

LEGISLATIVE COUNCIL BRIEF

Chinese Medicine Ordinance (Cap 549)

CHINESE MEDICINE ORDINANCE (COMMENCEMENT) NOTICE 2010 CHINESE MEDICINE (FEES) REGULATION (COMMENCEMENT) NOTICE 2010 CHINESE MEDICINES REGULATION (COMMENCEMENT) NOTICE 2010

INTRODUCTION

Pursuant to section 1(2) of the Chinese Medicine Ordinance (Cap 549), section 1 of the Chinese Medicine (Fees) Regulation (Cap 549 sub. leg. E) and section 1 of the Chinese Medicines Regulation (Cap 549 sub. leg. F), the Secretary for Food and Health has made the Commencement Notices at Annex A to commence the offences relating to the sale, import and possession of proprietary Chinese medicines (pCm) through registration and the requirements of label and package inserts.

JUSTIFICATIONS

Background

2. The Chinese Medicine Ordinance (Cap. 549) (“the Ordinance”) was enacted by the Legislative Council (LegCo) 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 (CMC) was established in September 1999 under the Ordinance to implement these regulatory measures.

3. Subsequently, the LegCo passed the resolution on the enactment of the Chinese Medicines Regulation (“the Regulation”) in December 2002 to provide

for the licensing requirements for Chinese medicines traders and the registration system for pCm. 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 (CMB) under 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;
- (ii) Proprietary Chinese medicines manufacturer licence; and
- (iv) Proprietary Chinese medicines wholesaler licence.

4. As the issuance of the licenses to the Chinese medicines traders has been completed, the legislative provisions relating to mandatory licensing of Chinese medicines traders and import and export of Chinese herbal medicines became fully effective on 11 January 2008¹.

The proprietary Chinese medicines registration system

5. Section 119 under the Ordinance stipulates, amongst others, that all pCm must be registered by the CMB before they can be imported, manufactured or sold in Hong Kong. To be registered, all pCm must meet the registration requirements prescribed by CMB regarding their safety, quality and efficacy.

6. To minimise disruption to the Chinese medicine trade, the Ordinance provides a transitional registration system for pCm manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong. Manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may apply for transitional registration for such pCm before 30 June 2004. Subject to CMB's vetting and approval, a "Notice of confirmation of transitional registration of proprietary Chinese medicines" will be issued for applications which meet the eligibility criteria for transitional registration.

¹ Legislative Council paper CB (2)264/07-08(04)

Progress of the processing of the applications for registration of proprietary Chinese medicines

7. As at September 2010, CMB has received about 16 710 applications for registration of pCm, of which about 14 100 also applied for transitional registration. CMB has assessed all the applications for transitional registration and issued "Notice of confirmation of transitional registration of pCm" for 9 150 applications and "Notice of confirmation of (non-transitional) registration of pCm" for 2 120 applications of non-transitional registration, in respect of which three acceptable basic test reports had been submitted (i.e. acceptable test reports on heavy metals and toxic element, pesticide residues and microbial limit).

Provisions proposed for commencement

8. At present, the following major provisions of the Ordinance are yet to be commenced –

- (i) Section 119 – No person shall sell; or import; or possess any proprietary Chinese medicine unless the pCm is registered under section 121;
- (ii) Section 143 – No person shall sell; or have in his possession for the purpose of selling, any pCm unless the package of the pCm is labelled in the prescribed manner; and
- (iii) Section 144 – No person shall sell; or have in his possession for the purpose of selling, any pCm without a package insert which complies with the prescribed requirements.

9. In view of the completion of CMB's assessment of all applications for transitional registration, we propose to put into full implementation the relevant provisions under the Ordinance, which would be phased on *3 December 2010* and *1 December 2011* as follows –

- (a) *3 December 2010* – commencement of section 119 and the sale, import or possession of unregistered pCm in Hong Kong will be an offence by then; and

- (b) *1 December 2011* – commencement of sections 143 and 144 to allow the trade to have adequate time to comply with the requirements of label and package inserts.

The lists of the legislative provisions proposed to be commenced, and the proposed commencement dates are at **Annex B**.

Other related regulatory measures on proprietary Chinese medicines

10. The requirement for mandatory registration of pCm is one of the important measures of the regulatory regime of Chinese medicines. Apart from this, other related measures have been put in place, including regulation of pCm manufacturers, setting up of product recall system, enforcing import control of pCm, conducting market surveillance on pCm, as well as other related laws to strengthen the regulation of pCm. Details of these measures are at **Annex C**.

THE COMMENCEMENT NOTICES

11. The Commencement Notices aim to put into effect on *3 December 2010* and *1 December 2011* the offences relating to the sale, import and possession of pCm through registration and the requirements of label and package inserts in the prescribed manners respectively.

