

**For discussion on  
12 November 2007**

**Legislative Council Panel on Health Services**  
**Commencement of Sections of Chinese Medicine Ordinance  
and Chinese Medicines Regulation**

**PURPOSE**

To fully effect the licensing regime of Chinese medicines traders and the import and export control of Chinese medicines, we plan to commence in January 2008 the provisions in the Chinese Medicine Ordinance (the Ordinance), which govern the control over the possession, sale, import and export of Chinese herbal medicines and over the manufacture, sale by way of wholesale, import and export of proprietary Chinese medicines. This paper informs Members of the details of the plan.

**BACKGROUND OF THE CHINESE MEDICINES TRADERS  
LICENSING REGIME**

2. Chinese medicine is widely used by the public in Hong Kong. It is therefore necessary to put in place an effective regulatory regime for Chinese medicine to foster its development and to protect public health. After the passage of the Ordinance in 1999, the Administration established the Chinese Medicine Council of Hong Kong (the CMC)<sup>1</sup> and first implemented the regulatory regime for Chinese medicine practitioners (CMPs) and processed applications for CMP registration.

3. Subsequently, the Legislative Council passed the resolution on

---

<sup>1</sup> The CMC is a statutory body established under the Ordinance to implement regulatory measures for CMPs and Chinese medicines. It comprises a Chairman, five CMPs, five persons from the trade of Chinese medicines, two persons from educational or scientific research institutions in Hong Kong, three lay persons and two public officers. The Director of Health is also an ex officio member.

the enactment of the Chinese Medicines Regulation (the Regulation) in December 2002 to provide for the licensing requirements and the conditions of practice for Chinese medicines traders. We commenced part of the provisions relating to the licensing of Chinese medicines traders in the Ordinance and the Regulation in April 2003. The Chinese Medicines Board under the CMC then started to issue four types of Chinese medicines trader licences, namely –

- (i) Chinese herbal medicines wholesaler licence;
- (ii) Chinese herbal medicines retailer licence;
- (iii) Proprietary Chinese medicines manufacturer licence; and
- (iv) Proprietary Chinese medicines wholesaler licence.

4. The issue of licences to Chinese medicines traders is subject to their compliance with the requirements of the Ordinance and the Regulation regarding premises, hygiene, storage, facilities and personnel qualifications. To enable those Chinese medicines traders who were already in business when the licensing regime came into force to continue their operation, the Ordinance provides for a transitional licensing arrangement. Those Chinese medicines traders who carried on Chinese medicines business on 3 January 2000 and submitted their applications within the transitional licensing application period (i.e. 5 May 2003 to 15 July 2003) would be issued a transitional certificate so that they could continue their business. However, the issue of a formal licence is still conditional on their compliance with the statutory licensing requirements.

5. At present, Chinese medicines traders are required to operate their business in accordance with the Regulation and the guidelines developed by the Chinese Medicines Board. Non-complying traders may be subject to such disciplinary actions as licence revocation or suspension, variation of licensing requirements or warnings.

## **PROGRESS OF THE PROCESSING OF LICENCE APPLICATIONS**

6. During the transitional licensing application period, the Chinese Medicines Board received a total of 6 648 applications, including 4 169 transitional and 2 479 formal licence applications. Of these applications, 5 593 (84.1%) were approved and 1 033 (15.6%) were rejected or cancelled, while the processing of the remaining 22 (0.3%) could not be finished due to incomplete information. During the interval between the end of the transitional licensing application period and 30 September 2007, the Chinese Medicines Board has received another 2 061 licence applications.

7. As at 30 September 2007, the Chinese Medicines Board has in total issued 3 570 transitional certificates and 3 535 formal licences. Of these, there are 960 Chinese herbal medicines wholesalers (13%), 3 875 Chinese herbal medicines retailers (55%), 552 proprietary Chinese medicines manufacturers (8%) and 1 718 proprietary Chinese medicines wholesalers (24%).

