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Health Update

Pandemic H1N1 Vaccine Update

September 28, 2009

- Four manufacturers of the 2009 pandemic H1N1 vaccine have been approved by the FDA, and licensing for one additional manufacturer is expected shortly (see page 2). Manufacturers are using the same processes that they use for making seasonal flu vaccines, which have a long record of producing safe influenza vaccines.
- States will be able to place their first orders for the 2009 H1N1 vaccine on Wednesday, September 30th 2009. Approximately 3 million doses of vaccine are expected to be available for nationwide ordering at that time.
- Keep in mind that while some doses of vaccine will be distributed beginning the first week of October, initial supplies are small and may take several days to weeks to reach clinics and doctors offices.
- During the upcoming weeks more vaccine will be available to the public in more places. The federal government has purchased enough product to provide a total of 250 million doses.
- Based on early results from a trial testing a 2009 H1N1 influenza vaccine in children, it is likely that all children younger than 10 years will need two doses of 2009 pandemic H1N1 flu vaccine. This is slightly different from CDC's recommendations for seasonal influenza vaccination, which state that children younger than 9 who are being vaccinated against influenza for the first time need to receive two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines.
- CDC recommends that the two doses of 2009 H1N1 vaccine be separated by 4 weeks. However, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.
- The national vaccine program will be voluntary. Those interested in vaccination for themselves or their children will receive accurate information about 2009 H1N1 influenza vaccine and the vaccine's benefits and risks so they can make an informed decision. The official H1N1 Vaccine Information Sheets (VIS) are not yet finalized.
- The five initial target groups for pandemic H1N1 vaccination efforts are unchanged. They are: pregnant women, persons who live with or provide care for infants aged <6 months, health care and emergency medical services personnel with direct patient care, children and young adults aged 6 months through 24 years, and persons aged 25 through 64 years who have medical conditions that put them at higher risk for influenza-related complications.
- Simultaneous administration of inactivated vaccines against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and 2009 H1N1 influenza viruses is **not** recommended. If both seasonal and H1N1 vaccines are to be administered simultaneously and one (seasonal or H1N1) is LAIV, the other vaccine (seasonal or H1N1) should be administered as inactivated.
- The Philadelphia Department of Health is currently working with hospitals, medical clinics serving high-risk populations, VFC providers, the Philadelphia School District, local Universities and colleges, and other agencies to make pandemic H1N1 vaccine available across the City. If you have questions about becoming a distribution site for H1N1 pandemic influenza vaccine, please email Vaccines@phila.gov.

FDA Approval of 2009 Novel H1N1 Vaccine: Summary

FDA approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, visit FDA's website at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

Manufacturer	Presentations	Age	Dosage ¹	Type
CSL Limited	<ul style="list-style-type: none"> • 0.5 mL prefilled single-dose syringe (thimerosal free) • 5 mL multi-dose vial containing 10 doses (with thimerosal) 	Adults 18 years of age and older	<ul style="list-style-type: none"> • Single 0.5 mL dose 	Inactivated virus; intramuscular injection
GlaxoSmithKline ²	Awaiting FDA licensure			
Novartis Vaccines and Diagnostics Limited	<ul style="list-style-type: none"> • 0.5 mL prefilled single-dose syringe (trace thimerosal) • 5 mL multi-dose vial (with thimerosal) 	Persons 4 years of age and older	<ul style="list-style-type: none"> • Two 0.5 mL doses approx. 1 month apart for children 4 to 9 • Single 0.5 mL dose for children 10-17 • Single 0.5 mL dose for adults 18 and older 	Inactivated virus; intramuscular injection
Sanofi Pasteur Inc.	<ul style="list-style-type: none"> • 0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod • 0.5 mL prefilled single-dose syringe (thimerosal free) • 0.5 mL single-dose vial (thimerosal free) • 5 mL multi-dose vial (with thimerosal) 	Persons 6 months and older	<ul style="list-style-type: none"> • Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age • Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years • Single 0.5 mL dose for children 10 years and older • Single 0.5 mL dose for adults 18 and older 	Inactivated virus; intramuscular injection
MedImmune, LLC	<ul style="list-style-type: none"> • 0.2 mL prefilled single-dose intranasal sprayer 	Persons aged 2 to 49 years	<ul style="list-style-type: none"> • Two 0.2 mL doses approx. 1 month apart for children 2 to 9 • Single 0.2 mL dose for persons 10-49 	LAIV; Intranasal spray

¹ Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

² The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).

For more information about the H1N1 influenza vaccine program visit <https://hip.phila.gov/>.