

TANZANIA FOOD AND DRUGS AUTHORITY



PRESS RELEASE

DEVIATIONS FROM U.S. CURRENT GOOD MANUFACTURING PRACTICES (cGMP) REQUIREMENTS AT RANBAXY'S MANUFACTURING FACILITIES AT DEWAS AND PAONTA SAHIB IN INDIA

As it has been reported by the media, the US Food and Drug Administration (FDA) on 16th September, 2008, issued two “warning letters” to Ranbaxy Laboratories Ltd of India and simultaneously established an “import alert” for medicines manufactured at or using raw materials from two Ranbaxy facilities located at Dewas and Paonta Sahib due to violations observed in relation to compliance with current Good Manufacturing Practices (cGMP) requirements. The action taken meant that any medicine and active pharmaceutical ingredient manufactured at these sites that are offered for import into the United States of America will be detained at the border point by US officials.

On Wednesday 17th September 2008, World Health Organization (WHO) issued a statement on the matter and outlined the steps which it is taking in relation to this situation and above all advised consumers not to interrupt their drug therapy while it is taking extra ordinary measures on top of its routine monitoring activities to ensure that Ranbaxy continue to meet all the necessary requirement pertaining to GMP.

Tanzania Food and Drugs Authority (TFDA) has registered medicines from the two facilities and currently the medicines are circulating in the market. In view of this, TFDA wishes to inform the public that it is monitoring closely products from Ranbaxy and is instituting a surveillance scheme including taking samples from consignments at port of entries for analysis to determine if there are any quality defects which may render products from the two facilities unsafe.

Meanwhile TFDA is advising consumers to continue using their medication and where necessary consult their doctors and TFDA incase of doubt.

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