## **PROVISIONS PROPOSED FOR COMMENCEMENT**

8. The processing of transitional certificate applications has largely come to a close. Most of the applications for formal licences have also been processed. Therefore, we propose commencing the provisions governing the control over the possession, sale, import and export of Chinese herbal medicines, and over the manufacture, sale by way of wholesale, import and export of proprietary Chinese medicines under the Ordinance and the Regulation on 11 January 2008, so as to fully effect the licensing regime for Chinese medicines traders.

9. We also plan to monitor the safety and quality of Chinese herbal medicines imported into and exported out of Hong Kong by imposing import and export control over 36 types of Chinese herbal medicines. Besides, at present, the issue of import and export licences for proprietary Chinese medicines is carried out pursuant to the Pharmacy and Poisons Ordinance. With the commencement of the provisions as

proposed, such import and export licences can be issued in accordance with the definition of proprietary Chinese medicines in the Ordinance.

10. The provisions of the Ordinance and the Regulation proposed for commencement are summarized as follows:

A. Provisions in the Ordinance

- (i) to provide that a licence shall be obtained for retail or wholesale dealings in Chinese herbal medicines, and for the manufacture of or wholesale dealings in proprietary Chinese medicines;
- (ii) to provide that a licence shall be obtained for the possession of toxic Chinese herbal medicines;
- (iii) to provide that a wholesale dealer in Chinese herbal medicines shall attach to or print on the container of Chinese herbal medicines an appropriate label;
- (iv) to provide for the liability of a holder of a licence for the act of his servants;
- (v) to provide that a magistrate may order the forfeiture of Chinese herbal medicines or proprietary Chinese medicines;
- (vi) to provide for penalty, defence and exemptions with respect to certain provisions;
- (vii) to amend the Customs and Excise Service Ordinance to facilitate the enforcement of the Ordinance by Customs Officers; and
- (viii) to amend the Import and Export (General) Regulations for the implementation of the import and export licensing system for toxic and potent Chinese herbal medicines and proprietary Chinese medicines.

## B. Provisions in the Regulation

- (i) to provide that toxic Chinese herbal medicines shall only be sold by a wholesale dealer in Chinese herbal medicines to prescribed categories of persons or entities;
- (ii) to provide that a wholesale dealer in Chinese herbal medicines shall attach to or print on the container of Chinese herbal medicines a label in the prescribed manner; and
- (iii) to provide for penalty with respect to certain provisions in the Regulation.

Details of the provisions are set out in **Annex 1**. Those Chinese herbal medicines in Schedule 1 to the Ordinance are listed in **Annex 2**.

## **IMPLICATIONS OF THE PROPOSAL TO THE COMMUNITY AND THE TRADE**

11. The commencement of the legislative provisions referred to in this paper will enhance the regulation of Chinese medicines traders; strengthen the control over the dispensing, possession and sale of Chinese herbal medicines; and facilitate a more effective monitoring of the origins and destinations of the Chinese herbal medicines and proprietary Chinese medicines imported into and exported out of Hong Kong. All these measures will further protect public health and enable the public to purchase Chinese medicines of a certain quality from licensed Chinese medicines traders.

12. Upon the commencement of the provisions referred to in this paper, Chinese medicines traders without a licence have to halt their business until they have obtained a licence upon application. Most Chinese medicines traders have already obtained a relevant licence. In addition, Chinese medicines traders importing or exporting proprietary Chinese medicines are already required to apply for import and export licences. After commencing the provisions, import and export licences

will also be required for the import and export of Chinese herbal medicines. In general, a licence can be issued within two working days. Commencing the provisions will enable us to combat more effectively illegal operation of Chinese medicines business. This will help create a favourable and fair business environment and boost public confidence in Chinese medicines, which will foster the development of Chinese medicine in Hong Kong.

## **PUBLICITY AND EDUCATION**

13. In order to familiarize the Chinese medicines trade with and prepare them for the proposed commencement of the legislative provisions, the Chinese Medicines Board has continuously carried out in the past two years a series of publicity and educational activities, including mounting posters at the shopping centres and markets of the Food and Environmental Hygiene Department, Housing Department and The Link; issuing circular memoranda to individual Chinese medicines traders and relevant organizations; conducting seminars and visiting business operators to remind them to apply for a licence and comply with the legislation and practising guidelines. The Chinese Medicines Board will launch a series of other publicity activities to announce to the trade the commencement date of the provisions.

