

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 Proprietary Chinese Medicines
List of Provisions under the Chinese Medicine Ordinance (Cap. 549) and
Its Subsidiary Legislation which Have Not Yet Commenced Operation**

Introduction

This paper seeks to brief Members on the provisions for the regulation of proprietary Chinese medicines under the Chinese Medicine Ordinance (Cap. 549) and its subsidiary legislation which have not yet commenced operation.

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. The Council has developed a registration system for Chinese medicine practitioners through a combination of examination, registration and disciplinary measures. In order to implement the registration system, the following regulations were made in May 2000 –

- (a) The Chinese Medicine Practitioners (Registration) Regulation, setting out certain registration procedures and related matters;
- (b) The Chinese Medicine Practitioners (Discipline) Regulation, setting out the disciplinary procedures to be followed in handling complaints against registered Chinese medicine practitioners; and
- (c) The Chinese Medicine Practitioners (Fees) Regulation, setting out the level of fees payable for registration as Chinese medicine practitioners and other related purposes.

4. The Council has also developed regulatory measures to control the trading and manufacture of Chinese medicines, which include the licensing of Chinese medicines traders and registration of proprietary Chinese medicines. To implement the regulatory control of Chinese medicines, the following regulations were made in October 2002 –

- (a) The Chinese Medicines Regulation, setting out the licensing requirements and practicing 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 regulation of proprietary Chinese medicines and related matters.

5. To tie in with the implementation of various regulatory measures, the provisions of the Ordinance were brought into operation by phases. The first phase of provisions that came into effect in August 1999 provides for the setting up of the Council, the Chinese Medicine Practitioners Board, the Chinese Medicines Board, committees and the making of subsidiary legislation. The second phase of provisions that came into effect in August 2000 provides for the control of Chinese medicine practitioners by way of registration. The third phase brought the provisions for offences relating to Chinese medicine practice and relevant consequential amendments into operation in March 2002. The

fourth phase of provisions that came into effect in April 2003 provides for the licensing of Chinese medicines traders. The provisions presently proposed to come into operation on 19 December 2003 are those providing for the registration of proprietary Chinese medicines and the consequential amendment of relevant ordinances in relation to the control of drugs. The remaining provisions of the Ordinance will commence at a later date to be decided.

6. As far as regulation of proprietary Chinese medicines is concerned, the provisions under the Ordinance which have yet to commence operation are at **Annex A** while those under its subsidiary legislation are at **Annex B**.

Discussion

7. Members are invited to note the list of provisions for the regulation of proprietary Chinese medicines.

Health, Welfare and Food Bureau
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Regulation of Proprietary Chinese Medicines
Provisions under the Chinese Medicine Ordinance (Cap. 549) Not Yet Commenced Operation

Provision	Description
109	Restriction on sale, etc. of Schedule 1 medicines
110	Possession of Schedule 1 medicines
111	Restriction on sale, etc. of Schedule 2 medicines
119	Proprietary Chinese medicines to be registered
*120	Application for registration of proprietary Chinese medicines to be made by manufacturers, importers, etc.
*121	Registration of proprietary Chinese medicines
*122	Factors relevant to determination of application for registration
*123	Duration and renewal of registration
*124	Variation of registered particulars of registered proprietary Chinese medicines

*125	De-registration of proprietary Chinese medicines
*126	Publication of registered proprietary Chinese medicines
*127	Certified copy of certificate of registration
*128	Provision for transitional registration of proprietary Chinese medicines
129	Clinical trials and medicinal tests
*130	Certificate of sale of proprietary Chinese medicines
131	Restriction on manufacture of proprietary Chinese medicines
134	Restriction on sale, etc. of proprietary Chinese medicines
142	Chinese herbal medicines to be labelled
143	Proprietary Chinese medicines to be labelled
144	Package inserts for proprietary Chinese medicines
150	Liability for acts of servants
152	Forfeiture

155	Offences and penalty
156	Defence
158	Exemptions
*162	Interpretation (Consequential Amendments to Public Health and Municipal Services Ordinance)
*163	Section substituted (Consequential Amendments to Pharmacy and Poisons Ordinance) - 37. Ordinance not to apply to Chinese herbal medicines and proprietary Chinese medicines, etc.
*167	Interpretation (Consequential Amendments to Undesirable Medical Advertisements Ordinance)
169	Ordinances referred to in sections 17 and 17A (Consequential Amendments to Customs and Excise Service Ordinance)
171	Application and exemption (Consequential Amendments to Import and Export (General) Regulations)
172	First Schedule amended (Consequential Amendments to Import and Export (General) Regulations)
173	Second Schedule amended (Consequential Amendments to Import and Export (General) Regulations)
174	Third Schedule amended (Consequential Amendments to Import and Export (General) Regulations)
*175	Registration of pharmaceutical product and substances (Consequential Amendments to Pharmacy and Poisons Regulations)

* Proposed to commence on 19.12.2003

Ends.

Regulation of Proprietary Chinese Medicines

**Provisions under the Subsidiary Legislation of
the Chinese Medicine Ordinance (Cap. 549) Not Yet Commenced Operation**

(a) Provisions under the Chinese Medicines Regulation Not Yet Commenced

Section	Description
12	Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 1 medicines – selling restrictions
*15	Particulars to be registered for proprietary Chinese medicines
22	Chinese herbal medicines to be labelled
23	Labelling of containers of Schedule 1 medicines by wholesale dealers
24	Labelling of containers of Schedule 2 medicines by wholesale dealers
25	Proprietary Chinese medicines to be labelled
26	Labelling of proprietary Chinese medicines to be sold in Hong Kong
27	Labelling of proprietary Chinese medicines to be exported
28	Requirements for package inserts

31	Offences and penalties
33	Exemptions for persons or institutions concerned with education or scientific research
34	Exemptions for proprietary Chinese medicines imported for re-export and conducting clinical trials or medicinal tests
35	Exemptions for proprietary Chinese medicines manufactured in Hong Kong and to be exported
36	Exemptions for proprietary Chinese medicines compounded by Chinese medicine practitioners or in accordance with prescriptions given by Chinese medicine practitioners
37	Exemptions for proprietary Chinese medicines manufactured in accordance with prescriptions given by Chinese medicine practitioners and to be administered or supplied to their patients
*38	Certificate of sale of proprietary Chinese medicine
Schedule 2	Offences and penalties
*Schedule 3	Certificate of sale of proprietary Chinese medicine

* Proposed to commence on 19.12.2003

(b) Provisions under the Chinese Medicine (Fees) Regulation not yet Commenced

Section	Description
*Item 12 of Schedule	(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
*Item 13 of Schedule	(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
Item 14 of Schedule	Application for a certificate for clinical trial and medicinal test
Item 15 of Schedule	Issue of a certificate for clinical trial and medicinal test
*Item 16 of Schedule	Renewal of the registration and issue of a certificate of registration of a proprietary Chinese medicine
*Item 17 of Schedule	Application for variation of registered particulars of a registered proprietary Chinese medicine
*Item 18 of Schedule	Issue of a certificate of sale of a proprietary Chinese medicine

* Proposed to commence on 19.12.2003

Ends.