

India's anti-malaria drug banned in Ghana

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Singapore: The US drug regulatory body, the Food and Drug Administration (FDA) has banned the distribution of Gsunate Plus, an anti-malaria drug for children that is imported into Ghana from India. The drug is manufactured by Bliss GVS and the FDA has banned it post investigations.

The FDA investigations revealed that "No clinical trial study had been conducted on the product, which is made up of the combination of Artesunate 25 mg and Amodiaquine 75 mg and manufactured by Bliss GVS Pharma, located at Maharashtra in India."

In its statement, the FDA said that the product had not been approved or registered by the pharmaceutical regulatory authority in India for sale or use.

"The efficacy of the combination of Artesunate and Amodiaquine through the rectal route has not been established, and therefore treatment of malaria in children with this drug could lead to therapeutic failures and complications," FDA chief executive Dr Stephen Opuni explained.

The FDA has now ordered hospitals, clinics, pharmacies, licensed chemical sellers and other health facilities with stocks of Gsunate plus suppository to immediately stop dispensing them and hand over the stocks to the FDA offices countrywide for safe disposal.