From: noreply-dphimmunizations@ct.gov <noreply@everbridge.net>
Sent: Friday, May 6, 2022 2:22 PM
Subject: COVID-19 Vaccine Pediatric (age 4 and under) Anticipated Roll out Update May 6, 2022



Dear Connecticut Vaccine Program (CVP) Providers,

UPDATES

Young Pediatric Rollout

Moderna has submitted a request for Emergency Use Authorization (EUA) for its COVID-19 vaccine for children under 6 years of age. Pfizer is expected to submit a request for EUA for children under 5 years of age in the coming days. The Food & Drug Administration (FDA) has tentatively scheduled some meeting dates to discuss the EUA submission(s)—details appear below. Currently we anticipate EUA and Advisory Committee on Immunization Practices recommendation with distribution of any new vaccine products sometime in June 2022. We will communicate information as it becomes available.

What can providers do now? In preparation of a COVID-19 vaccine recommendation for children under 5 years of age, providers should begin messaging parents/guardians of children 6 months – 4 years. Messaging should include:

- A strong provider recommendation; resources can be found here.
- Whether your office is planning to administer COVID-19 vaccine for this new age group
- If you aren't planning on administering COVID-19 vaccine, information on where your patients can go to receive vaccine. The DPH van clinics will be providing pediatric vaccines and the schedule can be found <u>here</u>. Please note, even if you do not plan on providing COVID-19 vaccine in your office, this does not preclude you from making a strong recommendation!

CVP providers not enrolled in the COVID-19 vaccine program should consider enrolling and/or completing their enrollment in preparation of the young pediatric rollout. There are several important steps that are required of you should you wish to administer COVID-19 vaccines to your patients. The steps are laid out on our <u>COVID-19</u> vaccine providers web site numbered steps one through 6. Please review the page and follow the steps. We encourage all interested CVP participating practices to enroll as they are able.

Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meetings

FDA announced its plans to hold virtual meetings of its VRBPAC in anticipation of EUA requests in the coming months. Pending submission of complete data, FDA is holding the following dates for VRBPAC meetings:

- June 7: EUA request for a COVID-19 vaccine manufactured by Novavax to prevent COVID-19 in individuals 18 years of age and older.
- June 8, 21 and 22, the FDA has held dates for the VRBPAC to discuss updates to the Moderna and Pfizer-BioNTech EUAs for their COVID-19 vaccines to include younger populations. As the sponsors complete their submissions and the FDA reviews that data and information, it will provide additional details on scheduling of the VRBPAC meetings to discuss each EUA request.
- June 28: whether SARS-CoV-2 strain composition of COVID-19 vaccines should be modified, and if so, which strain(s) should be selected for Fall 2022. This meeting is a follow-up to the April 6 VRBPAC meeting that discussed general considerations for future COVID-19 vaccine booster doses and the strain composition of COVID-19 vaccines to further meet public health needs.

Pfizer EUA Submission

Pfizer is expected to submit its EUA for its COVID-19 vaccine in children 6 months through 4 years of age later this quarter. Pfizer previously <u>announced</u> that they are testing a three $(3-\mu g)$ dose primary series in children under age 5.

Moderna EUA Submission

Moderna <u>announced</u> it has submitted a request for EUA for its COVID-19 vaccine (mRNA-1273) in children 6 months to under 2 years and 2 years to under 6 years of age to the FDA and that similar requests are underway with international regulatory authorities. The requests are based on a two-dose, 25 µg primary series of mRNA-1273. The EUA submission for children ages 6 months to under 6 years will be complete the week ending 5/6/22. Moderna is also currently studying booster doses for all pediatric cohorts. Additional information will be made available when possible.

Thank you for everything you are doing to ensure access to vaccines for children across Connecticut.

For the CT DPH Immunization Program, visit: Contact Us

For the COVID-19 webpage, visit: COVID-19 Vaccine Program

Note that all our communications are archived on our web site.

If you would like to unsubscribe from these communications, please send an email to <u>Dph.immunizations@ct.gov</u> with the subject line "Unsubscribe from COVID-19 Program communications".