

DR. STEPHEN K. OPUNI

FDA/COMM/PR/11/09/13

2nd October 2013

The News Editor

Dear Sir,

BLACKLISTING OF BLISS GVS PHARMA LTD, INDIA FROM MANUFACTURING MEDICINAL PRODUCTS FOR THE GHANAIAAN MARKET

The Food and Drugs Authority (FDA) as mandated by the Public Health Act, 2012 Act 851 has with immediate effect banned the importation and distribution of all medicinal products manufactured by Bliss GVS Pharma Limited, Dombivli (E) 421 201 Dist-Thane, India into Ghana.

This is as a result of the manufacture and distribution of medicinal products into the country without adherence to the registration requirements as enshrined in the Public Health Act of 2012, Act 851, a process which assures the quality, safety and efficacy of all medicinal products used in Ghana.

The company manufactured a fake antimalarial medicine (**GSUNATE PLUS SUPPOSITORIES**) which was imported onto the Ghanaian market. The efficacy and safety of this antimalarial medicine has not been ascertained since there has not been any clinical trial study to justify the use of this medicinal product for the treatment of Malaria.

The manufacturer has not registered this drug in the country of origin (India) even though malaria is prevalent in India. The manufacturer is therefore without the requisite regulatory authorization using Ghanaian children as clinical trial subjects.

The Director of Bliss GVS Pharma Ltd India, the company that manufactured Gsunate Plus Suppositories, has confessed to the FDA that this antimalarial medicine is not used for treatment of malaria in children in India. The Director of Bliss GVS Pharma Ltd, India also admitted that the Gsunate Plus Suppository is a **FAKE** antimalarial medicine.

Malaria is the number one cause of Out Patients Department (OPD) attendance and the highest cause of child mortality (death) in Ghana. The use of fake antimalarial medicine can result in treatment failures, complications and preventable deaths in children. This poses a threat to the attainment of the Millennium Development Goals Nos. 4 and 6, which seek to reduce child mortality and combat HIV, Malaria and other diseases respectively.

The company has also manufactured and distributed onto the Ghanaian market many other medicinal products which have not been evaluated and duly registered as required by law.

The quality, safety and efficacy of these medicines manufactured by GVS Bliss Pharma Ltd can therefore not be guaranteed as they could pose a threat to public health and safety.

Due to the above reasons and in order to ensure utmost protection of Public Health and Safety of Ghanaians, the Food and Drugs Authority has therefore **blacklisted BLISS GVS PHARMA LTD, INDIA from manufacturing of medicines and other medicinal products for the Ghanaian market.**

Additionally, information from the general public on persons in any practice possible of endangering public health and safety with respect to FDA's mandate is most welcome through any of the following contact numbers; 0244337235, 0544863418, 0246809509, 0244571563 or 0244337250.

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE