BioSpectrum the business of Bio & Health Sciences ASIA EDITION

GSK voluntarily recalls its six-in-one vaccine in Australia

19 October 2012 | News | By BioSpectrum Bureau

GSK voluntarily recalls Infanrix hexa in Australia

Singapore: GSK is working with the Therapeutic Goods Administration (TGA) to voluntarily recall for quality reasons six batches of Infanrix hexa in Australia. These were dispatched from GSK between August 2011 and January 2012 and are being recalled solely as a precautionary measure.

GSK has multiple quality controls in place for facilities, equipment and products. Testing by GSK has identified that one step of the vaccine manufacturing process was found to have a low level contamination. No contamination has been found in the vaccine itself and all vaccine batches and ingredients have passed the stringent quality and sterility testing required to be released for use in Australia. This recall is precautionary. Anyone vaccinated with a dose of Infanrix hexa does not need to take any action. There is no need for revaccination.

"Based on release specifications and safety report monitoring, GSK believes the effectiveness and safety profile of the vaccine remains unchanged. We also believe this issue poses no health risk to patients. This voluntary recall is being taken solely as a precautionary measure," said Dr Andrew Yeates, medical director, GSK.

GSK maintains a global database of side effects reported for medicines and vaccines manufactured by the company. A search of this database found no change in reporting pattern since the identified batches have been released. To date no reported adverse events have been directly linked to this issue. As usual, any adverse events following immunisation should be reported to GSK Medical Information on 1800 033 109.

Adverse events should also be reported to State and Territory Health Authorities. Infanrix hexa (administered at 2, 4 and 6 months of age) is provided as part of the National Immunisation Program and is used to protect against diphtheria, tetanus, whooping cough, hepatitis B, polio and Hib disease. The batches identified include A21CB144A, A21CB188D, A21CB188E, A21CB190A, A21CB197A, and A21CB221B. These were dispatched from GSK between August 2011 and January 2012.