



September 2024

IMPORTANT CORRECTION OF DRUG INFORMATION

Subject: Fluzone (Influenza Vaccine) Syringe Label-Formatting Error in the 2-Dimensional Data Matrix Barcode Encoding Lot Number and Expiration Date

Dear Health Care Provider:

Sanofi is notifying you of a formatting error in the 2-Dimensional (2-D) data matrix barcode on some Fluzone (Influenza Vaccine) syringe labels that could cause the data to not transfer appropriately in electronic medical recording systems. The human readable information on the syringe label including the National Drug Code (NDC), expiration date, and lot number are correct.

This letter is being sent to customers who have previously received prefilled syringes of Fluzone from the affected lots and is being provided to customers as they receive shipments of prefilled syringes from the affected lots. The affected product lot numbers are listed on pages 3 through 8 of this letter.

The 2-D data matrix barcode on the syringe (see Fig 1) is designed to be read by GS1 compliant scanners and encodes the NDC, product expiration date, and lot number. However, there is a formatting error affecting all doses from the listed lots, which prevents the data from being uploaded correctly. While the NDC, expiration date, and lot number are correct in the 2-D data matrix barcode, the order of the lot number and expiration date were reversed.

Please see pages 3 through 8 of this letter for a list of the affected lots and a corrected 2-D data matrix barcode for each lot number. Each 2-D data matrix barcode is unique to a specific lot number. For customers who scan this information electronically, please use the corrected 2-D data matrix barcode on pages 3 through 8 of this letter. Please verify you are using the correct 2-D data matrix barcode for the lot number printed on each syringe (Fig 1). For customers who manually enter this information as printed on the syringe label, there is no change to the process.

For customers who distribute Fluzone throughout their facility or have multiple locations where vaccine may be administered, please ensure the information in this letter, including the corrected 2-D data matrix barcodes, is provided to persons responsible for recording vaccination information.



Sanofi recognizes the disruption this error may introduce into your medical practice, and we sincerely apologize for the inconvenience. Corrective and preventive actions are being implemented to avoid this error in future vaccine labeling.

Please note that there are no vaccine quality or patient safety or effectiveness concerns associated with the syringe labels impacted by the 2-D data matrix barcode error.

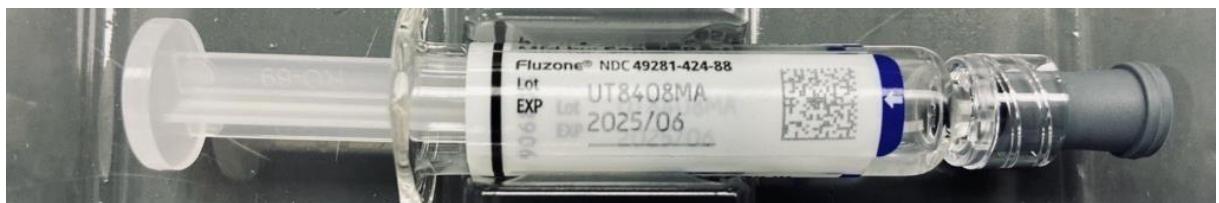
Please visit VaccineShop.com and Vaxserve.com where an electronic copy of this letter is also available. If you have further questions, please contact us at 1-800VACCINE (1-800-822-2463) or for Vaxserve at 1-800-752-9338.

Sincerely,

Ayman Chit
Head of Medical, Vaccines
North America

Figure 1. The label on each prefilled syringe of Fluzone® (Influenza Vaccine) contains a **2-D data matrix** (NDC + lot number + expiration embedded)

Below is an example of a syringe label with a 2-D data matrix barcode that will be uploaded incorrectly by electronic scanners. This image also shows the location of the printed NDC, lot number (Lot) and product expiration date (EXP).









MAT-US-2409282-v1.0-09/2024



Lot numbers and corrected 2-D data matrix barcodes:

Please verify you are using the correct 2-D data matrix barcode for the lot number printed on each dose.

UT8408KA 	UT8408MA 
UT8408NA 	UT8415JA 
UT8415KA 	UT8423JA 

UT8423JB



UT8423LA



UT8423NA



UT8434JA



UT8434LA



UT8459JA



UT8459LA



UT8459MA



UT8459NA



UT8468KA















UT8468NA



UT8475LA



<p>UT8475MA</p> 	<p>UT8475NA</p> 
<p>UT8485KA</p> 	<p>UT8485MA</p> 
<p>UT8485NA</p> 	<p>UT8488KA</p> 

<p>UT8488NA</p> 	<p>UT8496KA</p> 
<p>UT8496NA</p> 	<p>UT8506JA</p> 
<p>UT8506KA</p> 	<p>UT8506NA</p> 

UT8514JA



UT8514KA



UT8514MA

