Pfizer
COVID-19 Vaccine Program (BNT162) – Distribution and allocation of vaccine at Emergency Use Authorization

This letter includes information of an off-label nature. The candidate COVID-19 mRNA vaccine (BNT162b2) is an investigational product and currently not approved by the U.S. Food and Drug Administration (FDA) for use outside of the clinical trial setting.

HOW WILL VACCINE DOSES BE ALLOCATED AND DISTRIBUTED DURING AN EMERGENCY USE AUTHORIZATION (EUA)?

- During an EUA, the allocation of doses of COVID-19 vaccine to the appropriate populations within a country is a decision for local governments based on relevant health authority guidance.[1] Therefore, the vaccine will be distributed by the US Government, in coordination with state, local, and tribal authorities.

- Pfizer has posted a Distribution Fact Sheet, which is available at https://www.pfizer.com/news/hot-topics/covid_19_vaccine_u_s_distribution_fact_sheet.

- Pfizer is unable to allocate vaccine doses in any manner other than as described in the distribution process for EUA approved by the Centers for Disease Control and Prevention (CDC).

- The CDC's Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee comprised of medical and public health experts who develop recommendations on the use of vaccines in the US. ACIP holds regular meetings, which are open to the public and provide opportunity for public comment.[1]

- The FDA is solely responsible for authorizing or approving a vaccine. When or if FDA has issued an EUA for our COVID-19 vaccine candidate, it can be distributed for emergency use. The next important step would be for the ACIP to meet and provide guidance for the government to determine which groups should be prioritized for vaccination based on their risk.[1]

- As noted by the CDC, their planning will progress as information about any authorized or approved vaccines become available.[2]

- On December 1, 2020, in advance of the FDA's review of the Pfizer/BioNTech EUA application for the investigational COVID-19 vaccine, ACIP provided interim guidance to federal, state, and local jurisdictions on the allocation of initial doses of COVID-19 vaccine after authorization of the vaccine.[3]

    - ACIP recommended that health care personnel and residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program (defined as Phase 1a).[3]

- On November 23, 2020, the ACIP released a report that identified four candidate groups for recommendation of initial allocation of COVID-19 vaccine during an EUA in the United States.[4] Please refer to the above information, which provides updated guidance from the summary below.

    - These groups are as follows (not in order of priority): health care personnel; other essential workers; adults with high-risk medical conditions; and adults aged 65 years and older.[4]

- In this report, the ACIP also describes four ethical principles, which are in addition to scientific data and implementation feasibility, that will assist ACIP in formulating their recommendations for the allocation of COVID-19 vaccine while supply of vaccine is limited. These principles are as follows: maximize benefits and minimize harms; promote justice; mitigate health inequalities; and promote transparency.[4]

- You may also wish to review information from the CDC on COVID-19 vaccines at the following website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.[5]

- Additionally, the CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations is available at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.[6]

REFERENCES

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