

Hepatitis B drug labels were altered, says UK lab

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KAMPALA. Preliminary laboratory test results show that contents of Hepatitis B vaccines impounded from private health facilities in Uganda in March shows remarkable similarities with genuine Hepatitis B vaccines supplied by the government of Uganda, but with their labels altered.

A report issued by National Drug Authority (NDA) yesterday stated that samples of both the suspected fake vaccines together with the genuine were subjected to confirmatory tests by the United Kingdom's Medicines and Health products Regulatory Agency (MHRA).

"The findings from our laboratory and the UK-MHRA laboratories so far indicate that the falsified vaccine is highly likely to be Hepatitis B vaccine from the Serum Institute of India (SII) delivered to government Health facilities but diverted along the supply chain and sold to private medical facilities," the NDA statement reads in part.

Assistance

The World Health Organisation (WHO) offered technical assistance to do confirmatory tests on the falsified vaccines at MHRA.

The report indicates that suspect samples of the 10 millilitre vials purportedly manufactured by SII together with the genuine Hepatitis B vaccine samples were subjected to both qualitative tests at the National Drug Quality Control Laboratory in Kampala before being flown abroad.

The results of the UK-based laboratories contained in the April 25 report states: "There are no residual chemicals, contaminants, bacterial or fungi that could cause any adverse effects after administration."

The report adds that there were visible differences in labelling between the genuine Hepatitis B vaccines and falsified samples, which is consistent with the quality control laboratory tests earlier done in Kampala.

The falsified labelling on Hepatitis B vaccines were discovered by NDA's vigilance team in March.

WHAT NEXT?

Despite the laboratory findings indicating the vaccines pose no adverse effects after administration, NDA executive secretary Donna Kusemererwa said the vaccine is not genuine once its label has been tampered with. "Even if we confirm that Serum Institute of India made the content they cannot take responsibility for a product that is tampered with," Ms Kusemererwa said. She said NDA is awaiting a comprehensive report from WHO and MHRA that covers a full range of confirmatory tests.