

For discussion  
on 25 October 2002

**Legislative Council Panel on Health Services  
Meeting on 25 October 2002**

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

**Purpose**

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

**Background**

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

3. It is Government policy that fees and charges should in general be set at levels sufficient to recover the full cost of providing the services. In the case of Chinese medicine practitioners, the initial fees have been set at 70% of the cost of administering the registration system. We expect to recover the full cost in three years.

**Licensing of Chinese medicine traders**

4. In line with the cost recovery rate for Chinese medicine practitioners, we propose to recover initially 70% of the cost for administering the licensing system for Chinese medicines traders, rising to full cost recovery in three years.

**Registration of proprietary Chinese medicines**

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

every proprietary Chinese medicine manufactured and/or sold in Hong Kong. While product registration is a necessary step in the regulatory system, we will try our best to minimize disruption to the trade. We therefore propose to set the fees for registration and certification of proprietary Chinese medicines at the following levels initially –

- (a) \$1,000 for products of single active ingredient, representing cost recovery rate of 27.9%; and
- (b) \$2,000 for products of multiple active ingredients, representing cost recovery rate of 25.2%.

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

### **Consultation with the trade**

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

### **Way forward**

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

Health, Welfare and Food Bureau  
October 2002

**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 %
	<b>Licensing of Chinese Medicine Traders</b>		
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
<b>Registration of Proprietary Chinese Medicines</b>			
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	<u>500</u> 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	<u>1,000</u> 2,000	25.2
Application for a certificate for clinical trial and medicinal test		2,440	70
Certificate for clinical trial and medicinal test		<u>79</u> 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