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

Tel. No. : **2319 8468**
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圖文傳真

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香港九龍南昌街382號
公共衞生檢測中心三樓

27th December 2018

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Valproate Medicines

On 12th December 2018, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings for valproate medicines imposed by the drug regulatory authorities of the European Union, United Kingdom and Singapore, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing valproate medicines indicated for epilepsy, bipolar disorder and migraine in female patients who can have children should be updated and replaced by the following new safety information as appropriate:

Contraindications

(i) [Product Name / Generic Name] is contraindicated as treatment for bipolar disorder and prophylaxis of migraine during pregnancy;

(ii) [Product Name / Generic Name] is contraindicated as treatment for epilepsy during pregnancy unless there is no suitable alternative to treat epilepsy;

and

(iii) [Product Name / Generic Name] is contraindicated for use in women of childbearing potential unless pregnancy preventive measures, which include but not limited to effective contraception, have been implemented.

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 new 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. Paul WONG at 2209 9495.

Yours faithfully,

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

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

TK/PW/HL