BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Watchdogs find foreign particle in Mylan cancer vaccine

June 10, 2015 | Regulatory | By BioSpectrum Bureau

Watchdogs find foreign particle in Mylan cancer vaccine



Singapore: Mylan is recalling a series of intravenous injection due to the presence of visible foreign particulate matter that might cause potential of severe health consequences.

The recalled injections include Gemcitabine for ovarian cancer, breast cancer, non-small cell lung cancer and pancreatic cancer vaccine; Carboplatin, indicated for the treatment of advanced ovarian carcinoma; Methotrexate indicated for certain neoplastic diseases, severe psoriasis and adult rheumatoid arthritis; and Cytarabine Injection for acute non-lymphocytic leukemia

Intravenous administration has the potential to damage and/or obstruct blood vessels which could induce emboli, particularly in the lungs. If a right to left cardiac shunt is present, the particulate may lead to arterial emboli and result in stroke, myocardial infarction, respiratory failure, and loss of renal and hepatic function or tissue necrosis. Other adverse effects associated with intravenous injection of particulate matter include local inflammation, phlebitis, allergic response and/or embolization in the body and infection.

The products in question are packaged by Agila Onco Therapies Limited, a Mylan company located in Bangalore, India