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To: Nova Scotia Health Care Practitioners and Immunizers

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

Date: October 26, 2022

Re: Pfizer BioNTech Comirnaty Bivalent (BA.4/BA.5) Vaccine

On October 7, 2022, Health Canada authorized the Pfizer-BioNTech Comirnaty Bivalent (BA.4/BA.5) COVID-19 vaccine for use as a booster dose in persons aged 12 and older. On the same day, the National Advisory Committee on Immunization (NACI) published updated guidance on COVID-19 booster doses as part of the fall campaign.

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

- An age-appropriate Omicron-containing bivalent mRNA COVID-19 vaccine should be offered for the fall dose. These vaccines include:
  - Moderna Bivalent (BA.1) (50 mcg) for individuals aged 18 and older
  - Pfizer Bivalent (BA.4/5) (30 mcg) for individuals aged 12 and older

With this change, anyone in Nova Scotia aged 12 and older who has completed their primary series can receive the fall dose, regardless of the number of booster doses previously received, so long as the minimum interval since last vaccination has passed. Most individuals can receive the fall dose 168 days following their last vaccination or SARS-CoV-2 infection. The following groups can receive the fall dose 120 days following their last vaccination or SARS-CoV-2 infection: adults aged 70 and older; residents aged 12 and older living in long-term care or senior congregate living, African Nova Scotian adults aged 50 and older, adults aged 55 and older in or from First Nations communities, pregnant persons, and those aged 12 and older who are considered moderately to severely immunocompromised. While the minimum interval since last vaccination must be followed, individuals who choose not to wait the minimum recommended interval since SARS-CoV-2 infection should be advised to wait at least 3 months since infection in order to optimize their benefit from the vaccine.

Each dose of Pfizer Bivalent (BA.4/5) contains 15 mcg of mRNA encoding for the ancestral spike protein and 15 mcg of mRNA encoding for the Omicron BA.4/5 spike protein for a total of 30 mcg per 0.3 mL dose. Pfizer Bivalent (BA.4/5) presentation is a 6-dose vial that does not require dilution and has a gray cap and a gray label border. Please note that this cap and label border colour are the same as that for the original Pfizer Tris-formulation COVID-19 vaccine. 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.

While no clinical study data are currently available for the Pfizer Bivalent (BA.4/5) vaccine, the safety of this vaccine used as a booster in those aged 12 and older is inferred from clinical study and post-market safety data of Pfizer original vaccine and trials of Pfizer's BA.1 bivalent and BA.1 monovalent booster vaccine candidates. Available data suggests a similar safety profile of Pfizer Bivalent BA.4/5 compared to a Pfizer original booster dose. Immunogenicity of Pfizer Bivalent BA.4/5 was assessed pre-clinically and inferred from clinical trials of the Pfizer BA.1 bivalent vaccine candidate. Preclinical data demonstrated higher neutralizing antibody responses against Omicron BA.2 and BA.4/5 and equivalent neutralizing antibody responses against Omicron BA.1 compared to the Pfizer original booster.

Booster vaccination with Moderna Spikevax original (50 mcg) was found to be more effective than Pfizer-BioNTech Comirnaty original (30 mcg) within the first 12 weeks following vaccination, during a period of Delta followed by Omicron variant dominance. However, the relative effectiveness of a booster dose of Moderna Spikevax BA.1 Bivalent (50mcg) compared to Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) is not yet known due to the absence of head-to-head comparisons between Moderna and Pfizer bivalent vaccines. Because Pfizer Bivalent (BA.4/5) is the only bivalent COVID-19 vaccine authorized for those aged 12 to 17, it is the preferred product for this age group. However, for those aged 18 years and older, receipt of either Omicron-containing bivalent COVID-19 vaccine is expected to increase protection against Omicron sublineages and elicit a greater breadth of immune response, potentially providing additional protection against future variants of concern.

For more information, see Health Canada's authorization of Pfizer Bivalent (BA.4/5), the NACI statement and summary, and the product monograph.

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