UNDERSTANDING THE EMERGENCY USE AUTHORIZATION PROCESS FOR COVID-19 VACCINES

As the world continues to feel the impact of the COVID-19 pandemic, the biopharmaceutical industry is working around the clock to develop safe and effective vaccines to prevent infection, as well as new therapies to treat the coronavirus. A wide range of approaches are currently being tested in robust clinical trials, with participants from all walks of life, to improve the odds that one or more vaccine candidates will be successful in meeting this pressing need. These trials look at how the immune system responds to a vaccine, its effectiveness in producing immunity and the safety profile.

Recently, there have been a number of conversations about the role of the U.S. Food and Drug Administration (FDA) in reviewing different COVID-19 vaccine candidates, and exactly how they may be available for use outside the context of a clinical trial, including through the issuance of an emergency use authorization (EUA). An EUA is important to helping provide access to medical products during a public health emergency like COVID-19.

As vaccines continue being robustly tested for safety and efficacy, here are three things to keep in mind.

1) AN EMERGENCY USE AUTHORIZATION IS DIFFERENT THAN FDA LICENSURE OF A VACCINE.

EUAs are used in certain types of emergencies, like COVID-19, when there is no adequate, approved and available alternative to the EUA product. During these situations, the Federal Food, Drug and Cosmetic Act permits the FDA to issue EUAs to facilitate access to medical interventions, such as vaccines. Importantly, however, an EUA is not the same as an FDA approval or licensure. For example, there are different evidentiary requirements for licensure of a Biologics License Application (BLA) and issuance of an EUA for a vaccine. Furthermore, an EUA expires upon termination of the relevant emergency declaration, whereas there is no "termination" of a BLA.

The FDA may issue an EUA, when, among other things, the agency determines that based on all of the available scientific evidence, the known and potential benefits of the vaccine outweigh the known and potential risks. To underscore this, FDA Commissioner Stephen Hahn has said repeatedly in recent weeks and months that the agency would only consider an EUA if it felt the risks associated with the vaccine were "much lower than the risks of not having a vaccine and the potential benefit of having a vaccine."

The agency has further taken steps to ensure the robust vaccine candidate review process by engaging the Vaccines & Related Biological Products Advisory Committee (VRBPAC) to discuss the development and potential authorization of vaccines to prevent COVID-19 after issuing guidance on FDA's recommendations for an EUA submission for a COVID-19 vaccine.

2) COVID-19 EMERGENCY USE AUTHORIZATION STANDARDS ARE ROBUST.

Recently, the FDA issued guidance specifically on EUAs for COVID-19 vaccines. The recommendations include key information and data that FDA recommends to support issuance of an EUA, including chemistry, manufacturing and controls information, nonclinical and clinical data and regulatory and administrative information.

This FDA guidance clarifies that an assessment regarding any potential EUA for COVID-19 vaccines would be made on a case-by-case basis considering the target population, the characteristics of the vaccines, and the totality of the relevant available scientific evidence, including preclinical and human clinical study data on the vaccine's safety and effectiveness. The FDA plans to convene an open session of its VRBPAC (in addition to the general session held on October 22) prior to issuance of any EUA for a COVID-19 vaccine to discuss the request and whether the available safety and effectiveness data support the authorization.

3) EUAs LAST ONLY AS LONG AS THE HHS DECLARATION JUSTIFYING EUAS AND MAY BE REVISED OR REVOKED AT ANY TIME.

An EUA may only be issued after the Secretary of Health and Human Services makes a declaration that certain emergency circumstances exist justifying an EUA. EUAs issued under such declaration last only so long as the declaration is in effect; the EUA ceases to be effective upon termination of such declaration.

The FDA also has the authority revoke or revise an EUA at any time. The agency is directed to "periodically review the circumstances and the appropriateness" of an EUA, and the "progress made with respect to approval" or licensure of a product authorized under an EUA. The FDA may revise or revoke an EUA if the criteria for issuance are no longer met or other circumstances make such revision or revocation "appropriate to protect the public health or safety."

America's biopharmaceutical companies are supportive of the FDA's robust new EUA guidance that brings greater scientific transparency to the COVID-19 vaccine review process and have pledged 'to make the safety and well-being of vaccinated individuals the top priority in development' of these first vaccines.

For more information on COVID-19 vaccines currently in clinical development, visit https://phrma.org/Coronavirus/Activity-Tracker.