LEGISLATIVE TIMETABLE

12. The legislative timetable of the Commencement Notices is as follow –

Publication in the Gazette	8 October 2010
Tabling at the LegCo	13 October 2010
Date of Commencement	3 December 2010 (mandatory registration) 1 December 2011 (label and package inserts)

PUBLIC CONSULTATION

13. The trade and the stakeholders have been reported regularly of the progress of the processing of registration applications of pCm at the Retail Task Force of the Business Facilitation Committee. We consulted the LegCo Panel on Public Health on 12 July 2010² on the legislative proposal to commence the mandatory registration of pCm, and the requirements of label and package inserts. Prior to that, we held seven consultation/briefing sessions for the traders, trade associations and other stakeholders from end of May to July 2010. The views of the trade and stakeholders were collected through the consultation/briefing sessions as well as the Business Consultation e-Platform under the GovHK Portal (www.bce.gov.hk). The proposed commencement received support from the trade and other stakeholders.

14. We have subsequently conducted a consultation/briefing session on publicity programme of the commencement for the trade associations in September 2010. We will continue to exchange views and keep the trade informed of any publicity arrangements to ensure no disruption to the trade and the public at large.

IMPLICATIONS OF THE COMMENCEMENT NOTICES

15. Upon the commencement of the provisions referred to in **Annex B**, any person who sell; or import; or possess any unregistered pCm in Hong Kong will be an offence and shall be liable to a fine at level 6 (i.e. \$100,000) and imprisonment for two years. Unregistered pCm cannot be sold in the market until they have obtained registration status. Commencing the provisions will make the regulation of Chinese medicines more comprehensive and enhanced, and will provide a legal basis for combating more effectively the selling of unregistered pCm. This will help create a favourable and fair business environment, boost public confidence in Chinese medicines and in turn foster the development of Chinese medicine in Hong Kong.

16. The proposal is in conformity with the Basic Law, including the provisions concerning human rights. It has no productivity, environmental or

² Legislative Council Paper No. CB(2)1995/09-10(02)

sustainability implications.

PUBLICITY

17. A whole range of publicity programme will be launched by the Department of Health (DH) in consultation with the Consumer Council and other relevant departments. These include employment of Chinese medicines students as “ambassadors” to visit Chinese medicines traders and listed sellers of poisons and dispensaries with a view to assisting traders to familiarize with the statutory requirements relating to the selling, labelling and package inserts of pCm. We will soon publicise the commencement plan through various channels such as CMC and DH websites, the Consumer Council, and issuing letter to individual traders, Chinese medicine practitioners and other relevant associations.

ENQUIRY

18. For any enquiries on the brief, please contact Mr Sunny PAU, Assistant Secretary for Food and Health at 2973 8118.

**Food and Health Bureau
Department of Health
October 2010**

Chinese Medicine Ordinance (Commencement) Notice 2010

Under section 1(2) of the Chinese Medicine Ordinance (Cap. 549), I appoint—

- (a) 3 December 2010 as the day on which the following provisions of the Ordinance come into operation—
 - (i) section 119;
 - (ii) section 129;
 - (iii) section 150(1) (in so far as it relates to the contravention of section 119(1));
 - (iv) section 155 (in so far as it relates to the contravention of section 119(1));
 - (v) section 156(2);
 - (vi) section 158(5);
- (b) 1 December 2011 as the day on which the following provisions of the Ordinance come into operation—
 - (i) section 143;
 - (ii) section 144;
 - (iii) section 150(1) (in so far as it relates to the contravention of sections 143 and 144);
 - (iv) section 155 (in so far as it relates to the contravention of sections 143 and 144).



Secretary for Food and Health

5 Oct 2010

**Chinese Medicine (Fees) Regulation (Commencement)
Notice 2010**

Under section 1 of the Chinese Medicine (Fees) Regulation (Cap. 549 sub. leg. E), I appoint 3 December 2010 as the day on which items 14 and 15 of the Schedule to the Regulation come into operation.



Secretary for Food and Health

5 Oct 2010

Chinese Medicines Regulation (Commencement) Notice 2010

Under section 1 of the Chinese Medicines Regulation (Cap. 549 sub. leg. F), I appoint—

- (a) 3 December 2010 as the day on which section 37 (in so far as it relates to section 119 of the Chinese Medicine Ordinance (Cap. 549)) of the Regulation comes into operation;
- (b) 1 December 2011 as the day on which the following provisions of the Regulation come into operation—
 - (i) sections 25, 26, 27 and 28;
 - (ii) section 31 (in relation to the contravention of section 26(1) of the Regulation);
 - (iii) sections 33, 34, 35 and 36;
 - (iv) section 37 (in so far as it relates to section 144 of the Chinese Medicine Ordinance (Cap. 549));
 - (v) Schedule 2 (in relation to the contravention of section 26(1) of the Regulation).



