Food and Drugs Authority

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FDA/SMC/SMD/VGU/18/0388

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Dear Healthcare Professional,

SUSPENSION OF MARKETING AUTHORIZATION FOR ORAL KETOCONAZOLE PRODUCTS

The Food and Drugs Authority (FDA) in accordance with the recommendation by the Technical Advisory Committee on Safety of Medicines (TAC-SM) has suspended the registration, importation and the manufacture of oral ketoconazole products.

This is a follow up to the FDA's Dear Healthcare Professional letter (DHCPL) dated 2nd August 2013[1] in which the TAC-SM recommended a number of risk minimization measures to reduce the risk of severe liver injury, adrenal gland problems and harmful drug interactions associated with the use of oral ketoconazole.

Ketoconazole is a synthetic antifungal agent formulated as a tablet for oral administration and also as a cream or shampoo for topical application.

The Committee concluded that:

1. The additional risk minimization measures proposed in August 2013 were not effective in preventing the risk of hepatic related adverse drug reactions associated with the use of oral ketoconazole.

2. There are currently safer alternatives to oral ketoconazole; namely, itraconazole, terbinafine and fluconazole, which should be used in place of oral ketoconazole in order to minimize the risk of liver disease.

This suspension of marketing authorization does not affect topical preparations containing ketoconazole.

The FDA will like to advice healthcare professionals to educate patients on the possible side effect of all medicines and also report these to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER

[1] https://fdaghana.gov.gh/images/stories/pdfs/Dear%20Helthcare%20Prof/ORAL%20KETOCONAZOLE%20AND%20THE%20RISK%20OF%20SEVERE%20LIVER%20INJURY,%20ADRENAL%20GLAND%20PROBLEMS%20AND%20HARMFUL%20DRUG%20INTERACTIONS%20.pdf