For discussion on
12 July 2010

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

PURPOSE

We plan to commence in phases from December 2010 the provisions in the Chinese Medicine Ordinance (the Ordinance) and the Chinese Medicines Regulation (the Regulation) related to the mandatory registration of proprietary Chinese medicines (pCm), and the requirements of label and package inserts. This paper informs Members of the details of the plan.

BACKGROUND OF THE REGULATION OF CHINESE MEDICINES

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 (CMC) [1] 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 the enactment of the Regulation in December 2002 to provide for the licensing requirements for Chinese medicines traders and the registration system for

[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.

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 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.

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

4. For the registration of pCm, as stipulated in the Ordinance, for products that fall within the definition of pCm, application for registration of pCm must be made to the Chinese Medicines Board (CMB). CMB has started to accept applications for registration of pCm since 19 December 2003. To be registered, all pCm must meet the registration requirements prescribed by CMB regarding their safety, quality and efficacy. In view of the history of sales of pCm in Hong Kong, 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. CMB has started to issue "Notice of confirmation of transitional registration of pCm" for pCm which fulfil the requirements for transitional registration since 31 March 2008.

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

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

5. As at 30 June 2010, CMB has received about 16 560 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 2 110 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). In addition, about 4 610 applications for registration of pCm were rejected due to failure to furnish sufficient information. About 920 of the rejected cases have applied for review under section 140 of the Ordinance. About 220 applications for review were considered by CMB in accordance with the laid down review procedures and about 360 applications are being further processed as the required information has been furnished. CMB is now processing the remaining applications for review in batches. The latest progress of pCm registration is at **Annex A**.

PROVISIONS PROPOSED FOR COMMENCEMENT

6. 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

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 1 December 2010 and 1 December 2011 as follows –

(a) 1 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.

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

7. 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. These measures are set out as follows.

<u>Regulation of pCm manufacturers</u>

8. 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 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 CMB in all aspects. After the issuance of the licence, DH will conduct routine and unannounced inspections. Once any violation of 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.

9. 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 mandatory GMP requirements for manufacturing of pCm so as to regulate more effectively the manufacturing of pCm .

Setting up of product recall system

10. 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

11. 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

12. 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.

13. DH had 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

14. 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.

CONSULTATION WITH THE TRADE

15. 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 consultation activities –

(a) 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;

(b) 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;

(c) 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;

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

(e) held seven briefing sessions for the major trade associations, the trade/stakeholders from late May to early July 2010 to collect their feedback on the commencement of the legislative provisions;

(f) 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

(g) 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);

16. CMB and DH have conducted 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 this year, we have 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 and will be publicized through the "Chinese Medicines Traders Newsletter" and the CMC website.

PUBLICITY AND EDUCATION

17. It is also planned that the following publicity and educational activities will be carried out in the coming months –

(a) to 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; and

(b) to employ 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 familiarize with the statutory requirements relating to the selling, labelling and package inserts of pCm.

Details of the publicity and educational activities are in **Annex C**.

IMPLICATIONS OF THE PROPOSAL TO THE COMMUNITY AND THE TRADE

18. Upon the commencement of the provisions referred to in this paper, 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.

ADVICE SOUGHT

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

Food and Health Bureau

Department of Health

July 2010

Annex A

Progress of Proprietary Chinese Medicine (pCm) Registration as at 30 June 2010

Progress of pCm registration including those applied for transitional registration	**No. of Cases**
Issued with "Notice of Confirmation of Transitional Registration of pCm" (the Notice)	**9,150**
Notice to be issued	120
Assessed cases	135
Rejected for registration of pCm due to: (a) without the three acceptable test reports [1]; (b) application without the required documents, information, samples and/or other materials; (c) not fulfilling the eligibility to be the applicant; and (d) not fulfilling the definition of pCm.	**4,370**
Former rejected cases which have subsequently submitted three acceptable test reports[1] / the required documents, information, samples and/or other materials for further processing	5
Not eligible for transitional registration [2]	315
Withdrawn by applicants	5
Sub-total	**14,100**
Progress of non-transitional pCm registration [3]	
Submitted with the three test reports and issued with "Notice of Confirmation of (Non-transitional) Registration Application of pCm" (HKNT) [4]	**2,110**
Others (Rejected or newly submitted applications)	**350**
Sub-total	**2,460**
Total	**16,560**

[1] The test reports are : (1) heavy metals and toxic element test report; (2) pesticide residue test report; and (3) microbial limit test report.

[2] The Chinese Medicines Board will allow three months for the applicants concerned to submit documents and information required for non-transitional/formal application of pCms.

[3] Including cases which are not eligible for transitional registration and subsequently opted to apply for non-transitional registration.

[4] HKNT cases are cases not eligible for transitional registration and submitted with the three tests reports as stated in footnote 1.

