

FDA/HPT/SMC/SMD/VGU/21/0383

18<sup>th</sup> August 2021

Dear Healthcare Professional,

**SUBSTANDARD AND FALSIFIED CYTOTEC TABLETS IDENTIFIED ON THE GHANAIAN MARKET**

The Food and Drugs Authority (FDA) wishes to inform you that it has in collaboration with the World Health Organization identified substandard and falsified Cytotec tablets with the underlisted details on the Ghanaian market.

The details on the secondary package of the product are provided below:

- **Manufacturer** : Piramal Healthcare UK Limited, Morpeth, Whalton Road, Northumberland, NE61 3YA, United Kingdom (with Pfizer logo)
- **Active ingredient** : Misoprostol 200 microgram
- **Batch No.** : B16519
- **Mfg. date** : 05/209
- **Exp. Date** : 05/2022

This product is substandard and falsified because laboratory analysis of samples confirmed the product does not contain the active ingredient (Misoprostol) and also the batch number (B16519) does not correspond to genuine manufactured Cytotec tablets. The use of the falsified Cytotec tablets will lead to treatment failure which could be life threatening.

The FDA wishes to advise all healthcare professionals to:

- Report suspected falsified medicinal products to the FDA by completing the Adverse Reaction Reporting Form or online using the link <http://adr.fdaghana.gov.gh> or send an email to [drug.safety@fda.gov.gh](mailto:drug.safety@fda.gov.gh).
- Return Cytotec tablets with the details provided above to any of the FDA Offices or call the Safety Monitoring Department on Mobile No: 024 431 0297 or email to [drug.safety@fda.gov.gh](mailto:drug.safety@fda.gov.gh).

Meanwhile, the FDA has strengthened its post market surveillance activities at the borders and across the country with the view to identify and withdraw any falsified Cytotec tablets on the Ghanaian market.

Please, find attached Medical Product Alert N° 3/2021 from the WHO on substandard and falsified Cytotec tablets identified from other countries in Africa including Cameroon, Democratic Republic of Congo and Nigeria.

Yours faithfully,

Signed

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