



SHORTENED EXPIRATION PERIOD FOR SANOFI PASTEUR

2009 H1N1 VACCINE IN PRE-FILLED SYRINGES

QUESTIONS & ANSWERS

February 3, 2010

1. Why is Sanofi Pasteur changing the expiration dates of 2009 H1N1 vaccine in pre-filled syringes?

To ensure that its vaccine meets potency standards, Sanofi Pasteur (the manufacturer) is shortening the expiration period of all its 2009 H1N1 influenza vaccine in pre-filled syringes that are **not** included in either of the two previous Sanofi Pasteur H1N1 vaccine recalls [See [Non-Safety-Related Voluntary Recall of Sanofi Pasteur H1N1 Vaccine in Pre-filled Syringes Questions & Answers \(February 2010\)](#) and [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 \(December 2009\)](#)].

2. What is the new expiration date?

All lots of monovalent 2009 H1N1 influenza vaccine in pre-filled syringes manufactured by Sanofi Pasteur, not included in the two earlier recalls, should now be administered by February 15, 2010 regardless of the expiration imprinted on the package.

3. What was the original expiration date on these H1N1 vaccines before the manufacturer changed them?

The previous expiration dates were from March to June, 2011.

4. Are there any concerns about the safety of these vaccines?

There are **no safety concerns** with these lots of 2009 H1N1 vaccine. People who received vaccine from the lots with shortened shelf life **do not need to take any action**.

5. What lots are affected by this change in dating?

The dating is being shortened on all remaining doses of pre-filled syringes that are **not** included in either of the two previous Sanofi Pasteur H1N1 vaccine recalls [See [Non-Safety-Related Voluntary Recall of Sanofi Pasteur H1N1 Vaccine in Pre-filled Syringes Questions & Answers \(February 2010\)](#) and [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 \(December 2009\)](#)].

For specific lot numbers, see the official CDC Health Alert Network Update regarding [Sanofi Pasteur Monovalent 2009 \(H1N1\) Influenza Vaccine in Pre-Filled Syringes - Shortened Shelf Life of Certain Lots](#).

This shortened expiration period along with the two recent recalls [See [Non-Safety-Related Voluntary Recall of Sanofi Pasteur H1N1 Vaccine in Pre-filled Syringes Questions & Answers \(February 2010\)](#) and [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 \(December 2009\)](#) affects all of Sanofi Pasteur's 2009 H1N1 influenza vaccine in pre-filled syringes that were distributed this season. No additional Sanofi Pasteur pre-filled syringes will be available. However, 0.5 mL pre-filled syringes from Novartis and CSL remain available.

This shortened expiration period does not affect Sanofi Pasteur's 2009 H1N1 influenza vaccine in multi-dose vials.

6. How many doses were in these lots?

There were approximately 12 million doses in these lots.

7. What is being done to notify health care providers of this change in dating?

In the week of February 1, 2010, the manufacturer sent notification detailing the change in dating to health care providers who received shipments from the affected lots.