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

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22 October 2021

To: Holders of Licence for Manufacturer (Secondary Packaging)

Dear Sir/Madam,

Revised "Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products"

We write to inform you a revised ***Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products (Draft)*** **("*Draft Revised Guide*")** has been prepared for trade consultation.

In 2015, the Pharmacy and Poisons Board ("Board") issued the ***Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products*** (the "Guide") regarding secondary packaging of pharmaceutical products in pursuance of Regulation 28A(3) of the Pharmacy and Poisons Regulations, Cap. 138A, Laws of Hong Kong. The Guide was prepared with reference to the relevant and applicable parts of version 11 (PE 009-11) of the Guide to Good Manufacturing Practice for Medicinal Products published by the Pharmaceutical Inspection Cooperation Scheme ("PIC/S GMP Guide") for the secondary packaging of pharmaceutical products, and with suitable adjustments made according to local regulations.

Since 2015, PIC/S has updated and published different versions of the GMP Guide and the latest version is PE 009-15, i.e. version 15. For the Board to maintain its PIC/S membership, it is necessary for the pharmaceutical industry of Hong Kong, including the secondary packaging manufacturers, to upgrade their quality system with a view to meet the requirements of latest version of the PIC/S GMP Guide.

At the recent meeting of the Pharmacy and Poisons (Manufacturers Licensing) Committee (the Committee) under the Board, the ***Draft Revised Guide*** has been endorsed for trade consultation which serves to revise the Guide according to the updates of the latest versions of PIC/S GMP Guide that are applicable to secondary packaging of pharmaceutical products.

In order to comply with the latest requirements, secondary packaging manufacturers should involve in, among others, the revision of written policy to align with the concept of pharmaceutical quality system and involvement of senior management (Chapter 1 and 2), outsourced activities (Chapter 7), and handling of complaints/recalls (Chapter 8) set forth in the ***Draft Revised Guide.***

A copy of the ***Draft Revised Guide*** has been uploaded to the website of the Board at www.ppbhk.org.hk.

You are invited to provide your views on the ***Draft Revised Guide***. You may send your views on or before 22 April 2022 in writing through mail, facsimile or email to the Drug Office:

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Should you have any enquiries, please contact Ms. M. L. KONG at 2961 8162.

Yours faithfully,

(Y. F. YEUNG)
Secretary, the Pharmacy and Poisons
(Manufacturers Licensing) Committee