URGENT: Notification of VACCINE RECALL

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October 19, 2020

Dear Customer:

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

GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant), Lot R030456

Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc. ("Merck"), has initiated this voluntary recall because a limited number of units of GARDASIL®9 prefilled syringes from Lot R030456 were stored at temperatures outside their respective temperature specifications, during their shipment by a third-party delivery service, to the McKesson Medical Surgical Inc. ("McKesson") facility in Chino, California, prior to further shipment to customers of McKesson.

This recall only affects GARDASIL®9 prefilled syringes that:

- belong to Lot R030456; and
- were shipped from the McKesson facility in Chino, California; and
- were received and/or administered by customers of McKesson on or after August 12, 2020.

GARDASIL®9 is a temperature-sensitive vaccine and exposure to temperatures above the recommended storage conditions of 2-8°C (36-46°F) may reduce the potency of the vaccine and potentially impact vaccine effectiveness. Available stability data suggest that there will be little to no effect on the appearance of the vaccine or the integrity and performance of the syringe as a result of exposure to temperatures above the recommended storage conditions.

Merck recommends that health care providers (HCPs) receiving this notice immediately discontinue use of the GARDASIL®9 belonging to Lot R030456. Merck also suggests that HCPs receiving this notice review the records of individuals who were vaccinated with GARDASIL®9 on or after August 12, 2020 to determine if any individuals received a dose of a GARDASIL®9 prefilled syringe from Lot R030456. In the event that a dose from the affected lot was administered, another dose of GARDASIL®9 is recommended, considering the following schedule[1]:

- If a dose of vaccine from Lot R030456 was administered for the 1st dose in the vaccination series for a patient, restart the vaccination series no sooner than two months after the date on which the dose of vaccine was administered.

- If a dose of vaccine from Lot R030456 was administered as the 2nd dose in the vaccination series for a patient, administer one replacement dose no sooner than two months after the

[1] According to the ACIP recommendations for HPV vaccinations, the series does not need to be restarted if the vaccination schedule is interrupted. The number of recommended doses is based on age at administration of the first dose. Reference: Meites E, Kempe A, Markowitz LE. Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2016;65:1405–1408. DOI: http://dx.doi.org/10.15585/mmwr.mm6549a5.

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date on which first dose was administered, then continue the vaccination series as normal. For example:

  - administer a replacement second dose no sooner than two months after the date on which the dose from Lot R030456 was administered, then
  - administer a third dose no sooner than four months after the date on which the replacement dose was administered.

- If a dose of vaccine from Lot R030456 was administered as the 3rd dose in the vaccination series for a patient, administer one replacement dose no sooner than two months after the date on which the 3rd dose of vaccine was administered to complete the vaccination series.

The HCP should consider the individual clinical need and discuss with the individual/ caregiver the benefit-risk of vaccination.

In order to ensure an effective recall and return process, please examine your inventory and quarantine all remaining units of GARDASIL®9 belonging to Lot R030456. Once quarantined, product should be returned according to the following procedure:

- Please complete and return the enclosed postage-paid business reply card(s) and packing slip(s) as soon as possible. Please be sure to indicate the number of units of the affected lot that you have returned.
- Please complete and return a copy of the business reply card(s) and packing slip(s) even if you do not have in your inventory any remaining units of the affected lot, so that we can be sure to account for all units distributed or administered.
- Using the prepaid shipping label(s), please return the packing slip(s) and all units belonging to the affected lot in your inventory to:

Stericycle, Inc.
Attn: Event 5707
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you require additional prepaid shipping labels, packing slips or business reply cards, please contact Stericycle, Inc. at (888) 566-2512.

GARDASIL®9 Lot R030456 is the only lot of GARDASIL®9 affected by this recall. The units belonging to Lot R030456 were further distributed by McKesson to customers located solely within the United States (California and Nevada). This recall will not impact the supply of GARDASIL®9. There is adequate inventory to replace recalled product at this time.

For questions about the recall process, including how to return the units belonging to the affected lot, please contact:

- Stericycle, Inc. at (888) 566-2512

- If you have any other questions about this recall or wish to report any adverse events following vaccination, please contact:

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- the Merck National Service Center at (800) 672-6372 (Monday to Friday, 8:00 a.m. to 7:00 p.m. (EST)). Select Prompt #1 then Prompt #2.

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.

INDICATION

GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

GARDASIL 9 is indicated in males 9 through 45 years of age for the prevention of anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

GARDASIL 9 does not eliminate the necessity for vaccine recipients to undergo screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers as recommended by a health care provider.

GARDASIL 9 has not been demonstrated to provide protection against diseases caused by:

- HPV types not covered by the vaccine
- HPV types to which a person has previously been exposed through sexual activity

Not all vulvar, vaginal, anal, oropharyngeal and other head and neck cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

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SELECT SAFETY INFORMATION

GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.

The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in males were injection-site pain, swelling, and erythema.

The duration of immunity of GARDASIL 9 has not been established.

Before administering GARDASIL®9, please read the Prescribing Information. The Patient Information also is available. The Prescribing Information and Patient Information also can be obtained from the Merck National Service Center or at www.merckvaccines.com.

Customers will be reimbursed for the units impacted by the recall of GARDASIL®9 that are returned as described above. Customers with questions about units that have been administered to patients should call 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).

This recall is being conducted with the knowledge of the Food and Drug Administration.

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

Sincerely,

Richard M. Haupt, MD, MPH
Vice President and Head, Vaccines & Infectious Diseases
Global Medical & Scientific Affairs
Merck Research Labs
Merck Sharp & Dohme Corp.