Direct Healthcare Professional Communication

Vaxneuvance (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) suspension for injection in pre-filled syringe: Important information regarding the potential for breakage of Vaxneuvance pre-filled syringes.

Dear Healthcare Professional,

MSD in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Breakage at the flange and/or hub of the syringe, resulting in lacerations or needle puncture wounds, have been reported for Vaxneuvance suspension for injection in pre-filled syringe.**
- **Further investigation has revealed that this is related to a component issue. While corrective and preventive actions have been implemented to address this defect, all Vaxneuvance syringes currently on the market have the potential for these defects.**
- **To reduce the potential risk of injury to the patient, caregiver and/or healthcare professional, it is recommended that the glass syringe be carefully inspected for breakage before use and the dose discarded if breakage is observed or suspected prior to use of Vaxneuvance.**
- **If no breakage is observed prior to use, during vaccine preparation and administration, healthcare professionals should avoid exerting excessive force on the syringe (including on the hub of the syringe) when removing the tip cap or attaching the needle to the syringe, or post-administration (e.g., when activating a needle safety mechanism), and during disposal.**

Background

Vaxneuvance is available as a suspension for injection in pre-filled syringe. MSD has received reports of breakage at the syringe flange and/or hub that were identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or post-administration (e.g., when activating a needle safety mechanism). The breakage resulted in a small number of injuries reported as non-serious, including laceration and needle puncture wounds.

Investigation conducted by MSD to date has determined the breakage to result from a step in the syringe manufacturing process that causes weakness in the glass and, when a subsequent force is applied, results in glass breakage. Actions have been implemented at the syringe manufacturer to improve processes and 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 by the supplier.

The following recommendations are being proposed to help identify broken syringes before use and reduce the risk of injury. Please ensure that the staff in your institution involved in administering Vaxneuvance follow instructions available in the full product prescribing information and these additional instructions detailed below:

[1]Date of publication on EMA website

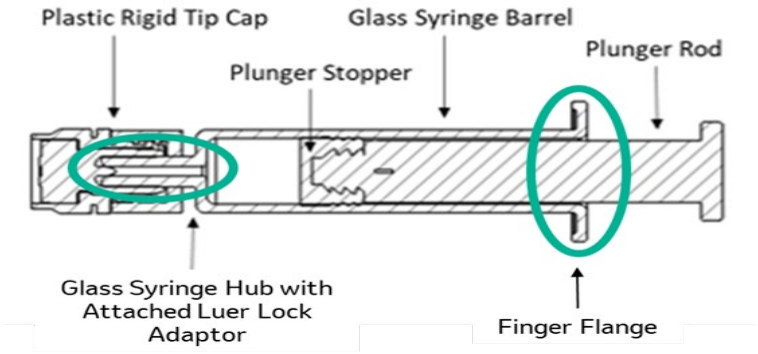
Prior to Use

- MSD recommends inspection of the syringe for breakage while in the package and after removal from the package.
- If breakage of the syringe is detected or suspected, please discard and do not attempt to administer the dose.

During Vaccine Preparation and Administration

- If no breakage is observed, proceed with administering the dose. Avoid exerting excessive force on the syringe, including on the hub of the syringe, when removing the tip cap, when securing the needle to the syringe, or post-administration (e.g., when activating a needle safety mechanism), and during disposal (Figure 1).

Figure 1.



Call for reporting

Healthcare professionals should report any suspected adverse reactions and/or product quality complaints associated with the use of Vaxneuvance in accordance with the national spontaneous reporting system *<include the details (e.g. name, postal address, fax number, web address) on how to access the national spontaneous reporting system>*.

Per the approved Summary of Product Characteristics:

- In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
- ▼Vaxneuvance is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Company contact points

Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address

Yours sincerely,

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Vaxneuvance (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) suspension for injection in pre-filled syringe
Marketing authorisation holder(s)	Merck Sharp & Dohme B.V.
Safety concern and purpose of the communication	Important information regarding the potential for breakage of Vaxneuvance pre-filled syringes.
DHPC recipients	Healthcare providers who administer Vaxneuvance (e.g. general practitioners, specialists, community pharmacists, hospital pharmacists, nurses). The target group will be further defined at the national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	Unless otherwise directed by their National Competent Authority, all EU Member States that have distributed doses of Vaxneuvance, as of 09Aug2023, which include: Austria, Belgium, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Iceland, Ireland, Italy, Latvia, Netherlands, Norway, Portugal, Romania, Spain, Sweden. For the remaining EU Member States where Vaxneuvance is approved but not distributed, which include: Bulgaria, Croatia, France, Hungary, Liechtenstein, Lithuania, Luxembourg, Malta, Poland, Slovakia, and Slovenia, dissemination of the DHPC will be determined at the national level.

Timetable	**Date**
DHPC and communication plan (in English) agreed by CHMP	30 Aug2023
Submission of translated DHPCs to the national competent authorities for review	06 Sep2023
Agreement of translations by national competent authorities	13 Sep2023
Dissemination of DHPC	20 Sep2023