DR. STEPHEN K. OPUNI

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Dear Healthcare Professional,

ORAL KETOCONAZOLE AND THE RISK OF SEVERE LIVER INJURY, ADRENAL GLAND PROBLEMS AND HARMFUL DRUG INTERACTIONS

The National Pharmacovigilance Centre at the Food and Drugs Authority (FDA) is writing to inform healthcare professionals that it has become aware of new safety information regarding severe liver injury, adrenal gland problems and harmful drug interactions associated with the use of oral Ketoconazole.

This follows regulatory reviews by the European Medicines Agency (EMA) and the United States Food and Drugs Administration (US FDA). These reviews and other safety information available to the Food and Drugs Authority (FDA) were presented to the Technical Advisory Committee on Safety which concluded that;

- No safety concerns have been identified with the use of oral Ketoconazole in Ghana.
- Oral Ketoconazole is clinically the drug of choice for dermatophyte and Candida infections in Ghana when used at the lowest recommended adult dose (200mg daily) for a short period of time (2 weeks).

The Committee therefore recommended the following for healthcare professionals in Ghana:

1. **Oral Ketoconazole should be prescribed at the lowest recommended dose and for the shortest possible period of time.**
2. **Oral Ketoconazole is registered by the FDA as Prescription-Only-Medicine and this should be taken into account when dispensing this drug.**
3. **Monitor patients on oral Ketoconazole for signs of liver injuries.**
4. **Report any suspected adverse drug reactions associated with the use of oral Ketoconazole to the Food and Drugs Authority using the blue Adverse Reaction Reporting Form.**

The Food and Drugs Authority has registered Oral Ketoconazole under different brand names (refer to the registered product list on the Food and Drugs Authority's website at; http://www.fdaghana.gov.gh/pdfs/Quick%20links/DRUG%20REGISTER%20MARCH%2021%202011.pdf

The Food and Drugs Authority has not received any report of severe liver injury, adrenal gland problems and harmful drug interactions relating to oral Ketoconazole. Healthcare professionals are therefore encouraged to report any adverse drug reactions to the National Pharmacovigilance Centre, Food and Drugs Authority by completing the blue Adverse Reaction Reporting Form or call **024 431 0297** or send e-mail to, **drug.safety@fdaghana.gov.gh**.

For further enquiries contact the FDA through the following address:

Postal address: The Chief Executive
Food and Drugs Authority
P. O. Box CT2783
Cantonments
Accra.
Telephone: 0302 235100 / 0302 233200
Fax: 0302 229794

Yours faithfully,

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE