



**NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE**
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April 12, 2018

Dear Colleague:

As you may be aware, Merck is experiencing a manufacturing issue that has caused the supply of its hepatitis B vaccine, Recombivax HB[®], to be reduced. The adult formulation is not anticipated to be available in 2018; the pediatric/adolescent formulation will be available only through the Vaccines for Children (VFC) program in 2018, and only in limited supply. For the month of April, the New York City VFC program is not experiencing any restrictions on hepatitis B vaccine; when restrictions do occur, a message will be posted on the VFC ordering screen in the Online Citywide Immunization Registry (CIR) ordering tool.

Because other hepatitis B-containing vaccines are available, little or no impact to routine childhood immunization is anticipated. Providers may use the other monovalent hepatitis B vaccine product (Engerix-B[®], GSK) or the hepatitis B-containing combination product (DTaP-IPV-HepB [Pediatrix[®], GSK]) as alternatives. At this time, it is anticipated that there will be adequate supplies of these other vaccines. Please note that by using these products, all children will be able to be fully immunized on time.

For adults, in addition to Engerix-B, providers may use the hepatitis A-hepatitis B combination product (Twinrix[®], GSK).

Please see the attached letter from the Centers for Disease Control and Prevention (CDC) that includes sample alternative childhood immunization schedules to use during the shortage. This information is also available on CDC's Current Vaccine Shortage & Delays website, at <https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html>. For questions about VFC orders, please contact the VFC program at 347-396-2405 or email us at nycimmunize@health.nyc.gov. For updated information from Merck on the shortage, please refer to <https://www.merckvaccines.com/SupplyStatus>.

We will continue to keep you informed as we receive additional information. Updates will be posted to the VFC ordering screen in the Online CIR. Thank you for keeping NYC children safe from vaccine-preventable diseases.

Sincerely,

A handwritten signature in black ink that reads 'Jane R. Zucker'.

Jane R. Zucker, MD, MSc

Pediatric Hepatitis B Vaccination Guidance during the 2018 Supply Shortage

Merck's supply of pediatric hepatitis B vaccine (Recombivax HB®) will continue to be limited for the remainder of 2018 due to a manufacturing issue. To supplement current vaccine availability, GSK will continue to make an increased amount of pediatric hepatitis B-containing vaccine available, including both single-component vaccine (Engerix-B®) and combination vaccine (Pediatrix®).

This increase is sufficient to address the gap in supply related to Merck's manufacturing issue so that infants and young children can continue to receive their recommended hepatitis B vaccine series on time. Importantly, sufficient single-component hepatitis B vaccine will be available to continue to deliver the birth dose of hepatitis B vaccine for infants.

CDC has provided general guidance for pediatric hepatitis B vaccine and an implementation plan that provides options for giving vaccine during this time.

Pediatric hepatitis B vaccine general guidance:

The recommendations for hepatitis B vaccination of infants have **not** changed.

Providers should continue with the recommendations as written in the [Advisory Committee on Immunization Practices \(ACIP\) hepatitis B vaccine recommendations](#).

- Only single-component hepatitis B vaccine should be used for any dose given before 6 weeks of age, including the birth dose.
- During this time, providers should prioritize birth dose vaccination and infant series completion over child and adolescent catch-up vaccination. However, children and adolescents who are at risk for infection as described in the [ACIP hepatitis B vaccine recommendations](#)¹ should be vaccinated.

For infants whose mothers are hepatitis B surface antigen (HBsAg)-negative:

- Administer single-component hepatitis B vaccine to infants:
 - Weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, within 24 hours of birth
 - Weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, at 1 month of age or when discharged from the hospital
- The third HepB dose can be administered at 6–18 months.
- In populations with high rates of childhood HBV infection (e.g., Alaska Natives, Pacific Islanders, and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), the first dose of HepB vaccine should be administered at birth and the final dose at age 6–12 months.

For infants whose mothers are HBsAg-positive or hepatitis B status unknown:

- Administer single-component hepatitis B vaccine to infants within 12 hours of birth. Complete the series within 6 months using available single-component or combination vaccine.
 - For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, the birth dose should not be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month.

For considerations of serology testing prior to vaccination, refer to the guidance on persons recommended to receive serologic testing prior to vaccination in the [ACIP hepatitis B vaccine recommendations](#).

For additional information, see the [Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger](#)².

¹ ACIP hepatitis B vaccine recommendations can be found at:

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF>.

² Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger can be found at:

<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.



Guidance for Completing the Hepatitis B Series during a Recombivax HB® Shortage: 2018

This document includes clinical considerations and sample schedules for completing the hepatitis B series for children using single-component and combination vaccine products during the Recombivax HB shortage.

Clinical considerations:

- **The recommendations for hepatitis B vaccination of infants have NOT changed.** Providers should continue to follow the recommended schedule outlined in the [Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger](#).
- Only single-component HepB vaccine (Engerix-B® or Recombivax HB) should be used for any dose administered BEFORE 6 weeks of age, including the birth dose. DTaP-IPV-HepB (Pediarix®) should NOT be administered before 6 weeks of age.
- The minimum age for the final (third or fourth) dose of hepatitis B vaccine is 6 months (24 weeks) of age.
- A vaccine series begun with a single-component vaccine can be completed using combination vaccines.
- Providers using single-component vaccine should note the third dose of HepB vaccine is recommended at 6–18 months of age. When vaccinating healthy infants born to hepatitis B surface antigen-negative mothers, single-component HepB vaccine may be administered later within the time frame recommended for the third dose.
 - In populations with high rates of childhood HBV infection (e.g., Alaska Natives, Pacific Islanders, and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), administer the final dose at age 6–12 months.
- Providers who are using Pediarix vaccine may continue vaccinating infants with no change to clinical practices. The supply of Pediarix vaccine is sufficient to support current immunization recommendations.
- Infants born to mothers who are hepatitis B surface antigen-positive mothers or mothers with unknown hepatitis B status:
 - These infants should complete the series within the first 6 months, followed by serologic testing.
 - Along with hepatitis B vaccine, hepatitis B immune globulin (HBIG) may be recommended. For recommendations regarding use of HBIG, see the [Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger](#).
- The same manufacturer's DTaP vaccine should be used for all doses in a series. If this is not possible, or if the manufacturer of previous doses is not known, administer any comparable vaccine that is available.

