For discussion
on 10 November 2003

Legislative Council

Subcommittee on Commencement Notices under the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese Medicines Regulation

Regulation of Chinese Medicines in Hong Kong

Introduction

This paper seeks to brief Members on the latest progress of the regulation of Chinese medicines in Hong Kong.

Background

2. In 1997, the Chief Executive announced in his Policy Address the Administration's commitment to establish a sound regulatory framework for Chinese medicine to safeguard public health. Upon the enactment of the Chinese Medicine Ordinance ("the Ordinance") in July 1999, the Chinese Medicine Council of Hong Kong was established under the Ordinance in September 1999 to devise and implement regulatory measures for the practice, use, trading and manufacture of Chinese medicine in Hong Kong.

3. The various sets of subsidiary legislation on the regulation of Chinese medicines (including the Chinese Medicines Regulation, the Chinese Medicines Traders (Regulatory) Regulation, and the Chinese Medicine (Fees) Regulation) were passed by the Legislative Council in December 2002. The regulatory measures for the licensing of Chinese medicines traders and registration of proprietary Chinese medicines (pCm) are implemented in phases.

Licensing of Chinese medicines traders

4. The licensing system for Chinese medicines traders has been implemented since May 2003. Four kinds of Chinese medicines traders including retailers and wholesalers of Chinese herbal medicines, and wholesalers and manufacturers of pCm, are required to apply for licences from the Chinese Medicines Board under the Chinese Medicine Council of Hong Kong before they can engage in the respective trade. As at mid October, the Board received more than 6,800 applications, which are now being processed.

5. The Ordinance provides for a transitional arrangement for Chinese medicines traders who were in the business on 3 January 2000. Where an application is made during the period specified by the Chinese Medicines Board (from 5 May to 15 July 2003), the trader or manufacturer would be deemed to be licensed until the application is accepted/refused, or such date as is appointed by the Secretary for Health, Welfare and Food, whichever is earlier.

Registration System for Proprietary Chinese Medicines

6. To safeguard public health, the Ordinance stipulates that all pCm manufactured, or sold, in Hong Kong must be registered. We propose that the legislative provisions for registration of pCm be commenced on 19 December 2003, thereafter the Board will receive applications for pCm registration. The commencement notices of the relevant provisions of the Chinese Medicine Ordinance, the Chinese Medicines Regulation, and the Chinese Medicine (Fees) Regulation were published in the Gazette on 24 October 2003. Brief description of the relevant provisions is at **Annex**.

7. Like the licensing system for Chinese medicines traders, section 128 of the Ordinance also provides for a transitional arrangement for the registration of pCm which were manufactured, or sold, in Hong Kong on 1 March 1999. The pCm will be eligible for transitional registration if the concerned Chinese medicines trader submits an application during the specified period for transitional registration.

8. In assessing an application for pCm registration, the Chinese Medicines Board shall take into consideration the safety, quality and efficacy of the pCm. The basic registration requirements to be taken into account include: the limits of heavy metal and toxic elements; the limits of pesticide residues and microbes; non-adulteration with western medicine; and compliance with the requirements of Animals and Plants (Protection of Endangered Species) Ordinance.

9. In devising the registration requirements for pCm, over 30 consultative forums were held with the Chinese medicine traders. They are in support of the proposed regulation and have generally found the registration requirements acceptable.

Chinese Medicines Traders Practising Guidelines and Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines

10. To raise the standards of practice of the Chinese medicines traders, the Board has, after extensive consultations with the trade and taking reference to international and regional experiences, developed practising guidelines for four kinds of Chinese medicines traders – "Practising Guidelines for Chinese Herbal Medicines Retailers", "Practising Guidelines for Chinese Herbal Medicines Wholesalers", "Practising Guidelines for Proprietary Chinese Medicines Manufacturers" and "Practising Guidelines for Proprietary Chinese Medicines Wholesalers". The Board also developed the "Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines" to ensure the quality of pCm production in Hong Kong. If a pCm manufacturer satisfies the Board that he has complied with the requirements of the Guidelines, he may apply for a "Certificate for Manufacturer (Good Manufacturing Practice in respect of Proprietary Chinese Medicines)".

Implementation of the System for Regulation of Chinese Medicines Traders

11. The Regulatory Committee of Chinese Medicines Traders has been established under the Chinese Medicines Board. It is responsible for investigation of complaints against licensed Chinese medicines traders, and making recommendations to the Chinese Medicines Board on the appropriate courses of disciplinary action.

Health, Welfare and Food Bureau
November 2003

Annex

CHINESE MEDICINE ORDINANCE (CAP. 549) (COMMENCEMENT) (NO. 2) NOTICE 2003

Under section 1(2) of the Chinese Medicine Ordinance, sections 120 to 128, 130, 162, 163, 167 and 175 of the Ordinance shall come into operation on 19 December 2003.

CMO Section	Explanatory Memorandum
120 to 127	To deal with the registration procedures, certification and de-registration of proprietary Chinese medicines.
128	To provide for a transitional period in which proprietary Chinese medicines are deemed to be registered.
130	To provide for the issue of certificate of sale.

Consequential Amendments :

162	The provisions in Public Health and Municipal Services Ordinance (Cap. 132) relating to "drug" shall apply to medicine and any Chinese medicines for internal or external use by man.
163	The Pharmacy and Poisons Ordinance (Cap. 138) shall not apply to Chinese herbal medicines and proprietary Chinese medicines. The Pharmacy and Poisons Ordinance shall however apply to pharmaceutical products containing both western medicine/chemicals and Chinese medicines as active ingredients/contents.
167	The definition of "medicine" in Undesirable Medical Advertisements Ordinance (Cap. 231) includes any kind of medicament or other curative or preventive substance, and whether a proprietary medicine, a patent medicine, a Chinese herbal medicine, a proprietary Chinese medicine or purported natural remedy.
175	To specify that pharmaceutical products containing both western medicines and Chinese medicines as active ingredients shall seek registration from the Pharmacy and Poisons Board. The Chinese Medicines Board shall take part in determining such an application for registration.

(COMMENCEMENT) (NO. 2) NOTICE 2003

Under section 1 of the Chinese Medicines Regulation, sections 15 and 38 and Schedule 3 to the Regulation shall come into operation on 19 December 2003.

CMR Section	Explanatory Memorandum
15	To prescribe the registration particulars required to be furnished on application for registration of a proprietary Chinese medicine.
38	To prescribe the form for Certificate of sale of proprietary Chinese medicine.
Schedule 3	The prescribed form for Certificate of sale of proprietary Chinese medicine.

CHINESE MEDICINE (FEES) REGULATION (CA. 549 SUB. LEG. E) (COMMENCEMENT) (NO. 2) NOTICE 2003

Under section 1 of the Chinese Medicine (Fees) Regulation, items 12, 13, 16, 17 and 18 of the Schedule to the Regulation shall come into operation on 19 December 2003.

CMR (FEES) Item	Relevant section of the Ordinance	Description of Fees Items
12	121(1)	a) Application for the registration of a proprietary Chinese medicine with single active ingredient; (b) Application for the registration of a proprietary Chinese medicine with multiple active ingredients.
13	121(2)	(a) Issue of a certificate of registration of a proprietary Chinese medicine with single active ingredient; (b) Issue of a certificate of registration of a proprietary Chinese medicine with multiple active ingredients.
16	123(3)	Renewal of the registration and issue of a certificate of registration of a proprietary Chinese medicine.
17	124(1)	Application for variation of registered particulars of a registered proprietary Chinese medicine.
18	130(2)	Issue of a certificate of sale of a proprietary Chinese medicine.