SFDA SAFTEY COMMUNICATION

20 June 2011

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Safety of Pioglitazone - (Actos®)

Recently, the French Medicine Agency has suspended marketing authorization of anti-diabetic drug Pioglitazone (Actos®). French agency action has been announced after the result of recent retrospective cohort study has become available. This study was carried out in France and suggested an excess increase in bladder cancer among pioglitazone and pioglitazone-containing product users, Adjusted Hazard Ration (HR) was (1.22 [95% CI: 1.05-1.43]).

The Study data were retrieved from French health insurance. All included patients were on anti-diabetic medicaments and were followed-up for four consecutive years (2006-2009).
On the other hand, The European Medicines Agency (EMA) has initiated a safety review of the pioglitazone and pioglitazone-containing product since March 2011.

In addition, the Committee for Medicinal Products for Human Use (CHMP) is intended to enclose the recent French study recommendations with respect to pioglitazone safety within their next meeting agenda. Furthermore, the United States Food and Drug Administration (US-FDA) is currently reviewing a ten-year epidemiological study concerning the association between the increased risk of bladder cancer and use of pioglitazone.

At this time, SFDA is currently reviewing all data on this safety concern and will release the results of this review when it finished. SFDA advises all healthcare professionals to continue to follow the recommendations in the drug label. In addition, SFDA advises patients not to stop taking pioglitazone (Actos®) and to talk to their doctors and/or pharmacists if they have any concern or contact the SFDA National Drug and Poison Information Center on the internet at /http://www.sfda.gov.sa/Ar/Drug/Topics/toxicinfo_dept

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 medication 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
Tel: 012759222 ext. 2334, 2317, 2353, 2354, 2356
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa
Website: www.sfda.gov.sa/NPC