For information
17 January 2011

Legislative Council Panel on Health Services
Progress of the Commencement of Sections of Chinese Medicine Ordinance and Chinese Medicines Regulation related to Mandatory Registration of Proprietary Chinese Medicines

PURPOSE

The provisions in the Chinese Medicine Ordinance (the Ordinance) related to the mandatory registration of proprietary Chinese medicines (pCm), and the requirements of label and package inserts has started to commence in phases from 3 December 2010. This paper informs Members of the progress of the commencement.

BACKGROUND OF THE REGULATION OF CHINESE MEDICINES

2. Chinese medicine is used widely and for long by the Hong Kong public. To strengthen the protection of public health and to foster the development of Chinese medicine, the Ordinance was passed in 1999 to provide a legal basis for the establishment of an effective regulatory regime for Chinese medicine.

3. After the passage of the Ordinance, the Administration established the Chinese Medicine Council of Hong Kong (CMC)[1] to implement the regulatory regime for Chinese medicine.

4. Regarding Chinese medicines, the Legislative Council (LegCo) passed the resolution on the enactment of the Chinese Medicines Regulation (the Regulation) in December 2002 to provide for the regulation on Chinese medicines traders and pCm.

5. As regards Chinese medicines traders, since April 2003, in accordance the provisions relating to the licensing of Chinese medicines traders in the Ordinance and the Regulation, the Chinese Medicines Board under CMC has started to issue four types of Chinese medicines trader

[1] CMC is a statutory body established under the Ordinance to implement regulatory measures for Chinese medicine practitioners (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.

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.

6. As the issuance of the licenses to the Chinese medicines traders has been completed, the legislative provisions relating the licensing of Chinese medicines traders and import and export of Chinese herbal medicines became fully effective on 11 January 2008[2].

THE PROPRIETARY CHINESE MEDICINES REGISTRATION SYSTEM

7. For the registration of pCm, as stipulated in the Ordinance, all products that fall within the definition of pCm should be registered. The following major provisions of the Ordinance are relating to pCm registration –

(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

8. All pCm must meet the registration requirements prescribed by CMB regarding their safety, quality and efficacy in order to register. CMB has started to accept applications for registration of pCm since 19 December 2003.

9. In view of the history of sales of pCm in Hong Kong, the Ordinance provides a transitional registration arrangement. Manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may apply for transitional registration before 30 June 2004 for pCm manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong.

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

PROGRESS OF THE PROCESSING OF THE APPLICATIONS FOR REGISTRATION OF PROPRIETARY CHINESE MEDICINES

10. As at 15 December 2010, CMB has received about 16 750 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 has also started to issue "Notice of confirmation of transitional registration of pCm" ("Notice") for pCm which fulfil the requirements for transitional registration since 31 March 2008. About 9 200 Notices have been issued so far.

11. Besides, CMB has issued "Notice of confirmation of (non-transitional) registration of pCm" for some 2 110 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).

12. For the remaining applications, about 5 800 applications for registration of pCm were rejected due to failure to furnish sufficient information. About 1 140 of the rejected cases have applied for review under section 140 of the Ordinance. About 940 applications for review were considered by CMB in accordance with the laid down review procedures.

PROVISIONS FOR COMMENCEMENT

13. Following the completion of CMB's assessment of all applications for transitional registration and communication with stakeholders, we have put into full implementation the relevant provisions under the Ordinance, stated in paragraph 7 above, in phases from 3 December 2010[3] as follows –

(a) 3 December 2010 – commencement of s119 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 s143 and s144 to allow the trade to have adequate time to comply with the labelling and package insert requirements.

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[3] Legislative Council paper FH CR 1/3911/07

We have consulted the LegCo Panel on Health Services on 12 July 2010 on the commencement of relevant provisions in phases. The relevant commencement notices were gazetted on 8 October 2010 and be effective on the specified dates after submission to LegCo for negative vetting on 13 October 2010. The lists of the relevant legislative provisions, dates of commencement, and details of the consultation and publicity activities are at **Annex**.

PROGRESS OF THE COMMENCEMENT

14. To tie in with the commencement of the legislation, DH has set up a hotline (2319 5119). As at 15 December 2010, DH has received about 513 phone calls on pCm general enquiries and registration enquiries. No complaint about suspected sale of unregistered pCm has been received so far.

15. Besides, DH will continue its efforts to monitor the sale of pCm on the market and to carry out investigation upon complaints or intelligence received. Moreover, DH has also established an enforcement unit to enhance market surveillance and to carry out proactive inspection of pCm manufacturers, wholesalers and retailers. Since the commencement of the legislation and up to 15 December 2010, some 62 Chinese medicine traders were inspected for any sale of unregistered pCm. No violation of regulation was found by DH in the active inspections of Chinese medicine traders.

CONCLUSION AND WAY FORWARD

16. From the experiences of the past month, commencement of the provisions is generally supported and welcomed by society. As a result, the progress of the commencement is rather smooth. The Administration will continue to collaborate with the Chinese medicine industry, with a view to safeguarding public health and fostering the development of Chinese medicine.

