

(f) the date on which the manufacturing process -

(i) begins; and

(ii) is completed.

(2) The licence holder shall also ensure that -

(a) the particulars mentioned in subsection (1) (other than those referred to in subsection (1)(b) and (f)(ii)) are recorded within 72 hours after the manufacturing process begins;

(b) the particulars mentioned in subsection(1)(b) and (f)(ii) are recorded within 72 hours after the manufacturing process is completed; and

(c) subject to subsection (3), the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years -

(i) in the case where the record relates to a batch of intermediate product, from the date of the last transaction in the batch of product or the date when the batch of product is used up by the licence holder, whichever is later; or

(ii) in the case where the record relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) Where the record prepared pursuant to subsection (1) relates to a batch of intermediate product and proprietary Chinese medicine, the record shall be retained until the expiry of 2 years from the latter of the dates referred to in subsection (2)(c)(i) or (ii).

19. Other duties of holders of manufacturer licences - keeping of transaction records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of every transaction whereby a batch of intermediate product generated or a batch of proprietary Chinese medicine manufactured in the course of manufacture is sold or distributed by him are recorded -

(a) the date of the transaction;

(b) the name and quantity of the batch of product or medicine sold or distributed, as the case may be;

(c) the name, address and telephone number of the person to whom he sells or distributes the batch of product or medicine, as the case may be;

(d) the batch number of the batch of medicine (applicable only where the transaction relates to a proprietary Chinese medicine); and

(e) the reference number of the invoice or other document evidencing the transaction.

(2) The licence holder shall ensure that -

(a) the particulars mentioned in subsection (1) are recorded within 72 hours after the completion of the transaction; and

(b) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years -

(i) in the case where the transaction relates to a batch of intermediate product, from the date of the transaction; or

(ii) in the case where the transaction relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) The licence holder shall also ensure that -

(a) every transaction mentioned in subsection (1) is evidenced by an invoice or other document which contains the particulars mentioned in that subsection; and

(b) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates from the date of the transaction until the expiry of 2 years from the dates referred to in subsection (2)(b)(i) or (ii), as the case may be.

PART 7

DUTIES OF HOLDERS OF WHOLESALER LICENCES IN PROPRIETARY CHINESE MEDICINES

20. General duties of holders of wholesaler licences in proprietary Chinese medicines

A holder of a wholesaler licence in proprietary Chinese medicines shall ensure that -

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing proprietary Chinese medicines are provided in the premises;

(c) the facilities for storing proprietary Chinese medicines are maintained in good condition;

(d) no proprietary Chinese medicine in his possession is sold or distributed after its expiry date;

(e) all proprietary Chinese medicines sold or distributed by him are packed using materials that are sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicine;

(f) no proprietary Chinese medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(g) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any proprietary Chinese medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

21. Other duties of wholesalers in proprietary Chinese medicines - keeping of transaction records

(1) A holder of a wholesaler licence in proprietary Chinese medicines shall ensure that every transaction whereby a proprietary Chinese medicine is acquired, received, exported, sold or distributed by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction -

(a) the date of the transaction;

(b) the name and quantity of the medicine acquired, received, exported, sold or distributed, as the case may be;

(c) the name, address and telephone number of -

(i) the person who imports, sells or distributes the medicine to him; or

(ii) the person to whom he exports, sells or distributes the medicine,

as the case may be; and

(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

PART 8

REQUIREMENTS REGARDING LABELLING OF CONTAINERS AND PACKAGES

22. Chinese herbal medicines to be labelled

For the purposes of section 142 of the Ordinance, a wholesale dealer in Chinese herbal medicines shall attach to 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.

23. Labelling of containers of Schedule 1 medicines by wholesale dealers

(1) A wholesale dealer in Schedule 1 medicines shall ensure that a label attached to or printed on a container in which a Schedule 1 medicine is stored -

(a) includes the particulars set out in subsection (2); and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) A label referred to in subsection (1) shall include the following particulars in respect of the medicine stored in the container -

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

(b) the name of the wholesale dealer as specified in its wholesaler licence;

(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) (if the warning referred to in paragraph (d) is to be available in English also) a warning containing the English text: "Toxic Chinese Medicine".

24. Labelling of containers of Schedule 2 medicines by wholesale dealers

A wholesale dealer in Schedule 2 medicines shall ensure that a label attached to or printed on a container in which a Schedule 2 medicine is stored -

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

(b) has the name of the medicine being clearly and distinctly set out and not in any way obscured or obliterated.

