Confidential

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IMPORTANT INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Subject: Voluntary Recall and Handling Instructions Due to Potential for Breakage of VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Pre-Filled Syringes

Dear Healthcare Professional:

Merck Sharp & Dohme LLC (herein referred to as "our Company") has initiated a voluntary recall of VAXNEUVANCE™ Lots W021510, W021512, W021637, W027250, and W028846 in the US market because our Company has received a higher than expected number of customer reports of breakage at the syringe flange and/or hub, including some associated with injuries.

The breakages were 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 needle safety mechanism). At this time, the breakages have resulted in a small number of reported injuries, including lacerations and needle punctures.

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. Actions have been implemented at the syringe manufacturer to improve processes to help prevent these defects from recurring in future batches. However, all VAXNEUVANCE™ syringes currently in the marketplace have the potential for these defects to be present because the syringes were manufactured before corrective actions were implemented at the supplier.

In response to this issue, Merck is proceeding with the following action:

Voluntary Recall of VAXNEUVANCE™ Lots in the US Market

As stated above, our Company has initiated a voluntary recall of VAXNEUVANCE™ Lots W021510, W021512, W021637, W027250, and W028846 in the US market. Accordingly, our Company recommends that if you have VAXNEUVANCE™ from any of the recalled lots at your facility, you immediately quarantine and discontinue use of these doses and return all of these prefilled syringes. Recall notifications are being issued to all customers who have received the lots above with instructions for return of product.

For questions about this recall, please contact:

Merck National Service Center: 800-672-6372. Select Prompt #1 then Prompt #2. (Monday to Friday 8:00 AM to 7:00 PM EST).

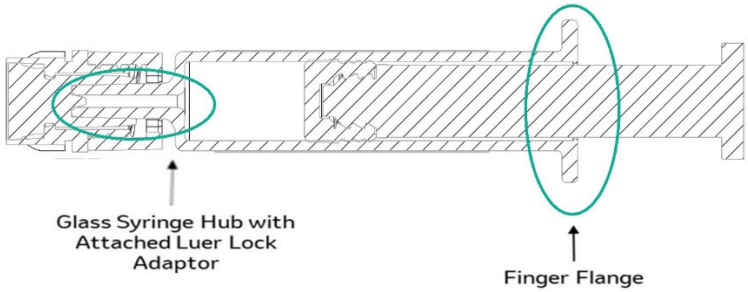
Instructions Before Handling and Use of Non-Recalled VAXNEUVANCE™ Lots

To reduce the potential risk of injury to the patient, caregiver, and/or healthcare professional, our Company recommends the following during the preparation of VAXNEUVANCE™:

- Carefully inspect the glass syringe for breakage while in the package and after removal from the package (see Figure 1).
- If breakage of the syringe is observed, do not attempt to administer the dose and please contact the Merck National Service Center at (800) 672-6372.

Please note that breakage may occur in syringes even if there are no visible defects.

Figure 1



*Green circles in the figure above represent breakage sites of the reported complaints.

Please ensure that the staff in your institution involved in administering VAXNEUVANCE™ are aware of these recommendations.

Reporting of Product Complaints and Adverse Events

For questions about this letter or to report any product complaints or adverse events, please contact the Merck National Service Center at (800) 672-6372. Select Prompt #1, then Prompt #2. (Monday to Friday 8:00 AM to 7:00 PM (EST)).

In addition, adverse events or quality problems experienced with the use of this product may be reported to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS) by calling (800) 822-7967 or online at www.vaers.hhs.gov.

We appreciate your immediate attention to and implementation of our Company's recommendations. Before administering VAXNEUVANCE™, please read the accompanying Prescribing Information. Patient Information is also available.

Sincerely,

Anne E. de Papp MD

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Vice President & Head US Medical Affairs
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