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

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13 October 2015

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Requirements for Registration of Biosimilar Products

In recent years, the expiration of patents and/or data protection for many biological products has ushered in an era of products that are designed to be 'similar' to the registered originator biological products. These products are referred as 'biosimilar' products. In line with the international practice and scientific consensus, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board consider that information for demonstration of similarity in terms of safety, quality and efficacy is important and required for registration of biosimilar products.

Therefore, based on the World Health Organization's guidelines on the evaluation of biosimilar products, registration requirements of some competent drug regulatory authorities, and comments received from the stakeholders after consultation, the Committee has endorsed a new set of guidelines for registration of biosimilar products which will be implemented with effect from **1 January 2016**. For details of the requirements, please refer to the "Guidance Notes for Registration of Biosimilar Products" at the website of the Drug Office at

www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Biosimilar_guidelines_revised_Final_ENG.pdf.

If you have any enquiries related to the registration of biosimilar products, please contact Ms Karena Lee at 2319 8458.

Yours sincerely

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