25. Proprietary Chinese medicines to be labelled

For the purposes of section 143 of the Ordinance, no person shall sell or have in his possession for the purpose of selling any proprietary Chinese medicine unless the package of the medicine is labelled in a conspicuous position.

26. Labelling of proprietary Chinese medicines to be sold in Hong Kong

(1) A person who sells in Hong Kong or has in his possession for the purpose of selling in Hong Kong a proprietary Chinese medicine shall ensure that a label on a package of the medicine -

(a) includes the particulars set out in subsection (2), (3) or (4), as the case may be; and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) Except as otherwise provided in subsections (3) and (4), a label on a package of a proprietary Chinese medicine to be sold in Hong Kong, whether being the outermost package to be sold or distributed to an ultimate user of the medicine or otherwise, shall include the following particulars, at least in Chinese -

(a) the name of the medicine;

(b) if -

(i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient; or

(ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients;

(c) the name of the country or territory in which the medicine is produced;

(d) the registration number of the medicine as specified in its certificate of registration;

(e) if the package –

(i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or

(ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;

(f) its packing specification;

(g) its dosage and method of usage;

(h) its expiry date; and

(i) its batch number.

(3) Except as otherwise provided in subsection (4), a label on a package of a proprietary Chinese medicine to be sold in Hong Kong, not being the outermost package to be sold or distributed to an ultimate user of the medicine, which -

(a) is in the form of a strip pack, blister pack or similar article, shall include, at least in Chinese, the name of the medicine, the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine, and the expiry date, packing specification and batch number of the medicine;

(b) is in the form of an ampoule, vial or similar receptacle, with not more than 10 ml capacity or equivalent, shall include, at least in Chinese, the name of the medicine; or

(c) contains a single dose in the form of a pill, shall include, at least in Chinese, the name of the medicine.

(4) A label on a package of a proprietary Chinese medicine which is -

(a) manufactured in the premises in respect of which a manufacturer licence is in force;

(b) manufactured by or under the supervision of a responsible person in accordance with a prescription given by a registered or listed Chinese medicine practitioner; and

(c) to be sold or distributed to the Chinese medicine practitioner,

shall include the following particulars, at least in Chinese -

(d) if the prescription is given to a patient under the direct care of the Chinese medicine practitioner, and the prescription indicates that the medicine is for internal application or both internal and external application -

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

(ii) the name and address of the manufacturer who produces the medicine;

(iii) its batch number;

(iv) the date on which it is produced;

(v) its dose form;

(vi) its packing specification;

(vii) its expiry date;

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

(ix) a statement containing the following Chinese text -

(A) "須按照中醫指示使用"; or

(B) "須按照中醫指示使用";

(x) (if the statement referred to in subparagraph (ix) is to be available in English also) a statement containing the English text: "To be used only in accordance with the instructions of a Chinese medicine practitioner";

(xi) 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"; and

(xii) (if the statement referred to in subparagraph (xi) is to be available in English also) 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";

(e) if the medicine is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner, and the prescription indicates that the medicine is for external application only -

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

(ii) the name and address of the manufacturer who produces the medicine;

(iii) its batch number;

(iv) the date on which it is produced;

(v) its dose form;

(vi) its packing specification;

(vii) its expiry date;

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

(ix) a statement containing the following Chinese text -

(A) "須按照中醫指示使用"; or

(B) "須按照中醫指示使用";

(x) (if the statement referred to in subparagraph (ix) is to be available in English also) a statement containing the English text: "To be used only in accordance with the instructions of a Chinese medicine practitioner";

(xi) 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) "只供中醫施用於或供應予由他直接治理的病人";

(xii) (if the statement referred to in subparagraph (xi) is to be available in English also) 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";

(xiii) a statement containing the Chinese text: "只供外用"; and

(xiv) (if the statement referred to in subparagraph (xiii) is to be available in English also) a statement containing the English text: "For external application only".

