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FDA/SMC/SMD/VGU/20/0004 9th January 2020

Audience: Patients and Healthcare Professionals

POTENTIAL CONTAMINATION OF METFORMIN WITH N-NITROSODIMETHYLAMINE

The Food and Drugs Authority (FDA) has become aware that some regulatory authorities have detected low levels of N-Nitrosodimethylamine (NDMA) in a small number of metformin-containing products.

It has not yet been confirmed that NDMA is present in any metformin-containing products registered and marketed in Ghana. The FDA is working with international regulatory authorities and manufacturers to further investigate this issue and determine what actions may be required.

Metformin-containing products are prescription only medicines (POMs) used to control high blood sugar in patients with type 2 diabetes and marketed in Ghana under multiple brand names.

Patients **SHOULD NOT STOP** taking their metformin-containing products unless instructed to by their health professional.

What should patients do?

- If you take metformin, **do not stop** your treatment without first consulting a doctor or pharmacist. It is very important to keep diabetes under control and stopping your diabetes medicines poses a greater and more immediate risk to your health than potential low-level contamination with NDMA.

- If you have any questions or concerns about this issue, you should speak to your health professional. Complications associated with uncontrolled diabetes include heart disease, nerve problems, kidney damage, eye problems and damage to the foot that can lead to amputations.

What should health professionals do?

- There is no reason to stop prescribing metformin. It has not yet been confirmed that NDMA is present in any metformin-containing products registered and marketed in Ghana.

- Remind patients of the importance of keeping diabetes under control and reassure them that that the risks posed by NDMA at the trace levels observed by other regulatory authorities are considered low.

What is the FDA doing?

- The FDA has requested marketing authorization holders and manufactures of metformin-containing products to undertake testing of their products to demonstrate the absence or the presence of NDMA below acceptable level and submit the results to the FDA. The FDA will also collect samples for testing to confirm the presence of NMDA.

- Manufacturers have also been requested by the FDA to take precautionary measures to mitigate the risk of nitrosamine formation or presence during the manufacture of all medicinal products containing chemically synthesized active pharmaceuticals ingredients.

The FDA recognizes the important role of metformin-containing products in managing diabetes in Ghana. Therefore, any regulatory action taken will consider the need to ensure continued availability of metformin in the interest of public health. The FDA will publish updated information when it becomes available.

How to Report Safety problems

The FDA will like to advice patients and healthcare professionals to report side effects of metformin-containing products 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 Mobile no: 024431 0297 or send an email to drug.safety@fdaghana.gov.gh.

Additionally, to report and receive the latest safety alerts and recalls, download the Med Safety App from Google Play or the App Store.

Yours faithfully,

SIGNED

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