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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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圖文傳真 FAX.:

24 November 2010

Dear Doctor,

**Commencement of the mandatory registration of
proprietary Chinese medicines under
the Chinese Medicine Ordinance**

I write to inform you the commencement of the mandatory registration of proprietary Chinese medicines under the Chinese Medicine Ordinance with effect from 3 December 2010.

The Chinese Medicine Ordinance (Cap. 549) (the Ordinance) was enacted by the Legislative Council (LegCo) in July 1999 to provide a statutory framework for the regulation of Chinese medicine in Hong Kong. The Chinese Medicine Council of Hong Kong (CMC), its Chinese Medicine Practitioners Board and the Chinese Medicines Board (CMB) were established under the Ordinance in the same year respectively to be responsible for regulation of the practice of Chinese medicine practitioners, licensing of Chinese medicines traders and registration of proprietary Chinese medicines (pCm). The Department of Health provides professional and executive support to CMC.

Proprietary Chinese medicines registration system

The registration system for pCm was commenced in December 2003. To minimise disruption to the Chinese medicine trade, 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. Subject to CMB's vetting and approval, a pCm registered under transitional arrangement has been issued with a registration number HKP-XXXXX and that with full registration has been issued a registration number HKC-XXXXX. Such registration number should appear on the external package of pCm on sale. Besides, a pCm not meeting transitional arrangement for HKP-XXXXX registration but provided the basic information

for safeguarding public health and submitted application before 1 April 2010 and has been issued an application number HKNT-XXXXXX.

Section 119 under the Ordinance stipulates that no person shall sell; or import; or possess any pCm unless the pCm is registered by the CMB. To be registered, all pCm must meet the registration requirements on safety, quality and efficacy as prescribed by CMB.

Commencement notices for section 119 and the related provisions, to take effect from 3 December 2010 were gazetted on 8 October 2010. Details can be accessed at the website: <http://www.gld.gov.hk/egazette>.

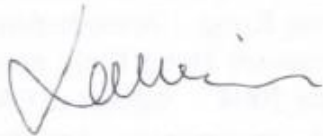
Implications of the commencement of section 119

With effect from 3 December 2010, any person who violates section 119 shall be liable upon conviction to a Level 6 fine (i.e. \$100 000) and imprisonment for two years. Moreover, registration is required for all importation of pCm, other than those for the purpose of re-export, those exempt under section 129 for the purpose of clinical trial and medicinal test, or under section 158(1) for the purpose of education or scientific research.

As a healthcare professional, your attention is drawn to the commencement of mandatory registration of proprietary Chinese medicines and its implications in the course of your practice. Details on procurement of pCm and a full list of pCm given the registration number have been uploaded to the CMC website: <http://www.cmchk.org.hk>. The list will be updated regularly. Your support is enlisted to ensure compliance of the laws and public education in this regard.

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

Yours sincerely



(Dr Ronald Lam)
for Director of Health