SFDA SAFETY COMMUNICATION

23/11/2016

Saudi Food and Drug Authority (SFDA) – Risk of hepatitis B reactivation in some patients treated with direct-acting antiviral drugs for hepatitis C

Saudi Food and Drug Authority (SFDA) would like to notify health care professionals (HCPs) that certain drugs used for treatment of chronic hepatitis C virus (HCV) infection, known as direct-acting antiviral (DAA) drugs, may reactivate the hepatitis B virus (HBV) infection in patients with a past or current history of HBV infection.

DAA drugs that are approved for marketing in Saudi Arabia includes Viekirax® (ombitasvir/paritaprevir/ritonavir), Exviera® (dasabuvir), Sovaldi® (sofosbuvir), Daklinza® (daclatasvir), Olysio® (simeprevir), Incivo® (telaprevir), Zepatier® (grazoprevir, elbasvir) and Harvoni® (ledipasvir/sofosbuvir).

The risk has been identified from internationally reported cases of HBV reactivation in patients infected with both HBV and HCV who were treated with DAA drugs and from published literature. In rare cases, HBV reactivation in patients treated with DAA drugs caused serious liver problems or death. Locally, the National Pharmacovigilance and Drug Safety Center (NPC) has not received any case reports about DAA and HBV reactivation.

The SFDA recommends that HCPs should screen all patients for HBV infection before starting DAA therapy for HCV infection. In addition, the SFDA advises HCPs to monitor patients for possible HBV reactivation during treatment as well as after treatment discontinuation. Patients should be advised to seek immediate medical help if they experience symptoms of serious liver problems such as fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stool.

The SFDA has already communicated with the marketing authorization holders of DAA drugs to update the summary of product characteristics (SPC) to address the new safety concerns based on the available 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: 011 2038222 ext. 2317, 2356, 2340,
Fax: 011 2057662
Email: NPC.Drug@sfda.gov.sa