FDA/SMC/SMD/VGU/18/0237  
3rd July 2018

Dear Healthcare Professional,

**INCREASED RISK OF LEG AND FOOT AMPUTATIONS WITH CANAGLIFLOZIN (INVOKANA, VOKANAMET) TABLETS**

The Food and Drugs Authority (FDA) wishes to bring to your attention a warning relating to increased cases of lower limb amputation (mostly affecting the toes) which has been observed in patients taking the Type 2 diabetes medicine **Canagliflozin** compared with those taking placebo in two clinical trials, CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus).

Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin lowers blood sugar by causing the kidneys to remove sugar from the body through the urine.

Results from two clinical trials, the CANVAS and CANVAS-R, showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo.

The CANVAS trial showed that over a year’s time, the risk of amputation for patients in the trial was equivalent to 5.9 out of every 1,000 patients treated with canagliflozin compared with 2.8 out of every 1,000 patients treated with placebo.

The CANVAS-R trial showed that over a year’s time, the risk of amputation for patients in the trial was equivalent to 7.5 out of every 1,000 patients treated with canagliflozin compared with 4.2 out of every 1,000 patients treated with placebo.

The FDA therefore advises healthcare professionals to consider factors which may predispose patients to the need for amputations including history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers before starting canagliflozin.

Healthcare professionals are also to monitor for the development of new pain or tenderness, sores or ulcers, or infections in the legs or feet of patients on canagliflozin.
The FDA will like to advice healthcare professionals to report adverse drug reactions to canagliflozin and all other medicines 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