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To: Nova Scotia Health Care Practitioners and Immunizers

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

Date: January 3, 2023

Re: Pfizer pediatric bivalent (BA.4/5) COVID-19 vaccine and changes to booster booking

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Pfizer pediatric bivalent (BA.4/5) COVID-19 vaccine

On December 9, 2022, Health Canada authorized Pfizer BioNTech Comirnaty Original & Omicron BA.4/5 COVID-19 vaccine (10 mcg) for use as a single booster dose in children ages 5 to 11 years. On the same day, NACI (National Advisory Committee on Immunization) published updated recommendations on COVID-19 booster doses in children 5 to 11 years of age.

In response, Nova Scotia updated its COVID-19 vaccine program as follows:

- Nova Scotia continues to recommend that children who are at high risk of severe COVID-19 disease (as outlined in the NACI recommendations) should receive a booster dose and other children in this age group may receive a dose. Providers should take the opportunity to discuss COVID-19 immunization with children and families of children who are at high risk for severe disease to encourage uptake.
- Pfizer pediatric bivalent (BA.4/5) vaccine (10 mcg) is the preferred product to be used for the booster dose to children aged 5 to 11 years going forward.

At this time, only a **single booster dose** is recommended for children aged 5 to 11 years, given the absence of evidence on additional booster doses in this population. Any child who has already received a booster of the original Pfizer vaccine is expected to have good protection and does not need to receive another booster with the bivalent vaccine. However, children who are at particularly **high risk** of severe COVID-19 disease and who have already received a booster dose of the original Pfizer vaccine may receive an additional bivalent vaccine dose once the appropriate interval since their first booster dose has passed (120 days for moderately to severely immunocompromised: 168 days for all others).

Pfizer's pediatric bivalent (BA.4/5) vaccine presentation is in a 10-dose vial which must be diluted prior to use. The vial has an orange cap and orange label colour which is identical to the ancestral Pfizer vaccine presentation in this age group. The differentiating feature is the bivalent descriptor on the product label. Providers are reminded to carefully read the product label to ensure the correct product is administered. Each 0.2 mL dose contains 5 mcg mRNA encoding for the ancestral SARS-CoV-2 strain and 5 mcg mRNA encoding for the Omicron (BA.4/5) variant for a total of 10 mcg per dose.

At present, there is no direct clinical evidence for Pfizer's pediatric bivalent (BA.4/5) vaccine in children aged 5 to 11 years. Safety and efficacy were inferred from indirect evidence from trials of the Pfizer BA.1 and BA.4/5 bivalent vaccines and Pfizer monovalent BA.1 vaccine candidate in ages 12 years and older, and from Pfizer's original pediatric vaccine. Preliminary post-market data shows that BA.4/5 bivalent vaccines are well tolerated in ages 12 years and older and demonstrate improved vaccine effectiveness against symptomatic infection in ages 18 years and older.

For more information, please consult the Comirnaty Original & Omicron (BA.4/5) page of the COVID-19 vaccines and treatments portal, the NACI statement and summary, and the product monograph.

Additionally, all bivalent vaccines, including Pfizer's pediatric bivalent (BA.4/5 vaccine), are currently only authorized in Canada as booster doses and not for the primary series. If a bivalent vaccine is administered in error as a dose in the primary series, the dose does not need to be repeated and can be considered valid. Additional guidance on administration errors can be found in the Public Health Agency of Canada's resource on managing vaccine administration errors or deviations.

Change to booking for booster doses

Starting today, individuals will only be able to book a bivalent vaccine for booster doses in people 5 years and older, as bivalent vaccines are the preferred product for doses after the primary series is complete. If, at the time of the appointment, a client requests an ancestral vaccine, it can be given with informed consent and is considered valid. Ancestral vaccine appointments already booked for booster doses will not be automatically cancelled.

Immunizers should continue to obtain informed consent before vaccine administration to ensure that individuals consent to the vaccine they are receiving.

Thank you for your continued commitment to Nova Scotia's COVID-19 vaccine program.