

TANZANIA FOOD AND DRUGS AUTHORITY



PUBLIC NOTICE

CLARIFICATION ON INSPECTION OF OVERSEAS PHARMACEUTICAL MANUFACTURING FACILITIES BY TFDA

TFDA would like to clarify on misleading information that appeared in the Guardian Newspaper of Wednesday December 14th, 2011 with the heading 'TFDA explains why overseas inspections sometimes falter'. The reporter explains that TFDA fails to implement its duties particularly those on Good Manufacturing Practices (GMP) because the cost of accommodation and food for its officials are born by the manufacturing firms especially in Asian countries of China and India. The newspaper further stated that due to lack of enough funds to conduct inspection, TFDA is facilitated by the suppliers of merchandise in those countries to discharge its duties. The reporter also indicated that between 20 and 30 manufacturing facilities have qualified for selling medicines in Tanzania.

The Authority would like to clarify that local and overseas pharmaceutical manufacturers do pay Good Manufacturing Practices Inspection fees as per the *Fees and Charges Regulations* developed under the Tanzania Food, Drugs and Cosmetics Act, 2003 and that travel, accommodation and other expenses for inspectors are born by the Authority. For the past five years, TFDA has been inspecting an average of 35 overseas pharmaceutical manufacturing facilities annually, most of them being from India and China whereby an average of 25 facilities per year comply with the minimum Good Manufacturing Practice (GMP) requirements for pharmaceuticals.

The Authority would also wish to inform the public that it does not and has never condoned the so called "public figures" involved in counterfeits trafficking of any of the regulated product as claimed earlier by some reporters.

Furthermore, TFDA would also like to clarify that GMP inspections are conducted all-over the world and not in India and China alone. Facilities which fail GMP requirements are given opportunity to rectify the deficiencies observed before being re-inspected as opposed to the interpretation provided in the Daily Newspaper of 14th December, 2011 following an interview of one of the TFDA staff by the reporters.

Issued by:

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