For information
16 January 2012

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

PURPOSE

This paper updates Members of the implementation progress after the commencement of the relevant provisions related to the requirements of label and package insert of proprietary Chinese medicines (pCm).

BACKGROUND

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 Chinese Medicine Ordinance (the Ordinance) was enacted in 1999 to provide a legal basis for the establishment of an effective regulatory regime for Chinese medicine. The Administration then established the Chinese Medicine Council of Hong Kong (CMC) to implement the regulatory regime for Chinese medicine.

3. The Ordinance stipulates that all products that fall within the definition of pCm must be registered. The Chinese Medicine Board (CMB) under the CMC has started to accept applications for registration of pCm since 19 December 2003. Relevant provisions related to the mandatory registration of pCm were commenced on 3 December 2011. Those related to the requirements of label and package insert were commenced on 1 December 2011.

4. In the last Subcommittee meeting, members discussed detailed arrangements for the commencement of label and package inserts requirements. Members requested the Administration to report to the Subcommittee the implementation progress after the commencement of the relevant provisions.

COMMENCEMENT OF PROVISIONS RELATED TO LABEL AND PACKAGE INSERT REQUIREMENTS

5. Major provisions in the Ordinance and the Chinese Medicines Regulation (the Regulation) related to the requirements of label and package insert are in **Annex 1**. Details of the statutory requirements were approved and promulgated by the Legislative Council in early 2003.

6. In order to allow sufficient time for the trade to prepare for compliance with the relevant requirements, the Administration decided to commence the label and package insert requirements approximately one year after the commencement of the mandatory registration of pCm. The pCm trade have the responsibility to ascertain whether their registered products have fulfilled the label and package insert requirements as stipulated in the Regulation. To provide assistance to the trade, CMB and DH have all along maintained close communication with the trade to understand their situation and launched a whole range of publicity programmes detailed in **Annex 2**. The Administration will continue to launch publicity programmes to enhance the understanding of the trade and general public about the statutory requirements.

7. Moreover, having considered the actual operation of the trade, if a pCm is found in violation of the label and package insert requirements after the commencement on 1 December 2011, the Administration will require the pCm trader concerned to cease selling that non-compliant pCm immediately and issue a warning letter to the trader, provided no hazard to public health will be caused[1]. Selling of the pCm concerned 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.

PROGRESS AFTER THE COMMENCEMENT

8. Since the commencement of the provisions related to the label and package insert requirements on 1 December 2011, DH has conducted inspection over 1 930 pCm, which involve 64 retailers, 112 wholesalers of pCm and 25 manufacturers of pCm. Of these, 64 non-compliant cases have been found (about 3% of the total pCm inspected). A majority of these non-complaint cases involves missing items on label and package insert.

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[1] DH may bring immediate prosecution against serious offence.

9. DH has issued warning letters to the traders concerned requiring them to cease selling those non-compliant pCm and requiring them to rectify the labels and package inserts in question for DH's approval before selling. Details of the non-compliant cases have been uploaded to the website of the Chinese Medicine Division of DH (www.cmd.gov.hk) for reference by the public and the trade.

CONCLUSION AND WAY FORWARD

10. In conclusion, the commencement of the provisions relating to pCm registration as well as the requirements of label and package insert is generally supported by society. Implementation of the relevant provisions has also been smooth. The Administration will continue to communicate with the trade and stakeholders, provide appropriate assistance to them, and continue to launch publicity programmes to keep the trade abreast of the latest information. If necessary, DH representatives will continue to attend the meetings or briefings held by the trade association(s)/trade to exchange views and explain the statutory requirements of pCm registration.

11. Commencement of mandatory registration of pCm and the requirements of label and package insert has marked the full implementation of the regulatory regime of Chinese medicines. This will enhance the confidence of the general public in using Chinese medicine service and thus contribute positively to the long-term development of Chinese medicine.

ADVICE SOUGHT

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

Department of Health
January 2012

Annex 1

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

I. The Ordinance

Section No.	Description
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
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 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-

Section No.	Description
	(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.
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;

Annex I

Section No.	Description
	(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.
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 2

Publicity and Educational Programmes for the Commencement of the Provisions Relating to the Requirements of Label and Package Insert

- Between mid-2009 and end of 2010, Department of Health (DH) and the Chinese Medicines Board (CMB) have conducted or participated in a total of eleven briefing sessions to help the trade to familiarise with the contents of the "Guidelines on labels of proprietary Chinese medicines" and the "Guidelines on package inserts of proprietary Chinese medicines";
- 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;.
- 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 were 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 attended 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 attended 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 invited the representatives of six major retailers associations and pharmaceutical products retailers in November 2011 to brief them on the commencement of the label and package insert requirements and the enforcement arrangement;
- has issued letters to the 18 District Councils to brief their members of the commencement of the relevant legislative provisions; and
- continue to launch TV and radio Announcements in the Public Interest (APIs) on label and package insert requirements of pCm.