27. Labelling of proprietary Chinese medicines to be exported

A person who exports or has in his possession for the purpose of exporting a 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 -

(a) includes the following particulars -

(i) the name of the medicine;

(ii) the name of the holder of the certificate of registration of the medicine as specified in the certificate; and

(iii) the registration number of the medicine as specified in its certificate of registration; and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

PART 9

REQUIREMENTS FOR PACKAGE INSERTS

28. Requirements for package inserts

(1) For the purposes of section 144 of the Ordinance, no person shall sell in Hong Kong or have in his possession for the purpose of selling in Hong Kong any proprietary Chinese medicine without a package insert which -

(a) includes the particulars set out in subsection (2); and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) A package insert of a proprietary Chinese medicine to be sold in Hong Kong shall include, at least in Chinese, the following particulars in respect of the medicine -

(a) the name of the medicine;

(b) if -

(i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient and its quantity; or

(ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients and their respective quantities;

(c) either the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces 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.

PART 10

DURATION OF LICENCES AND CERTIFICATES

29. Duration of licences

(1) A licence issued under section 114(3), 115(3), 132(2) or 135(2) of the Ordinance shall be for a period of 2 years.

(2) A licence renewed under section 116(3) or 136(3) of the Ordinance shall be for a period of 2 years or for such shorter period as considered appropriate by the Medicines Board.

30. Duration of certificates

(1) A certificate issued under section 121(2) of the Ordinance shall be for a period of 5 years.

(2) A certificate renewed under section 123(3) of the Ordinance shall be for a period of 5 years or for such shorter period as considered appropriate by the Medicines Board.

(3) A certificate issued under section 133 of the Ordinance shall be for a period of 2 years or for such shorter period as considered appropriate by the Medicines Board.

PART 11

OFFENCES AND PENALTIES

31. Offences and penalties

A person who contravenes a provision of this Regulation set out in column 1 of Schedule 2 commits an offence and is liable on conviction to the penalty set out opposite that provision in columns 2 and 3 of that Schedule.

PART 12

EXEMPTIONS

32. Exemptions for applications for retailer licences

Section 114(2)(b) of the Ordinance shall not apply in respect of an application for a retailer licence if the application states that no Chinese herbal medicine is to be dispensed in the premises to which the application relates.

33. Exemptions for persons or institutions concerned with education or scientific research

The Medicines Board may exempt, with or without conditions or restrictions, a person or institution concerned with education or scientific research from the application of sections 143 and 144 of the Ordinance if the proprietary Chinese medicine in question is required for the purpose of education or scientific research.

34. Exemptions for proprietary Chinese medicines imported for re-export and conducting clinical trials or medicinal tests

Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is -

(a) imported by a wholesaler in proprietary Chinese medicines for the purpose of re-exporting by the same wholesaler; or

(b) imported by a holder of a valid certificate for clinical trial and medicinal test issued under section 129 of the Ordinance and to be used for the purpose of the clinical trial or medicinal test to which the certificate relates.

35. Exemptions for proprietary Chinese medicines manufactured in Hong Kong and to be exported

Section 144 of the Ordinance shall not apply in the case where a person is in possession of a proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting the medicine.

36. Exemptions for proprietary Chinese medicines compounded by Chinese medicine practitioners or in accordance with prescriptions given by Chinese medicine practitioners

Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is -

(a) compounded by or under the supervision of a registered or listed Chinese medicine practitioner at the premises where he practises if, and only if, such proprietary Chinese medicine is being used for the purpose of administering or supplying to a patient under his direct care; or

(b) individually prepared or compounded -

(i) by a responsible person; or

(ii) under the supervision of such person,

at the premises in respect of which a retailer licence is in force and in accordance with a prescription given by a registered or listed Chinese medicine practitioner.

37. Exemptions for proprietary Chinese medicine manufactured in accordance with prescriptions given by Chinese medicine practitioners and to be administered or supplied to their patients

(1) Sections 119 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine if -

(a) the medicine is manufactured -

(i) in the premises in respect of which a manufacturer licence is in force; and

(ii) by or under the supervision of a responsible person in accordance with a prescription given by a registered or listed Chinese medicine practitioner;

(b) the medicine is -

(i) 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

(ii) 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

(c) 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 including the particulars set out in subsection (2) and being accompanied by an undertaking referred to in subsection (3).

(2) A notification referred to in subsection (1)(c) shall include -

(a) the quantity of the medicine to be manufactured;

(b) the names and quantities of each ingredient listed in the prescription;

(c) its dose form;

(d) the name and address of the registered or listed Chinese medicines practitioner; and

(e) the date on which the Chinese medicine practitioner entrusts the manufacturer to manufacture the proprietary Chinese medicine.

