

**HIBERIX®**  
**[*Haemophilus influenzae* type b (Hib) vaccine]**

- ◆ Hiberix®, manufactured by GlaxoSmithKline (GSK), is approved in the U.S. for use as a booster dose for children 15 months through four years of age.
- ◆ This newly approved vaccine is for the prevention of invasive disease caused by *Haemophilus influenzae* type b (Hib), an often severe and potentially deadly bacterial infection that can cause meningitis. The review of Hiberix for the booster indication was conducted under accelerated approval regulations due to the shortage of Hib vaccine supply in the U.S.
- ◆ Hiberix is approved for use as the booster dose for children who have received the primary series of any other licensed Hib conjugate vaccine. The Centers for Disease Control and Prevention (CDC) recommends that children receive the complete Hib vaccination series. The series includes a booster dose in the second year of life, in addition to a complete primary series of immunization in infants.
- ◆ Earlier this summer, the CDC reinstated the routine Hib booster dose due to an increase in supply. However, supply was not sufficient to support a mass catch-up effort for the millions of children who did not receive the booster dose during the shortage. Hiberix will help restore supply so children who missed the booster dose can get caught-up. Additionally, children coming in for routine visits can receive the Hib booster dose on time.
- ◆ Hiberix is expected to be available within several weeks.

**About Hib Disease**

- ◆ Invasive Hib disease is caused by bacteria called *Haemophilus influenzae* type b (Hib). Hib disease is an often serious, potentially life-threatening illness, with a number of complications. The most common type of invasive Hib disease is meningitis.
- ◆ Hib disease usually occurs in children under five years of age, and immunization is the best preventive measure against the disease. In the U.S., Hib occurs primarily in underimmunized children and among infants too young to have completed the primary immunization series. Due to routine use of the Hib conjugate vaccines in the late 1980s, the incidence of Hib disease in infants and young children in the U.S. has decreased by more than 99 percent.
- ◆ The Hib vaccine shortage began in 2007 when another vaccine manufacturer temporarily suspended manufacturing of its Hib containing vaccines. This led the CDC to recommend temporary deferral of the booster dose for healthy children not at increased risk for Hib disease. Since 2008, small outbreaks of invasive Hib disease, including several deaths, have been reported across the country.

**Immune Response and Safety Profile**

- ◆ GSK submitted safety and efficacy information from clinical studies conducted outside the U.S. for this review. In those studies, a booster dose of Hiberix following primary series vaccination provided protective levels of antibodies against Hib bacteria, regardless of the priming vaccine that was used.
- ◆ More than 54 million doses of Hiberix have been distributed outside the U.S. since the 1996 launch in Germany, and the vaccine is currently registered in nearly 100 countries.
- ◆ Hiberix is indicated for active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b. Hiberix is approved for use in children 15 months through 4 years of age (prior to fifth birthday). In clinical studies, adverse events in children receiving Hiberix included pain and redness at the injection site, fever, fussiness, loss of appetite, and restlessness. A severe allergic reaction (e.g. anaphylaxis) after a previous dose of any Hib or tetanus toxoid-containing vaccine or any component of Hiberix is a contraindication. If Guillain-Barré syndrome has occurred within six weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give Hiberix should be based on careful consideration of the potential benefits and possible risks. Vaccination with Hiberix may not protect 100% of susceptible individuals.

**GlaxoSmithKline: A Worldwide Leader in Vaccines**

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. GlaxoSmithKline Biologicals is a global vaccine company which has shown to be a leader in innovation. The company is active in the fields of vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development.