MERCK

URGENT: VACCINE RECALL

January 2024

Dear Customer,

This is to inform you of a voluntary product recall of:

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection
Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735

See enclosed product label for ease in identifying the product at the wholesale/CDC or user levels.

We previously contacted you regarding the voluntary product recall of certain lots of VAXNEUVANCE™. This is to inform you that Merck has expanded the voluntary recall for VAXNEUVANCE™ Lots **W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735** in the US market to **the user level.** The Company has received reports of breakage at the syringe flange and/or hub that could be identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or during post-administration (e.g., when activating a safety needle). The breakage resulted in a small number of injuries, including laceration and needle puncture.

Our Company's investigation to date has determined the breakage to result from a step in the syringe supplier manufacturing process that causes weakness in the glass and a subsequent force that results in glass breakage. Corrective Action and Preventative Actions (CAPA) have been implemented at the syringe manufacturer to improve processes to help prevent these defects from recurring in future lots. VAXNEUVANCE™ syringes from ten Lots (**W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735)** under the scope of this recall have the potential for these defects to be present. Merck has accelerated the supply of post-CAPA material to the U.S. market and has established a stable supply of this post-CAPA VAXNEUVANCE™ material to U.S. customers. Therefore, the recall is being expanded given the stable supply of post-CAPA material at this time.

Accordingly, Merck recommends that if you have VAXNEUVANCE™ from Lots **W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735** or any of the recalled lots at your facility, you immediately quarantine and discontinue use of these doses and return all these pre-filled syringes in accordance with the attached recall notification. This product was distributed between 16-Nov-2022 through 28-Jul-2023.

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Immediately examine your inventory and quarantine product subject to this recall.

This recall should be carried out to the user level, including healthcare professionals and administering institutions. Your assistance is appreciated and necessary to prevent further potential injuries.

Please complete the enclosed Business Reply Cards and the Packing Slips labeled "Non-VFC (Vaccines For Children) or Non-CDC Vaccine" and "CDC VFC (Vaccines for Children) and CDC Adult Vaccine," including the entry of number of cartons / syringes returned as soon as possible.

This recall is being made with the knowledge of the United States Food and Drug Administration.

Martha Bomar

Martha Bomar
Associate Vice President, West Point Quality Operations