(3) A notification referred to in subsection (1)(c) shall be accompanied by a written undertaking given by the registered or listed Chinese medicine practitioner to the manufacturer, stating that the medicine will only be administered or supplied to -

(a) (in the case where the medicine is for internal application or both internal and external application) the patient to whom the prescription is given and who is under his direct care; or

(b) (in the case where the medicine is for external application only) a patient or patients under his direct care.

PART 13

FORMS

38. Certificate of sale of proprietary Chinese medicine

A certificate issued under section 130(1) of the Ordinance shall be in the form prescribed in Schedule 3.

39. Manufacturer licence

A licence issued under section 132(2) of the Ordinance shall be in the form prescribed in Schedule 4.

40. Certificate for manufacturer

A certificate issued under section 133 of the Ordinance shall be in the form prescribed in Schedule 5.

SCHEDULE 1 [ss. 3 & 5]

MINIMUM REQUIREMENTS REGARDING KNOWLEDGE AND EXPERIENCE OF RESPONSIBLE PERSONS

1. A responsible person nominated under section 114(2)(b) of the Ordinance shall -

(a) (i) hold a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 6 months' practical experience in dispensing Chinese herbal medicines in Hong Kong;

(b) (i) hold a diploma in Chinese medicines awarded by a university in Hong Kong;

(ii) hold a diploma in Chinese medicines awarded by the Vocational Training Council; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 1 year's practical experience in dispensing Chinese herbal medicines in Hong Kong;

(c) in the case where he is a registered or listed Chinese medicine practitioner, have 6 months' practical experience in dispensing Chinese herbal medicines in Hong Kong;

(d) in the case where he is a pharmacist registered under the Pharmacy and Poisons Ordinance (Cap. 138) -

(i) hold a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 1 year's practical experience in dispensing Chinese herbal medicines in Hong Kong;

(e) (i) hold a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120 hour course;

(ii) hold a certificate in Chinese medicines awarded by the Vocational Training Council on completion of a 120 hour course; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 3 years' practical experience in dispensing Chinese herbal medicines in Hong Kong; or

(f) have 5 years' practical experience in dispensing Chinese herbal medicines in Hong Kong.

2. A responsible person nominated under section 132(1)(b) of the Ordinance shall -

(a) (i) hold a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;

(b) (i) hold a diploma in Chinese medicines awarded by a university in Hong Kong;

(ii) hold a diploma in Chinese medicines awarded by the Vocational Training Council; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 1 year's practical experience in manufacturing proprietary Chinese medicines in Hong Kong;

(c) in the case where he is a registered or listed Chinese medicine practitioner, have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;

(d) in the case where he is a pharmacist registered under the Pharmacy and Poisons Ordinance (Cap. 138) -

(i) hold a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;

(e) (i) hold a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120 hour course;

(ii) hold a certificate in Chinese medicines awarded by the Vocational Training Council on completion of a 120 hour course; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 3 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong; or

(f) have 5 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong.

SCHEDULE 2 [s. 31]

OFFENCES AND PENALTIES

Column 1 Section	Column 2 Fine	Column 3 Imprisonment
7(h)(i) or (ii)	level 6	2 years
7(k)	level 6	--
8(1), (2) or (3)	level 6	--
9(1) or (2)	level 6	--
10	level 6	2 years
11(g)(iv), (v) or (vi)	level 6	--
12	level 6	2 years
13(1), (2) or (3)	level 6	--
14(1), (2) or (3)	level 6	--
17(1), (2) or (3)	level 6	--
18(1) or (2)	level 6	--
19(1), (2) or (3)	level 6	--
21(1), (2) or (3)	level 6	--
23(1)	level 6	2 years
24	level 6	2 years
26(1)	level 6	2 years

SCHEDULE 3 [s. 38]

CERTIFICATE OF SALE OF PROPRIETARY CHINESE MEDICINE

CHINESE MEDICINE ORDINANCE
(Chapter 549)

CERTIFICATE OF SALE OF PROPRIETARY CHINESE MEDICINE

Name of the proprietary Chinese medicine: (Chinese) _____

(English) _____

Dose form: _____

Packing specification: _____

Names and quantities of its active ingredients (as set out in a package insert of the medicine required to be supplied for its sales in Hong Kong): _____

_____

Manufacturer(s) name: _____

Address: _____

_____

It is certified that -

(a) the proprietary Chinese medicine specified in this Certificate is registered under section 121 of the Chinese Medicine Ordinance;
Certificate no.: _____
Date of registration: _____

(b) the premises in Hong Kong in which the proprietary Chinese medicine is manufactured are subject to regular inspections;

(c) other statements (if applicable): _____

_____

The proprietary Chinese medicine is allowed to be sold in Hong Kong.

