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

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16 October 2015

Dear Sirs / Madams,

Implementation of PIC/S GMP Requirements
for Registration of Imported Pharmaceutical Products

According to the recommendation of the Review Committee on Regulation of Pharmaceutical Products, the Hong Kong Good Manufacturing Practice (GMP) standards should be upgraded to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards to be on par with the international best practice. In August 2013, the Pharmacy and Poisons Board (the Board) lodged a membership application to PIC/S. It is anticipated that Hong Kong will be the 47th member of PIC/S at the beginning of 2016.

Consequentially, the registration requirements of pharmaceutical products manufactured in Hong Kong or overseas should be complied with PIC/S standards. In September 2015, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Board considered the captioned subject, and decided to implement the PIC/S GMP requirements for registration of imported pharmaceutical products according to the following timeline:

(a) New applications for registration of pharmaceutical products (received before 1 January 2016)

For all the new applications for registration of pharmaceutical products received before 1 January 2016 but have not been completed for registration before 1 January 2017, the applicants will be required to provide evidence that the manufacturers comply with the PIC/S GMP standards before the approval of the applications.

(b) New applications for registration of pharmaceutical products (received on or after 1 January 2016)

With effect from 1 January 2016, all the new applications for registration of pharmaceutical products must include evidence that the manufacturers comply with the PIC/S GMP standards. Otherwise, the applications will not be accepted for evaluation.

(c) Renewal applications of registered pharmaceutical products

With effect from 1 January 2017, all the renewal applications for registration of pharmaceutical products must include evidence that the manufacturers comply with the PIC/S GMP standards. Otherwise, the products will not be renewed for registration.

You are therefore required to ensure that the manufacturer(s) of all new applications and renewal applications for registration of pharmaceutical products will comply with the PIC/S GMP standards according to the above timeline. Otherwise, the new applications will not be accepted or the products will not be renewed for registration.

For additional information related to the PIC/S GMP standards, and the arrangement on inspections of overseas manufacturers by the GMP inspectors of the Department of Health (DH) for assessment of the PIC/S GMP standards compliance, please visit the following websites:

PIC/S GMP standards:
- http://www.picscheme.org/pics.php

Implementation timeline and Arrangement on inspections of overseas manufacturers by DH GMP inspectors:
- http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/home.html

If you need further assistance, please contact Ms Mandy Ho at 2319 8458.

Yours faithfully,

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

c.c. DH DO PRIE/7-15/3