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Subject: COVID-19 Vaccine Pediatric (age 4 and under) Anticipated Roll out and Program Updates May 3,

2022



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May 3, 2022

Dear Connecticut COVID-19 Vaccine Providers,

This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our web site.

Thank you for everything that you are doing to continue the roll-out of the COVID-19 vaccine program. Please continue your outreach to parents/individuals age 5 and older and encourage everyone to <u>stay up-to-date</u> with COVID-19 vaccines.

<u>UPDATES</u>

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.

<u>What can providers do now?</u> 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!

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-µg) 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.

Vaccine Finder Inventory Cadence

As of May 1, 2022, providers must report COVID-19 vaccine supply levels at least weekly <u>by close of business on Fridays</u>. All other provisions regarding data remain unchanged.

We appreciate your efforts to update data in VaccineFinder. If you have completed the process, thank you. For those who have not yet updated VaccineFinder information, please see the details below. It is very important that you zero out providers that are no longer participating in COVID-19 vaccination efforts. Old inventory numbers will impact your own and aggregate performance metrics.

How to Add Inventory:

To report inventory for COVID-19 vaccines that are not already listed in your COVID-19 Locating Health Portal account, please follow the <u>Add Vaccine</u> link to add COVID-19 vaccine NDCs to your location.

You can follow this process for all new COVID-19 vaccines that are authorized and recommended in the U.S. Once added, you can begin reporting the number of doses on hand for that vaccine.

Quick tips:

- Make sure depots/hubs are updating inventory in VaccineFinder regularly; these facilities represent the largest inventory numbers and greatly impact supply chain estimates.
- 2. Providers no longer participating in COVID-19 vaccination must be zeroed out; old inventory numbers can impact performance metrics.
- 3. Regular reporting of inventory is part of the COVID-19 Vaccination Program Provider Enrollment Agreement.

Guides for reporting inventory and public display information can be found on the Provider Resources page. If you need support, please contact CARS_Helpdesk@cdc.gov or 1-833-748-1979.

J&J Expiration:

The FDA announced the approval of a shelf-life extension for the J&J/Janssen COVID-19 vaccine for an additional two months. The shelf-life of this vaccine has been updated from 9 months to 11 months. This decision is based on data from ongoing stability assessment studies that demonstrate that the vaccine is stable at 11 months when refrigerated at temperatures of $36^{\circ} - 46^{\circ}$ Fahrenheit ($2^{\circ} - 8^{\circ}$ Celsius). This shelf-life extension applies to refrigerated vials of J&J COVID-19 vaccine that have been held in accordance with the manufacturer's storage conditions.

The expiration date can be obtained by entering the lot number from the carton or vial using the website www.vaxcheck.jnj or by phone using an automated response system at 1-800-565-4008. This critical process should take less than one minute to complete.

Pfizer Expiration:

The FDA has approved an amendment to the emergency use authorization (EUA) for Pfizer Tris COVID-19 vaccine extending the shelf-life of the following Pfizer product formulations **from 9 to 12 months**:

- Pfizer Tris Pediatric vaccine (Orange Cap for ages 5 through 11, with diluent)
- Pfizer Adult Tris (**Gray Cap** for ages 12+, no diluent)

Vials stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) may remain in use **for up to 12 months beyond the date of manufacture** printed on the vials and cartons. Vials stored in refrigerated vials (2°C to 8°C) are **NOT** eligible for extension, regardless of the expiration date.

Pfizer Orange and Gray Cap Tris Vaccine expiry dates based on 12 months from the date of the manufacture are shown below and at Expiry Information for Pfizer COVID-19 Vaccines.

Printed Manufacturing Date	12-Month Expiry Date
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023

CT WiZ Enhancement

CT WiZ will be offline **May 9**th **from 8pm-10pm** for this month's release. Please plan reports and queries around this scheduled downtime. Visit: CT WiZ Training

Thank you for all your ongoing work and support of our COVID-19 vaccine rollout in Connecticut.

For the CT DPH Immunization Program, visit: Contact Us
For the COVID-19 webpage, visit: COVID-19 Vaccine Program

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