Vaccine supply updates and questions:

- Updates for vaccine supply will be posted on the [CDC Current Vaccine Shortages and Delays](#) web page.
- Health care personnel who have questions or need additional information—contact your state or local health department's immunization program or nipinfo@cdc.gov.

2018 Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger: <https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>

Advisory Committee on Immunization Practices (ACIP) Hepatitis B vaccine recommendations: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html>

CDC Current Vaccine Shortages & Delays webpage:

<https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html>



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

These sample immunization schedules apply to infants born to hepatitis B surface antigen-negative mothers

1. Using Pediarix for all doses after the birth dose

| Birth ¹ | 2 months | 4 months | 6 months ² | 12–15 months | 15–18 months |
|--------------------|---------------------------|---------------------------|---------------------------|--------------|-------------------|
| HepB | Pediarix DTaP-HepB-IPV | Pediarix DTaP-HepB-IPV | Pediarix DTaP-HepB-IPV | | |
| | | | | | DTaP ³ |
| | Hib | Hib | Hib ⁴ | Hib | |

2. Using Pediarix and single-component DTaP and IPV

| Birth ¹ | 2 months | 4 months | 6 months ² | 12–15 months | 15–18 months |
|--------------------|---------------------------|----------|---------------------------|--------------|-------------------|
| HepB | Pediarix DTaP-HepB-IPV | DTaP | Pediarix DTaP-HepB-IPV | | |
| | | IPV | | | DTaP ³ |
| | | Hib | Hib ⁴ | Hib | |

3. Using Pentacel[®] and single-component HepB vaccine

| Birth ¹ | 2 months | 4 months | 6 months ² | 12–15 months | 15–18 months |
|--------------------|--------------------------|--------------------------|--------------------------|--------------|-------------------|
| HepB | HepB | | HepB | | |
| | Pentacel DTaP-IPV/Hib | Pentacel DTaP-IPV/Hib | Pentacel DTaP-IPV/Hib | | DTaP ³ |
| | | | | Hib | |

4. Completing the hepatitis B series using all single-component vaccines

| Birth ¹ | 2 months | 4 months | 6 months ² | 12–15 months | 15–18 months |
|--------------------|----------|----------|-----------------------|--------------|-------------------|
| HepB | HepB | | HepB | | |
| | DTaP | DTaP | DTaP | | DTaP ³ |
| | IPV | IPV | IPV | | |
| | Hib | Hib | Hib ⁴ | Hib | |

¹For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, vaccine given at birth should NOT be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches 1 month of age. Complete the series within 6 months.

²For infants weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, vaccine given at birth DOES count as part of the vaccine series. Two additional doses (for a total of 3 doses) should be administered. A series that includes 4 doses is acceptable, but not required. Complete the series within 6 months.

³The 4th dose of DTaP may be administered as early as age 12 months, provided at least 6 months have elapsed since the 3rd dose.

⁴If using PedvaxHIB a dose at 6 months is not needed.

These sample immunization schedules apply to infants born to hepatitis B surface antigen-positive or unknown status mothers

1. Completing the hepatitis B series using Pediarix for all doses after the birth dose

| Birth¹ | 2 months | 4 months² | 6 months | 12–15 months | 15–18 months |
|--------------------------|---------------------------|-----------------------------|---------------------------|---------------------|---------------------|
| HepB | Pediarix DTaP-HepB-IPV | Pediarix DTaP-HepB-IPV | Pediarix DTaP-HepB-IPV | | |
| | | | | | DTaP ³ |
| | Hib | Hib | Hib ⁴ | Hib | |

2. Completing the hepatitis B series using Pentacel

| Birth¹ | 2 months | 4 months² | 6 months | 12–15 months | 15–18 months |
|--------------------------|--------------------------|-----------------------------|--------------------------|---------------------|---------------------|
| HepB | HepB | HepB | HepB | | |
| | Pentacel DTaP-IPV/Hib | Pentacel DTaP-IPV/Hib | Pentacel DTaP-IPV/Hib | | DTaP ³ |
| | | | | Hib | |

3. Completing the hepatitis B series using all single-component vaccines

| Birth¹ | 2 months | 4 months² | 6 months | 12–15 months | 15–18 months |
|--------------------------|-----------------|-----------------------------|------------------|---------------------|---------------------|
| HepB | HepB | HepB | HepB | | |
| | DTaP | DTaP | DTaP | | DTaP ³ |
| | IPV | IPV | IPV | | |
| | Hib | Hib | Hib ⁴ | Hib | |

¹For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, vaccine given at birth should NOT be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches 1 month of age. Complete the series within 6 months.

²For infants weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, vaccine given at birth DOES count as part of the vaccine series. Two additional doses (for a total of 3 doses) should be administered. A series that includes 4 doses is acceptable, but not required. Complete the series within 6 months.

³The 4th dose of DTaP may be administered as early as age 12 months, provided at least 6 months have elapsed since the 3rd dose.

⁴If using PedvaxHIB a dose at 6 months is not needed.