



October 13, 2015

Dear Public Health Customer,

MedImmune/AstraZeneca appreciates your continued commitment to FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal). Information regarding FluMist Quadrivalent supply will evolve throughout the season, but we are committed to providing our customers the latest and most accurate updates regarding the timing of doses into the market.

We have been actively engaged with the CDC throughout the season regarding FluMist Quadrivalent delivery and timing. The CDC has been receiving doses since September and we expect to meet the CDC's full order by late December. The CDC supports vaccinating as long as flu viruses are circulating and we continue to support vaccination as soon as product is available and throughout the season.

We apologize for the challenges this delivery schedule may create for your clinics and programs and ask for your continued patience as we manage our schedule. Please work with the CDC to understand the quantity of product that is available for your location.

AstraZeneca places the highest priority on patients and medical need, and the impact that access to our products may have on overall public health. Ensuring a high quality product and timely supply is of utmost importance for all of our medicines, including influenza vaccines. All levels of the organization are committed to ensuring we continue delivering product throughout the season, and every opportunity for more timely delivery in subsequent seasons is being assessed and implemented.

### **Important Safety Information**

FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal) is a vaccine indicated for active immunization of persons 2-49 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluMist Quadrivalent is for intranasal administration only.

FluMist Quadrivalent is contraindicated in persons who have had a severe allergic reaction to any vaccine component including egg protein or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received trivalent FluMist (Influenza Vaccine Live, Intranasal). Children <5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following FluMist Quadrivalent administration. FluMist Quadrivalent has not been studied in persons with severe asthma or active wheezing.

If Guillain-Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist Quadrivalent should be based on careful consideration of the potential benefits and risks. FluMist Quadrivalent has not been studied in immunocompromised persons. The safety of FluMist Quadrivalent in individuals with underlying medical conditions



predisposing them to wild-type influenza infection complications has not been established. FluMist® Quadrivalent may not protect all individuals receiving the vaccine.

The most common solicited adverse reactions (occurring  $\geq 10\%$  in vaccine recipients and at least 5% greater than in placebo) reported after FluMist were runny nose or nasal congestion in all persons 2-49 years, fever  $>100^{\circ}\text{F}$  in children 2-6 years, and sore throat in adults 18-49 years. Among children 2-17 years who received FluMist Quadrivalent, 32% reported runny nose or nasal congestion and 7% reported fever  $>100^{\circ}\text{F}$ . Among adults 18-49 years who received FluMist Quadrivalent, 44% reported runny nose or nasal congestion and 19% reported sore throat.

**Please see accompanying complete Prescribing Information for FluMist® Quadrivalent, including Patient Information.**

Please feel free to contact your MedImmune/AstraZeneca representative or contact 1-800-236-9933 if we can be of further assistance.

Sincerely,

MedImmune/AstraZeneca