BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

UK drugs regulator to halt approvals for clinical trials firm Quest Life Sciences

22 July 2016 | News | By BioSpectrum Bureau

UK drugs regulator to halt approvals for clinical trials firm Quest Life Sciences

Singapore: The UK's healthcare regulator has decided to suspended marketing approval for a widely used antibiotic that had won clearance based on clinical trials conducted by India's Quest Life Sciences Pvt. Ltd, due to concerns over the integrity of trial data.

The Medicines and Healthcare products Regulatory Agency (MHRA) might also deny other pending drug approval requests that rely on studies conducted by Quest, the UK agency said in a letter dated 22 June, a copy of which was seen by Reuters.

The MHRA's decision bars the sale of a generic version of erythromycin that is being sold in the UK by Dawa Ltd, a Kenyan drug maker, an MHRA spokesman said. The MHRA said it is in contact with the involved parties, who have the right to appeal and submit new data to prove that the drugs in question meet the required standards.

The agency added that it does not believe there to be any risk to public health and that its decision to suspend marketing approval is purely a precautionary measure.
Quest's President Yati Chugh told Reuters the company plans to appeal the suspension as he believes the agency relied on a two-year-old study and the following inspection report to reach its decision, and that it did not review the company's latest quality management systems.

He said Quest had significantly improved its quality systems since 2014, and would ask the MHRA to re-inspect its site, as MHRA's move means four other drugs Quest performed trials on that are awaiting approval with the UK regulator will not be approved until the agency clears its facility.