For information
22 November 2011

Subcommittee on Registration of Proprietary Chinese Medicines Progress of the Commencement of Sections of Chinese Medicine Ordinance related to Mandatory Registration of Proprietary Chinese Medicines and the Requirements of Label and Package Insert

PURPOSE

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) have commenced on 3 December 2010, and those related to the requirements of label and package insert will commence on 1 December 2011. This paper updates Members of the progress of the registration of pCm, the Administration's launching of publicity programmes in preparation for the commencement of the provisions related to label and package insert, and the enforcement arrangement after 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 enacted in 1999 to provide a legal basis for the establishment of an effective regulatory regime for Chinese medicine.

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

4. 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

[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.

(Details are set out in **Annex I**)–

(i) Section 119 –No person shall sell; or import; or possess any proprietary Chinese medicine unless the pCm is registered under section 121[2] ;

(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

5. All pCm must meet the registration requirements prescribed by the Chinese Medicine Board under the Chinese Medicine Council (CMB)[3] regarding their safety, quality and efficacy in order to register. CMB has started to accept applications for registration of pCm since 19 December 2003.

6. 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.

PROGRESS OF THE REGISTRATION OF PROPRIETARY CHINESE MEDICINES

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

7. As of early November 2011, CMB has received about 16 990 applications for registration of pCm, of which about 14 100 also applied for transitional registration. So far, CMB has issued 9 123 "Notice of confirmation of transitional registration of pCm" and 134 "Certificate of Registration of pCm". Besides, CMB has issued 1 177 "Notice of

[2] Under Sec.121of the Ordinance, application for the regulation of a pCm shall be made to CMB, and shall be in such form and accompanied by such documents, information, samples and other materials as the Medicines Board may determine.

[3] 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.

confirmation of (non-transitional) registration of pCm" (i.e. applications accompanied by three acceptable basic test reports on heavy metals and toxic element, pesticide residues and microbial limit).

8. For the remaining applications, about 6 100 applications for registration of pCm were rejected due to failure to furnish sufficient information. Among the rejected cases, 1 209 review applications under section 140 of the Ordinance have been received. Most applicants have requested longer time for preparing various product safety test reports required by CMB. CMB considered about 1 194 applications for review in accordance with the established review procedures. Progress on the processing of review applications is in **Annex II**.

Commencement of provisions related to mandatory registration of proprietary Chinese medicines

9. Since the commencement of the relevant provisions on 3 December 2010, the Department of Health (DH) has kept up its efforts to conduct market surveillance of pCm and proactive inspection of traders, and has set up an enquiry hotline (2319 5119) to answer public enquiries on pCm registration. Four violation cases have been found so far. From the experience of the past one year, implementation of the provisions has been smooth and is generally supported by the public.

PREPARATION FOR THE COMMENCEMENT OF PROVISIONS RELATED TO THE REQUREMENTS OF LABEL AND PACKAGE INSERT

10. In order to allow the trade sufficient time to prepare for the label and package insert requirements, commencement of the requirements have been planned to come into effect approximately one year after the commencement of the mandatory registration of pCm on 3 December 2010. The applicants for pCm registration have the responsibility to ascertain whether their registered products have fulfilled the requirements of label and package insert as stipulated in the Ordinance so as to avoid non-compliance upon the commencement. In fact, subsequent to the enactment of the provisions relating to the requirements of label and package insert under the Regulation in early 2003, details of the statutory requirements were promulgated. The requirements on label and package insert as stipulated in the Regulation are in Annex I. To provide assistance to the applicants, CMB and DH have all along maintained close communication with the trade to understand their

situation. A whole range of publicity programmes have also been launched as elaborated below.

11. DH has regularly sent representative(s) to attend meetings of the Retail Task Force under the Business Facilitation Advisory Committee to report the progress of the pCm registration and to understand the concerns of the trade and stakeholders. DH has taken follow-up actions and addressed concerns of the trade as appropriate.

12. Back in December 2003, CMB published the "Application Handbook for Registration of Proprietary Chinese Medicines" which set out detailed statutory requirements of label and package insert. In parallel, DH set up an enquiry hotline to handle applicants' enquiries on pCm registration as well as label and package insert requirements. To facilitate the trade to have a good grasp of the relevant requirements, CMB and DH drew up the "Guidelines on labels of proprietary Chinese medicines" and "Guidelines on package inserts of proprietary Chinese medicines" in July 2009. Briefing sessions were also held to familiarise the trade with the contents of the guidelines, which were also uploaded on the CMC website for the traders' reference and compliance. Between mid-2009 and end of 2010, DH and CMB had conducted or participated in a total of eleven such briefing sessions.

