SFDA SAFTEY COMMUNICATION

May 29th , 2013

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Cases of Necrotizing Fasciitis Reported with AVASTIN®

The Saudi Food and Drug Authority (SFDA) would like to share some recent information regarding use of AVASTIN® (Bevacizumab) **that is not approved for any indication in Saudi Arabia.**. Necrotizing fasciitis, including fatal cases, have been reported in patients receiving AVASTIN in clinical trials and in the post-marketing setting. The reported cases of necrotizing fasciitis in Roche clinical trials and global safety database occurred in patients with several types of cancer. Regarding associated medical conditions; the majority of the patients had gastrointestinal perforation, fistula formation or wound healing complications preceding the development of necrotizing fasciitis. Some of these patients died due to complications of necrotizing fasciitis. So it is recommended that AVASTIN is discontinued and appropriate therapy initiated promptly upon diagnosis of necrotizing fasciitis. As a consequence, Dear Healthcare Professional Letter (DHCPL) has been distributed in agreement with SFDA to warn healthcare providers about aforementioned risk.

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 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: 8002490000
Tel: 011-2038222 ext. 2354, 2317,2340
Fax: 011-2057662
Email: NPC.Drug@sfda.gov.sa