衞生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

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

Dear Healthcare Professionals,

FDA warns about severe worsening of multiple sclerosis after stopping the medicine Gilenya (fingolimod)

Your attention is drawn to the US Food and Drug Administration's (FDA) warning that when the multiple sclerosis (MS) medicine Gilenya (fingolimod) is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability. As a result, FDA has added a new warning about this risk to the prescribing information of the Gilenya drug label and patient medication guide.

Healthcare professionals should inform patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya. When Gilenya is stopped, patients should be carefully observed for evidence of an exacerbation of their MS and treated appropriately.

Patients should be advised to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya is stopped. These symptoms vary and include new or worsened weakness, increased trouble using arms or legs, or changes in thinking, eyesight or balance. Gilenya treatment may have to be stopped for reasons such as adverse drug reactions, planned or unplanned pregnancy, or because the medicine is not working. However, patients should not stop taking it without first talking to their prescribers, as stopping treatment can lead to worsening MS symptoms.

In the 8 years since Gilenya was approved in Sep 2010, FDA identified 35 cases of severely increased disability accompanied by the presence of multiple new lesions on magnetic resonance imaging (MRI) that occurred 2 to 24 weeks after Gilenya was stopped. Most patients experienced this worsening in the first 12 weeks after stopping. FDA analyses include only reports submitted to FDA and those found in the medical literature, so there may be additional cases about which FDA is unaware.

The severe increase in disability in these patients was more severe than typical MS relapses, and in cases where baseline disability was known, appeared unrelated to the patients' prior disease state. Several patients who were able to walk without assistance prior to discontinuing Gilenya progressed to needing wheelchairs or becoming totally bedbound. In patients experiencing worsening of disability after stopping Gilenya, recovery varied. Seventeen patients had partial recovery, 8 experienced permanent disability or no recovery, and 6 eventually returned to the level of disability they had before or during Gilenya treatment.

Please refer to the following website in FDA for details:
https://www.fda.gov/Drugs/DrugSafety/ucm626095.htm

In Hong Kong, Gilenya Hard Capsules 0.5mg (HK-61192) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Limited, and is a prescription-only medicine. So far, the Department of Health (DH) has received one case of adverse drug reaction related to fingolimod, but this case is not related to worsening of multiple sclerosis after stopping the drug. In light of the above FDA's announcement, the matter will be discussed by 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.

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 faithfully,

(Joseph LEE)
for Assistant Director (Drug)