Secretary for Food and Health

5 Oct 2010

Provisions Proposed for Commencement

I. The Chinese Medicine Ordinance (Cap.549)

Section No.	Description
Proposed commencement date: 3 December 2010	
119	No person shall sell; or import; or possess any proprietary Chinese medicine unless the proprietary Chinese medicine is registered under section 121.
129	An application for a certificate for clinical trial and medicinal test shall be made for the purpose of the conduct of a clinical trial or medicinal test of any proprietary Chinese medicine.
150(1)	(1) Where a servant of a holder of a licence issued under this Ordinance commits an offence for contravening section 119 the holder of the licence shall, without prejudice to the liability of any other person, also be guilty of that offence but shall not be liable to any term of imprisonment; and (2) Where a prosecution is brought against a holder of a licence by virtue of this section in respect of an offence committed by a servant, it shall be a defence if the holder of the licence 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.
155(1)	Any person who contravenes section 119(1) commits an offence and is liable to a fine at level 6 and to imprisonment for 2 years.
156(2)	In any proceedings for a contravention of section 119(1), it shall be a defence for a person charged to prove that he- (a) did not know; (b) had no reason to suspect; and (c) could not with reasonable diligence have discovered, that the proprietary Chinese medicine was not registered under section 121.

Section No.	Description
158(5)	Nothing in section 119 shall apply in respect of a proprietary Chinese medicine which is – (a) imported by a wholesaler in proprietary Chinese medicines for the purpose of re-exporting by the same wholesale dealer; or (b) imported by a holder of a valid certificate for clinical trial and medicinal test issued under section 129 and to be used for the purposes of the clinical trial or medicinal test to which the certificate relates. (Remarks: Except sections 158(4) and 158(6) in relation to a person who continues to practise Chinese medicine by virtue of section 90(7))
Proposed Commencement Date: 1 December 2011	
143	No person shall sell, or have in his possession for the purpose of selling any proprietary Chinese medicine unless the package of the proprietary Chinese medicine is labelled in the prescribed manner.
144	No person shall sell, or have in his possession for the purpose of selling any proprietary Chinese medicine without a package insert which complies with the prescribed requirements.

II. The Chinese Medicine (Fees) Regulation (Cap.549E)

Item No.	Relevant Section No.	Description
Proposed commencement date : 3 December 2010		
14	129(2)	Application for a certificate for clinical trial and medicinal test.
15	129(3)	Issue of a certificate for clinical trial and medicinal test.

III. The Chinese Medicines Regulation (Cap.549F)

Section No.	Description
Proposed commencement date: 3 December 2010	
37	Proprietary Chinese medicine manufactured in accordance with prescriptions given by Chinese medicine practitioners and to be administered or supplied to their patients is exempted from registration.
Proposed commencement date: 1 December 2011	
25	The package of the proprietary Chinese medicines is labelled in a conspicuous position.
26	<p>A label on a package of a proprietary Chinese medicine to be sold in Hong Kong, the outermost package shall has the following particulars being clearly and distinctly set out –</p> <ul style="list-style-type: none">(a) the name of the medicine;(b) if-<ul style="list-style-type: none">(i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient; or(ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients;(c) the name of the country or territory in which the medicine is produced;(d) the registration number of the medicine as specified in its certificate of registration;(e) if the package-<ul style="list-style-type: none">(i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or(ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;(f) its packing specification;(g) its dosage and method of usage;(h) its expiry date; and(i) its batch number.

Section No.	Description
	(Remark: Except as otherwise provided in this section)
27	<p>A proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting, shall have a label on the outermost package of the medicine with the following particulars being clearly and distinctly set out –</p> <ul style="list-style-type: none"> (a) the name of the medicine; (b) the name of the holder of the certificate of registration of the medicine as specified in the certificate; and (c) the registration number of the medicine as specified in its certificate of registration.
28	<p>For the purpose of selling in Hong Kong any proprietary Chinese medicine shall have a package insert which includes the particulars set out in this subsection and has the particulars being clearly and distinctly set out –</p> <ul style="list-style-type: none"> (a) the name of the medicine; (b) if- <ul style="list-style-type: none"> (i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient and its quantity; or (ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients and their respective quantities; (c) either the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine; (d) its dosage and method of usage; (e) its functions or pharmacological action; (f) its indications (if any); (g) its contra-indications (if any); (h) its side-effects (if any); (i) its toxic effects (if any); (j) the precautions to be taken regarding its use (if any); (k) its storage instructions; and (l) its packing specification.
31	In relation to the contravention of s26(1) on labelling.