17. To further enhance the regulation of Chinese medicines, it is stated in the 2010-11 Policy Address that the Administration would actively engage the industry to work out a timetable for mandatory compliance with the Good Manufacturing Practice for the manufacture of proprietary Chinese medicine.

ADVICE SOUGHT

18. Members are invited to note the contents of this paper.

Department of Health
January 2011

Annex

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A. The Ordinance

Section No.	Description
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 (HKD100,000) 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 No.	Description
	section 121.
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.

B. The Regulation

Section No.	Description
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.

Section No.	Description
Proposed commencement date: 1 December 2011	
25	The package of the proprietary Chinese medicines is labelled in a conspicuous position.
26	A label on a package of a proprietary Chinese medicine to be sold in Hong Kong, the outermost package shall have the following particulars being clearly and distinctly set out, at least in Chinese – (a) the name of the medicine; (b) if- (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- (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. (Remark: Except as otherwise provided in this section)
27	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 – (a) the name of the medicine;

Section No.	Description
	(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	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 have the particulars being clearly and distinctly set out, namely – (a) the name of the medicine; (b) if- (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.
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.

Section No.	Description
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.

C. Exchanges and Consultation

To prepare the Chinese medicines trade for the full implementation of the mandatory registration of pCm, CMB and DH have already carried out the following exchange and consultation activities –

(a) started accepting applications for pCm registration from December 2003;

(b) held a number of briefing sessions from February to June 2004 to explain the registration requirements and application details;

(c) held a number of briefing sessions in 2009 to facilitate the trade to have a better understanding of the requirements of product quality documents and guidelines on labels and package inserts of pCm;

(d) uploaded the guidelines on the label and package insert requirements and other relevant information on registration of pCm on the CMC website for the traders' reference;

(e) publicised the statutory requirements of pCm registration in the "Chinese Medicine Traders Newsletter", which was distributed to all licensed Chinese medicine traders and trade associations;

(f) attended meetings of Chinese medicines traders associations to facilitate the trade in understanding the pCm registration requirements;

(g) held eight briefing sessions for the major trade associations, the trade/stakeholders from late May to early September 2010 to brief

them on the commencement of the relevant legislative provisions and collect their feedback;

(h) attended the meetings of the Retail Task Force under the Business Facilitation Advisory Committee to report the progress of the pCm registration regularly and to understand the concerns of the trade and stakeholders regarding the commencement of the relevant legislative provisions; and

(i) consulted the trade and stakeholders on the commencement of the legislative provisions through the Business Consultation e-Platform under the GovHK Portal (www.bce.gov.hk).

CMB and DH have conducted numerous briefing sessions in 2009 to inform the trade that the Government would plan to commence the legislative provisions related to the mandatory registration of pCm shortly, and also through attending meetings of the Retail Task Force under the Business Facilitation Advisory Committee to report the progress of pCm registration regularly. Since late May 2010, DH has held consultation/briefing sessions for the trade and stakeholders, who have indicated their support to the implementation plan and the related timeframe. The views on the implementation details collected from the trade in the consultation/briefing sessions have been reported to CMB. The progress of the implementation details has also been publicized through the "Chinese Medicines Traders Newsletter", "Newsletter of Chinese Medicine Practitioners Board"[1] and the CMC website.

Besides, well before the commencement of the relevant provisions, DH has all along maintained a close communication with the trade to listen to their views on the commencement and explain to them the Government's stance on the commencement.

D. Publicity

[1] To enhance communication with the profession and to convey information, the Chinese Medicine Practitioners Board of the Chinese Medicine Council publishes 3 issues of the "Newsletter of Chinese Medicine Practitioners Board" annually.

Various communication channels showed that both the public and the trade supported the mandatory registration of pCm.

From the hotline enquiries, the public shows great concern about whether the pCm they use have been registered by the Chinese Medicines Board. DH will continue to provide the hotline service and will strengthen publicity & education to the public.

Through different communication channels, the trade in general has showed support in the mandatory registration of pCm. Individual traders have expressed views on the regulation of pCm (eg. Product registration classification, enquiry channels, pCm advertising, product recalls, etc). DH will provide appropriate assistance and guidance accordingly.

To tie in with the commencement of the relevant provisions, DH has carried out the following publicity and educational activities –

(a) held a press conference, attended a radio programme, and issued press release to publicise the commencement of the relevant provisions;

(b) produced radio Announcement in the Public Interest (API) and television programme;

(c) released related news and information through websites of the CMC and DH;

(d) published articles in “Choice” magazine of the Consumer Council, and publications of District Councils to introduce the regulatory provisions related to pCm to the public;

(e) issued letters to Chinese medicine practitioners associations and Chinese medicines traders associations to publicise the commencement; and

(f) employed Chinese medicines students in tertiary education institutions as “ambassadors” to visit Chinese medicines traders and listed sellers of poisons and dispensaries with a view to assisting traders to familiarise with the statutory requirements relating to the selling, labelling and package inserts of pCm.

DH will continue to publicise the legislative provisions relating to the regulation of pCm through a variety of activities, such as roving exhibitions, television API, and promotion pamphlets to enhance the public's understanding on the regulatory provisions.