This Certificate is valid until _____

Date of issue: _____

_____

for Chinese Medicines Board

Hong Kong Special Administrative Region

SCHEDULE 4 [s. 39]

MANUFACTURER LICENCE

CHINESE MEDICINE ORDINANCE
(Chapter 549)

MANUFACTURER LICENCE

_____ of _____

_____

is licensed to manufacture proprietary Chinese medicines at _____ from _____ to _____ (both dates inclusive), subject to the conditions specified in this licence.

Dated this _____ day of _____

_____
for Chinese Medicines Board

Hong Kong Special Administrative Region

CONDITIONS

SCHEDULE 5 [s. 40]

CERTIFICATE FOR MANUFACTURER

CHINESE MEDICINE ORDINANCE
(Chapter 549)

CERTIFICATE FOR MANUFACTURER
(Good manufacturing practice in respect of proprietary Chinese medicines)

It is hereby certified that _____ of _____

(1) is the holder of a manufacturer licence -

(a) Licence no.: _____

(b) Duration of licence: _____

(c) Date of issue: _____;

(2) is licensed to manufacture proprietary Chinese medicines;

(3) _____

(the address of the premises in Hong Kong in which proprietary Chinese medicines are manufactured) is subject to regular inspections and the inspections show that the manufacturer follows the requirements of good practices in manufacture and quality control of proprietary Chinese medicines.

This Certificate is valid until _____

Date of issue: _____

_____
for Chinese Medicines Board

Hong Kong Special Administrative Region

Chairman,
Chinese Medicine Council of Hong Kong

2002

Explanatory Note

This Regulation is made under section 161 of the Chinese Medicines Ordinance (Cap. 549)("the Ordinance"). The main purpose of the Regulation is to provide for the further regulation and supervision of the sale and manufacture of Chinese herbal medicines and proprietary Chinese medicines.

2. Part 1 comprising sections 1 and 2 is preliminary and, in section 2, the terms used in the Regulation are defined.

3. Part 2 provides for the licensing requirements in respect of applications for retailer, wholesaler and manufacturer licences (sections 3 to 6 and Schedule 1).

4. Part 3 specifies the duties of a holder of a retailer licence in Chinese herbal medicines (sections 7 to 10).

5. Part 4 specifies the duties of a holder of a wholesaler licence in Chinese herbal medicines (sections 11 to 14).

6. Part 5 deals with particulars required to be registered for a proprietary Chinese medicine (section 15).

7. Part 6 specifies the duties of a holder of a manufacturer licence in proprietary Chinese medicines (sections 16 to 19).

8. Part 7 specifies the duties of a holder of a wholesaler licence in proprietary Chinese medicines (sections 20 and 21).

9. Part 8 provides for the requirements regarding the labelling of containers and packages of Chinese herbal medicines and proprietary Chinese medicines -

(a) section 22 provides for the manner in which a label is to be attached to or printed on a container of Chinese herbal medicines for the purposes of section 142 of the Ordinance;

(b) section 23 provides for the requirements in respect of a label attached to or printed on a container of Schedule 1 medicines by a wholesale dealer in Chinese herbal medicines;

(c) section 24 provides for the requirements in respect of a label attached to or printed on a container of Schedule 2 medicines by a wholesale dealer in Chinese herbal medicines;

(d) section 25 provides for the manner of labelling of packages of proprietary Chinese medicines for the purposes of section 143 of the Ordinance;

(e) section 26 provides for the requirements in respect of labels on packages of proprietary Chinese medicines to be sold in Hong Kong; and

(f) section 27 provides for the requirements in respect of labels on packages of proprietary Chinese medicines manufactured in Hong Kong which are to be exported.

10. Part 9 specifies the requirements of package inserts of proprietary Chinese medicines to be sold in Hong Kong for the purposes of section 144 of the Ordinance (section 28).

11. Part 10 specifies the duration of certain licences and certificates (sections 29 and 30).

12. Part 11 provides for offences and penalties in respect of contraventions of certain provisions of the Regulation (section 31 and Schedule 2).

