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## IMMUNE DEFICIENCY FOUNDATION

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*The National Organization Dedicated To Research And Education For The Primary Immune Deficiency Diseases.*

### **Questions and Answers: Shortage of Killed Influenza Vaccine and FluMist® Influenza Vaccine**

#### **UPDATED INFORMATION, OCTOBER 11, 2004**

#### **Q1: Will there be a shortage of killed virus flu vaccine in the United States during the 2004-2005 influenza season?**

A1: Yes, a severe shortage of killed influenza vaccine is anticipated this Fall. Chiron Corporation notified the Centers for Disease Control and Prevention (CDC) on October 5, 2004 that its manufacturing license had been suspended in the United Kingdom and none of its influenza vaccine (FluViron®) will be available for distribution in the United States for the 2004-2005 influenza season. This will result in a 50% reduction of the expected supply of killed flu vaccine (flu shot) available in the U.S. this flu season. The CDC estimates that 54 million doses of FluZone®, manufactured by Aventis Pasteur, SA and 1.1 million doses of FluMist® will be available this season.

#### **Q2: How will this shortage impact public access to the killed flu vaccine?**

A2: The CDC in coordination with its Advisory Committee for Immunization Practices (ACIP), has issued interim recommendations for influenza vaccination during the 2004-2005 season. The priority groups for vaccination with inactivated influenza vaccine (flu shot) this season are:

- all children aged 6–23 months;
- adults aged 65 years and older;
- persons aged 2–64 years with underlying chronic medical conditions;
- all women who will be pregnant during the influenza season;
- residents of nursing homes and long-term care facilities;
- children aged 6 months–18 years on chronic aspirin therapy;
- health-care workers involved in direct patient care; and
- out-of-home caregivers and household contacts of children aged <6 months.

Furthermore, persons who are not included in one of the priority groups described should forego or defer vaccination.

**Q3: Are primary immune deficiency diseases included in the priority groups for killed flu vaccinations?**

A3: Yes, individuals with primary immune deficiency diseases are considered to have an underlying chronic medical condition and should be included in the priority group to receive vaccinations. Additionally, if the vaccine is available, your family members should seriously consider receiving the killed version of the flu vaccine to reduce the risk of bringing the flu virus home to their family member with primary immune deficiency. See Q and A # 12 for more information.

**Q4: Where are killed flu shots being administered?**

A4: The CDC recommends persons in the priority groups identified above should be encouraged to search locally for vaccine if their regular health-care provider does not have vaccine available. Your local health department may be the best resource to learn where vaccinations are being administered in your community. Retail pharmacy chains may also have vaccination information. A useful web site to help find flu shot clinics is: <http://www.findaflushot.com/lungusa/>.

**Q5: What protection is available to primary immune deficient patients if killed flu vaccine is not available?**

Q5: During an influenza outbreak, physicians may wish to consider the use of antiviral agents in their primary immune deficient patients with T-cell defects. One antiviral agent, Tamiflu® (Roche) has been approved by the FDA for prevention of Types A and B Influenza in those 13 years of age and older. It is given once daily for up to 42 days and may have benefit if given within 2 days of exposure to influenza strains.

**Q6: What is FluMist®?**

A6: FluMist® is a **live virus influenza vaccine**. It was approved by the U.S. Food and Drug Administration in June 2003 and is the first nasally administered vaccine to be marketed in the United States. FluMist® is approved to prevent influenza illness due to influenza A and B viruses in healthy children and adolescents, ages 5-17 and healthy adults, aged 18-49. FluMist® is produced by MedImmune Vaccines and distributed by Wyeth.

**Q7: How is FluMist® different from the traditional flu shot?**

A7: FluMist® is a live virus vaccine and administered through a nasal spray. The flu shot is an inactivated (killed virus) vaccine. Killed virus vaccines can be taken by individuals with primary immune deficiencies and their families.

**Q8: What is influenza?**

A8: Influenza, or “the flu”, can cause serious respiratory illnesses in normal people. Those with primary immune deficiency diseases may be at an increased risk for the flu and experience more serious complications. There are two types of influenza virus that cause human disease, Type A and Type B. Each year these types undergo changes, which make individuals susceptible to infection even though they may have antibodies to other strains of influenza from prior infections or immunizations.

**Q9: How is influenza spread and what are its symptoms?**

A9: Influenza is spread by coughing and sneezing. After infection, there is an incubation period of one to four days. Infected individuals can infect others before symptoms begin and for about five days after symptoms begin. Symptoms include fever, cough, muscle aches, headache, sore throat, runny nose, and fatigue. The cough and fatigue can last a few weeks. Pneumonia and other complications can be very severe.

