



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

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26 July 2024

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)**

Your attention is drawn to the Gazette Notice published on 26 July 2024 in pursuance of Regulation 28A(4) and 28A(5) of the Pharmacy and Poisons Regulations, Cap. 138A (“PPR”). 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. 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 current GMP Guide and the revised GMP Guide are both 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 prevailing GMP Guide issued by the Board and hence the revised GMP Guide once it comes into effect. If, in the Committee's opinion, the licensed manufacturer has contravened the GMP Guide issued by the Board, it 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,

A handwritten signature in black ink, appearing to be 'T. K. YIM', written in a cursive style.

(T. K. YIM)

Secretary, Pharmacy & Poisons  
(Manufacturers Licensing) Committee