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(來函請註明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

22 Mar 2023

Dear Healthcare Professionals,

Epilim® (valproate): Risk of neurodevelopmental disorders including autism spectrum disorders in children after paternal exposure

Your attention is drawn to the Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Sanofi-Aventis Singapore Pte. Ltd. to inform healthcare professionals of new safety information regarding a higher risk of neurodevelopmental disorders (NDDs), including autism spectrum disorders, in children after paternal exposure to valproate as compared to lamotrigine or levetiracetam.

This finding was from a retrospective observational study on electronic medical records in 3 European Nordic countries where there was an increased risk of NDDs in children (0 to 11 years old) born to men treated with valproate at the time of conception compared to those treated with lamotrigine or levetiracetam.

The Singapore package insert for Epilim® (valproate) is being revised. There are also revised and new educational materials for healthcare professionals and patients. Healthcare professionals are advised to inform male patients of this potential risk and consider alternative therapeutic options with the patients. In men initiating or remaining on valproate treatment, it is recommended for healthcare professionals to discuss with the patient, at least annually, the need for effective contraception, and to ensure that the male patient has acknowledged the risk and precautions associated with valproate use.

Please refer to the following website in HSA for details:

[https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/epilim-\(valproate\)---risk-of-neurodevelopmental-disorders-including-autism-spectrum-disorders-in-children-after-paternal-exposure](https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/epilim-(valproate)---risk-of-neurodevelopmental-disorders-including-autism-spectrum-disorders-in-children-after-paternal-exposure)

In Hong Kong, there are 10 registered pharmaceutical products containing valproate. All products

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are prescription-only medicines. So far, the Department of Health (DH) has received 14 cases of adverse drug reaction related to valproate, but these cases were not related to the risk of NDDs in children after paternal exposure to valproate. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Terence MAN)

for Assistant Director (Drug)