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Health Advisory

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MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine: Shortened Shelf Life of Certain Lots

MedImmune announces limited, voluntary, non-safety-related recall of unused affected lots

Through routine, ongoing stability testing of its 2009 H1N1 influenza nasal spray vaccine, MedImmune discovered that the potency (strength) of 13 lots of the vaccine had fallen below a pre-set limit, or were in danger of falling below that limit in the next week. Any doses from these lots remaining in providers' inventory are being recalled out of concern that the vaccine potency will decrease over time to a level that would not provide adequate protection against H1N1 influenza.

Doses that have already been administered from the recalled lots are believed to be just as safe and effective as doses from any other lots of MedImmune H1N1 nasal sprayers. Most of this vaccine was administered while fully potent and within specifications. No doses from affected lots need to be repeated, and no increase in side effects has been reported among individuals who received affected doses. MedImmune will continue to monitor the potency of all of its lots, and providers will be notified if the shelf life of any additional lots is shorter than expected.

A more detailed Q&A about the recall follows this advisory.

Recommendations:

- People who received vaccine from the recalled lots do not need to take any action.
- There is no need to repeat doses administered from these lots.
- As is recommended for all 2009 H1N1 vaccines, all children who were less than 10 years old at the time they received their first H1N1 vaccine should get the recommended second dose of H1N1 vaccine approximately a month later for optimal immune response. Therefore, children who were less than 10 years old at the time they received their first H1N1 vaccine and have received only one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.
- Concerned patients should be told that:
  - There are no safety or efficacy issues with vaccine doses that were given using the recalled lots.
  - Individuals who received vaccine from the recalled lots do not need to take any action, unless a child needs two doses and has not yet completed their two-dose H1N1 series.

The affected lots are:

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

Providers who received vaccine from affected lots:

- PDPH is notifying all immunization providers participating in Philadelphia's H1N1 Vaccine Program who received doses from the affected lots. Any affected doses remaining will be picked up by PDPH staff and replaced if necessary.
- Identify any affected vaccine and set it aside, clearly marking it "DO NOT USE." Do not send affected lots back to MedImmune, even though MedImmune may send you instructions for returning vaccine to them. Providers should hold affected lots until pickup from PDPH staff.

Other H1N1 vaccine products

Although this recall does not affect other H1N1 MedImmune doses or other 2009 H1N1 vaccine products produced by other manufacturers, a **separate** voluntary recall last week involved four lots of sanofi pasteur's injectible H1N1 vaccine, packaged as 0.25 mL pre-filled syringes. This recall was also related to a drop in potency discovered in post-distribution testing. Doses that were given to children from those affected lots are also considered ***safe and effective.*** Providers were already notified about any affected lots of that vaccine that they may have received, and arrangements were made for their pickup and replacement. See https://hip.phila.gov/xv/DiseaseInformation/SwineFlu/tabid/184/Default.aspx or https://kids.phila.gov/flu.aspx or for more information about the sanofi recall.

For More Information about the MedImmune recall:

- CDC's information about the recall: http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_ga.htm.
- MedImmune's information about the recall: http://www.medimmune.com/pdf/H1N1_Recall_QandA_122209.pdf
- CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, available 24 hours a day, every day.

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

Questions and Answers

Adapted from http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_qa.htm

Why are some lots of the nasal spray 2009 H1N1 flu vaccine being recalled?
As part of its quality assurance program, MedImmune, the manufacturer of the monovalent 2009 H1N1 nasal spray flu vaccine, performs routine, ongoing stability testing of its product. Stability testing means measuring the potency (strength) of the vaccine over time to make sure it does not go below a pre-specified limit during the vaccine's "shelf life." On December 18 and 21, the manufacturer notified CDC and FDA that the potency in 13 batches (called "lots") of nasal spray vaccine had decreased below the pre-specified limit, or were at risk of falling below that limit within the upcoming week. The vaccine was within the specified range at the time the vaccine was distributed. The slight decrease in potency should not affect how the vaccine works in persons who were immunized with vaccine(s) from the recalled lots.

What does potency mean for the nasal spray 2009 H1N1 vaccine?
Potency is determined by the measurement of the concentration of antigen (the active ingredient) 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 2009 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. There is no need to re-administer a dose to those who received vaccine(s) from these lots. The vaccine potency is or will soon be only slightly below the limit. In addition, much of this vaccine has already been administered while fully potent and within specifications. The vaccine in these lots is still expected to be effective in stimulating a protective response.

What action(s) should persons who have received vaccine from the recalled lots take?
Persons who received vaccine(s) from the recalled lots do not need to take any special actions. As is recommended for all 2009 H1N1 vaccines, all children who were younger than 10 years old when they received their first H1N1 dose should get the recommended two doses of 2009 H1N1 vaccine approximately a month apart for optimal immune response. Therefore, children who were younger than 10 years old at the time they received their first H1N1 dose who have received only one dose of the nasal spray vaccine thus far should still receive a second dose of 2009 H1N1 vaccine. It is recommended, but not necessary, to use the same type of vaccine for the first and second dose.

What action(s) should providers who have received vaccine from the recalled lots take?
PDPH is notifying all immunization providers participating in Philadelphia's H1N1 Vaccine Program who received doses from the affected lots. Any affected doses remaining will be picked up by PDPH staff and replaced if necessary. Identify any affected vaccine and set it aside, clearly marking it "DO NOT USE." Do not send affected lots back to MedImmune, even though MedImmune may send you instructions for returning vaccine to them. Providers should hold affected lots until pickup from PDPH staff.

What are the affected lot numbers?

500754P	500759P	500761P	500764P
500751P	500758P	500762P	500765P
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500757P			

Is the potency issue related to this recall limited to the 13 lots of nasal spray vaccine?
The voluntary recall described here is specific to the 13 lots of nasal spray 2009 H1N1 flu vaccine noted above. 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. As per routine practice, the manufacturer will continue to monitor the potency of those lots, and will notify healthcare providers if the shelf life of any additional lots is shorter than expected

This recall does not affect 2009 H1N1 vaccine produced by other manufacturers. However, a similar recall was conducted recently, which involved four lots of Sanofi Pasteur's pediatric 2009 H1N1 vaccine in 0.25 mL pre-filled syringes. PDPH contacted providers who had received affected lots and arranged for pickup and replacement of any remaining inventory from those lots.

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

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 October and early November, during a time when the vaccine potency was still at or above the recommended level. The manufacturer is recalling any doses from these lots that may still be unused.

Where were the affected lots of vaccine distributed?
Vaccine from these 13 lots was distributed throughout the United States. Five lots were distributed in Philadelphia.