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July 23, 2009

To: Hospitals, Providers, Local Health Departments

From: New York State Department of Health, Bureau of Immunization

**HEALTH ADVISORY: UPDATED RECOMMENDATIONS FOR THE USE OF
HAEMOPHILUS INFLUENZAE TYPE B (HIB) VACCINE:
REINSTATEMENT OF THE BOOSTER DOSE AT 12-15 MONTHS
Please distribute immediately to all patient and primary care areas.**

SUMMARY

- On December 13, 2007, certain lots of *Haemophilus influenzae* type b (Hib) vaccine marketed as PedvaxHIB® (monovalent Hib vaccine) and Comvax® (Hib-HepB vaccine), manufactured by Merck & Co., Inc., were recalled voluntarily, and the company temporarily suspended production of these vaccines.
- To conserve the limited supply of Hib-containing vaccines, the Centers for Disease Control and Prevention (CDC), on December 18, 2007, recommended that vaccination providers temporarily defer the routine Hib vaccine booster dose administered to most healthy children at age 12-15 months.
- Production of Merck Hib vaccine products is still suspended; however, two other Hib-containing vaccines manufactured by Sanofi Pasteur have been available for use in the United States during this shortage: monovalent Hib vaccine (ActHIB®) and DTaP-IPV/Hib (Pentacel®).
- Beginning in **July 2009**, the manufacturer of these two vaccines will have a sufficient number of doses of these two products to reinstate the Hib vaccine booster dose.
- Effective immediately, the CDC is recommending reinstatement of the booster dose of Hib vaccine for children aged 12-15 months who have completed the primary 3-dose series. Infants should continue to receive the primary Hib vaccine series at ages 2, 4, and 6 months. Children aged 12-15 months should receive the booster dose on time.
- Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter. Supply is not sufficient to recall all children who did not receive the 12-15 month booster.
- The CDC states there is enough **Hib containing vaccine** for a four dose series. However, it does not specify the availability of any particular Hib containing vaccine. **At present the majority of product currently available to the New York State (NYS) Vaccine Program**

is **Pentacel®**. Providers will need to use this product to reinstate the 4 dose series for as many children as possible.

REINSTATEMENT OF HIB BOOSTER DOSE

Effective immediately, the CDC, in consultation with the Advisory Committee on Immunization Practices (ACIP), American Academy of Family Practitioners (AAFP), and the American Academy of Pediatrics (AAP), is recommending reinstatement of the booster dose of Hib vaccine for children aged 12-15 months who have completed the primary 3-dose series. Infants should continue to receive the primary Hib vaccine series at ages 2, 4, and 6 months. Children aged 12-15 months should receive the booster dose on time. Older children for whom the booster dose was deferred should receive their Hib booster dose at the next routinely scheduled visit or medical encounter. Although supply is sufficient to reinstate the booster dose and begin catch-up vaccination, supply is not yet ample enough to support a mass notification process to contact all children with deferred Hib booster doses. Please note that the NYS Immunization Information System (NYSIIS) can assist with identifying children due for the booster dose.

At each routinely scheduled appointment or medical encounter, clinicians should discuss with parents the reasons for the change in recommendation and consider (1) reviewing electronic or paper medical records or immunization information system records to identify children in need of a booster dose before physician encounters, (2) evaluating children's vaccination status during their scheduled visit, and (3) sharing immunization schedules with parents to make them aware of this plan.

USE OF COMBINATION VACCINES

During the Hib shortage, children may have received Hib and other vaccines for their primary vaccination series with various available combination vaccines (e.g., DTaP-IPV/Hib [Pentacel®] and DTaP-IPV-HepB [Pediarix®]) and monovalent vaccines (e.g., ActHib®, HepB, and IPV). Therefore, a mismatch might exist between patient vaccination needs and the available stock of vaccine formulations (e.g., combination products versus single-antigen vaccines) in local provider offices.

This situation presents a challenge for providers to administer vaccines that ensure appropriate coverage while minimizing extra doses of unneeded vaccine. For example, if a provider is using Pentacel® vaccine to protect infants against Hib disease, the provider should attempt to ensure that adequate stock of monovalent HepB vaccine is available to complete the HepB vaccine series. Children who need the Hib booster and who already have received 4 doses of DTaP should receive monovalent Hib vaccine (ActHIB®) as their Hib booster dose. However, if DTaP-IPV/Hib is the only Hib-containing vaccine available, this combination product can be used to complete the series of Hib vaccinations, even if the child will receive extra doses of DTaP and IPV.

HIB VACCINE SUPPLY

Vaccination providers with questions about their supplies of monovalent Hib vaccine (ActHIB®) or Pentacel® purchased with nonpublic funds should contact Sanofi Pasteur's customer service department (telephone, 1-800- 822-2463). Sanofi Pasteur will work directly with physicians to

increase allotments of Hib-containing vaccines on the basis of previous purchasing patterns or practice birth cohort and estimates of additional vaccine doses needed.

Vaccination providers with questions about public vaccine supply, including the Vaccines for Children Program (VFC) and the State Child Health Insurance Program (Child Health Plus or CHIP), should contact the Bureau of Immunization's Vaccine Program Hotline (1-800-543-7468) to obtain information.

The CDC states there is enough **Hib containing vaccine** for a four dose series. However, it does not specify the availability of any particular Hib containing vaccine. **At present the majority of product currently available to the New York State (NYS) Vaccine Program is Pentacel®.** Providers will need to use this product to reinstate the 4 dose series for as many children as possible.

MORE INFORMATION

This recommendation reflects CDC's assessment of the existing national Hib vaccine supply and will be updated if the supply changes. Information about the national Hib vaccine supply and Questions and Answers for providers and parents are available at:

<http://www.cdc.gov/vaccines/vac%2Dgen/shortages/>

For additional information on the total number of HIB doses required for children, please see Table 1, Catch Up schedule at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5751a5.htm?s_cid=mm5751a5_e

Additional information on Protecting Infants against Hepatitis B Virus Infection when using Pentacel® Vaccine during the Hib Vaccine Shortage is available at:

<http://www.cdc.gov/vaccines/vac-gen/shortages/downloads/eo-hib-hepb-cov.pdf>

To access a complete web-text (HTML) version of Updated Recommendations for the Use of *Haemophilus Influenzae* Type B (Hib) Vaccine: Reinstatement of the Booster Dose at 12-15 Months, published in the Morbidity and Mortality Weekly Report on (MMWR) on June 26, 2009, go to:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5824a5.htm>