

PHARMACY AND POISONS ORDINANCE (CHAPTER 138)

藥劑業及毒藥條例 (第138章)

APPLICATION FORM FOR REGISTRATION OF A DRUG / PHARMACEUTICAL PRODUCT / SUBSTANCE

藥品 / 藥劑製品 / 物質註冊申請書

Note : A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application.

Supplementary documentation and supporting documents issued by the health authority in the country of origin should be submitted if required.

註：藥品 / 藥劑製品的銷售樣品或物質的樣品以及有關的說明書須連同申請表一併呈交。如有需要，原產國家的衛生主管當局發出的補充文件及作支持用的文件亦須呈交。

Name of the Drug/Product/Substance* : (*Delete as appropriate)

藥品 / 製品 / 物質* 的名稱 : (*刪去不適用者)

Dose Form/Package Size(s) :

劑型 / 包裝大小 :

Detailed Qualitative and Quantitative Composition :

詳細的素質及分量成分組合 :

Indications :

用途 :

Registered and Marketed in Which Countries/Places :

在那一個國家/地區註冊及那一個國家/地區的市場出售 :

Name of Applicant :

申請人姓名或名稱 :

Business Registration No.:

商業登記號碼 :

In What Capacity the Applicant Makes This Application:

申請人以何身份提出此申請 :

Business Address of Applicant :

申請人營業地址:

Tel. No. :

電話號碼 :

Facsimile No. :

傳真號碼 :

Email Address:

電郵地址 :

Name of Manufacturer :

製造商名稱 :

Address of Manufacturer :

製造商地址 :

DECLARATION OF APPLICANT 申請人聲明

I wish to apply for registration of the said pharmaceutical products under the Pharmacy and Poisons Ordinance. I hereby declare that, to the best of my knowledge and belief, the information given in this application is correct.

本人欲根據《藥劑業及毒藥條例》申請註冊上述藥劑製品。本人現聲明盡本人所知及所信，本申請書所報資料均屬正確。

I further declare that the said pharmaceutical product has not infringed and does not infringe the patent rights of other registered pharmaceutical products in Hong Kong. In addition, I understand and agree that the registration of the said pharmaceutical product, if approved by the Pharmacy and Poisons Board (the Board), is subject to the condition that the product does not infringe any patent rights, and the product may be deregistered or its registration suspended if the Board is of the opinion that such condition is contravened.

本人進一步聲明上述藥劑製品從沒有及現沒有侵犯在香港其他註冊藥劑製品的專利權。此外，本人明白及同意如上述藥劑製品獲藥劑業及毒藥管理局（管理局）批准註冊，會附帶條件訂明該產品沒有侵犯任何專利權，如管理局認為本人違反此條件，該產品可能會被撤銷註冊或暫時吊銷註冊。

.....

Signature 簽署

.....

Date 日期

.....

Name (block letters) 姓名 (正楷)

.....

Position held 職位

For Office Use Only 只供本辦事處填寫

Date Received 收件日期	Legal Classification 法律分類	Fees Paid 已繳費用	Registration Approved 獲准註冊	Certificate Issued 已發的證明書	Registration 註冊