

香港特別行政區政府
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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
CHINESE MEDICINE DIVISION
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本署檔號 OUR REF.: DH TCMD CMS/6-20/21 Pt.2

來函檔號 YOUR REF. :

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Dear Chinese Medicine Practitioners,

Commencement of the mandatory registration of proprietary Chinese medicines

To safeguard public health and safety, the Chinese Medicine Ordinance (Cap. 549) (the Ordinance) was enacted in 1999. The Chinese Medicine Council of Hong Kong and its Chinese Medicine Practitioners Board and the Chinese Medicines Board (CMB) were established to formulate and implement regulatory measures stipulated under the Ordinance. The registration system for proprietary Chinese medicines (pCm) was commenced in December 2003 and registration applications should be submitted to the CMB as required. CMB will consider each application in terms of safety, quality and efficacy with professional and executive support provided by the Department of Health. In view of the long history of sale of pCm in Hong Kong, section 128 of the Ordinance provides that pCm manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong shall be eligible for transitional registration.

CMB has processed the registration application of pCm as required by the arrangements and situations stipulated in the Ordinance, and issued three types of documents to products meeting the vetting requirements, these include:-

1. Notice of confirmation of transitional registration of proprietary Chinese medicines (with transitional registration number HKP-XXXXX);
2. Notice of confirmation of (non-transitional) registration of pCm (with application number HKNT-XXXXX); and
3. Certificate of Registration (with registration number HKC-XXXXX).

Details of products issued with the "Notice of confirmation of transitional registration of proprietary Chinese medicines", "Notice of confirmation of (non-transitional) registration of pCm" and products to be issued with the "Certificate of Registration" are uploaded to:
http://www.cmchk.org.hk/pcm/chi/idx_dis.htm.

Commencement of mandatory registration of proprietary Chinese medicines

In view that CMB has processed and vetted all applications for transitional registration of pCm, the legislative provisions related to the mandatory registration of pCm and the requirements of label and package inserts will be commenced. The **mandatory registration of pCm** in Section 119 under the Ordinance shall **come into effect on 3 December 2010**. Thereafter, no person shall sell, or import, or possess any pCm that has not been registered. Sections 143 and 144 under the Ordinance on the **labeling and package inserts requirements for pCm** shall **come into effect on 1 December 2011**. Thereafter, no person shall sell any pCm without label or package inserts as required by sections 26 to 28 of the Chinese Medicines Regulation (the Regulation). Any person who violates the above shall be liable upon conviction to a Level 6 fine (i.e. HK\$100,000) and imprisonment for two years. Details of the provisions under the Ordinance and the Regulation are available at <http://www.legislation.gov.hk>.

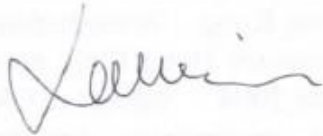
Implications of the commencement of mandatory registration of proprietary Chinese medicines

As a practising Chinese medicine practitioner (CMP), you are reminded to comply with the aforementioned legal requirements, that is, to **procure and provide registered pCm**. Attention should be paid to the descriptions on **pCm labels and package inserts** as required under the law.

Also, CMPs should note the exemptions given to the pCm administered or supplied by a registered or listed CMP as stipulated under section 158(6) of the Ordinance, and the pCm entrusted to be manufactured by a licensed pCm manufacturers. Details of the provisions are available at <http://www.legislation.gov.hk>.

If you have any enquiries concerning the above, please feel free to contact the Chinese Medicines Section of the Chinese Medicine Division at 2319 5119.

Yours sincerely



(Dr Ronald Lam)
for Director of Health