SFDA SAFTEY COMMUNICATION

September 9th, 2013

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Case of Progressive Multifocal Leukoencephalopathy (PML)Reported with Gilenya®

The Saudi Food and Drug Authority (SFDA) would like to share some recent information regarding use of Gilenya® (fingolimod). It has been recently found that Gilenya may be associated with Progressive Multifocal Leukoencephalopathy (PML). One case was reported in USA for a patient who was taking Gilenya for the treatment of Multiple Sclerosis (MS) and he did not receive Tysabri previously (as Tysabri is known to be associated with higher risk of PML). This rare brain infection could lead to death or severe disability. Patients should not stop taking Gilenya before discussing any concern or questions with their health care providers. SFDA will continue to monitor the safety of Gilenya and any reported cases will be investigated deeply.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other medications to the SFDA either online, by regular mail or by fax using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll Free: 8002490000
Tel: 011-2038222 ext. 2354, 2317,2340
Fax: 011-2057662
Email: NPC.Drug@sfda.gov.sa
Online: http://ade.sfda.gov.sa/