New Hib Booster Vaccine Shores Up Supply

BY ELIZABETH MECHCATIE

The Food and Drug Administration has approved a new Haemophilus influenzae type b (Hib) vaccine for use as a booster dose in children aged 15 months through 4 years, providing another option for children whose boosters were deferred as a result of the nationwide Hib vaccine shortage that began almost 2 years ago.

The monovalent Hib vaccine is Hiberix (*Haemophilus* b conjugate vaccine [tetanus toxoid conjugate]), which is manufactured by GlaxoSmithKline (GSK). It was first marketed in Germany in 1996, and is now available in almost 100 countries, including the United States, according to the GSK Web site.

"This approval will provide an additional safe and effective vaccine to help ensure that there is an adequate Hib vaccine supply during necessary catch-up vaccinations," Dr. Karen Midthun, acting director of the FDA's Center for Biologics Evaluation and Research, said in a statement.

Under its accelerated approval program, the FDA concluded that Hiberix was safe and effective as a booster dose in the United States, based on data from seven studies of more than 1,000 children that was conducted in Europe, Latin America, and Canada. As a condition of the accelerated approval, GSK will conduct a postmarketing study of Hiberix in the United States, which will evaluate the safety and immunogenicity of Hiberix as a booster and primary vaccine, compared with a Hib vaccine that is already available in the United States, according to the statement.

The nationwide shortage of Hib vaccine dates back to December 2007, a result of a voluntary recall and subsequent suspension of Merck & Co.'s PedvaxHIB and COMVAX, two of the four Hib vaccines licensed in the United States for primary and booster doses. The shortage prompted the Centers for Disease Control and Prevention to recommend that the Hib booster be deferred for children who were not at high risk for infection, which was in effect from Dec. 18, 2007, through June 25, 2009. But after Sanofi-Aventis increased production of its Hib-containing vaccine doses in July 2009, the CDC recommended that the booster dose be reinstated with "limited catch-up" with the available monovalent and combination products.

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DR. SCHUCHAT

Almost 3 weeks before the FDA's announcement, Dr. Anne Schuchat, director of the CDC's National Center for Immunization and Respiratory Diseases, stressed the "critical importance" of reinstating the booster dose of Hib vaccine in children aged 12-15 months, in a July 30 letter to health care providers. She said that the CDC was aware of some providers who were delaying administering the catch-up booster dose until supplies of a monovalent vaccine became available, but advised against this practice.

She noted that although there was enough Hib vaccine available to return to providing the three doses of primary vaccinations and the booster dose, the supply of the combination vaccine Pentacel (DTaP-IPV/Hib) was increasing, and the supply of the monovalent vaccine was "near stable." (At that time, Hiberix was not yet approved.) Therefore, "to reinstate the booster dose and maximize the number of children protected from Hib, most practices will need to incorporate DTaP-IPV/Hib, even if this is not their preference," she said.

"We believe that we are in the final stretch of the Hib vaccine shortage," Dr. Schuchat said in the July 30 letter. She said that CDC's Hib experts have not seen an increase in invasive Hib disease, but because of the potential for increased nasopharyngeal carriage of the Hib bacterium, "it is critical that providers continue to provide children with the full primary series and return to including the booster at this time." ■