Progress of applications for review made to the Chinese Medicines Board	**No. of Cases**
Processed cases ( ) cases resubmitted with required information and being further processed by the Chinese Medicines Committee	580 (360)
Pending processing	340
Total	**920**

Provisions Proposed for Commencement

I. The Ordinance

Section No.	Description
Proposed commencement date: 1 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.
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;

Section No.	Description
	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 Regulation

Section No.	Description
Proposed commencement date: 1 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	A label on a package of a proprietary Chinese medicine to be sold in Hong Kong, the outermost package shall has the

Section No.	Description
	following particulars being clearly and distinctly set out – (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; (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.

Section No.	Description
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 has the particulars being clearly and distinctly set out – (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.
35	Section 144 of the Ordinance shall not apply to proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting the medicine.

Section No.	Description
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.

Annex C

Publicity Plan for the Commencement of Legislative Provisions related to the Mandatory Registration of Proprietary Chinese Medicines

To prepare for the full implementation of the mandatory registration of proprietary Chinese medicines (pCm), the Chinese Medicines Section of the Department of Health (DH) proposes the following publicity activities to announce the implementation of the relevant legislation provisions to the trade and the members of public –

Time	Publicity Activities
Phase 1: July 2009 to May 2010 [completed]	(a) To hold briefing sessions for the Chinese medicines (CM) traders, representatives of laboratories, and holders of "Notice of confirmation of transitional registration of pCm" (2 sessions in July 2009). (b) To hold seminars with CM traders, CM trade associations/group and representatives of laboratories (in July, September and November 2009, as well as January and April 2010). (c) To issue letters to individual CM traders and applicants of pCm registration reminding them of the need to comply with the requirements of the relevant legislative provisions related to the mandatory registration of pCm. (Issued on 6 May 2010).
Phase 2: From June 2010 and prior to the commencement	(a) To hold briefing sessions for: • CM trade associations/ representative from the secretariat of the Retail Task Force under the Business Facilitation Advisory Committee • pCm manufacturers, importers/wholesalers, applicants of pCm registration, listed sellers of poisons and dispensaries, and representatives of retailers from the Retail Task Force under the Business Facilitation Advisory Committee. (b) To send letters to individual CM trade associations/groups, retailer associations, and the Hong Kong General Chamber of Pharmacy Ltd. /groups

Time	Publicity Activities
	informing them of the commencement date of the relevant legislative provisions. (c) To inform registered and listed Chinese medicine practitioners of the implementation details and the exemptions under the legislative provisions related to the mandatory registration of pCm through the "Newsletter of the Chinese Medicine Practitioners Board". (d) To send letters to education or scientific research institutions explaining the conditions for exemptions for mandatory registration of pCm. (e) To publicise through "Chinese Medicines Traders Newsletter" the implementation plan. (f) To consult 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). (g) To publicise and educate the public the commencement plan through various channels (such as CMC and DH websites, the Consumer Council) regarding the implementation of the relevant provisions to enhance their knowledge of registered pCm.
Phase 3: Before and after the commencement (Starting October 2010)	To announce the legislative provisions related to the mandatory registration of pCm to be/have been commenced: (a) publish by Gazette (b) hold press conference (if required) (c) issue press release (d) publish "Frequently Asked Questions" on the CMC website (e) announce on the telephone hotline system of the CMC and DH

Time	Publicity Activities
	(f) issue letters to licensed CM traders, applicants of CM traders licenses, applicants of pCm registration, registered and listed Chinese medicine practitioners, and the Hong Kong General Chamber of Pharmacy Ltd. (g) provide information to applicants of pCm wholesaler and manufacturer licenses regarding the legislative requirements of mandatory registration of pCm, labelling and package inserts (h) provide information to pCm wholesalers and manufacturers regarding the legislative requirements of mandatory registration of pCm, labelling and package inserts by DH officers during inspections (i) carry out publicity activities, including distribution of publicity pamphlets/ posters, and employ students of tertiary education institutions as "ambassadors" to visit about 9,000 CM traders with a view to assisting them to familiarize with the statutory requirements relating to the selling, labelling and package inserts on pCm (j) inform related bureaux and government departments of the commencement of the relevant provisions and measures

Time	Publicity Activities
Current regular arrangements	(a) publish the information of the Chinese Medicine Ordinance, Chinese Medicines Regulation, Practicing Guidelines of CM traders, lists of licensed CM traders, holders of "Notice of Confirmation of Transitional Registration of pCm", list of registered Chinese medicine practitioners and list of listed Chinese medicine practitioners on the CMC website (b) updated the details of registered pCm on the CMC website regularly (c) answer enquires about application of pCm registration through telephone hotline (d) distribute "Handbook for Registration of pCm" and application form through： • the CMC website • the Chinese Medicines Section of DH • the Pharmaceutical Service of DH • the IVRS of DH (e) publicise the latest information of pCm registration through the "Chinese Medicines Traders Newsletter"