**SFDA SAFETY COMMUNICATION**

**14-12-2015**

## Saudi Food and Drug Authority (SFDA) – Risk of serious symptomatic bradycardia associated with the concomitant use of amiodarone with simeprevir and sofosbuvir

The Saudi Food & Drug Authority (SFDA) would like to inform health care professionals (HCPs) about new safety concern regarding risk of serious slow heart rate, known as symptomatic bradycardia that can occur when amiodarone is concomitantly used with simeprevir and sofosbuvir containing regimen, due to drug-drug interaction. The risk might increase in patients with pre-existing cardiac or liver disease, or in patients receiving beta-blockers therapy. There have been several internationally reported cases of severe bradycardia and pacemaker placement when amiodarone is combined with simeprevir and sofosbuvir.

The SFDA advises that HCPs should not prescribe amiodarone in combination with simeprevir and sofosbuvir. If amiodarone therapy is essential, patients should be educated to monitor their heart rate particularly during the early weeks of treatment. In addition, patients should be advised to seek immediate medical help if they experience symptoms of bradycardia. The SFDA also instructs the Marketing Authorization Holders (MAHs) that the label of these medications should be updated to include this information.

### Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any 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 number: 8002490000
Tel: 01 2038222 ext. 2317, 2356, 2340, 5769
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa