**Malta, 22 January 2010**

**Circular No. P02/2010**

Dear Healthcare Professional,

**Re: European Medicines Agency recommends additional measures to better manage risk of progressive multifocal leukoencephalopathy (PML) with Tysabri**

The European Medicines Agency (EMA) has finalised a review of Tysabri (natalizumab) and the risk of progressive multifocal leukoencephalopathy (PML), a rare brain infection caused by the JC virus. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the risk of developing PML increases after two years of use of Tysabri although this risk remains low. However, the benefits of the medicine continue to outweigh its risks for patients with highly active relapsing-remitting multiple sclerosis, for whom there are few treatment options available.

Due to the importance of detecting PML early, the Committee recommended a number of measures to ensure that patients and doctors are fully aware of the risks of PML. These include:

- an update of the product information to add information about the increase in the risk of PML after two years of treatment and additional advice on how to manage patients who show signs of PML;
- forms to be signed by patients at the beginning of treatment with Tysabri, and again after two years of treatment, after in-depth discussions about the risk of PML with their doctor.

The new measures are designed to complement the existing recommendations that patients, and their carers, partners and families should be made aware of the symptoms of PML and that patients should be closely monitored throughout treatment.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full **press release** and **Q&A document** issued by the EMA, attached here for your perusal.

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



Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt