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FDA/HPT/SMC/SMD/VGU/21/0383 18th 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, Northhumberlad, NE61 3YA, United Kingdom (with Pfizer logo)
- **Active ingredient** : Misoprostol 200 microgram
- **Batch No.** : B16519
- **Mfg. date** : 05/2019
- **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 advice 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.
- 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.

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,

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

World Health Organization

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Ref. RPQ/REG/ISF/Alert N°3.2021 August 2021

Medical Product Alert N° 3/2021

Falsified CYTOTEC identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to two batches of falsified CYTOTEC (misoprostol) 200 microgram tablets identified in the WHO Region of Africa and reported to WHO in July 2021. The genuine manufacturer of CYTOTEC has confirmed that the products listed in this Alert are falsified because these products failed laboratory analysis and/or display falsified variable data. These falsified products have been reported at wholesale and patient level in Cameroon, the Democratic Republic of Congo, Ghana and Nigeria.

Misoprostol is listed on the WHO Model List of Essential Medicines. Genuine Cytotec (misoprostol) is indicated for the treatment of duodenal and gastric ulcers. Other uses of misoprostol as recommended by current WHO guidelines include induction of labour and postpartum haemorrhage prophylaxis, treatment of missed and incomplete miscarriages, induction of abortion, and cervical preparation before uterine instrumentation.

The risk to patient health from falsified Cytotec (misoprostol) is ineffective or delayed treatment for all of the above uses and could also be life threatening in some circumstances. It is important to detect and remove any falsified Cytotec (misoprostol) from circulation so as to prevent harm to patients.

The products identified in this Alert are confirmed as falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition or source:

- Batch B16519 – batch number does not correspond to genuine manufactured CYTOTEC. Laboratory analysis of samples has also confirmed the product does not contain any active ingredient and does not comply with specifications;
- Batch 14660 – the expiry date (12/2021) on this product is falsified.

Table 1: Products subject of WHO Medical Product Alert N°3/2021

Product Name	CYTOTEC 200 microgram tablets	
Stated manufacturer	PFIZER	
Stated active ingredient	misoprostol	
Batch / Lot	B16519	B14660
Mfg. date	05/2019	Not Stated
Exp date	05/2022	12/2021
Packaging language	English	Spanish
Identified in	Camerpon, Democratic Republic of Congo, Ghana	Cameroon, Nigeria

For photographs of the above products, please refer to Table 2 on pages 2 & 3 of this Alert.

Advice to regulatory authorities and the public

WHO requests increased vigilance within the supply chains of countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

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All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

If you are in possession of the above falsified products, please do not use them.

