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To: Nova Scotia Health Care Practitioners and Immunizers

From: Dr. Shelley Deeks, Deputy Chief Medical Officer of Health

Date: November 8, 2022

Re: Pfizer BioNTech Comirnaty COVID-19 vaccine for ages 6 months to 4 years

On September 9, 2022, Health Canada authorized Pfizer-BioNTech Comirnaty (3 mcg) for use in ages 6 months up to and including 4 years. On October 21, 2022, the National Advisory Committee on Immunization (NACI) published recommendations on the use of this vaccine.

In response, Nova Scotia has made the following changes to its COVID-19 vaccine program:

- Children aged 6 months to 4 years who are not moderately to severely immunocompromised may be immunized with a primary series of either mRNA vaccine, with a dosing interval of 8 weeks between doses:
  - Moderna 25 mcg as a **two-dose** primary series.
  - Pfizer 3 mcg as a **three-dose** primary series.
- For children aged 6 months to 4 years who are **moderately to severely immunocompromised**:
  - Moderna 25 mcg is preferred and should be offered as a **three-dose** primary series with 4 weeks between the first two doses and 8 weeks between the second and third dose. Moderna is preferred because it takes less time to complete the series given that there is one less dose and therefore will provide protection earlier.
  - If Moderna is not readily available, or Pfizer 3 mcg is requested, Pfizer 3 mcg may be offered as a **four-dose** primary series with 4 weeks between the first three doses and 8 weeks between the third and fourth dose.
- Children who received one or two doses of Pfizer (3 mcg) and turn 5 prior to completing the primary series should receive the age-appropriate dose(s) of Pfizer (10 mcg) to complete the primary series. The number of doses required to complete the series is based on the Pfizer 6 month to 4-year schedule (i.e., 3 doses for immunocompetent children and 4 doses for moderately to severely immunocompromised children).
- For children aged 6 months to 4 years, the same product should be used for all primary series doses, as opposed to a mixed series. This is to reduce the complexity of the program as the two products have different schedules. If a mixed series is inadvertently administered or given out of necessity, PHAC's Quick Reference Guide can be consulted for valid schedules.

- As a precautionary measure, given that Pfizer (3 mcg) is a newly authorized vaccine in the 6 month to 4-year age group, it should not **routinely** be given concurrently with other vaccines. It is recommended to wait 14 days before or after administration of other vaccines. However, there is no contraindication to administering a COVID-19 vaccine with other vaccines at the same time and individual circumstances must be considered.

Seroprevalence studies from other jurisdictions demonstrate that a high proportion of children under 5 have already been infected with SARS-CoV-2. Indirect evidence from adults shows that hybrid immunity (i.e., protection from both vaccination and infection) appears to confer immunity that is more durable and of greater breadth than either vaccination or previous infection alone. While COVID-19 disease is typically mild in younger age groups, severe outcomes can occur and children younger than 5 years have higher rates of hospitalization and ICU admission compared to older pediatric age groups.

Pfizer 3 mcg was evaluated in pediatric clinical trial participants aged 6 months to 4 years. Efficacy against confirmed SARS-CoV-2 infection was estimated at 73.2% starting 7 days after the third primary series dose and no safety signals were identified. Most adverse events, apart from fever, were reported at a lower rate than seen among children 5 to 11 years. Post-market data from administration of approximately 1.5 million doses of mRNA vaccine (Pfizer or Moderna) in this age group have demonstrated no safety signals (including myocarditis).

Each dose of Pfizer for ages 6 months to 4 years contains 3 mcg of mRNA encoding for the ancestral SARS-CoV-2 spike protein. The presentation is a 10-dose vial with a maroon cap and maroon label colour. This product requires dilution with 2.2 mL sterile 0.9% Sodium Chloride Injection USP (supplied), for a volume of 0.2 mL per 3 mcg dose.

Providers should continue to carefully read the product label before administering any dose of COVID-19 vaccine given the complexity of the COVID-19 vaccination program and the potential for error.

For more information, see the NACI statement and summary, Health Canada's regulatory decision summary, and the product monograph. For general information on the COVID-19 vaccine program, Nova Scotia's Information for Health Care Professionals document can also be consulted.

Thank you for your ongoing commitment to the COVID-19 vaccination program in Nova Scotia.