VFC Update

Vaccines for Children Program

January 19, 2024

Expanded Vaccine Recall of Certain Lots of Merck's VAXNEUVANCE™

Dear VFC Provider,

In July 2023, Merck and the VFC Program had previously sent notices about a voluntary recall of certain lots of VAXNEUVANCE™ vaccine. The VFC Program has been made aware that Merck is expanding the voluntary recall for VAXNEUVANCE™ (NDC# 00006-4329-03) due to customer reports of breakage at the syringe flange and/or hub. This voluntary partial recall is specific to defects in the syringe and is not related to a quality or safety concern with the vaccine substance manufactured by Merck that is inside the syringe. Details about this recall are included in the attached notification packet that Merck is sending to all providers who received vaccine from one or more of the recalled lots, with specific instructions on returning remaining products.

This recall is only for the following ten lot numbers and does not apply to any other lots:

Lot Number	Expiration Date
W037992	10Dec2024
W027275	09Jul2024
W036242	01Oct2024
W039033	01Oct2024
X004289	10Dec2024
X005583	10Dec2024
X011328	01Jan2025
X011332	01Jan2025
X012044	10Jan2025
X011735	10Jan2025

If you have any of the recalled lots at your practice, immediately quarantine and discontinue use of these doses and return to Merck according to their recall notification. If you no longer have the affected lots, complete Merck's business reply card anyway so that they can account for all product distributed.

To address some questions your practice may have about the recalled vaccine:

- If already administered, are the recalled lots considered a valid dose?
    - Any administered doses of the recalled lots would still be considered valid. Merck's recall is regarding the syringe breakage and not about the quality of the vaccine itself.

- How should providers account for the recalled vaccine?
    - Since the recalled lots should be returned to Merck via Sedgwick, VFC Providers will not be able to return the vaccines as they would other VFC vaccines. Instead, please submit a Wastage Form through your myVFCvaccines account to report these doses as non-usable but cannot be returned to the VFC Program.

- If you received one of the recalled lots, how can you receive more vaccine?
    - You can place a supplemental vaccine order on myVFCvaccines to request more VAXNEUVANCE™ vaccine. If your last order was more than 30 days ago, please include your full vaccine inventory for your other available vaccines on your order form to help with vaccine accountability.

For questions about the recall process (including how to return the recalled product), please contact Sedgwick, Inc: (877)-650-9404.

For questions about this recall or to report any adverse events, please contact Merck's National Service Center: 800-672-6372, Select Prompt #1, then Prompt #2. Adverse events should also be reported to the Vaccine Adverse Event Reporting System (VAERS).

For any other VFC questions, please reach out to the VFC Customer Service Center at 877-243-8832.

Thank you,

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