

Ref. RPQ/REG/ISF/Alert N°2.2021

26 March 2021

Medical Product Alert N°2/2021

Falsified COVID-19 Vaccine BNT162b2 identified in WHO region of the Americas

Alert Summary

This WHO Medical Product Alert refers to falsified COVID-19 Vaccine identified as “BNT162b2” detected in Mexico in February 2021 and recently confirmed as falsified to the WHO. The falsified product was supplied and administered to patients outside authorised vaccination programs.

This falsified COVID-19 Vaccine may still be in circulation in the region and may continue to be offered to patients outside authorised vaccination programs.

Laboratory analysis of the contents of the falsified products is pending and this Alert will be updated as soon as results are available.

Genuine COVID-19 Vaccine BNT162b2 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older. The use of genuine COVID-19 vaccines should be in accordance with official guidance from national regulatory authorities.

Falsified COVID-19 vaccines pose a serious risk to global public health and place an additional burden on vulnerable populations and health systems. It is important to identify and remove these from circulation.

The product identified in this Alert is confirmed falsified on the basis that it deliberately/fraudulently misrepresents identity, composition or source:

- the genuine manufacturer of COVID-19 Vaccine BNT162b2 confirmed they did not manufacture the product
- the batch number and expiry dates are falsified
- the glass vials and label are different from genuine COVID-19 Vaccine BNT162b2 vials

Table 1: Products subject of WHO Medical Product Alert N°2/2021

Product Name	COVID-19 Vaccine BNT162b2
Stated manufacturer	Pfizer BIONTECH
Lot number	783201
Exp date	AUG 24
Packaging language	English
Identified in	Mexico

For photographs of the above products, please refer to Table 2 on page 2 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 centers, wholesalers, distributors, pharmacies and any other suppliers of medical products.

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 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 products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact the [WHO Global Surveillance and Monitoring System](#) via rapidalert@who.int

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

Falsified COVID-19 Vaccine BNT162b2, identified in Mexico (Lot number 783201)



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

For more information, please visit the web pages of the [WHO Global Surveillance and Monitoring System](#) or
Email: rapidalert@who.int