## 衛生署藥物辦公室 藥物評審及進出口管制科 香港九龍觀塘巧明街 100 號 友邦九龍大樓 20 樓 2002-05 室



## DEPARTMENT OF HEALTH DRUG OFFICE DRUG EVALUATION AND IMPORT/EXPORT CONTROL DIVISION

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(來函請敍明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Date:

Name and Address of Cert. Holder

Dear Sir/Madam,

## Notification for Renewal of Registration Certificate 註冊證明書續期通知書

Please be informed that according to regulation 36(7) (a) and (b) of the Pharmacy and Poisons Regulation (Cap. 138A), the registration certificate shall be renewable on payment of prescribed fee and provision of up-to-date information specified by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee regarding the pharmaceutical product or substance. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committees.

現致函告知,根據《藥劑業及毒藥規例》(第138A章)第36(7)(a)及(b)條,在繳付訂明費用及提供藥劑業及毒藥(藥劑製品及物質註冊:臨床試驗及藥物測試證明書)委員會指明有關藥劑製品或物質的最新資料後,註冊證明書予以續期。衞生署為藥劑業及毒藥管理局及其轄下委員會提供專業及行政支援。

Registration certificate of the pharmaceutical product or substance listed in PRS2.0 Renewal Notification will expire soon. Please complete the renewal procedure at least 10 working days before the expiry date of the certificate. If you make online payment via PRS2.0, please complete the relevant payment transaction at least 5 working days before the expiry date of the certificate. If you make the payment in person or by post, please print the Notification of Payment from the PRS2.0 to facilitate the processing of renewal.

PRS2.0 Renewal Notification所列出的藥劑製品或物質的註冊證明書有效期即將屆滿。請於證明書到期前至少10個工作天完成續期手續。如通過PRS2.0進行網上繳費,請於證明書到期前至少5個工作天完成相關繳費手續。如親身或郵寄繳費,請從PRS2.0列印繳費通知書以供處理有關的續期。

If the above registration certificate is not renewed, please ensure the product or the substance has been successfully and completely recalled from the market for proper disposal at or before the expiry of registration certificate. Please be reminded that regulation 36(1) of the Pharmacy and Poisons Regulation (Cap. 138A) stipulates that no person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product or substance unless the product or substance is registered. Contravention may be subject to maximum penalty of level 6 fine (currently HK\$100,000) and imprisonment for 2 years.

若上述註冊證明書不獲續期,請確保上述製品或物質於證明書有效期屆滿時或前已全部從市面回收、且獲妥善處置。請注意,《規例》第36(1)條規定任何人不得銷售、要約出售或分發,或為銷售、分發或其他用途而管有任何藥劑製品或物質,除非該製品或物質已註冊。違例者的最高罰則為第6級罰款(現時為港幣10萬元)及監禁2年。

Yours faithfully,

Pharmacist Signature and Name

for Director of Health