



**FDA ADVISORY**  
No. **2021-0681**

30 MAR 2021

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

**SUBJECT: Public Health Warning on Falsified COVID-19 Vaccine BNT162b2 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 a COVID-19 vaccine identified as “BNT162b2”, was detected in Mexico last February 2021 and was recently confirmed as falsified to the WHO by the manufacturer. It was reported that this product was supplied and was administered to patients outside the authorized vaccination programs:

DRUG PRODUCT	<b>COVID-19 Vaccine BNT162b2</b>	
LOT NO./EXP. DATE	<b>783201</b>	<b>AUG 24</b>
STATED MANUFACTURER	<b>Pfizer BIONTECH</b>	
PACKAGING LANGUAGE	<b>English</b>	



Figure 1. Falsified COVID-19 Vaccine BNT162b2 detected in Mexico

The FDA strongly advises the public to be vigilant on the circulation of this falsified COVID-19 vaccine 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 this vaccine was not manufactured by them, batch number and expiry date were falsified,



and glass vials and labels were different from the authentic COVID-19 vaccine BNT162b2 vials.

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 since there is still no importation of COVID-19 vaccine from Pfizer.

For more information and inquiries, please e-mail us at [cdrr\\_postmarketsurveillance@fda.gov.ph](mailto:cdrr_postmarketsurveillance@fda.gov.ph). To report unauthorized sale, distribution, or administration of the abovementioned, kindly e-mail us via [covidresponse@fda.gov.ph](mailto: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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