13. Part 12 sets out the exemption provisions. Section 32 sets out the circumstances under which applications for retailer licences are exempt from section 114(2)(b) of the Ordinance. Sections 33 to 37 provide exemptions for

certain proprietary Chinese medicines from the application of sections 119 (proprietary Chinese medicines to be registered), 143 (proprietary Chinese medicines to be labelled) and 144 (package inserts for proprietary Chinese medicines) of the Ordinance.

14. Part 13 (sections 38 to 40) and Schedules 3, 4 and 5 prescribe the forms of a certificate of sale of proprietary Chinese medicines, a manufacturer licence and a certificate for manufacturer.

CHINESE MEDICINES TRADERS (REGULATORY) REGULATION

CONTENTS

PART 3

PROCEDURES OF MEETING HELD BY THE BOARD FOR CONSIDERING COMPLAINT OR INFORMATION

CHINESE MEDICINES TRADERS (REGULATORY) REGULATION

(Made by the Chinese Medicine Council of Hong Kong under section 161(5) of the Chinese Medicine Ordinance (Cap. 549) with the approval of the Secretary for Health, Welfare and Food)

PART 1

PRELIMINARY

1. Commencement

This Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice published in the Gazette.

2. Interpretation

In this Regulation, unless the context otherwise requires –

"Board" (中藥組) means the Chinese Medicines Board established by section 12(b) of the Ordinance;

"Board chairman" (中藥組主席) means the chairman of the Board mentioned in section 14(a) of the Ordinance;

"Board secretary" (中藥組秘書) means the secretary of the Board appointed under section 23(2) of the Ordinance;

"Committee" (小組) means the Regulatory Committee of Chinese Medicines Traders established under section 25(1)(b)(iii) of the Ordinance;

"Committee chairman" (小組主席) means the chairman of the Committee mentioned in section 31(b)(i) of the Ordinance;

"Committee secretary" (小組秘書) means the secretary of the Committee;

"complainant" (申訴人) means a person from whom a complaint or information has been received by the Board under section 3;

"defendant" (被告人), in relation to a complaint or information, means a licensed Chinese medicines trader in respect of whom a complaint or information has been made;

"licensed Chinese medicines trader" (持牌中藥業者) means a Chinese medicines trader who holds a licence to which section 139 of the Ordinance applies.

PART 2

PROCEDURES BEFORE THE BOARD HOLDS A MEETING FOR CONSIDERING A CASE

3. Receipt and submission of complaint or information

(1) Any complaint or information alleging that the conduct of a licensed Chinese medicines trader is such that the Board may exercise powers under section 139 of the Ordinance shall be made or given to the Board.

(2) Where a complaint or information is received by the Board under subsection (1), the Board secretary shall submit the complaint or information to the Committee for investigation and consideration in accordance with the procedures laid down in this Regulation.

4. Clarification and support for complaint or information

(1) The Committee chairman may –

(a) require the complainant to set out in writing the specific allegations constituting the complaint or information and the grounds for the allegations;

(b) require the complainant to make clarifications or furnish evidence about the complaint or information;

(c) direct the Committee secretary to seek any legal advice or any necessary assistance or advice from any relevant authorities with regard to the evidence about the complaint or information; and

(d) require that any allegation in the complaint or information be supported by one or more statutory declarations, unless the complaint or information is in writing and made by a public officer in the discharge of his duties.

(2) A statutory declaration referred to in subsection (1) –

(a) shall state the name, address and the Hong Kong Identity Card number or details of another document of identification of the declarant; and

(b) shall state all the facts of the complaint or information to the best of the declarant's knowledge, or if any fact declared is not within his personal knowledge, state the source of the declarant's information and the grounds for his belief in the truth of those facts.

5. Submission of case to Committee

(1) Where the Committee chairman considers that –

(a) all further clarifications, evidence and statutory declarations that are necessary to enable the Committee to consider the complaint or information have been furnished; or

(b) it is impracticable to seek further clarifications, evidence or statutory declarations,

he shall fix a date for the Committee to consider the complaint or information.

(2) When the Committee chairman has fixed a date under subsection (1), he shall arrange to notify the defendant in writing at least 1 month before the date fixed –

(a) of the receipt of the complaint or information, and of any allegations that constitute the complaint or information; and

(b) of the date on which the Committee will meet to consider the complaint or information.

