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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圖文傳真

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公共衞生檢測中心三樓

21st June 2019

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

Risk Minimisation Measures on Use for Valproate Medicines in Relation to the High Teratogenic Potential and Developmental Disorders in Women of Childbearing Potential

Further to the letter dated 27th December 2018 regarding update on the sales pack labels and / or package inserts of registered pharmaceutical products containing valproate medicines, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee, having considered the risk minimisation measures for valproate medicines in relation to the high teratogenic potential and developmental disorders in women of childbearing potential based on the local situations and made reference to the measures imposed by the drug regulatory authorities of the European Union, United Kingdom and Singapore, decided in the meeting on 20th June 2019 that the Certificate holders of registered pharmaceutical products containing valproate medicines are required to implement the following risk minimisation measures:

(i) A patient information leaflet in both Chinese and English should be provided, highlighting the teratogenic potential and children exposed in utero to valproate have a high risk for congenital malformations and neurodevelopmental disorders;

(ii) A letter to be sent to all doctors to whom the product is supplied, to advise them of the high teratogenic potential and developmental disorders in pregnancy of the product and the precautions associated with the use of the product, and that the product should only be supplied to patients along with the above-mentioned patient information leaflet; and

(iii) To provide education materials to healthcare professionals and patients to reinforce the warnings and provide guidance regarding use of valproate in women of childbearing potential and details of the risk minimisation measures in relation to the high teratogenic potential and developmental disorders in pregnancy. A patient guide and patient card should be provided to all women of childbearing potential using valproate.

You are therefore required to implement the above risk minimisation measures within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not renewed by the Committee.

If you have any enquiries on the above issue, please contact Mr. Paul WONG at 2209 9495.

Yours faithfully,

(T.K. YIM)
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