

衛生署藥物辦公室
藥物註冊及進出口管制部

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本署編號 OUR REF.:

(來函請註明此檔案號碼) DH DO PRIE/7-30/15
(IN REPLY PLEASE QUOTE THIS FILE REF.)

BY FAX

26 June 2019

The Chairman
The College of Surgeons of Hong Kong - Specialty Board in Neurosurgery
(Fax Number: 2515 3198)

Dear Sirs,

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

Thank you for your views on the proposed risk minimisation measures on valproate medicines in relation to the high teratogenic potential and developmental disorders in women of childbearing potential ("WOCP") dated 3 June 2019.

On 20 June 2019, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial / Medicinal Test) Committee ("the Committee") of the Pharmacy and Poisons Board of Hong Kong, having considered your comments and local situations and made reference to the risk minimisation measures for valproate medicines when used in WOCP implemented in the European Union, United Kingdom and Singapore, decided that the Certificate holders of valproate medicines registered in Hong Kong are required to implement the following risk minimisation measures by 20 August 2019:

- (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.*

Please disseminate the above information to your members concerned. If you have any enquiries on the above issue, please contact Mr. Paul WONG at 2209 9495.

Yours faithfully,



(Henry LAU)
for Director of Health