13. In view of the imminent commencement of the requirements of label and package insert, further publicity and educational programmes have been/will be launched as follows. Details of the publicity and educational programmes are listed in **Annex III**.

(a) part-time "ambassadors" employed will continue to visit Chinese medicines traders, listed sellers of poisons and dispensaries to familiarise the trade with the statutory requirements relating to the selling, labelling and package insert of pCm;

(b) five briefings for major trade associations, traders and stakeholders have been conducted from mid-February to mid-March 2011 to brief the trade on the label and package insert requirements.

(c) pamphlets have been distributed to members of public through elderly homes and patient organizations as well as to travellers to raise their awareness of the use and purchase of pCm;

(d) the "Chinese Medicines Traders' Newsletter and the "Newsletter of Chinese Medicine Practitioners Board " have been distributed to individual traders and Chinese medicine practitioners respectively to

introduce the label and package insert requirements. Similar articles will be published again in the above-mentioned Newsletters in November and December 2011 respectively;

(e) roving exhibitions will continue to be held in the 18 districts of Hong Kong;

(f) letters have been issued to 18 District Councils to brief their members of the commencement of relevant legislative provisions; and

(g) radio and television Announcements in the Public Interest (APIs) have been launched and media briefings will be held soon.

14. Apart from the above, to facilitate applicants of pCm registration to know whether the labels and package inserts of their products have complied with the statutory requirements, DH has issued letters to individual holders of "Notice of confirmation of transitional registration of pCm", "Notice of confirmation of (non-traditional) registration of pCm" and "Certificate of Registration of pCm", informing them of the labels and package inserts information of the pCm concerned for their verification. If necessary, the applicants may also request an interview with the DH officer to ascertain the contents of the labels and package inserts information of their products.

ENFORCEMENT ARRANGEMENT AFTER THE COMMENCEMENT OF PROVISIONS RELATED TO THE REQUREMENTS OF LABEL AND PACKAGE INSERT

15. Despite the fact that adequate time has been given to the trade to prepare for the commencement, the Administration note that some traders have difficulties in recalling the pCm already on sale to replace labels and package inserts. The trade has therefore requested the Administration to adopt a flexible approach in enforcement.

16. Having considered the actual operation of the trade, a pCm found in violation of the label and package insert requirements after their commencement on 1 December 2011, the Administration will first require the trader of the pCm concerned to cease selling that non-compliance pCm and issue a warning letter to the trader, provided no hazard to public health will be caused[4]. Importing, wholesaling and selling of the pCm concerned

[4] DH may bring immediate prosecution against serious offense.

will only be allowed when the product is examined to be in compliance with the label and package insert requirements. Depending on the compliance of the traders, the above arrangement will be reviewed one year after the commencement.

CONCLUSION AND WAY FORWARD

17. In conclusion, the commencement of the provisions relating to pCm registration is generally supported by the society. The progress of the commencement is smooth. The Administration will continue to communicate with the trade and stakeholders, provide appropriate assistance to them, and launch publicity programmes to keep the trade abreast of the latest information. If necessary, DH representatives will attend the meetings or briefings held by the trade association(s)/trade to exchange views and explain the relevant statutory requirements with a view to implementing the provisions relating to label and package insert on 1 December 2011 smoothly.

ADVICE SOUGHT

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

Department of Health
November 2011

Annex I

Provisions for commencement of mandatory registration of proprietary Chinese medicines and the requirements of label and package insert

I. 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 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))
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**
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.
Commencement date: 1 December 2011	
25	The package of the proprietary Chinese medicines is labelled in a conspicuous position.

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Section No.	Description
26	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, 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; (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.

