



FDA ADVISORY
No. **2021-2264**

06 SEP 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning on Falsified COVID-19 Vaccines "COVISHIELD" 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 COVID-19 vaccines identified as "COVISHIELD", was detected in the African and South-East Asian regions on July and August 2021 and was recently confirmed as falsified by WHO by the manufacturer. It was reported that this product was at patient level in Uganda and India:

DRUG PRODUCT	COVISHIELD		
STATED DOSE/BATCH NO./EXP. DATE	5 mL (10 doses)	4121Z040	10.08.2021
	2 mL (4 doses)	Not stated	Not stated
STATED MANUFACTURER	Serum Institute of India Pvt. Ltd.		
PACKAGING LANGUAGE	English		

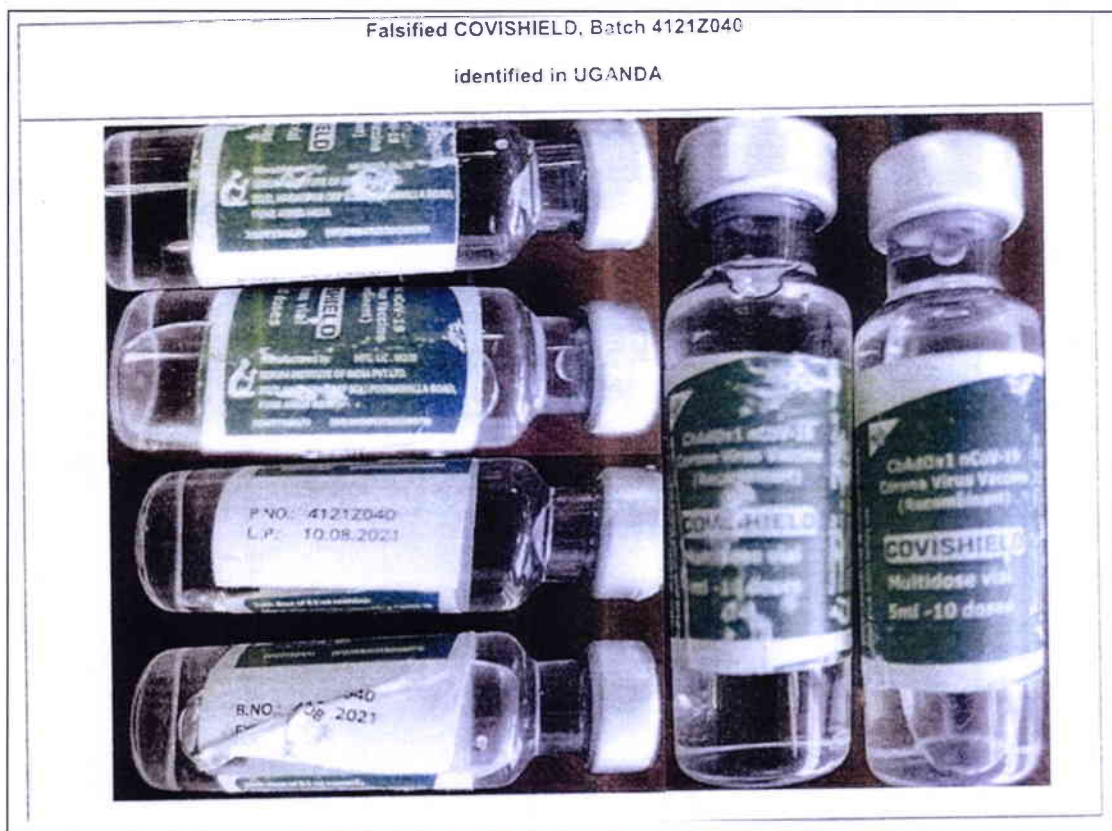


Figure 1. Falsified 5 mL COVID-19 vaccine "COVISHIELD" detected in Uganda





Figure 2. Falsified 2mL COVID-19 vaccine “COVISHIELD” identified in India

The FDA strongly advises the public to be vigilant on the circulation of this falsified COVID-19 vaccines since this poses a serious risk to global public health and further increases the burden on vulnerable populations and health systems. A falsified vaccine deliberately or fraudulently misrepresents identity, composition, or source, and upon confirmation with the genuine manufacturer, it was confirmed that the 2mL doses are not produced by them and the 5 mL doses are falsified.

Authentic COVID-19 vaccine BNT162b2 is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older, which should be used in accordance with official guidance from national regulatory authorities.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that these falsified COVID-19 vaccines 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, distribution, or administration of the abovementioned, kindly e-mail us via covidresponse@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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