## **CONCLUSION**

14. Members are invited to note the proposal in this paper.

**Food and Health Bureau  
Department of Health  
November 2007**

**Annex I**

**Provisions Proposed for Commencement**

**I. The Ordinance**

<b>Section No.</b>	<b>Description</b>
109	(1) No Chinese herbal medicines specified in Schedule 1 shall be sold by retail or dispensed without a retailer licence in Chinese herbal medicines, at any place other than the specified premises, or except in accordance with a prescription given by a registered Chinese medicine practitioner; and (2) no Chinese herbal medicines specified in Schedule 1 shall be sold by way of wholesale or possessed for the purpose of wholesale without a wholesaler licence in Chinese herbal medicines or at any place other than the specified premises.
110	No person shall have in his possession any Chinese herbal medicines specified in Schedule 1 without a licence.
111	(1) No Chinese herbal medicines specified in Schedule 2 shall be sold by retail, dispensed or possessed for the purpose of retail without a retailer licence in Chinese herbal medicines or at any place other than the specified premises; and (2) no Chinese herbal medicines specified in Schedule 2 shall be sold or distributed by way of wholesale or possessed for the purpose of wholesale without a wholesaler licence in Chinese herbal medicines or at any place other than the specified premises.
131	No proprietary Chinese medicines shall be manufactured without a manufacturer licence in proprietary Chinese medicines or at any place other than the specified premises.

<b>Section No.</b>	<b>Description</b>
134	No proprietary Chinese medicines shall be sold or distributed by way of wholesale or possessed for the purpose of wholesale without a wholesaler licence in proprietary Chinese medicines or at any place other than the specified premises.
142	A wholesale dealer in Chinese herbal medicines shall attach to or print on any container of Chinese herbal medicines a label in the prescribed manner.
150(1) (in so far as it relates to the contravention of sections 109, 110, 111, 131, 134 and 142)	Where a servant of a holder of a licence commits an offence for contravening section 109, 110, 111, 131, 134 or 142, the holder of the licence shall also be guilty of that offence but shall not be liable to any term of imprisonment.
150(2)	It shall be a defence if the holder of the licence charged shows that he exercised such control over the servant as would ensure that the servant was not likely to act in contravention of the provision in question.
152	A magistrate may order to be forfeited any Chinese herbal medicines or proprietary Chinese medicines, or any article or substance in respect of which an offence under this Ordinance has been committed
155 (only involving contravention of Sections 109,110,111,131,134, 142,146(3) and (4), 153(3) and 154)	Any person who contravenes section 109, 110, 111, 131, 134, 142, 146(3) or (4), 153(3) or 154 commits an offence and shall be liable to a fine at level 6 and to imprisonment for 2 years.
156(1)	In any proceedings for a contravention of section 110, it shall be a defence for a person charged to prove that he

<b>Section No.</b>	<b>Description</b>
	(a) did not know;(b) had no reason to suspect; and(c) could not with reasonable diligence have discovered, that the Chinese herbal medicine was not supplied to him in accordance with this Ordinance.
158(1)	The Chinese Medicines Board may exempt a person or institution concerned with education or scientific research from the application of sections 109(2), 110, 111(2), 119, 131 and 134 if the Chinese herbal medicines or proprietary Chinese medicines in question are required for the purposes of education or scientific research.
158(2)	Nothing in sections 109(1), 110 and 111(1) shall apply to a registered Chinese medicine practitioner if the Chinese herbal medicines in question are being used for the purpose of administering to a patient under his direct care and dispensed on a prescription given by him and at the premises where he practises.
158(3)	Nothing in section 110 shall apply to a person in bona fide possession of any Chinese herbal medicine specified in Schedule 1 if such medicine has been supplied to him (a) by a person who is the holder of a licence to trade in such Chinese herbal medicines; (b) in accordance with a prescription given by a registered Chinese medicine practitioner; or (c) in accordance with the Ordinance.
158(4) (in so far as it relates to listed Chinese medicine practitioners)	Nothing in section 111(1) shall apply to a listed Chinese medicine practitioner if the Chinese herbal medicine in question is being used for the purpose of administering to a patient under his direct care and dispensed on a prescription given by him and at the premises where he practises.
158(6) (except in relation to	Nothing in sections 119 and 131 shall apply in respect of a proprietary Chinese medicine which is (a)

