

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	<u>1,572</u>	<u>1,421</u>	<u>1,572</u>	<u>4,132</u>	<u>1,363</u>	<u>1,363</u>	<u>1,212</u>	<u>3,478</u>	<u>197</u>	<u>1,002</u>	<u>38,102</u>	<u>3,580</u>		<u>7,926</u>		<u>3,478</u>	<u>113</u>	<u>1,674</u>	<u>2,551</u>	<u>387</u>
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 1,000	27.9
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 2,000	25.2
Application for a certificate for clinical trial and medicinal test		2,440	70
Certificate for clinical trial and medicinal test		79 2,519	70
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

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.