

## **VOLUNTARY NON-SAFETY-RELATED RECALL OF SPECIFIC LOTS OF NASAL SPRAY VACCINE FOR 2009 H1N1 INFLUENZA**

### **Questions and Answers**

#### **Why are some lots of the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal being recalled from use?**

As part of its quality assurance program, the manufacturer of the nasal spray monovalent H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of its influenza A (H1N1) vaccine during the vaccine's "shelf life", that is after the vaccine has been shipped to providers until its expiration date. Stability testing means measuring the strength (also called potency) of vaccine over time to make sure it does not go down below the pre-specified limit. On December 16 and 21, the manufacturer notified CDC and FDA that the potency of 13 batches (called "lots") of nasal spray vaccine had fallen slightly below a pre-specified limit may fall below that pre-specified limit in the upcoming weeks. The slight decrease in potency should not affect how the vaccine works. However, MedImmune is sending providers directions for returning any unused vaccine from these lots.

#### **What does potency mean for the nasal spray H1N1 vaccine?**

Potency (or strength) is determined by the measurement of the concentration of the active component in the H1N1 vaccine.

#### **Are there any concerns about safety of vaccines from these lots?**

No. There are no safety concerns with these lots of H1N1 vaccine. All lots successfully passed pre-release testing for safety, purity and potency.

#### **Should people who received vaccines from these lots be revaccinated?**

No. The vaccine potency is only slightly below what it is supposed to be. The vaccine in these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots.

#### **What action(s) should parents of children who have received vaccine from the recalled lots take?**

Parents of children who received vaccine from the recalled lots do not need to take any special actions. As is recommended for all 2009 H1N1 vaccines, all children 9 years of age and younger should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. Therefore, children less than 10 years old who have only received one dose of the nasal spray vaccine thus far should still receive a second dose of 2009 H1N1 nasal spray vaccine.

**What are the affected lot numbers?**

The affected lot numbers are:

- 500754P
- 500751P
- 500756P
- 500757P
- 500758P
- 500759P
- 500760P
- 500761P
- 500762P
- 500763P
- 500764P
- 500765P
- 500776P

**How many doses are in these lots?**

There were approximately 4.7 million doses in these lots that were distributed to providers. Most of the doses were shipped to vaccine providers in the first few weeks of the vaccination campaign, during a time when the vaccine potency was still at or above the recommended level. MedImmune is recalling any doses from these lots that may still be unused.

**Is the potency issue related to this recall isolated to just the 13 lots of nasal spray vaccine?**

The voluntary recall described here is specific to the nine lots of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal noted above. Four subsequent lots of the vaccine were produced with a slightly higher potency to decrease the chance that they would fall “below specification” before their expiration dates. These four lots currently remain within specification but are being recalled as a precautionary measure since they may fall slightly below the specification prior to their labeled expiration dates. As per our routine practice, MedImmune will continue to monitor the potency of representative lots of vaccine, and will notify healthcare providers if the shelf life of any additional lots needs to be shortened.

**What testing was performed on these lots of vaccine before they were released?**

Before they were shipped, the lots being recalled now passed all quality controls and met all specifications for safety, purity, and potency.

**What is being done to notify providers who received vaccine from the affected lots?**

MedImmune is sending a notification to providers who received doses from any of the 13 lots of vaccine so that they can return any unused vaccine.

**Where were the affected lots of vaccine distributed?**

Vaccine from these 13 lots was distributed throughout the United States.