(3) A notification under subsection (2) shall be accompanied by –

(a) a copy of the complaint or information;

(b) a copy of any statutory declaration furnished under section 4(1)(d); and

(c) an invitation to the defendant –

(i) to submit in writing not less than 7 days before the meeting to the Committee any explanation for his conduct or for any matter alleged in the complaint or information, any representations or any statement in mitigation; and

(ii) to attend the meeting to make oral representations, if necessary.

(4) If the Committee chairman considers that in the particular circumstances of a case it is desirable that any personal particulars of any person contained in any documents mentioned in subsection (3)(a) or (b) should not be disclosed to the defendant, he may arrange for such necessary obliteration or other editorial modification of the copies of those documents to be supplied to the defendant so that those personal particulars are not disclosed.

6. Consideration of complaint, etc. by Committee

(1) A meeting of the Committee to consider a complaint or information shall be held in private.

(2) Within a reasonable period before any meeting of the Committee to consider a complaint or information, the Committee secretary shall provide all members of the Committee who will consider the complaint or information with copies of all the documents relating to the complaint or information that he has received.

(3) The Committee may postpone its consideration or decision of a complaint or information, in whole or in part, to such date or adjourn a meeting from time to time as it thinks fit.

(4) Where the Committee considers that any allegations notified to the defendant under section 5(2) should be amended, the Committee may direct the Committee secretary to –

(a) make the amendment;

(b) advise the defendant of the amendment; and

(c) invite him to submit any further explanation, representations or statement in mitigation.

(5) Before coming to a decision regarding a recommendation to the Board under subsection (7), (8) or (9), the Committee may cause to be made such further investigations or further clarifications from the defendant with regard to the case being considered by the Committee and with regard to his explanation, representations and statement in mitigation, and may seek such additional advice or assistance as it considers desirable.

(6) The Committee shall, having regard to any explanation, representations and statement in mitigation provided by the defendant and all the materials before it, consider the case.

(7) If the Committee is of the opinion that the conduct of the defendant is such that the Board may exercise powers under section 139 of the Ordinance, the Committee shall recommend to the Board accordingly.

(8) If the Committee is of the opinion that the case may be adequately disposed of by the Committee issuing a letter of advice to the defendant regarding the subject matter of the complaint or information against him and

without the Board exercising its powers under section 139 of the Ordinance, the Committee shall recommend to the Board accordingly.

(9) If the Committee is of the opinion that –

(a) the matter of which the defendant is alleged, even if proven to be true, does not affect his practice as a licensed Chinese medicines trader;

(b) the complaint or information is frivolous or groundless;

(c) the defendant has ceased to be a licensed Chinese medicines trader; or

(d) the complaint or information has previously been considered and disposed of by the Committee and no additional information has been provided,

it shall recommend the Board not to exercise its powers under section 139 of the Ordinance.

(10) The Committee shall by written notification submit the case to the Board for consideration as to the exercise by the Board of powers under section 139 of the Ordinance specifying –

(a) the findings of the Committee;

(b) the recommendation of the Committee as to the exercise by the Board of powers under section 139 of the Ordinance; and

(c) the reasons for making the recommendation.

7. Date to be fixed for Board meeting for consideration of complaint or information

(1) On receipt of a notification under section 6(10), the Board chairman shall fix the date of the meeting of the Board for considering the complaint or information.

(2) Unless the Board directs a shorter period of notice to which the defendant has consented in writing, the Board secretary shall, within 2 months of the receipt of the notification under subsection (1) and at least 1 month before the date fixed for the meeting under that subsection, serve on the defendant a notice of meeting together with a copy of this Regulation and shall inform the complainant of the date.

(3) A notice of meeting served under subsection (2) –

(a) shall specify the matters in respect of which the meeting is to be held;

(b) shall state the date, time and place at which the meeting is to be held; and

(c) shall include a summary of the findings, recommendations and reasons for the recommendations of the Committee.

(4) The Board may invite the defendant –

(a) to submit in writing not less than 7 days before the meeting for the Board's consideration any explanation, representations or statement in mitigation; and

(b) to attend the meeting to make oral representations, if necessary.

8. Consolidation of complaints

(1) Where the Board secretary receives any further complaint or information that he thinks is similar in nature to a complaint or information before the Board against the same defendant, he shall submit it to the Committee as soon as practicable.

