SFDA SAFTEY COMMUNICATION

December 23nd, 2013

Subject: The use of pegaspargase and risk of allergic reactions

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare providers and patients about increased number of reports of serious allergic reactions following the use of pegaspargase (Oncaspar®). According to the international versions of the package insert, allergic reactions including anaphylaxis are the most common adverse reaction when taking pegaspargase. It has been found that children and young adult are more susceptible to this risk when taking pegaspargase.

Therefore, the following measures should be considered before and during the use of this product:

1- Avoid using pegaspargase in patients with known hypersensitivity to other form of L-asparginase.
2- When using pegaspargase, observe patients for 1 hour after administration of pegaspargase in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis.
3- Discontinue pegaspargase in patients with serious allergic reactions.

Please note that this product is not yet registered in Saudi Arabia.

For further information please contact us using the following 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: 0112038222 ext. 2317, 2353, 5118, 2356, 2340, 5721.

Fax: 0112057662

Email: NPC.Drug@sfda.gov.sa

You are also encouraged to report any adverse events through this link:

http://ade.sfda.gov.sa