

Head Office

Mail: P.O. Box CT 2783, Cantonments-Accra, Ghana

(+233)-302-233200/235100 (+233)-551-112223/4/5 (Hotline)

Email: fda@fda.gov.gh . Digital Address: GA-237-7316

FDA/HPT/VVC/SMD/VGU/23/0163

19th May 2023

Dear Healthcare Professional,

SAFETY ALERT: FALSIFIED MERONEM IV ON THE GHANAIAN MARKET

The Food and Drugs Authority (FDA) wishes to alert you on falsified medical product, **Meronem IV** on the Ghanaian market.

The details on the primary package of the substandard and falsified Meronem IV are provided below:

Product Name

: Meronem (Meropenem) IV

Batch Number

: 4A19G161

Manufacturing date: 07/2020

07/2020

Expiry date

: 06/2024

The falsified product had an unusual plain coloured presentation after reconstitution contrary to the straw colour of a reconstituted genuine Meronem IV.

Meronem with batch number 4A19G161 is a legitimate batch manufactured by Pfizer Specialties Limited for the Egyptian market, however it was manufactured on 03/2018 and expired on 02/2022.

The FDA wishes to advice all healthcare professionals to:

- Stop using the falsified Meronem IV with Batch No: 4A19G161, Manufacturing date: 07/2020 and Expiry date: 06/2024 and return any samples to the nearest FDA offices for safe disposal.
- Call the FDA on Mobile No: 024 431 0297/ 055 111 2224 or email to <u>drug.safety@fda.gov.gh</u> for enquiries or further guidance.

Meanwhile, preliminary investigations by the FDA have not identified falsified Meronem IV on the Ghanaian market apart from the initial reporting source. The FDA has put in measures to increase post market surveillance activities at the borders and across the country with the view to identify any falsified Meronem IV on the Ghanaian market.

Yours faithfully,

Bones

DR. DELESE A. A. DARKO CHIEF EXECUTIVE OFFICER

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ISO 9001 (2015) Certified Institution, ISO 17025 (2017) Accredited Laboratory, WHO Prequalified Laboratory, Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials, Pharmacovigilance and Drug Registration WHO Maturity Level 3 National Regulatory Authority

