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:

RECOMBIVAX HB® [Hepatitis B Vaccine (Recombinant)]
Pediatric/Adolescent 0.5 mL Vials
Lot T007984

Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc. ("Merck"), has initiated this voluntary recall because a limited number of units of RECOMBIVAX HB® (pediatric) vials belonging to Lot T007984 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 RECOMBIVAX HB® (pediatric) vials that:

- belong to Lot T007984; 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.

RECOMBIVAX HB® (pediatric) 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 on the integrity and performance of the vial as a result of exposure to temperatures above the recommended storage conditions.

Merck recommends that healthcare providers (HCPs) receiving this notice immediately discontinue use of vials of RECOMBIVAX HB® (pediatric) belonging to Lot T007984. Merck also suggests that HCPs receiving this notice review the records of individuals who were vaccinated with RECOMBIVAX HB® (pediatric) on or after August 12, 2020 to determine if any individuals received a dose of RECOMBIVAX HB® (pediatric) from Lot T007984. In the event that a dose from the affected lot was administered, another dose of RECOMBIVAX HB® (pediatric) is recommended consistent with Advisory Committee for Immunization Practices (ACIP) Recommendations (please see "Interrupted Schedules and Minimum Dosing Intervals")[1] as follows:

"Inadequate doses of HepB vaccine or doses received after a shorter-than-recommended dosing interval should be readministered, using the correct dosage or schedule."

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

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[1] Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Recommendations and Reports / January 12, 2018 / 67(1);1–31. Available at https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF.

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In order to ensure an effective recall and return process, please examine your inventory and quarantine all remaining units of RECOMBIVAX HB® (pediatric) belonging to Lot T007984. 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 from the recalled 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.

RECOMBIVAX HB® (pediatric) Lot T007984 is the only lot of RECOMBIVAX HB® (pediatric) affected by this recall. The units belonging to Lot T007984 were further distributed by McKesson to customers located solely within the United States (Arizona, California, and Hawaii). This recall will not impact the supply of RECOMBIVAX HB® (pediatric). 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:
    - 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 AND USAGE

RECOMBIVAX HB is indicated for prevention of infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB is approved for use in individuals of all ages.

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SELECTED SAFETY INFORMATION

Do not administer RECOMBIVAX HB to individuals with a history of severe allergic or hypersensitivity reactions (eg, anaphylaxis) after a previous dose of any hepatitis B-containing vaccine or to any component of RECOMBIVAX HB, including yeast.

The vial stopper and the syringe plunger stopper and tip cap contain dry natural latex rubber, which may cause allergic reactions in latex-sensitive individuals.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including RECOMBIVAX HB, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. For RECOMBIVAX HB, this assessment should include consideration of the mother's hepatitis B antigen status and high probability of maternal transmission of hepatitis B virus to infants born to mothers who are HBsAg positive if vaccination is delayed.

Hepatitis B vaccination should be delayed until 1 month of age or hospital discharge in infants weighing <2000 g if the mother is documented to be HBsAg negative at the time of the infant's birth. Infants weighing <2000 g born to HBsAg positive or HBsAg unknown mothers should receive vaccine and hepatitis B immune globulin (HBIG) in accordance with ACIP recommendations if HBsAg status cannot be determined.

Hepatitis B virus has a long incubation period. RECOMBIVAX HB may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccination.

Vaccination with RECOMBIVAX HB may not protect all individuals.

In healthy infants and children (up to 10 years of age), injection site reactions and systemic adverse reactions were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis.

Before administering RECOMBIVAX HB® (pediatric) please read the Prescribing Information. The Prescribing 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 RECOMBIVAX HB® (pediatric) 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.

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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.