SFDA SAFETY COMMUNICATION

17/05/2017

Saudi Food and Drug Authority (SFDA) – Trastuzumab Use May be Associated with Increased Cardiovascular Risk

The Saudi Food and Drug Authority (SFDA) would like to remind health care professionals (HCPs) that trastuzumab use might be associated with increased risk of congestive heart failure (CHF) and decreased left ventricular ejection fraction (LVEF). The cardiac risk appears to increase when trastuzumab is given along with other chemotherapy medicines known to cause heart complications and in patients with a history of high blood pressure, CHF, coronary heart disease and older age.

Accordingly, the summary of product characteristics (SPC) and patient information leaflet (PIL) of this product were amended to include necessary warnings and precautions. In addition, a direct healthcare professional communication (DHPC) was distributed to aware the HCPs about the aforementioned risk.

A new DHPC had been circulated to remind the concerned HCPs about the importance of cardiac monitoring during trastuzumab therapy to reduce the frequency and severity of left ventricular dysfunction and CHF (For more details click here).

The SFDA emphasizes that HCPs should monitor the cardiac functions of their patients before starting trastuzumab therapy, then every three months while taking trastuzumab. Cardiac function assessment should be repeated every six months for additional 24 months after stopping the treatment.

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: 01 2038222 ext. 2317-2356-2340.
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa