

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

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12 August 2015

To: All Licensed Pharmaceutical Manufacturers

Dear Sirs,

Re: The Good Manufacturing Practice Guide
for holders of Licence for Manufacturer

Please be informed that, the Pharmacy and Poisons Board of Hong Kong has adopted version 11 of the Guide to Good Manufacturing Practice for Medicinal Products and its annexes published by the Pharmaceutical Inspection Cooperation Scheme ("PIC/S GMP Guide") as the GMP Guide which will take effect on 1 October 2015 in pursuance of Regulation 28A(3) of the Pharmacy and Poisons Regulations (Chapter 138A). The corresponding Gazette Notice (Number 31, Volume 19, Government Notice No. 5680) was published on 31 July 2015.

You are hereby reminded to comply with the PIC/S GMP Guide accordingly. Please also be reminded that, subject to regulation 29(4) and (4A) of the Regulations, the Committee may take the following actions against a licensed manufacturer if, in the Committee's opinion, the manufacturer has contravened the PIC/S GMP Guide:

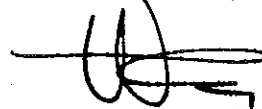
- Reg. 29(4) : "... .., the Committee may-
- (a) *revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit;*
 - (b) *issue a warning letter to the licensed manufacturer; or*
 - (c) *vary a condition of the licence....."*

The PIC/S GMP Guide is available for download from the following website :

<http://www.picscheme.org/publication.php>

The PIC/S GMP Guide will also be available for inspection at the Secretariat of the Board at 1/F, Shun Feng International Centre, 182 Queen's Road East, Wan Chai, Hong Kong during office hours from 1 October 2015 onwards.

Yours faithfully,

A handwritten signature in black ink, consisting of a large, stylized 'C' followed by a horizontal line and some smaller strokes.

(C. S. CHIANG)

Secretary, Pharmacy & Poisons
(Manufacturers Licensing) Committee