<b>Section No.</b>	<b>Description</b>
a proprietary Chinese medicine which is compounded by or under the supervision of a person who continues to practise Chinese medicine by virtue of section 90(7) or individually prepared or compounded in accordance with a prescription given by him)	compounded by or under the supervision of a registered Chinese medicine practitioner or a 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; and (b) individually prepared or compounded by a person responsible for the supervision of the dispensing of Chinese herbal medicines or his deputies or 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 Chinese medicine practitioner or a listed Chinese medicine practitioner.
158(7)	Nothing in sections 109(2), 110, 111(2) and 134 shall apply to a person licensed as a manufacturer of proprietary Chinese medicines if the Chinese herbal medicines or proprietary Chinese medicines in question are imported or obtained by the manufacturer as raw materials for the purpose of manufacturing his own products.
158(8)	Nothing in section 134 shall apply to a person licensed as a manufacturer of proprietary Chinese medicines if he sells by way of wholesale the proprietary Chinese medicines manufactured by himself.
169	Adding the Ordinance to Schedule 2 to the Customs and Excise Service Ordinance.
171-174	Regulation 6(1)(c)(i) and Schedules 1, 2 and 3 of the Import and Export (General) Regulations are amended by adding the Chinese herbal medicines specified in Schedule 1 to the Ordinance, five Chinese herbal medicines specified in Schedule 2 to the Ordinance and the proprietary Chinese medicines.

## II. The Regulation

Section No.	Description
12	A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 Chinese herbal medicines may distribute Schedule 1 Chinese herbal medicines only to designated persons or entities, including holders of retailer/wholesaler licences in Chinese herbal medicines in respect of Schedule 1 Chinese herbal medicines; holders of manufacturer licences; registered Chinese medicine practitioners; persons or institutions exempted under section 158(1) of the Ordinance for the purpose of education or scientific research; Government departments or public officers; purchasers outside Hong Kong; hospitals or clinics managed or controlled by the Hospital Authority; or hospitals within the meaning of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance.
22	A wholesale dealer in Chinese herbal medicines shall attach to or print on each container of Chinese herbal medicines a label in a conspicuous position.
23	A wholesale dealer in Chinese herbal medicines shall attach to or print on the container of a Chinese herbal medicine specified in Schedule 1 to the Ordinance a label with the prescribed particulars being clearly and distinctly set out, including the name, at least in Chinese, of the medicine, the name of the wholesale dealer, the batch number of the medicine, a warning containing the Chinese text: “毒性中藥” or “毒性中药” and a warning containing the English text: “Toxic Chinese Medicine” (if the warning is to be available in English also).
24	A wholesale dealer in Chinese herbal medicines shall attach to or print on a container of a Chinese herbal medicine specified in Schedule 2 to the Ordinance a label

<b>Section No.</b>	<b>Description</b>
	with the name of the medicine, at least in Chinese, being clearly and distinctly set out.
31 (except in relation to the contravention of section 26(1) of the Chinese Medicines Regulation)	A person who contravenes a provision set out in Schedule 2 to the Chinese Medicines Regulation commits an offence and is liable to the penalty as set out.
Schedule 2 (except in relation to the contravention of section 26(1) of the Chinese Medicines Regulation)	Penalties for contravention of sections 7(h)(i) or (ii), 7(k), 8(1), (2) or (3), 9(1) or (2), 10, 11(g)(iv), (v) or (vi), 12, 13(1), (2) or (3), 14(1), (2) or (3), 17(1), (2) or (3), 18(1) or (2), 19(1), (2) or (3), 21(1), (2) or (3), 23(1), 24 and 26(1) of the Chinese Medicines Regulation (The maximum penalty is a fine at Level 6 and imprisonment of 2 years.)

