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TO: California Vaccines for Children (VFC) Program Providers

FROM: John Talarico, D.O., M.P.H., Chief
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SUBJECT: HIBERIX™ (HAEMOPHILUS INFLUENZAE TYPE B (HIB) CONJUGATE VACCINE) IS NOW AVAILABLE FROM VFC

This memo is divided into sections to enable you to quickly access the information

SUMMARY

On August 19, 2009, the United States Food and Drug Administration (FDA) licensed Hiberix™ (GlaxoSmithKline Biologicals (GSK) as the Hib booster (final) dose for children 15 months through 4 years who have previously received the primary Hib vaccination series. Hiberix™ is a *Haemophilus influenzae* type b conjugate (tetanus

toxoid conjugate) vaccine. The Advisory Committee on Immunization Practices (ACIP) recommends Hib booster vaccination for children at ages 12 through 15 months. Hiberix™ (Hib conjugate vaccine) is now available from VFC in California. This document summarizes information about the use of Hiberix ™ in the VFC program and provides updated recommendations as supplies of Hib-containing vaccine increase in the United States. Because the available Hib containing vaccines are confusing, we encourage you to review this information with your clinic or office staff.

BACKGROUND AND COMPOSITION

Hiberix™ is a *Haemophilus influenzae* type b (Hib) conjugate vaccine composed of *H. influenzae* type b capsular polysaccharide (polyribosyl-ribitol-phosphate) conjugated to inactivated tetanus toxoid (PRP-T). Hiberix™ is supplied as a lyophilized powder for reconstitution with sterile 0.9% saline solution which is supplied as a separate prefilled syringe. Hiberix™ does not contain thimerosal or latex (in the stopper or syringe).

It is important to use the correct diluent and lyophilized vaccine together. **Do not** use any other sterile liquid or other sterile saline diluent (e.g., 0.4% saline diluent (vial) used for ActHIB™) to reconstitute the lyophilized Hiberix™ vaccine. Use only the provided prefilled syringe diluent for reconstitution of Hiberix™. The diluent syringe can be stored at room temperature before reconstitution.

RECOMMENDATIONS FOR VACCINE USE

Eligible Groups for Receipt of VFC Supplies of Hiberix™

VFC supplies of Hiberix™ may be given to VFC-eligible young children aged 12 months through 4 years.

Licensed Dosing Schedule

Hiberix™ is licensed to be given as the booster (final) dose for Hib vaccination for children 15 months through 4 years who have received a primary Hib vaccination series. Hiberix™ is not licensed for the primary vaccination series. ACIP recommends the Hib booster dose at ages 12 through 15 months. Hiberix™ may be administered as early as age 12 months, if the minimum interval of 8 weeks has been met since the last dose of Hib vaccine. Please see the package insert for further information on Hib conjugate vaccine administration. Hiberix™ is not licensed for use for the primary Hib vaccination series; however, if Hiberix™ is inadvertently administered during the primary series, the dose can be counted as valid.

Minimum age and interval for Hib booster dose:

- Minimum age: 12 months
- Minimum interval between last dose of the primary series and the booster dose: 8 weeks

Recommended Schedule Based on Hib Vaccine Supplies

In December 2007, one of the major manufacturers of Hib vaccine in the U.S. voluntarily recalled and suspended production of their Hib vaccine products. This manufacturer produced approximately half the doses of Hib vaccine in the U.S. The Centers for Disease Control and Prevention (CDC) subsequently recommended deferring the Hib booster dose for all non-high-risk children. After FDA licensure of Pentacel™, a combination vaccine containing DTaP, IPV, and Hib vaccine components, CDC recommended reinstatement of the booster dose of Hib vaccine for children aged 12 through 15 months who have completed the primary 3-dose series and also recommended a booster dose for older children for whom the booster dose was deferred at their next health care visit.

