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

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27 June 2025

To: Holders of Licence for Manufacturer, Holders of Licence for Manufacturer (Secondary Packaging), and Prospective Applicants

Dear Sir/Madam,

Revised Good Manufacturing Practice Guide
(Effective from 1 July 2025)

According the Gazette Notice published on 26 July 2024, the Pharmacy and Poisons Board ("the Board") approved the revision of the Good Manufacturing Practice ("GMP") Guide, which will take effect from 1 July 2025 in pursuance of Regulation 28A(4) and 28A(5) of the Pharmacy and Poisons Regulations, Cap.138A ("PPR"). The revised GMP Guide consists of the following:

(a). Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products (July 2024) ("HK GMP Guide"); and

(b). Part I, Part II and Annexes of the Guide to Good Manufacturing Practice for Medicinal Products (PE 009-17) published by the Pharmaceutical Inspection Co-operation Scheme ("PIC/S GMP Guide').

The revised GMP Guide is available on the website of the Board (http://www.ppbhk.org.hk) and the Drug Office of the Department of Health (http://www.drugoffice.gov.hk). The revised GMP Guide will also be available for inspection at the office of the Secretary of the Board at 1/F, Shun Feng International Centre, 182 Queen's Road East, Wan Chai, Hong Kong during normal office hours from 1 July 2025 onwards.

You are hereby reminded to comply with the revised GMP Guide effective from 1 July 2025 accordingly. If, in the opinion of the Pharmacy and

Poisons (Manufacturers Licensing) Committee ("the Committee"), the licensed manufacturer has contravened the GMP Guide issued by the Board, the Committee may in accordance with Regulation 29(4) of the PPR, revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit, issue a warning letter to the licensed manufacturer or vary a condition of the licence.

Yours faithfully,

(N.M. LO)
Secretary, Pharmacy & Poisons
(Manufacturers Licensing) Committee