

Vaccine Supply Update

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



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Outline

- **Vaccine updates:**
 - **Hib vaccines**
 - **Varicella-containing vaccines**
 - **Hepatitis A vaccines**

Hib Vaccines, I

- Shortage began in December 2007 with a voluntary recall of certain lots by Merck
 - CDC's interim recommendations called for deferral of booster dose at age 12-15 months, except for infants at increased risk for Hib disease
 - Vaccine availability during the shortage to date
 - Hib vaccines manufactured by sanofi pasteur (ActHIB and Pentacel) have been used for all children except AI/AN living in AI/AN communities
 - AI/AN children living in AI/AN communities have received Merck's unrecalled PedvaxHib from CDC stockpile
- Merck originally projected to return to US market during 4th quarter of 2008

Hib Vaccines, II

- **October 17, 2008: Merck released a public statement that they will not return to the US market until mid-2009**
- **Reason for delayed return is an additional manufacturing process change requiring a regulatory filing with FDA that must be approved prior to return to market**

Hib Vaccines, III

- **No change in Hib recommendations at this time**
 - Continue deferral of booster dose for children 12-15 months of age, except for those at increased risk of Hib disease
 - Children at increased risk of Hib disease include those with asplenia, sickle cell, leukemia and other malignant neoplasms, and AI/AN children
 - AI/AN children living in AI/AN communities will be provided with PedvaxHib from CDC's stockpile
 - Providers should register and track children in whom the booster dose is deferred to facilitate recall

Hib Vaccines, IV

- **CDC is currently working closely with sanofi pasteur as they review their current Hib vaccine supply and capacity to serve the US market**
 - **At this time, sanofi pasteur is confident that they have sufficient hib doses (ActHIB and Pentacel) to cover the 3 dose series through mid 2009.**
- **The CDC stockpile currently has sufficient PedvaxHib to provide vaccine for AI/AN children living in AI/AN communities for the new expected duration of the shortage**

Varicella-containing Vaccines

- **Current/projected supply of single antigen varicella vaccine is sufficient for anticipated demand in 2008, 2009 (including 2nd dose catch-up)**
- **Zoster vaccine is being produced but there are currently distribution delays of approximately 8-14 weeks**
- **MMRV vaccine is not currently available. Merck will provide an update on return to market once production capacity issues for zoster vaccine are resolved.**

Hepatitis A Vaccines

- **Merck is not currently accepting orders for pediatric and adult hepatitis A vaccines (Pediatric & Adult VAQTA®)**
 - **Merck estimates that Pediatric VAQTA® will be available in fourth quarter 2008 and Adult VAQTA® in first quarter 2009**
- **GSK production and supply of their pediatric and adult hepatitis A vaccines (Pediatric & Adult Havrix®) and their Adult hepatitis A/hepatitis B combination vaccine (Twinrix®) are currently in good supply to meet demand.**