ALERT - UNREGISTERED TURKISH BRAND OF GALVUS MET (50MG/1000MG) TABLETS ON THE **GHANAIAN MARKET**

FDA/CSD/CPE/PRS/23/025

6th September 2023

The Food and Drugs Authority (FDA) has detected the presence of unregistered Turkish brand of GALVUS MET **TABLETS** (Vidagliptin/ Metformin Hydrochloride 50mg/1000mg) in some pharmacies in the country.

Details of the unregistered product are as follows:

Product name: Galvus Met Tablet

Strength: 50mg/1000mg

Manufacturer: Novartis Pharmaceuticals

Country of origin: Turkey

Language of Instruction: Turkish

Batch Nos: KJM25, KLX74, KLY93, KLN34, KLP92, KLP93,

KLR95, KLP38, KLW59

The public is to note that the affected batches with only Turkish inscriptions have not been registered and therefore the quality, safety and efficacy cannot be ascertained.

The use of batches of this unregistered Turkish brand has been associated with suspected therapeutic failure and

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result in serious or life-threatening risks to health. To protect public health and safety, the FDA has taken steps to remove the product from the pharmacies where they were detected.

Importers and retailers of pharmaceutical products are advised to immediately stop supplying all the listed batches and return any stock to the nearest FDA office for safe disposal.

The FDA is taking the necessary regulatory actions to prevent any future occurrence and will not hesitate to apply the strictest sanctions, including criminal prosecution and the imposition of administrative fines to any individual or facility found to be importing or distributing such products.

The FDA assures the public of the integrity of its regulatory processes which ensure that medicinal and other regulated products registered for use on the Ghanaian market are safe, efficacious, and of the right quality.

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The public is once again reminded that all products marketed in Ghana must be labelled in or translated into English.

The registration status of all regulated products can be checked from the FDA website: www.fdaghana.gov.gh and on the ProPer Platform (https://bit.ly?ProPerFDA_Verify) before purchase in order to avoid any harm.

For further information, please contact the FDA on any of the contacts below:

Signed

Chief Executive Officer Food and Drugs Authority

Your Well-being, Our Priority.

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