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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 II

Statistics on application for review lodged by applicants for registration of proprietary Chinese medicines pursuant to section 140 of the Chinese Medicine Ordinance (position as at 2 November 2011)

Reasons for rejection by the Chniese Medicine Committee (CMSC)	No. of application for review received	Progress of processing				
		Application for review considered by the Chinese Medicines Board (CMB)				No. of application for review pending consideation by CMB
		No. of cases to be followd up by applicants/ CMB/CMSC	Decision of CMSC upheld	No. of cases withdrawn by the applicants	Sub-total	
Applicant fails to proof that he is the qaulified applicant for the pCm under application as stipulated in the Ordinance	39	39	-	-	39	-
The pCm under application does not fulfill the definition of pCm as stipulated in section 2 of the Ordinance (note 1)	80	15	64	1	80	-
Applicant fails to provide the required documents, information, samples and other materials of the pCm under application that are required by the CMB	198	44	90	57	191	7
Applicant fails to provide the three basic test reports of the pCm under application (note 2)	584	345	151	88	584	-
Applicant fails to provide the required qaulity specification, method and testing report; acute toxicity test report and/ or stability test report	308	169	126	5	300	8
	1,209	**612**	**431**	**151**	**1,194**	**15**

Note:

1. The active ingredients of the product, which does not solely composed of herbal, animal or mineral origin customarily used by the Chinese, therefore does not fulfill the definition of pCm as stipulated in section 2 of the Ordinance

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

Annex III

Publicity and educational programmes for the commencement of the provisions relating to the requirements of label and package insert

- continue to send out part-time "ambassadors" to visit Chinese medicines traders, listed sellers of poisons and dispensaries to familiarise the trade with the statutory requirements relating to the selling, labelling and package insert of pCm;
- attend meetings of the Retail Task Force under the Business Facilitation Advisory Committee and update members on the progress of the commencement of the provisions relating to label and package insert requirements regularly;
- has conducted five briefings for major trade associations, traders and stakeholders from mid-February to mid-March 2011 on the statutory requirements of label and package insert;
- pamphlets on "What You Should Know When Purchasing Proprietary Chinese Medicines" have been distributed to travellers and to members of public through elderly homes, and patient organisations to raise their awareness of the use and purchase of pCm since February 2011;
- roving exhibitions were held in 18 districts from June 2011;
- has published articles on label and package insert requirements of pCm in the "Chinese Medicines Traders' Newsletter" (published in June 2011), "Newsletter of Chinese Medicine Practitioners Board" (published in August 2011), "Choice Magazine" and "Community Health Partnership Communication" of the District Council published in September 2011. Similar articles will be published again in the "Chinese Medicines Traders' Newsletter" and the "Newsletter of Chinese Medicine Practitioners Board" in November and December 2011 respectively;
- has met three trade associations including the Hong Kong General Chamber of Pharmacy Ltd., Hong Kong Chinese Prepared Medicine Traders Association Ltd. and Hong Kong Chinese Patent Medicine Manufactures' Association Ltd. from July to August 2011 to brief them on the statutory requirements of label and package insert;

- has met individual trade associations to brief their members on the commencement of the relevant provisions since August 2011;
- has held a briefing on 10 August 2011 to brief participating traders of the "International Conference and Exhibition of the Modernization of Chinese Medicine and Health Products 2011" (the Exhibition) on the regulatory system of Chinese medicines in Hong Kong, including label and package insert requirements of pCm. During 11 to 15 August 2011, DH also participated in the Exhibition to introduce the registration system of pCm;
- has attended a meeting of the Alliance of Patient Mutual Help Organizations on 10 August 2011 to brief the attendees of the legislative requirements of label and package insert;
- has launched a 1-min TV mini-programme on TVB to promote the issue from 15-19 August 2011;
- has conducted a briefing on 8 September 2011 for retailer associations/ organizations to brief their members on the statutory requirements of label and package insert;
- has attend a seminar on 23 September 2011 regarding statutory requirements of label and package insert, co-organised by the Hong Kong Chinese Medicine Industry Association, the Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd. and the Hong Kong Chinese Prepared Medicine Traders Association;
- has attend a seminar on 19 October 2011 regarding statutory requirements of label and package insert, co-organised by the Hong Kong Medicine Dealers Guild and the Hong Kong Society of Chinese Medicines;
- has issued letters to the 18 District Councils to brief their members of the commencement of the relevant legislative provisions;
- has launched TV and radio Announcements in the Public Interest (APIs) on label and package insert requirements of pCm,; and
- will hold media briefings in November 2011 before the commencement of the relevant provisions.