With the licensure of Hiberix™ for the Hib booster dose, CDC is anticipating increased supplies of Hib-containing vaccine. CDC now recommends that providers begin recalling children in need of a booster dose when feasible and monovalent Hib vaccine supply in the office is adequate.

Current Recommendations:

- Infants should receive their primary Hib series at ages 2, 4, 6 months, and a Hib booster dose on time at 12 through 15 months of age.
- Children aged 12 months through 4 years (before fifth birthday) who did not receive a booster dose because of the recent shortage of Hib vaccine should receive a booster with any of the available Hib-containing vaccines at the earliest opportunity.
- With licensure of Hiberix™ and anticipated distribution, the increased supply of Hib-containing vaccines may be sufficient to support a provider-initiated notification process to contact all children whose Hib booster dose had been deferred.
- Until supplies are adequate, providers should continue to follow previous recommendations to provide the booster dose at the child's next regularly scheduled visit.

We are still encouraging practices that are still not using a pentavalent vaccine during infancy to consider using one of the available pentavalent vaccines to decrease the number of shots during infancy, which should benefit your families as well as your staff. We will work with you in your transition in ordering appropriate supplies of vaccine for your patients. Infants already started on single-entity vaccines can finish the series with separately administered DTaP, IPV, and Hib vaccines.

Because of the Hib-containing vaccine shortage since December 2007, physician offices have had to change their normal vaccination routine for Hib-containing vaccines (e.g., changing type of Hib-containing vaccines, deferring the booster dose, etc.). CDPH realizes that this may have been difficult for providers and their staff. Because both ActHIB™ and Hiberix™ are lyophilized vaccines, offices which carry both vaccines should carefully review the differences between the two vaccines with their staff,

including the different diluents and age indications. Please make sure that staff use the correct diluent for each vaccine and do not confuse the two vaccines. Writing the age indications with the names of the vaccines on labels may be useful for staff to help distinguish the two vaccines during a busy clinic. Storing the correct accompanying diluent with the lyophilized vaccine vial might also be helpful so that the correct diluent is used for each vaccine.

Administration
Instructions for reconstitution and administration of Hiberix™ (see package insert for details or manufacturer's website for more information (http://www.hiberix.com/packaging-dosage-administration.html):

- Cleanse vial stopper.
- Attach safety-engineered needle to the prefilled syringe (diluent) and insert needle through stopper of the vial of lyophilized Hiberix.™
- Inject the diluent into the vial.
- With needle still inserted, shake vial vigorously.
- After reconstitution, immediately withdraw reconstituted Hiberix™ vaccine into syringe and administer intramuscularly.
- Hiberix™ should be used promptly after reconstitution or stored at 2 to 8 °C and administered within 24 hours.
- Store vaccine at 2 to 8 °C (35 to 46 °F). Store diluent refrigerated at 2 to 8 °C (36 to 46 °F) or at a controlled room temperature at 20 to 25 °C (68 to 77 °F). Do not freeze diluent.
- Discard reconstituted vaccine if not used within 24 hours.

Administration with other vaccines
Hiberix™ may be given at the same time as other recommended vaccines. Hiberix™ should be given at a separate site with a different syringe.

HOW SUPPLIED

Hiberix™ is provided in a 10 dose package containing 10 vials of lyophilized vaccine. Prefilled TIP-LOK syringes (without needles) containing saline diluent are packaged separately from the vials of Hiberix™ in cartons of 10 disposable syringes.

The Product No. is 58160-80605.

DILUENT INFORMATION

CDPH, Immunization Branch was informed by CDC that some Hiberix™ product may not have cartons of accompanying diluent included in their shipment with the Hiberix™ lyophilized vaccine. Providers should check their shipments of Hiberix™ for both the cartons of lyophilized vaccine (vials) and cartons of sterile 0.9% saline diluent in pre-

filled syringes. If there are no cartons of diluent included in shipments of Hiberix™, providers should contact GSK:

1. Call the GSK Vaccine Service Center at 1-866-475-8222.
2. Request the sterile saline diluent, NDC 58160-951-11, for use with Hiberix™

The diluent will be shipped to you directly at no cost by GSK. Please make sure to contact GSK, not McKesson, regarding missing Hiberix™ diluent. Please do NOT use any other diluent for reconstitution of Hiberix™.

