

Health Update:

2009 H1N1 Influenza Update 16: Recall of Certain Lots of H1N1 Pediatric Vaccine in Pre-Filled Syringes, Updated Recommendations for the Use of Antiviral Medications

December 15, 2009

This document will be updated as new information becomes available. The current version can always be viewed at <http://www.dhss.mo.gov>.

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Health Update
December 15, 2009

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DIRECTOR

SUBJECT: 2009 H1N1 Influenza Update 16: Recall of Certain Lots of H1N1 Pediatric Vaccine in Pre-Filled Syringes, Updated Recommendations for the Use of Antiviral Medications

This Health Update provides information on: 1) the recall of certain lots of H1N1 pediatric vaccine, and 2) updated recommendations for the use of antiviral medications.

Recall of Certain Lots of H1N1 Pediatric Vaccine in Pre-Filled Syringes

The following is taken from a Health Update issued December 15 by the Centers for Disease Control and Prevention (CDC).

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

Office of the Director
912 Wildwood
P.O. Box 570

Jefferson City, MO 65102

Telephone: (800) 392-0272

Fax: (573) 751-6041

Web site: <http://www.dhss.mo.gov>

- 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.

Updated Recommendations for the Use of Antiviral Medications in Treatment and Prevention of Influenza

On December 7, CDC updated its recommendations for the use of antiviral drugs for treatment and prevention of influenza. *Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season* is available at <http://www.cdc.gov/h1n1flu/recommendations.htm>. Specific updates include the following:

1. Information regarding use of intravenous peramivir under an Emergency Use Authorization.
2. Information on availability of renal dosing for peramivir.
3. Updated oseltamivir dosing instructions for children younger than 1 year of age based on weight.
4. Antiviral treatment and chemoprophylaxis considerations for patients vaccinated with 2009 H1N1 and seasonal influenza vaccines.

5. Guidance on early empiric antiviral treatment for patients with progressive or severe influenza-like illness, regardless of underlying medical conditions.
 6. Guidance on early empiric antiviral treatment for patients with underlying medical conditions placing them at risk for complications.
 7. Clarification of treatment considerations for patients with illness longer than 48 hours.
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Links to comprehensive information and guidance for medical professionals on 2009 H1N1 influenza are available at http://www.dhss.mo.gov/BT_Response/MedProfs.html. Links to comprehensive information and guidance on seasonal influenza are found at <http://www.dhss.mo.gov/PandemicInfluenza/MedSeasonalFlu.html>.

Missourians, including Missouri medical professionals, now have access to a toll-free H1N1 influenza information line. Named the **H1N1 InfoLine**, and sponsored by DHSS, it can provide information and guidance on 2009 H1N1 influenza and H1N1 vaccine to both the public and medical providers. This service is available 24 hours a day, seven days a week at 1-877-FLU-4141 (1-877-358-4141).

