Summer Enteroviruses: Avoid Antibiotics

BY MICHAEL E. PICHIChERO, M.D.

The Food and Drug Administration has determined that the antibiotic telithromycin (Ketek) may be associated with serious liver injury and liver failure, and has been linked to fatal cases of liver failure and 4 deaths since its approval in 2004. “We’re engaged in ongoing discussions with the FDA regarding a detailed medical evaluation of hepatic events reported in connection with Ketek use,” said Sanofi spokesman Melissa Feltmann.

Ketek is currently approved for use in adults to treat community-acquired pneumonia, sinusitis, and acute exacerbation of chronic bronchitis.

Emmy Tsui, also a Sanofi spokesman, said therapy will continue according to protocol in children already enrolled in the five pediatric trials, but that Sanofi would not enroll any new trial participants until it was certain that its development program “remains consistent with the current thinking of the FDA regarding the structure and design of antibiotic drug development in pediatrics.”

The Senate Finance Committee has been investigating Ketek’s approval, as well as a postmarketing safety study that was later found to be fraudulent. Committee chairman Charles Grassley (R-Iowa) said that he has been stonewalled by the FDA in his attempts to meet with the agency’s special agent who investigated the fraud. In mid-June, he visited the Department of Health and Human Services headquarters to demand such a meeting.

“I have gone on, I smell a cover-up,” Sen. Grassley said in a statement issued after his HHS foray.

Company Halts Enrollment in Pediatric Studies of Telithromycin

INFECTION CONTROL

Precollege Rush for Menactra

BY HEIDI SPLETE

Washington — Despite a recommendation to prioritize 11- to 12-year-olds, distribution of the meningococcal conjugate vaccine was especially high among 18-year-olds and was evenly distributed among 11- to 17-year-olds during its first year on the market, Dr. Gregory Wallace reported at a meeting of the National Vaccine Advisory Committee.

The rationale for the recommendation was to help establish an adolescent vaccine visit, and was not generated because of an increased disease risk among 11- to 12-year-olds, explained Dr. Wallace, chief of the Vaccine Supply and Assurance Branch at the Centers for Disease Control and Prevention.

The vaccine is also recommended for adolescents entering high school who have not been previously vaccinated, as well as for college freshmen living in dorms.

Demand for the meningococcal conjugate vaccine (MCV4), marketed as Menactra, was high starting in June 2005 after the publication and promotion of the vaccination recommendations by the CDC’s Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.

The demand was initially highest for 18-year-olds, and the peak months were June and July 2005. The high demand then decreased during the fall of 2005, as did patients’ and parents’ concerns about the vaccine supply.

The overall vaccine distribution rate from March 2005 to March 2006 was approximately 10% for 11- to 17-year-olds, but nearly 16% among 18-year-olds, based on physicians’ claims data provided by the vaccine’s manufacturer, Sanofi Pasteur USA.

About 4.2 million doses were distributed between March 2005 and March 2006. Although the manufacturer projects that 6 million doses will be available for 2006-2007, the amount currently available for the summer months of 2006 is approximately the same as last year, Dr. Wallace said.

Sanofi Pasteur expects the demand for the vaccine to exceed supply this summer. To handle the anticipated summer rush among 18-year-olds this year, CDC recommends that physicians defer the vaccination of 11- to 12-year-olds.

TO HANDLE THE ANTICIPATED SUMMER RUSH AMONG 18-YEAR-OLDS THIS YEAR, CDC RECOMMENDS THAT PHYSICIANS DEFER THE VACCINATION OF 11- TO 12-YEAR-OLDS.

To handle the anticipated summer rush among 18-year-olds this year, CDC recommends that physicians defer the vaccination of 11- to 12-year-olds.

Sanofi Pasteur expects the demand for the vaccine to exceed supply this summer. To handle the anticipated summer rush among 18-year-olds, the CDC and other organizations have recommended that physicians defer the vaccination of 11- to 12-year-olds until further notice from the manufacturer that the shortage has been resolved. The current supply of vaccines should be sufficient to cover adolescents entering high school, dorm-dwelling college freshmen, and other high-risk groups, including military recruits and travelers to areas where the risk of meningococcal disease is high. For periodic vaccine supply updates, visit www.cdc.gov/nip/news/shortages/default.htm.

ID CONSULT

Summer Enteroviruses: Avoid Antibiotics

BY MICHAEL E. PICHIChERO, M.D.

The Food and Drug Administration has determined that the antibiotic telithromycin (Ketek) may be associated with serious liver injury and liver failure, and has been linked to fatal cases of liver failure and 4 deaths since its approval in 2004. “We’re engaged in ongoing discussions with the FDA regarding a detailed medical evaluation of hepatic events reported in connection with Ketek use,” said Sanofi spokesman Melissa Feltmann.

Ketek is currently approved for use in adults to treat community-acquired pneumonia, sinusitis, and acute exacerbation of chronic bronchitis.

Emmy Tsui, also a Sanofi spokesman, said therapy will continue according to protocol in children already enrolled in the five pediatric trials, but that Sanofi would not enroll any new trial participants until it was certain that its development program “remains consistent with the current thinking of the FDA regarding the structure and design of antibiotic drug development in pediatrics.”

The Senate Finance Committee has been investigating Ketek’s approval, as well as a postmarketing safety study that was later found to be fraudulent. Committee chairman Charles Grassley (R-Iowa) said that he has been stonewalled by the FDA in his attempts to meet with the agency’s special agent who investigated the fraud. In mid-June, he visited the Department of Health and Human Services headquarters to demand such a meeting.

“I have gone on, I smell a cover-up,” Sen. Grassley said in a statement issued after his HHS foray.