Dear Healthcare Professional Communication (DHPC)

Date: 18 April 2018

Subject: FEGONA® (Fingolimod) – Contraindication in Patients with Cardiac Condition

Dear Healthcare Professional,

We SAJA Pharmaceuticals CO. Ltd. in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

Warnings against the use of FEGONA (Fingolimod) in patients with underlying cardiac disorders have been strengthened; fingolimod is now contraindicated in the following patients:

- Patients with myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attacks, decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months.
- Patients with severe cardiac arrhythmias requiring treatment with class la (e.g. quinidine, procainamide, disopvramide) and class III (potassium-channel blockers, e.g. amiodarone. sotalol, ibutilide, dofetilide) anti-arrhythmic drugs.
- Patients with second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick-sinus syndrome, if they do not wear a pacemaker.
- Patients with a baseline QTc interval ≥ 500 milliseconds.

Background

FEGONA is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy.
- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

The risk of serious cardiac rhythm disturbances with fingolimod including polymorphic ventricular arrhythmia (PVA) is already described in the product information. However, cases of PVA including fatalities have been reported. Therefore, to minimize the risk of severe adverse events in patients with cardiac conditions, contraindications are being introduced. The

warnings and precautions on the immunosuppressive effect of fingolimod potentially leading to serious infections and cancer are also being updated.

Cases of basal cell carcinoma (BCC) and other cutaneous neoplasms (e.g. melanoma) have been reported in patients receiving fingolimod. Vigilance for BCC and other cutaneous neoplasms is warranted.

Cases of lymphoma have been reported in patients treated with Fingolimod. Therefore monitoring for lymphoma signs and symptoms is advised and extensive evaluation should be performed promptly if lymphoma is suspected.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Please see the accompanying complete updated Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL).

Reporting adverse events:

To report any suspected adverse event associated with the use of FEGONA please contact:

Saudi Arabian Japanese pharmaceutical company limited
Jeddah – Saudi Arabia
P.O. Box: 42600, Jeddah 21551, KSA
Tel: + 966 12 606 6667 **Ext:** 210
Email: Drug.safety@sajapharma.com
Website: www.sajapharma.com

Or

The National Pharmacovigilance and Drug Safety Centre (NPC)
Toll free Number: 8002490000
Fax: +966-11-205-7662
E-mail: npc.drug@sfda.gov.sa
Website: www.sfda.gov.sa/npc

Sincerely,

18 Apr 2018

Roa Bayazid

Qualified Person Responsible for Pharmacovigilance