(2) Upon the notification under section 6(10) by the Committee to the Board of any further complaint or information against the same defendant, the Board may direct that –

(a) the further complaint or information or any part thereof be considered at the same meeting that the Board is to hold in

respect of the defendant, and where the Board makes that direction, evidence relating to the further complaint or information may be introduced at the meeting; and

(b) the notice of meeting be amended accordingly and served on the defendant within such period of time as may be specified in the direction.

9. Amendment of notice of meeting

(1) Where before the opening of the meeting or in the course of the meeting, it appears to the Board chairman that a notice of meeting is defective, the Board chairman may give such directions for its amendment as he thinks necessary to remedy the defect unless, having regard to the merits of the case, he thinks that to make the required amendment will be unjust to the defendant.

(2) The Board secretary shall, as soon as it is practicable after a notice of meeting has been amended under subsection (1), give notice of the amendment to the defendant and to the complainant.

PART 3

PROCEDURES OF MEETING HELD BY THE BOARD FOR CONSIDERING COMPLAINT OR INFORMATION

10. Procedures of meeting

At a meeting for consideration of any complaint or information, the Board secretary shall put before the Board –

(a) a copy of the notice of meeting served on the defendant;

(b) the written notification mentioned in section 6(10);

(c) the complaint or information received;

(d) any statutory declaration received in respect of the complaint or information;

(e) any written explanation, representations or statement in mitigation submitted by the defendant; and

(f) any evidence obtained or any document, statement or report concerning the case or any matter in the nature of evidence relevant to or in support of the complaint or information and which is available.

11. Adjournment of meeting

(1) The Board may postpone its consideration or determination of a case, in whole or in part, to such date or adjourn a meeting from time to time as it thinks fit.

(2) The Board secretary shall, when he is so directed by the Board chairman, give notice of a postponement or adjournment to the defendant and to the complainant as directed.

12. Deliberation of the Board

(1) In the taking of the votes of the Board on any matter to be decided by it, the Board chairman shall call upon the members to signify their votes and shall thereupon declare the decision of the Board in respect of such matter.

(2) Where the decision of the Board so declared by the Board chairman is challenged by any member of the Board, the Board chairman shall call upon each member severally to declare his vote, declare his own vote and announce the number of members of the Board who have voted each way, and the result of the vote.

(3) No person other than members of the Board and the legal adviser to the Board may be present when the Board votes on any matter.

13. Informing defendant of the Board's decision

(1) The Board secretary shall cause to be served on the defendant a notice in writing of the Board's decision and the reasons for the decision.

(2) Where the Board decides to issue a warning to the defendant under section 139(2)(d) of the Ordinance, the Board secretary shall cause to be served the warning together with the notice under subsection (1) on the defendant.

(3) Where the Board decides that a case is to be disposed of by the Committee issuing a letter of advice to the defendant, the Board secretary shall inform the Committee who shall act accordingly.

14. Suspension or revocation of licence not to take immediate effect

A decision of the Board to suspend or revoke a licence under section 139(2)(a) or (b) of the Ordinance shall not take effect –

(a) until after the expiry of the time within which an appeal may be lodged under section 141(1) of the Ordinance; or

(b) in the case of an appeal having in fact been lodged under section 141(1) of the Ordinance, until after a decision of the Court of First Instance has been made.

15. Board not required to inquire into conviction

When considering a record of conviction of a Chinese medicines trader for the purposes of section 139 of the Ordinance –

(a) the Board shall not be required to inquire into the question as to whether the licensed Chinese medicines trader was properly convicted; but

(b) the Board may consider any record of the case in which such conviction was recorded and any other evidence that may be available and is relevant as showing the nature and gravity of the offence.

Chairman,
Chinese Medicine Council
of Hong Kong

2002

Explanatory Note

This 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).

Annex C

Chinese Medicines Regulation
Chinese Medicines Traders (Regulatory) Regulation

Implications of the Proposals

Economic Implications

The regulatory system on Chinese medicines traders and proprietary Chinese medicines will bring benefits in terms of public health protection and safety. The licensing and registration systems will facilitate the development of Hong Kong as an international centre of Chinese medicine. There will be additional cost and compliance work imposed on Chinese medicines traders by the new regulatory framework, but the additional control will facilitate their products to gain international acceptance. Consultation with the traders concerned suggest that the proposed fees should not impose a significant financial burden on Chinese medicines traders.

Financial and Civil Service Implications

The Department of Health will require a complement of 20 staff at an annual cost of about $17.8 million to administer the licensing system of Chinese medicines traders and registration system of proprietary Chinese medicines.