

衛生署藥物辦公室
藥物註冊及進出口管制部

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(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Gilenya (fingolimod): FDA warns about cases of rare brain infection

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement regarding cases rare brain infection in patients taking Gilenya (fingolimod).

The FDA is warning that a case of definite progressive multifocal leukoencephalopathy (PML) and a case of probable PML have been reported in patients taking Gilenya for multiple sclerosis (MS). These are the first cases of PML reported in patients taking Gilenya who had not been previously treated with an immunosuppressant drug for MS or any other medical condition. As a result, information about these recent cases is being added to the drug label.

In an August 2013, FDA reported that a patient developed PML after taking Gilenya. PML could not be conclusively linked to Gilenya in this case because prior to Gilenya treatment the patient had been treated with an immunosuppressant drug that can cause PML, and during Gilenya treatment the patient had received multiple courses of intravenous corticosteroids, which can weaken the immune system.

Gilenya is an immunomodulator shown to benefit patients with relapsing forms of MS. This type of MS causes attacks or relapses, which are periods of time when symptoms get worse. Immunomodulators alter the immune system to reduce inflammation. PML is a rare and serious brain infection caused by the John Cunningham (JC) virus. The JC virus is a common virus that is harmless in most people but can cause PML in some patients who have weakened immune systems, including those taking immunosuppressant drugs.

Healthcare professionals are advised to stop Gilenya and perform a diagnostic evaluation if PML is suspected.

Please refer to the FDA's website for details:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm457183.htm>

In Hong Kong, Gilenya Hard Capsules 0.5mg (HK-61192) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Ltd (Novartis), and is a prescription-only medicine. Related news has been released by the US FDA, and was posted on the Drug office website on 30 August 2013. So far, the Department of Health (DH) has not received any adverse drug reaction case related to fingolimod. Novartis has applied to the DH to update the package insert of the product to include the relevant warning, and the application is under evaluation. In view of the latest announcement by the US FDA on update of label, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*



DEPARTMENT OF HEALTH
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BY FAX

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Please report any adverse events caused by drugs to the Pharmacovigilance 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 sincerely,



(Grant NG)

for Assistant Director (Drug)