Questions and Answers about Emergency Use Instructions (EUI)
Below are answers to frequently asked questions about Emergency Use Instructions (EUI). Refer to the EUI Fact Sheet for Healthcare Providers and Fact Sheet for Recipients and Caregivers for detailed information regarding the EUI for Pfizer-BioNTech's COVID-19 Vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States.

What are Emergency Use Instructions (EUI)?
Emergency Use Instructions (EUI) allow CDC to inform healthcare providers and recipients about certain uses of medical products approved (licensed) by the U.S. Food and Drug Administration (FDA) that are needed during public health emergencies without the FDA needing to issue an Emergency Use Authorization (EUA). The CDC Director has legal authority to create, issue, and disseminate EUI before or during an emergency for FDA-approved medical products with instructions to inform healthcare providers and recipients about such products' approved, licensed, or cleared conditions of use under circumstances that go beyond the scope of the approved labeling (package insert). EUI consist of fact sheets for healthcare providers and recipients that provide information regarding the emergency use of an FDA-approved medical product.

What EUI did CDC issue and why?
On November 17, 2021, CDC issued EUI (amended 12/9/2021)* to allow additional primary and booster doses of the COVID-19 vaccine by Pfizer-BioNTech in certain individuals. CDC issued the EUI and updated its interim clinical considerations to ensure that certain people who were vaccinated outside of the United States, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. While this only impacts a small number of people, the EUI and CDC's guidance help to ensure these individuals can get an additional primary dose or booster dose of COVID-19 vaccine by Pfizer-BioNTech so they can be better protected against COVID-19. This is important with cases of COVID-19 still high across the United States and globally.

Because the EUI can only be issued for an FDA-approved medical product, only Pfizer-BioNTech's COVID-19 vaccine can be used at this time under CDC-issued EUI for an additional primary or booster dose in persons who were vaccinated with certain non-FDA authorized or approved COVID-19 vaccines.

The COVID-19 vaccine by Pfizer-BioNTech (brand name Comirnaty) was approved by FDA in August 2021 as a 2-dose primary series for active immunization to prevent COVID-19 in persons ages 16 years and older. Because theFDA-approved use does not include additional primary or booster doses, FDA also amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize an additional primary dose in certain immunocompromised persons ≥ 12 years, a homologous booster dose in persons ≥ 16 years, and a heterologous booster dose in persons ≥ 18 years following primary vaccination with the COVID-19 vaccine by Pfizer-BioNTech or a different FDA-authorized COVID-19 vaccine. CDC issued EUI to allow use of the COVID-19 vaccine by Pfizer-BioNTech for additional primary or booster doses in certain individuals who completed primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines.

Who is eligible for an additional primary dose or booster dose under the EUI?
People who were vaccinated outside of the United States, who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. The recommendations are similar to those for people who received an FDA-authorized COVID-19 vaccine primary series:

- A single additional primary dose of Pfizer-BioNTech may be given to certain moderately and severely immunocompromised individuals ages 12 years and older who completed a primary series with certain COVID-19 vaccines that are not FDA authorized or approved.

* EUI issued by CDC on November 17, 2021 to allow additional primary dose in certain immunocompromised persons ages 12 years and older and a booster dose in persons ages 18 years and older. EUI amended on December 9, 2021 to update the age for booster dose to ages 16 years and older.

- A single booster dose of Pfizer-BioNTech may be given to persons ages 16 years and older who have completed a primary series with certain COVID-19 vaccines that are not FDA authorized or approved.

More information can be found on CDC's Interim Clinical Considerations webpage and on the EUI Fact Sheet for Healthcare Providers and EUI Fact Sheet for Recipients and Caregivers.

What is the recommended dose and interval of an additional primary dose of Pfizer-BioNTech under EUI? What about the booster dose recommendation?
Under EUI, a single additional primary dose of Pfizer-BioNTech may be given to certain individuals ages 12 years and older who are moderately or severely immunocompromised at least 28 days after completion of primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines.

Under EUI, a single booster dose of Pfizer-BioNTech may be administered in persons ages 16 years and older at least six months after completion of primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines. Refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.

What are the risks and benefits of mix-and-match uses of non-FDA authorized/approved vaccines with the COVID-19 vaccine by Pfizer-BioNTech?
Available data on the safety or efficacy of an additional primary or booster dose of Pfizer-BioNTech's COVID-19 vaccine after receipt of a non-FDA authorized or approved COVID-19 vaccine are limited. However, based on available information, the known and potential risks of an additional primary or booster dose of Pfizer-BioNTech's COVID-19 vaccine might be outweighed by its likely benefit to enhance or restore protection by the primary vaccination, which might have waned over time. Refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.