



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



PRESS STATEMENT
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FDA Philippines Grants Emergency Use Authorization to Pfizer-BioNTech COVID19 Vaccine

Today, the Food and Drug Administration (FDA) grants its first Emergency Use Authorization (EUA) to Pfizer-BioNTech COVID19 Vaccine (BNT162b2) Suspension for IM Injection (Puurs, Belgium Site).

Through Executive Order No. 121 s. 2020, vaccines under development can be granted an EUA where there is no adequate, approved and available alternative to a vaccine for preventing COVID-19 during this present public health emergency. The granting of the EUA is not a marketing authorization or a Certificate of Product Registration, hence this cannot be used to market the vaccine commercially.

Evaluation was based on current available data. The assessment ensured that the benefits outweigh the known and potential risks of the product. The safety and efficacy were reviewed by a panel of clinical experts and the quality data was reviewed by technical experts from FDA Center for Drugs Regulation and Research (CDRR). “After a thorough review of the currently available data by medical and regulatory experts, the FDA is granting Emergency Use Authorization to Pfizer-BioNTech COVID-19 vaccine. The interim data from the ongoing phase 3 trial shows that the vaccine has an efficacy of 95% in the study population and at least 92% among all racial groups”, Director General Eric Domingo said.

Adverse events following immunization shall be closely monitored. DG Domingo also said that, “The roll out of the vaccine and use in more than 5 million people worldwide has identified severe allergic reaction in a few individuals. Therefore, the vaccinations must be done by health professionals trained to recognize and manage adverse reactions and they should have resources at hand to adequately respond”. Reporting of the patient’s response to the vaccine shall be through the pharmacovigilance system that will be activated once the vaccination program is implemented.

The FDA commits to continue its job to ensure that Filipinos can have access to vaccines that hold greater benefits and outweighs the risk and possible adverse effects during this time of pandemic. “The development of these vaccines is still ongoing. We will keep track of the progress and FDA will provide our public with the correct information on the authorized products for transparency, to aid the decision making of Filipinos,” DG Domingo concluded.

