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

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

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15th December 2016

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Safety Information for Clozapine

On 14th December 2016, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest overseas recommendations on neutropenia monitoring and treatment algorithm for clozapine, and new safety information on impairment of intestinal peristalsis associated with clozapine. After deliberation, the Committee decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing clozapine should include the following new safety warning:

Probably on account of its anticholinergic properties, Clozapine has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, faecal impaction and paralytic ileus. On rare occasions these cases have been fatal.

You are therefore required to review and revise, if necessary, the sales pack labels and/or package inserts of the concerned products registered by your company to ensure that the products comply with the above requirements. The revised sales pack labels and/or

package inserts should be submitted to the Committee for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products by the Committee.

If you have any enquiries on the above issue, please contact Mr Arthur Lee at 2319 8453.

Yours sincerely,

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

c.c. 7-15/3, Product Files

CC/ART