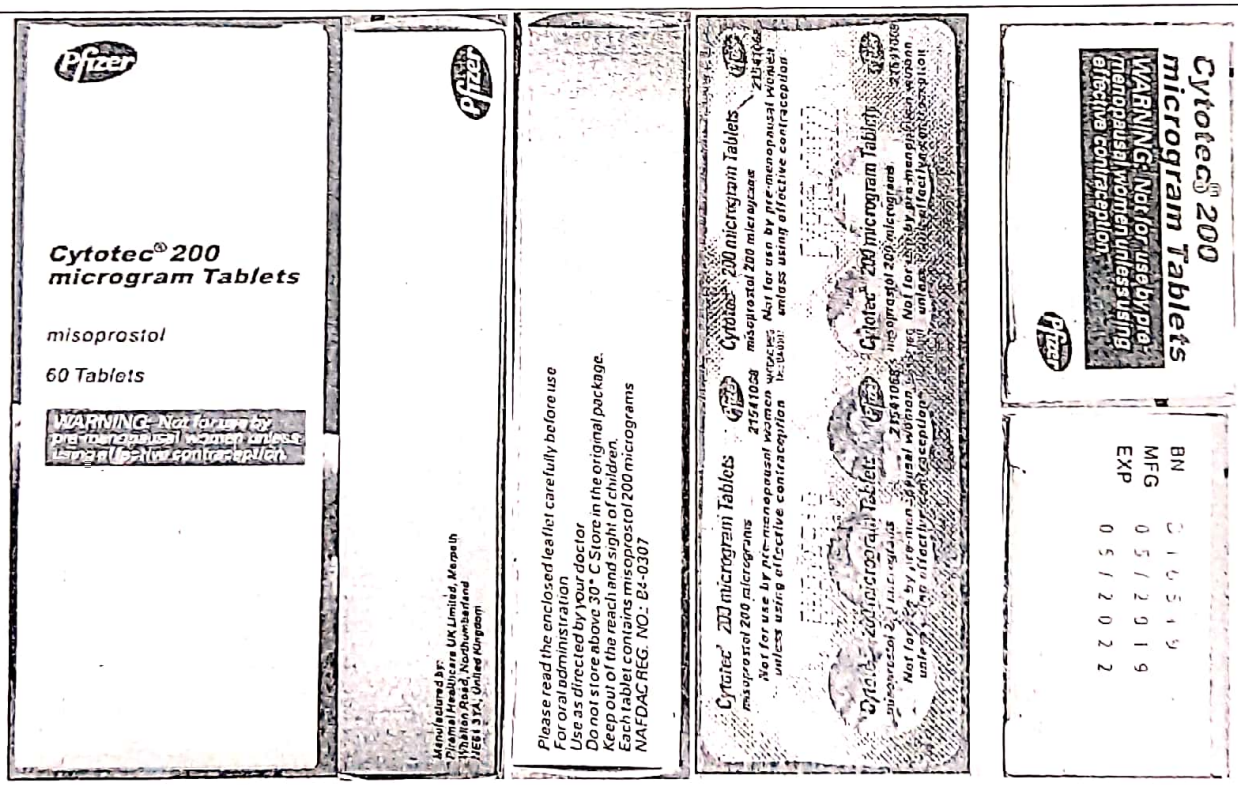
If you have used these products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities / National Pharmacovigilance Centre.

National regulatory / health authorities are advised to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

Table 2: Photographs of products subject of WHO Medical Product Alert N°3/2021

Falsified CYTOTEC (misoprostol) 200mcg tablets, Batch B16519

identified in Cameroon, Democratic Republic of Congo, Ghana



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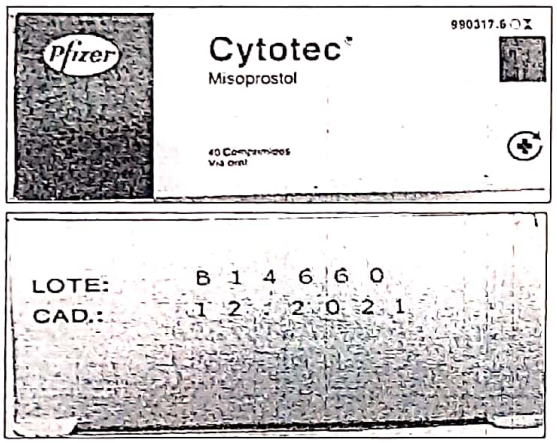
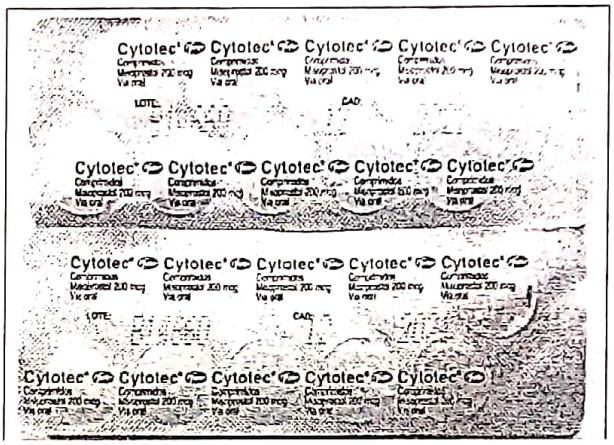
Falsified CYTOTEC (misoprostol) 200mcg tablets, *Batch number* B14660

identified in Cameroon and Nigeria





WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For more information, please visit our website

Email: rapidalert@who.int