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Ask the Pharmacist: Emergency Use Authorization

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How Does Emergency Use Authorization Differ from Full Approval of a Treatment or Vaccine?

The immediate and urgent changes that a global pandemic demands have proven to be an enormous challenge, and with those personal, professional and societal challenges over the past year came the urgent need for safe and effective COVID-19 treatments and vaccines. As of Jan. 5, 2021, two vaccines have received Emergency Use Authorization (EUA) from the Federal Drug Administration (FDA). While EUA may have been added to the 2020 lexicon, let's take a closer look at the term and its implications for 2021.

Emergency Use Authorization, An Overview

The EUA program was developed after 9/11 to be used in emergencies, such as Ebola or MERS. According to the FDA, "An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, [the] FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives." Importantly, the COVID-19 vaccines currently receiving Emergency Use Authorization have followed the same testing protocol that is required of any vaccines pursuing full FDA approval. The makers of these vaccines recruit tens of thousands of clinical trial participants and enroll them in strict study protocols designed to generate convincing clinical, non-clinical and manufacturing data in support of their use in patients. The Moderna phase 3 trial had 30,000 participants and the Pfizer/Biontech phase 3 trial had more than 43,000 participants. The phases for receiving full FDA approval for a vaccine are as follows:

- **Pre-clinical:** Vaccine tested in lab to determine safety information.
- **Phase 1:** Evaluate early safety data in small group of volunteers.

- **Phase 2**: Randomized controlled studies on larger group of volunteers to determine common short-term side effects and risks, etc.
- **Phase 3**: Treatment evaluated more widely in human subjects for demonstrated evidence of safety and effectiveness.
- **Approval Stage**: "After FDA determines that a COVID-19 vaccine candidate is safe and effective, the Advisory Committee on Immunization Practices (ACIP), a committee comprising medical and public health experts, reviews available data before making vaccine recommendations to the CDC. (Learn more about how the CDC is making COVID-19 vaccine recommendations.)"
    - EUA
    - Full Licensure
- **Phase 4**: Post approval monitoring and research.

EUA requests for COVID-19 vaccines are submitted to the FDA based on completed phase 3 trials or interim analyses of these, if the progress in the trial to date indicates the study's primary effectiveness endpoint has been met. A panel of independent experts commissioned by the FDA (the ACIP) then vote to attest that the known and potential benefits of the vaccine outweigh the known and potential risks. The FDA also notes that, "efforts to speed vaccine development to address the ongoing COVID-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety." Once authorized, the FDA expects vaccine manufacturers to submit and execute plans for ongoing safety surveillance in support of continuance requests for the EUA, if necessary. They also expect that clinical trials of EUA-authorized treatments in late stage progress will continue, obtaining additional safety and effectiveness information to support full licensure approval. For example, the CDC has received reports of a few people experiencing allergic reactions to the COVID vaccine and has provided safeguards and recommendations for vaccination providers. The FDA requires that persons receiving an Emergency Use Authorization vaccine are informed that the FDA has authorized its emergency use, "of its known and potential benefits and risks, the extent to which such benefits and risks are unknown." This information is also communicated publically via patient fact sheets, which are posted on the FDA website. Additionally, the CDC has a website with detailed clinical resources and production information available here. Access the Moderna fact sheet here. Access the Pfizer/BioNTech fact sheet here. COVID-19 EUAs, including those for drugs and biological products, personal protective equipment, in-vitro diagnostic products, ventilators and other medical devices presently number in excess of 300. In addition to the first two U.S. EUA approved SARS-CoV2 vaccines listed above, there are several more vaccines close behind them in progressing clinical trials. Additional resources are available below:

- CDC: COVID-19 Vaccine FAQs for Healthcare Professionals (Including EAU Information)
- CDC: Clinical Considerations
- CDC: Recipient Education



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