Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2299

14 SEP 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning on Falsified Drug Product "CYTOTEC" Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the Medical Product Alert provided by the WHO, wherein drug product Misoprostol 200 microgram (mcg) tablets with brand name "CYTOTEC", was detected in the African region on July 2021 and was recently confirmed as falsified by WHO by the manufacturer. It was reported that this product was at wholesale and patient level in Cameroon, the Democratic Republic of Congo, Ghana, and Nigeria:

DRUG PRODUCT	**Misoprostol 200 mcg Tablet (CYTOTEC)**		
BATCH NO./EXP. DATE/PACKAGING LANGUAGE	**B16519**	**05/2022**	**English**
	B14660	**12/2021**	**Spanish**
STATED MANUFACTURER	**Pfizer, Inc.**		

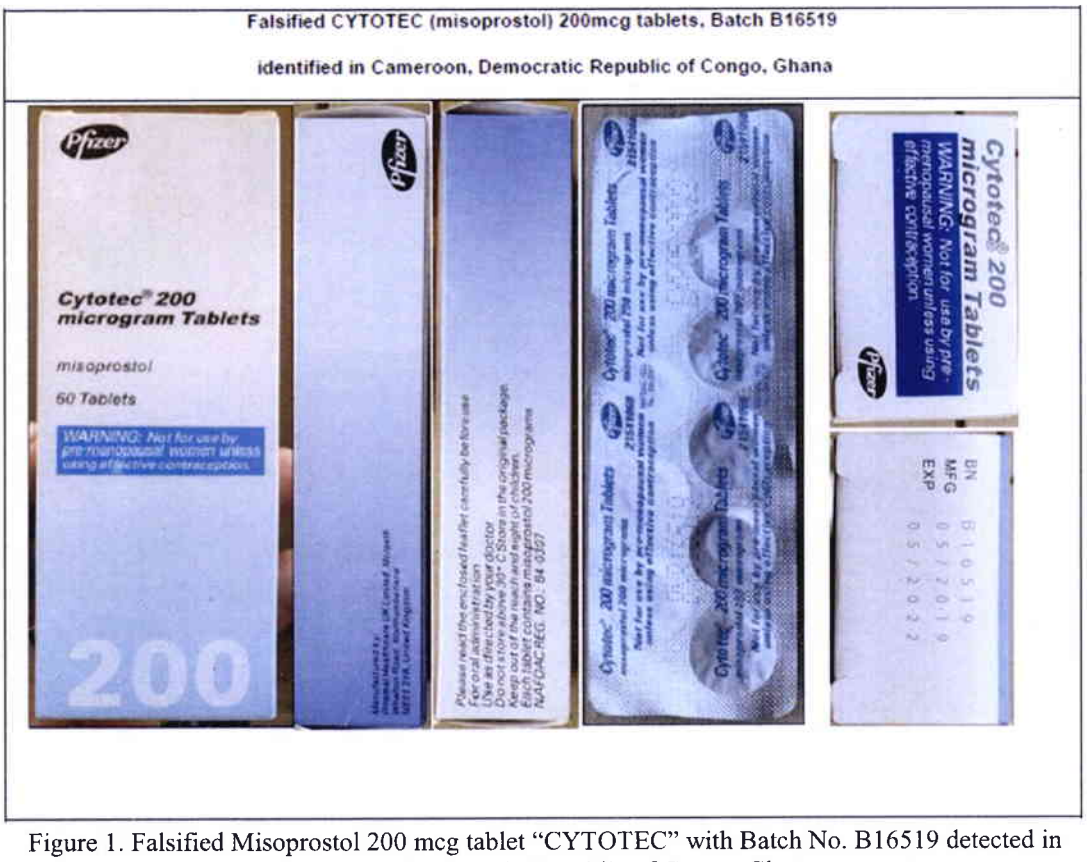

Figure 1. Falsified Misoprostol 200 mcg tablet "CYTOTEC" with Batch No. B16519 detected in Cameroon, Democratic Republic of Congo, Ghana

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

identified in Cameroon and Nigeria

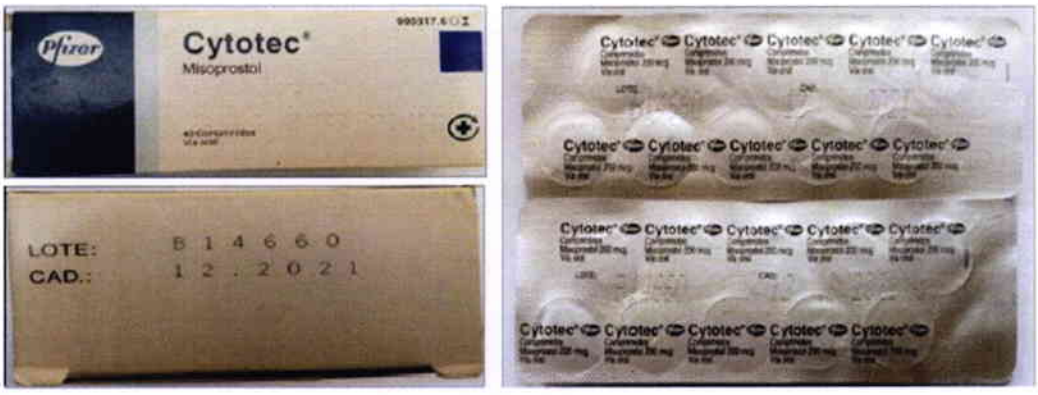

Figure 2. Falsified Misoprostol 200 mcg tablet "CYTOTEC" with Batch No. B14660 detected in Cameroon and Nigeria

The FDA strongly advises the public to be vigilant on the circulation of this falsified drug product since this poses a serious risk to global public health and could be also life threatening in some circumstances. A falsified drug product deliberately or fraudulently misrepresents identity, composition, or source, and upon confirmation with the genuine manufacturer, it was confirmed that the Batch No. B16519 does not correspond to genuine manufactured "CYTOTEC" and upon analysis, it does not contain any active pharmaceutical ingredient (API) and confirmed as non-compliant to its specifications. For Batch No. B14660, the expiry date on the said product is falsified.

This is to emphasize that Misoprostol (CYTOTEC) 200 mg tablet is not registered with FDA. Authentic Misoprostol 200 mcg tablet "CYTOTEC" is indicated for the treatment of duodenal and gastric ulcers.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that these falsified drug products are not sold or not administered to patients in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale, or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

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Director General

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