**Q10: Who should not receive the FluMist® vaccine?**

A10: FluMist® should not be given for any reason to the following:

- ***People with primary immune deficiency diseases or their close contacts***
- People with weakened immune systems due to HIV infection, certain cancers, or immunosuppressive agents used to treat cancer or organ transplantation
- People with asthma or other reactive airway diseases
- Children younger than 5 years and adults older than 50 years
- People with a history of Guillan-Barre syndrome, chronic diseases of the cardiovascular or pulmonary system, or allergies to eggs
- Pregnant women

**Q11: What are the potential complications of the FluMist® vaccine?**

A11: The most common adverse events associated with the vaccine in normal individuals were nasal congestion, runny nose, sore throat and a cough. Although there is no specific information available, it is anticipated that if a person with a primary immune deficiency receives FluMist® (s)he would be more likely to develop complications. If a close contact is vaccinated, the resulting viral shedding could cause a person with a primary immune deficiency disease to become infected with the flu vaccine strains. (See A7 below)

**Q12: What is the risk to individuals with primary immune deficiency disorders if a close contact is vaccinated with FluMist®?**

A12: During a clinical trial with FluMist® in a day care center, there was documented transmission from vaccinated children to unvaccinated children. Viral shedding following the administration of FluMist® typically continues for about a week on the average, but may be as long as three weeks. The risk of transmission in the day care center setting was estimated at 2.4% or one in approximately 42 children. The risk could be higher if different children in the center receive the vaccine at different times over the fall.

Healthcare workers who receive FluMist® may also present a possible way for a person with a primary immune deficiency disease to become infected with the flu vaccine strains. Although there is no data about transmission of the live vaccine virus from vaccinees to immune compromised contacts and subsequent development of disease, the Centers for Disease Control and Prevention have stated that the inactivated vaccine (flu shot) is preferred over live, intranasal influenza vaccine (FluMist®) for physicians, nurses, family members, or anyone else coming in close contact with anyone with a weakened immune system.

**Q13: Is the killed virus flu vaccine (flu shot) recommended for those with primary immune deficiencies or their close contacts?**

A13: People with primary immune deficiency diseases may choose to receive the inactivated influenza vaccine shot. This is the killed version of the vaccine and will not cause the flu! The only risks of receiving the shot are soreness at the injection site, and less often fever, tiredness, muscle aches, and headache. Those allergic to eggs should not receive the vaccine shot, as there is a risk for more serious reactions. Even if you do not develop antibody titers high enough to prevent influenza, you still might benefit from receiving the shot every year. Receiving the shot may reduce your risk for hospitalization, pneumonia, and other complications. Your family members should seriously consider receiving the killed version of the flu vaccine to reduce the risk of bringing the flu virus home to their family member with primary immune deficiency.

**Q14: How can you reduce your risk of complications from the FluMist® vaccine?**

A14: To reduce the risk of contracting the flu vaccine strains, the Immune Deficiency Foundation's Medical Advisory Committee FluMist® Working Group has made the following recommendations:

- Because it is a live virus vaccine, people with primary immune deficiency diseases should NOT receive the FluMist® vaccine.
- The FluMist® vaccine is not recommended for close contacts of primary immune deficient patients.
- Primary immune deficient patients should talk to their doctors to see if it may be advisable to receive preventive medicine to avoid becoming infected with the FluMist® strains of the flu.
- Primary immune deficient patients exposed through close contact to FluMist®, should see their doctor immediately, as (s)he may advise a treatment medicine.
- School authorities may want to advise their immune deficient pupils if FluMist® is being administered in the school system. This information may be especially useful to those with T cell or combined T and B cell immune deficiencies.
- Family members and healthcare workers in close contact with immune deficient patients should be advised to receive the killed virus flu shot, rather than the FluMist® vaccine.

**Q15: How do you evaluate the risk of FluMist® vaccine complications for you or your family member?**

A15: The FluMist® vaccine is not recommended for individuals with primary immune deficiency disorders and/or any of the above listed medical conditions (A5). It is best to consult with your physician when evaluating the risk of complications for you or your family members.

**Q16: Is treatment available for individuals who develop complications from the FluMist® vaccine?**

A16: One antiviral agent, Tamiflu (Roche) has been approved by the FDA for prevention of Types A and B Influenza in those 13 years of age and older. It is given once daily for up to 42 days and may have benefit if given within 2 days of exposure to influenza strains. However, there are no studies of the use of Tamiflu in primary immune deficient patients exposed to FluMist® influenza strains. If exposed to FluMist® strains of influenza, a primary immune deficient patient should contact his or her physician immediately.

**Q17: How can I find out if FluMist® is being given in my local community?**

A17: For information about FluMist®, contact your state or local health department and/or school system.

**Q18: Where can I find more information?**

A18: Please utilize the following websites:

- Centers for Disease Control: [www.cdc.org](http://www.cdc.org) (click on Influenza).
- Centers for Disease Control and Prevention, National Immunization Program: [www.cdc.gov/nip](http://www.cdc.gov/nip).
- Immune Deficiency Foundation: [www.primaryimmune.org](http://www.primaryimmune.org)
- Clinical Focus on Primary Immune Deficiency Diseases: Immunization of the Immunocompromised Host: [www.primaryimmune.org](http://www.primaryimmune.org) . Go to “Literature” and then to “Clinical Focus”. It is the October 1998 issue.
- U.S. Food and Drug Administration, Center for Biologics Evaluation and Research: [www.fda.gov/cber](http://www.fda.gov/cber).