

COVID-19: Emergency Use Authorization Frequently Asked Questions



What does this mean?

An Emergency Use Authorization (EUA) is a medical product that gets special authorization by the FDA to be used during an emergency.

Why is this used?

Declaration of a public health emergency by the federal government allows the FDA to issue Emergency Use Authorizations, which facilitate the distribution of unapproved drugs or the off-label use of approved drugs to the public.

How does it work?

The FDA's Vaccines and Related Biological Products Advisory Committee, made up of 15 leading authorities in various scientific fields relevant to vaccine development, meets to review the chemistry, manufacturing and control information for the drug. This process takes at least a month, as cross-references and other data are carefully evaluated. The Office of Vaccine Research and Review then develops a timeline for an EUA request. A drug-maker may submit an EUA request only after these steps have been successfully completed.

What is the benefit?

The EUA process allows for the rapid release of vaccines and other drugs during a public health emergency by creating a scientifically-sound process to ensure the safety and efficacy of drugs of high priority.

How will the vaccine be distributed?

Because the initial supply of vaccine is very limited, it will be distributed first to people most at risk for COVID-19, such as health care workers, first responders and staff/residents of long-term care facilities and nursing homes. The next phase of vaccinations will be available to higher risk individuals and essential workers.

The final phase will be for the general population. [Click to view the phased distribution approach table.](#)

While the state is planning to act swiftly, the process could take several months, or potentially more than a year, to distribute to everyone who wants a vaccine, especially because the Pfizer vaccine, and most of the vaccine candidates, require two doses. The state is working closely with local public health agencies, health care providers and diverse community partners to distribute the vaccine as equitably and efficiently as possible.