

**PHARMACY AND POISONS BOARD**  
**HONG KONG**  
香港藥劑業及毒藥管理局

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貴處檔號

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20 November 2015

To: Certificate holders of  
registered pharmaceutical products

Dear Sirs / Madams,

**Patent Declaration and New Guidance Notes/Application Form**  
**for Registration of Pharmaceutical Products**

In response to the concern on patent infringement of registered pharmaceutical products raised by various stakeholders, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) has deliberated the issue in September 2015. The Committee noted that there is no direct linkage between patent right and registration of pharmaceutical products under the respective Ordinances in Hong Kong. However, having considered the overseas practice in patent protection for pharmaceutical products, the Committee, empowered to impose registration conditions on registration of pharmaceutical products under the Pharmacy and Poisons (Amendment) Ordinance 2015, decided to impose relevant condition on patent protection for registration of pharmaceutical product.

In this regard, the applicants will be required to declare on the application form, and to agree it as a registration condition, that their products do not infringe any patent right of another pharmaceutical product. The pharmaceutical products may be

deregistered, or their registration be suspended when such condition is contravened. This new requirement on patent declaration in registration of pharmaceutical products will be effective from 1 January 2016. For the updated guidance notes and application form, please visit the following website - <http://www.drugoffice.gov.hk>

If you need further assistance related to patent declaration in registration of pharmaceutical products, please contact Ms Iris Lee at 2319 8474.

Yours sincerely,



(Clive CHAN)

Secretary of the Pharmacy and Poisons  
(Registration of Pharmaceutical Products and Substances:  
Certification of Clinical Trial/Medicinal Test)  
Committee