Section No.	Description
33	A person or institution concerned with education or scientific research may be exempted from the application of sections 143 and 144 of the Ordinance.
34	Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is imported for re-export and to be used for the purpose of clinical trial or medicinal test.
35	Section 144 of the Ordinance shall not apply to proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting the medicine.
36	Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is compounded by Chinese medicine practitioners or in accordance with prescriptions given by Chinese medicine practitioners.
Schedule 2	In relation to the contravention of s26(1) on labelling.

Other related regulatory measures on proprietary Chinese medicines (pCm)

Apart from the mandatory registration of pCm, other related measures to strengthen the regulation of pCm are set out below.

Regulation of pCm manufacturers

2. Regarding the regulation of pCm manufacturers, the licensing requirements include sanitary premises, suitable environment of humidity, lighting, temperature and ventilation for manufacturing and storage areas, and adequate and suitable fittings and equipment for the manufacturing of pCm. Furthermore, the person who supervises the manufacturing process should possess an appropriate level of knowledge and experience, as prescribed in the Chinese Medicines Regulation. Before issuing a manufacturer licence in pCm, the Department of Health (DH) will conduct inspection to ensure that the relevant premises and facilities meet the requirements set by the Chinese Medicines Board (“CMB”) in all aspects. After the issuance of the licence, DH will conduct routine and unannounced inspections. Once any violation of the Chinese Medicine Ordinance (“the Ordinance”) or the practising guidelines is detected, DH will take enforcement actions and may consider prosecution. The case will also be referred to CMB for disciplinary actions.

3. Moreover, pursuant to Section 133 of the Ordinance, manufacturers holding a pCm manufacturer licence may apply to CMB for a Certificate for Manufacturer (Good Manufacturing Practice in respect of Proprietary Chinese Medicines) (GMP Certificate), certifying that they follow the requirements of good practices in manufacture and quality control of pCm. To facilitate the implementation of quality management, CMB has issued the “Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines” to provide guidance to pCm manufacturers. However, at present the GMP system is not a statutory requirement and therefore licensed pCm manufacturers

can decide on their own whether it would apply to CMB for a GMP Certificate. To enhance the standard of the trade, the Government will actively enter into discussion with CMB and the trade to work out a timeframe for the introduction of mandatory GMP requirements for manufacturing of pCm so as to regulate more effectively the manufacturing of pCm .

Setting up of product recall system

4. Licensed pCm traders have to observe the law and the requirements of practising guidelines, which include the need to make sure that the pCm manufactured and distributed meet the requirements as to their quality. Besides, there should also be a proper recall system in place to ensure prompt recall of any defective pCm from the market.

Enforcing import control

5. Import control of pCm will be enforced in accordance with the Import and Export Ordinance (Cap. 60). An import licence issued by the Director of Health must be obtained for each consignment of pCm imported into Hong Kong. DH will consider whether the pCm to be imported meet the basic safety requirements before a licence is issued.

Conducting market surveillance

6. DH will collect samples of pCm from the market on a regular basis for testing. If any problem is detected (e.g. adulteration with western medicines, exceeding the limits for heavy metals), DH will conduct investigation and take appropriate actions in accordance with the relevant regulations. If necessary, DH may order the importers or manufacturers to recall the products in question. Where registered pCm are involved, the cases may be referred to CMB for consideration as to whether the registration of the products should be de-registered in order to safeguard public health.

7. DH has adopted a risk based approach to collect samples of registered pCm under transitional arrangement from licensed pCm manufacturers and pCm wholesalers for testing and will also monitor cases of adverse drug reactions.

Other related legislation

8. Apart from the Ordinance governing the mandatory registration for sale, import and possession of pCm, other relevant laws include –

- (a) the Pharmacy and Poisons Ordinance (Cap. 138) imposes regulation on drugs containing any western medicine as ingredients. pCm should not contain any western medicine as ingredients.
- (b) the Public Health and Municipal Services Ordinance (Cap.132) imposes regulation on medicines including pCm on whether they are suitable for human consumption, and the affixing of false label;
- (c) the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586) imposes regulation on pCm containing ingredients of endangered species;
- (d) the Trade Descriptions Ordinance (Cap. 362) imposes regulation on counterfeit medicines and false representations;
- (e) the Undesirable Medical Advertisements Ordinance (Cap.231) imposes regulation on advertising of medicines (including pCm); and
- (f) the Waste Disposal Ordinance (Cap. 354) imposes regulation on the disposal of waste.