BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Certain diabetes drug may cause adverse reaction, warns FDA

19 May 2015 | Regulatory | By BioSpectrum Bureau

Certain diabetes drug may cause adverse reaction, warns FDA

Singapore: US Food and Drug Administration (FDA) has raised warnings against type 2 diabetes medicines including canagliflozin, dapagliflozin, and empagliflozin marketed by Janssen, Bristol-Myers Squibb and Boehringer Ingelheim respectively, for producing high levels of blood acids called ketones that might cause adverse health condition.

FDA has notified that health warning may include difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness.

The drugs in question are SGLT2 inhibitors, a class of prescription medicines that are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes.

A search of the FDA Adverse Event Reporting System (FAERS) database identified 20 cases of acidosis reported as diabetic ketoacidosis (DKA), ketoacidosis, or ketosis in patients treated with SGLT2 inhibitors from March 2013 to June 6, 2014.