23rd January 2012

Circular No. P02/2012

Dear Healthcare Professional,

Re: European Medicines Agency starts review of Gilenya (fingolimod)

The Medicines Authority would like to inform you that the European Medicines Agency (EMA) has begun a review of the benefits and risks of the multiple-sclerosis medicine Gilenya which is authorised and marketed throughout the European Union including Malta. This review was started following concerns over the effects that the medicine may have on the heart after the first dose.

Gilenya has been authorised in the European Union since March 2011 for the treatment of relapsing-remitting multiple sclerosis in patients whose disease has failed to respond to a beta-interferon or is severe and getting worse rapidly. It contains the active substance fingolimod. Treatment with Gilenya may only be started when a patient is under the supervision of a specialist.

Since its authorisation, more than 30,000 patients have received Gilenya worldwide. The risk of bradycardia after the first dose of Gilenya was known when it was authorised and the product's information already includes recommendations to observe patients for signs and symptoms related to this side effect for at least six hours after the first dose.

Since its authorisation there have been reports of other heart problems in patients taking Gilenya, as well as the death of one patient in the United States less than 24 hours after the first dose. The exact cause of this patient's death is still unexplained. The Marketing Authorisation holder has taken action on this and additional Risk Minimisation Measures for monitoring with Gilenya have been introduced which include (1) a Prescriber's Checklist; summarising what needs to be done prior to treatment, during and after treatment and (2) a Patient Card on important things for patients to remember and observe when starting Gilenya.

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While the review is ongoing, doctors are advised to increase their level of monitoring of patients after the first dose of the medicine. This includes electrocardiogram (ECG) monitoring before treatment and then continuously for the first six hours after the first dose, and measurement of blood pressure and heart rate every hour. After six hours, any patients with clinically important heart-related effects, such as bradycardia or atrioventricular block should continue to be managed and monitored until their condition has improved.

Gilenya's Marketing-Authorisation Holder, Novartis, has committed to supplying the EMA's Committee on Medicines for Human Use (CHMP) with the results of its ongoing investigations into the cardiovascular effects of this medicine. The CHMP will take this information into account while carrying out its full review of the balance of benefits and risks of the medicine. This review is expected to be finalised by March 2012.

Patients are advised to immediately report any symptoms that could suggest they have a heart problem, such as chest pain, weakness or dizziness, to their doctor. Patients who have any questions should speak to their doctor or pharmacist.

Healthcare professionals are encouraged to maintain vigilance on Gilenya. Suspected Adverse Drug Reactions may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder or their local representatives.

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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