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DATE: December 21, 2007 IZB-FY0708-06
TO: Public and Private Sector Vaccines for Children (VFC) Providers
FROM: Howard Backer, M.D., M.P.H., Chief Immunization Branch
SUBJECT: *Haemophilus Influenzae*, Type B (Hib) Vaccine Shortage

The recent suspension of production by Merck & Co., Inc. of PedvaxHIB[®] and Comvax[®] and Merck's subsequent voluntary recall of certain lots of both vaccines have led to a significant disruption in the supply of *Haemophilus influenzae* type b (Hib) containing vaccines. The Centers for Disease Control and Prevention (CDC) is making some Hib vaccine available from its stockpile, and Sanofi Pasteur is increasing production of its licensed Hib vaccines, ActHIB[®] and TriHIBit[®] (DTaP/Hib) to attempt to meet the current demand for Hib vaccine in the United States. However, a significant temporary shortage of Hib-containing vaccines is now expected.

NEW INTERIM RECOMMENDATIONS

A CDC Dispatch has been published in the Morbidity and Mortality Weekly Report, which can be found at: <http://www.cdc.gov/mmwr/pdf/wk/mm56d1219.pdf>.

It provides additional details on the expected shortage and interim recommendations. In brief, recommendations include:

- Temporary deferral of the routine Hib vaccine booster dose administered at 12-15 months of age except for children who are at increased risk for invasive Hib disease, as described below. A register and tracking system should be developed to facilitate recalling these children when vaccine supply improves. Those providers who are on the registry should use it to track and recall patients once vaccine is again available.
- Children at increased risk for invasive Hib disease should continue to receive the recommended booster dose of Hib vaccine at 12-15 months of age. Children at increased risk include: American Indian and Alaskan Native children (AI/AN), and children with sickle cell disease, HIV infection, anatomic or functional asplenia, malignancies or other immunocompromising conditions. Any Hib-containing vaccine licensed for use at 12-15 months of age (PedvaxHIB[®], ActHIB[®], or TriHIBit[®]) can be administered. TriHIBit[®] is only licensed to be administered at the 12-15 month of age visit.

- The primary series of PRP-OMP (PedvaxHIB[®]) is two doses, whereas PRP-T (ActHIB[®]) requires a three-dose primary series (see Table 1).

Table 1. Primary and Booster Hib Vaccination Schedule

| Vaccine | 2 Months | 4 Months | 6 Months | 12-15 Months |
|--|----------|----------|----------|--------------|
| PRP-T (ActHIB [®]) | Dose 1 | Dose 2 | Dose 3 | DEFERRED |
| PRP-OMP (PedvaxHIB [®] or ComVax [®]) | Dose 1 | Dose 2 | | DEFERRED |

When it becomes necessary to complete a series with ActHIB[®] that was started with PedvaxHIB[®] or ComVax[®], the following guidelines should be followed:

- If the first two doses of PedvaxHIB[®] or Comvax[®] were administered as the primary series, no further doses are needed to complete the primary series.
- If only one dose of PedvaxHIB[®] or Comvax[®] has been administered, the primary series should be completed with two additional doses of ActHIB[®].

Physicians who serve predominantly American Indian/Alaska Native populations should attempt to give a PRP-OMB containing vaccine as the first dose because of the high risk of invasive Hib disease at an early age in this population and the more rapid protective antibody response seen with PRP-OMB. The CDC will prioritize distribution of remaining stocks of PRP-OMB containing vaccines for use in AI/AN children living in predominantly AI/AN communities.

VACCINE ORDER PROCESSING

The VFC Program has been given a limited allocation for Hib vaccine from CDC. Orders may be reduced due to the new recommendations and limited supply. The VFC Program will make every effort to ensure that providers have enough vaccine on hand to complete the primary series. Orders received by the VFC Program requesting PedvaxHIB[®] will be substituted with Sanofi Pasteur's ActHIB[®]. The only exception will be for Tribal/Indian Health Service Clinics that see predominantly Native Americans living in predominantly American Indian communities.

Although Sanofi is increasing production of their DTaP/Hib combination vaccine, TriHIBit[®] (only licensed for the administration of the booster dose), this vaccine is not available through California's VFC Program.

VACCINE RETURNS

Stericycle, the company that is handling vaccine returns for Merck, will send a standard packet to each VFC provider that received recalled vaccine. The packet contains

detailed instructions on how to send the vaccines to Stericycle, along with a pre-paid mailing label. Please note that providers should send the vaccine to Stericycle and not to our regular vaccine distributor, McKesson Specialty. Providers may return both private and VFC vaccine in the same container as long as they are clearly marked. Detailed instructions can also be found on Merck's website: <http://www.merckvaccines.com/PCHRecall.pdf>.

For a listing of additional products that are currently unavailable through VFC, please visit the VFC program's website at www.vfcca.org.

QUESTIONS?

If you have any questions, please contact VFC Customer Service at 1-877-243-8832 (1-877-2GET-VFC).

Enclosures: MMWR Dispatch

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