NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Thomas Farley, MD, MPH
Commissioner

December 15, 2009

Dear Provider:

The Centers for Disease Control and Prevention (CDC) distributed the attached Health Alert Network (HAN) today regarding the voluntary, non-safety-related recall of four lots of Sanofi Pasteur H1N1 influenza vaccine in 0.25 ml pre-filled syringes. Three of these four lots (UT023DA, UT028CB and UT030CA) were distributed to facilities in New York City. Preliminary estimates are that 22,000 doses of the affected vaccine lots were distributed to approximately 128 medical facilities.

Providers are being asked to return any vaccine to the manufacturer because of potency levels that are lower than required. While the antigen content of these lots is below the required specification, CDC and the US Food and Drug Administration agree that the small decrease in antigen content is *not* likely to result in a significant lack of immunity among vaccinated patients. For this reason, there is no need to revaccinate patients who have received vaccine from these lots. The CDC alert, which follows this letter, is available online at www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm.

Children from birth to 4 years of age are more likely than older children and adults to be hospitalized with H1N1 influenza, highlighting the importance of vaccinating this younger age group. In the wake of this recall, providers should use vaccine from multi-dose vials from either Sanofi Pasteur or CSL to immunize children between 6 months 35 months of age. Both have been approved for use in persons 6 months of age and older. For detailed guidance on options for vaccinating young children please go to: http://nyc.gov/html/doh/flu/downloads/pdf/providers/h1n1_provider_letter_1120.pdf.

While children who received vaccine from the affected lots do not need to be revaccinated, they do need to receive two doses of H1N1 vaccine to be fully protected.

If you need to obtain H1N1 vaccine for use in children 6 months to 35 months of age, please email the Health Department at nycflu@health.nyc.gov so we can order needed vaccine for your facility or practice. Thank you.

Sincerely,

Jane R. Zucker

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunization

Department of Health and Human Services
Centers for Disease Control and Prevention

This is a message from the HAN	
Alert Id:	CDCHAN-000303-2009-12-15-UPD-N
Alert Title	Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes
Program type	UPDATE
Status Type	Actual
Severity	Unknown
Acknowledgement Required?	YES
Sensitive?	NO
Message Expiration	UNDETERMINED
Urgency	The Urgency is not known.
Delivery Time	Within 15 Minutes

The text of the message follows:

This is an official CDC Health Update

Distributed via Health Alert Network
December 15, 2009, 10:04 EST (10:04 AM EST)
CDCHAN-00303-09-12-15-ADV-N

Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes

Summary: As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications.In recent testing of the amount of antigen in its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found four distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL.) vaccine with antigen content lower than required potency levels. The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine.

Background

After performing these tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in

one lot of pediatric syringes that had been distributed to providers was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that had fallen below pre-specified limits. This means that doses from these four vaccine lots no longer meet the specifications for antigen content.

Recommendations

While the antigen content of these lots is now below the specification limit for the product, CDC and FDA are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

Providers are being asked to return any vaccine to the manufacturer in the following lots that remains unused to the manufacturer:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25): UT023DA, UT028DA, UT028CB

- 0.25 mL pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70): UT030CA

These lots were shipped in November and are intended for children 6 months through 35 months of age. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers.

All vaccines are thoroughly tested prior to release and shipping to determine that they meet all manufacturer and FDA standards for purity, potency and safety. The affected vaccine met all specifications at the time of release. CDC and FDA have determined that there are no safety concerns for children who have received this vaccine. Sanofi Pasteur has discontinued distribution of the 0.25 mL syringes of H1N1 pediatric vaccines.

The drop in antigen content below the required specification that is described here is specific to Sanofi Pasteur's pediatric H1N1 monovalent vaccine in 0.25 mL pre-filled syringes. The same vaccine packaged in other forms, such as 0.5 mL pre-filled syringes for older children and adults and multi-dose vials, continue to meet specifications.

The antigen content in the affected lots of vaccine is only slightly below the specification limit. The slightly reduced concentration of vaccine antigen found in retesting 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. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multidose vials is that the multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine is produced in single units that do not contain thimerosal.

For More Information:

- For Questions and Answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm
- Call CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.

This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations

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Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes Questions & Answers

CDC, December 15, 2009, 9:00 AM ET

Why are some lots of pediatric H1N1 vaccine manufactured by Sanofi Pasteur in pre-filled syringes being recalled from the market?

As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine

over time. It is performed because sometimes the strength of a vaccine can go down over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one batch (called a "lot") of pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while properly filled at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots.

What does potency mean for the H1N1 vaccine?

Potency (or strength) is determined by the measurement of the concentration of the active ingredient (also called antigen) 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 purity, potency and safety.

Should infants and children who received vaccines from these lots be revaccinated?

No. The vaccine potency is only slightly below the "specified" range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen. There is no need to re-administer a dose to those who received vaccine from these lots. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old 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 vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

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 action, other than to complete the two-dose immunization series if not already completed.

What are the lot numbers affected by this recall?

Vaccine doses with the following lot numbers are included in the recall:

0.25 ml pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25): UT023DA, UT028DA, UT028CB

0.25 ml pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70): UT030CA

How many doses of the pediatric H1N1 vaccine are affected by this recall?

Approximately 800,000 doses of vaccine in these lots were distributed to providers.

Is the potency issue related to this recall isolated to just the pediatric H1N1 vaccine for 6-35 month olds?

The potency problem described here is specific to the four lots of Sanofi Pasteur's pediatric H1N1 vaccine in 0.25 mL pre-filled syringes. Sanofi Pasteur is investigating what caused the problem. The same vaccine packaged in other dosing forms, such as pre-filled syringes for older children adults, and multi-dose vials, continues to meet specifications. This recall does not affect H1N1 vaccine produced by other manufacturers.

Were these lots of vaccine shipped after failing a required test?

No. The lots being recalled passed all quality controls and met all specifications before they were shipped.

All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

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

Sanofi Pasteur will send a notification to providers who received doses from any of the four lots of vaccine so that they can return any unused vaccine.

Where were the affected lots of vaccine distributed?

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

For U.S. children 6-35 months old, what other options are available currently for vaccination against H1N1 influenza?

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials has not experienced this drop in potency and meets all standards of safety, purity and potency. As with all multidose vials of vaccines, these multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation in the 6-35 month age group is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. This vaccine is produced in single-units that do not contain thimerosal. However, it is important that children receive both doses of H1N1 vaccine from the same type of vaccine (both doses as inactivated, injectible, or both doses as live, attenuated, nasal spray vaccine).