When you receive the replacement 0.9% saline diluent in prefilled syringes from GSK, please do not confuse this with actual vaccine. The diluent must be only used to reconstitute the lyophilized Hiberix™ vaccine (packaged in vials). We are sorry for any inconvenience or confusion this may cause your practice.

ORDERING AND BILLING

How to order

VFC providers may order Hiberix™ using the attached VFC order form (DHS 8501, 10/09), which has been modified to include this new product. Remember to complete all sections of the VFC order when submitting your vaccine request. Requests for this product should be included with your routine VFC vaccine request, as you will need to provide current vaccine inventory on hand for all VFC vaccines and their corresponding usage in order for VFC to process your request. Please be aware that your request may be adjusted, especially during this introductory phase and during the transition with Hib vaccine supplies.

Billing Information for VFC Vaccine

CHDP: Claims may be submitted for doses of Hiberix™ administered using the same Hib vaccine administration code used for other Hib conjugate vaccines. The CHDP administration fee is $9.00 using CHDP code **38**.

CHDP Provider Information Notices can be found at http://www.dhcs.ca.gov/services/chdp/Pages/CHDPPLPIN.aspx.

Medi-Cal Fee-For-Service (FFS): The CPT code for administration of Hiberix™ by VFC providers for Medi-Cal is **90648-SL.**

Other codes for the use of Hiberix™ that is not supplied by VFC:

- The CPT code for Hiberix™ is **90648 (***Haemophilus influenzae* type b [Hib]—tetanus toxoid conjugate).
- The ICD-9-CM code for Hiberix™ is **V03.81**.

POTENTIAL VACCINE REACTIONS

- The most common reported local adverse events noted within 4 days of vaccination with Hiberix were:
  - Redness and pain at the injection site
- Common general adverse events reported include fever, fussiness, loss of appetite, restlessness, and sleepiness.

Report suspected reactions to Hiberix™ or other vaccines to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or http://vaers.hhs.gov.

CONTRAINDICATIONS

- History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of Hib-containing vaccine, any ingredient of Hiberix™ vaccine, or tetanus toxoid-containing vaccine.

PRECAUTIONS

- Moderate to severe acute illness.

DOCUMENTATION

Vaccine Information Statement (VIS) and fact sheet: A Hib Vaccine Information Statement (12/16/98) is available for use. This VIS sheet can be found at http://www.cdc.gov/vaccines/pubs/vis/default.htm. Additional information on vaccines and vaccine preventable diseases can be found at: http://www.cdc.gov/vaccines/.

Product Insert: Refer to the product package insert for Hiberix™ for additional vaccine information. This may be found at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM179530.pdf

VFC Resolution No. 6/08-5 (Vaccines to Prevent *Haemophilus influenzae type b*):
The VFC resolutions for Hib-containing vaccines may be found at:
http://www.cdc.gov/vaccines/programs/vfc/acip-vfc- resolutions.htm.

ACIP and AAP recommendations: ACIP recommendations for Hib vaccine use are posted at http://www.cdc.gov/vaccines/pubs/ACIP-list.htm. AAP vaccine recommendations and other information about Hib vaccines are available to AAP members at http://www.cispimmunize.org/ .

Licensure of Hiberix™ and updated recommendations for use of Hib vaccine:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm?s_cid=mm5836a5_e

General Recommendations on Immunization (includes minimum ages and intervals): http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf

Vaccine Injury Compensation Program (VICP): Hiberix™ is covered by the federal VICP. Information on the federal VICP and Hib-containing vaccines may be found at: http://www.hrsa.gov/vaccinecompensation/.

Enclosures: Order Form (10/09)
Immunization Schedule with Combination Vaccine

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