

Circular 16 S.119 of Chinese Medicine Ordinance <IMPORTANT>

With effect from 3 December 2010, under s.119 of the Chinese Medicine Ordinance (Cap. 549), all proprietary Chinese medicines must be registered under the Ordinance with the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong before they can be imported, possessed or sold in Hong Kong. Any person who sells, or imports, or possesses any unregistered proprietary Chinese medicine shall commit an offence and upon conviction shall be sentenced at maximum for a fine at HK\$100,000 and imprisonment for 2 years.

For the purposes of the Ordinance, the following terms are interpreted as follows:

- "proprietary Chinese medicine" (中成藥) means any proprietary product-

(a) composed solely of the following as active ingredients-

(i) any Chinese herbal medicines; or

(ii) any materials of herbal, animal or mineral origin customarily used by the Chinese;
or

(iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;

(b) formulated in a finished dose form; and

(c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body"

- "Chinese herbal medicine" (中藥材) means any of the substances specified in Schedule 1 or 2 of the Ordinance (copy attached). The sale, possession, location and distribution of the Chinese herbal medicine listed in the Schedules are subject to the licensing requirements of a respective retailer or wholesaler licence in Chinese herbal medicines granted by the Chinese Medicines Board under the Ordinance. All Hong Kong and overseas exhibitors are reminded that they must fulfil the obligations imposed by the Chinese Medicine Ordinance before they can possess, sell, market, display, exhibit or deal in any other ways with proprietary Chinese medicines in the Fair(s). Brief summaries of the operation of the Ordinance in respect of proprietary Chinese medicines can be found on the website of the Chinese Medicine Council of Hong Kong at <http://www.cmchk.org.hk/>. An extract from the December 2010 issue of Chinese Medicines Traders Newsletter (Chinese version only) is attached for easy reference. For a full text of the Ordinance, please browse the website of the Bilingual Law Information System at <https://www.elegislation.gov.hk/>.

If you have any questions concerning the regulation of Chinese medicines in Hong Kong, please contact the Chinese Medicine Council of Hong Kong at (852) 2574-9999 or browse its website at <http://www.cmchk.org.hk/>

Hong Kong Trade Development Council

通告 16 香港法例第 549 章《中醫藥條例》第 119 條 <重要通告>

香港法例第549章《中醫藥條例》（下稱“該條例”）第119條有關中成藥註冊的法規已2010年12月3日起生效，所有中成藥必須經香港中醫藥管理委員會轄下的中藥組註冊，方可在本港進口、銷售和管有。任何人銷售、進口或管有任何未經註冊的中成藥即屬違法，定罪後可被判處港幣100,000元罰款及入獄2年監禁。

根據該條例第2條的釋義：

—“中成藥” (proprietary Chinese medicine) 是指任何符合下述說明的專賣產品 —

(a) 純粹由下述項目作為有效成分組成 —

(i) 任何中藥材；或

(ii) 慣常獲華人使用的任何源於植物、動物或礦物的物料；或

(iii) 第(i)及(ii)節分別提述的任何藥材及物料；

(b) 配製成劑型形式；及

(c) 已知或聲稱用於診斷、治療、預防或紓緩人的疾病或症狀，或用於調節人體機能狀態。

—“中藥材” (proprietary Chinese medicine) 是指該條例附表1或2內指明的任何物質（見附件）。附表內之中藥材的銷售、管有、存置和分配都必須遵照中藥組根據該條例授予有關中藥業者之零售商或批發商牌照的規範執行。所有香港和外地的參展商都必須滿足該條例的規定才可在展場內管有、銷售、推廣、展示或以任何方式處理中成藥物品。有關該條例的簡介可參看香港中醫藥管理委員會的網頁：

<http://www.cmchk.org.hk/>，現附上2010年12月出版的《中藥商通訊》中相關資料以供參考。

參展商亦可於雙語法例資料系統的網頁：<https://www.elegislation.gov.hk/>閱讀及列印該條例的全文。參展商如對香港監管中成藥的法規有任何疑問，請向香港中醫藥管理委員會查詢。電話：(852) 2574-9999 或瀏覽其網頁：<http://www.cmchk.org.hk/>。

香港貿易發展局