**Annex II**

**Chinese Herbal Medicines Listed in Schedule 1 to the Ordinance**

<b>Name</b>	<b>Description</b>
Radix Sophorae Tonkinensis	Root or rhizome of Sophora tonkinensis Gapnep
Mercury	Medicinal
Unprocessed Semen Euphorbiae	Unprocessed ripe seed of Euphorbia lathyris L
Unprocessed Radix Aconiti	Unprocessed parent root tuber of Aconitum carmichaeli Debx
Unprocessed Semen Hyoscyami	Unprocessed ripe seed of Hyoscyamus niger L
Unprocessed Rhizoma Arisaematis	Unprocessed tuber of Arisaema erubescens (Wall.) Schott., Arisaema heterophyllum Bl. or Arisaema amurense Maxim
Unprocessed Fructus Crotonis	Unprocessed ripe fruit or seed of Croton tiglium L
Unprocessed Rhizoma Pinelliae	Unprocessed tuber of Pinellia ternate (Thunb.) Breit

Name	Description
Unprocessed Radix Kansui	Unprocessed root tuber of Euphorbia Kansui T. N. Liou ex T. P. Wang
Unprocessed Rhizoma Typhonii or Radix Aconiti Coreani	Unprocessed tuber of Typhonium giganteum Engl. or root tuber of Aconitum coreanum (Levl.) Raipaics
Unprocessed Radix Aconiti Lateralis	Unprocessed daughter root of Aconitum carmichaeli Debx
Unprocessed Radix Euphorbiae Fischerianae, Radix Euphorbiae Ebracteolatae or Radix Stellerae	Unprocessed root of Euphorbia fischeriana Steud, Euphorbia ebracteolata Hayata or Stellera chamaejasme L
Unprocessed Radix Aconiti Kusnezoffii	Unprocessed root tuber of Aconitum Kusnezoffii Reichb
Unprocessed Semen Strychni	Unprocessed ripe seed of Strychnos nux-vomica L. or Strychnos pierriana A. W. Hill
Unprocessed Resina Garciniae Morellae	Unprocessed gum-resin of Garcinia morella Desv
Mercurous chloride and mercuric chloride	Crystal of mercurous chloride and mercuric chloride, medicinal
Cinnabaris	Mineral of sulphides of Cinnabar group, medicinal
Lytta	Body of Lytta caraganae Pallas

Name	Description
Arsenolite	Mineral of oxides of Arsenolite or the processed product of Arsenopyrite or Realgar, medicinal
Arsenic trioxide	Medicinal
Flos Daturae Metelis	Flower of Datura metel L
Huechys	Body of Huechys sanguinea De Geer
Hydrargyri Oxydum Rubrum	Red mercuric oxide, medicinal
Radix or Rhizoma Podophylli emodis, or Radix or Rhizoma Dysosmatis	Rhizome or root of Podophyllum emodi (Wall.) Ying, Dysosma versipellis (Hance) M. Cheng or Dysosma pleiantha (Hance) Woodson
Radix Aconiti Brachypodi or Radix Aconiti Szechenyiani	Root tuber of Aconitum brachypodum Diels, Aconitum pendulum Busch (Aconitum szechenyianum Gay.) or Aconitum subrosullatum Hand. Mazz. (Aconitum nagarum Stapf var. lasiandrum M. T. Wang)
Realgar	Mineral of sulphides of Realgar group, medicinal
Mylabris	Body of Mylabris phalerata Pallas or Mylabris cichorii Linnaeus
Calomelas	Crystal of mercurous chloride, medicinal

<b>Name</b>	<b>Description</b>
Orpiment	Mineral of sulphides of Orpiment group, medicinal
Flos Rhododendri Mollis	Flower of Rhododendron mole G. Don
Venenum Bufonis	Secretion of Bufo bufo gargarizans Cantor or Bufo melanostictus Schneider