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Dear Healthcare Professional,

NEW SAFETY MEASURES ON THE USE OF ISOTRETINOIN

The Food and Drugs Authority (FDA) wishes to inform you of the new safety measures to reduce the risk of sexual and psychiatric adverse reactions. The risk of sexual adverse reactions includes erectile dysfunction, decreased libido, vulvovaginal dryness, orgasm difficulties and genital hypoesthesia whiles psychiatric adverse reactions include depression, anxiety, and psychotic symptoms following the use of isotretinoin.

Isotretinoin is a retinoid that is indicated for the treatment of severe acne that has failed to respond to standard treatment with antibiotics and topical treatments.

The new safety measures are as follows:

- Addition of new warnings for the risk of sexual dysfunction, including the possibility of persistence of sexual dysfunction after treatment discontinuation.

- Development of consistent monitoring requirements for potential psychiatric and sexual side effects in all patients throughout treatment with isotretinoin.

- Initiation of treatment in patients younger than 18 years will require 2 prescribers to agree a patient's acne is severe and that there is no other effective treatment before initiation of isotretinoin therapy.

Advice for healthcare professionals

Healthcare professionals are advised to:

- Ask patients about symptoms or signs of sexual dysfunction prior to starting treatment with isotretinoin and monitor patients for the development of new sexual disorders during treatment.

- Assess the mental health of the patient before initiating isotretinoin and monitor them regularly for development or worsening of psychiatric disorders.

- Educate patients on the potential risks and benefits of isotretinoin before prescribing.

- Advise patients to seek professional help if they notice changes in their sexual and/or mental health.

Advice for patients

- Patients should consult a healthcare professional before initiating isotretinoin therapy.

Healthcare professionals and the public are requested to report adverse reactions to isotretinoin-containing products and all other products including lack of therapeutic effect and medication errors through the following:

- Download and complete the Med Safety App from Google Play Store or App Store.
- Complete and submit the report online at http://adr.fdaghana.gov.gh/
- Download and complete the Adverse Reaction Reporting Form available on the FDA website at www.fda.gov.gh.

For additional information you may call the FDA on the hot line 0551112224/5 or the Safety Monitoring Department (National Pharmacovigilance Centre) on +233 244 310 297.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER