recommended following adverse events associated with the previous rotavirus vac- cines, including intussusception and Kawasaki disease, and a new signal for pneumonia death, as well as a higher rate of convulsions in Rotarix trials.

GSK Biologics has a postmarketing plan in place—which includes prospective clinical trials, the analysis of large ongoing phase III trials, will be monitored in postmarketing surveillance System nor the active Vaccine Safety Datalink identified an increase in intussusception cases with RotaTeq within 31 days after any Rotarix dose. In eight clinical trials, including in the United States, Latin America, Europe, and Asia, there were 27 reports of Kawasaki disease, which of 22 cases were in a large ongoing phase III study in Asia (13 cases in Rotarix recipients and 9 after placebo). For the comparative risk of 1/100,000 there was no temporal evidence of an association with the vaccine and Kawasaki disease in all the trials, according to GSK.

In the Latin American study, there were 6 cases of intussusception within 31 days of vaccination among the Rotarix recipients versus seven in the placebo group, with a relative risk of 1.33 (0.5 to 3.4). Dr. Robert Davis, a panel member and director for the Perma- nent Center for Health Research/South east, in Atlanta, said that assuming the increase in pneumonia deaths is real, the risk would need to be “considerably greater” by a decrease in deaths due to natural ro- tavirus disease, although there were no data to show this effect.

In the Latin American study, there were 16 (0.03%) pneumonia deaths among vaccine recipients versus 6 (0.02%) among placebo recipients, which was not a sig- nificant difference. Nonetheless, the com- pany plans to follow this issue after ap- proval. In the studies, the only cause of death not balanced between placebo and vaccine recipients was pneumonia.

There also was a higher rate of convul- sions over the course of the study among vaccine recipients, compared with placebo recipients (0.02% versus 0.00%). No deaths occurred within 31 days of vaccination was similar.

The company also presented data show- ing that the vaccine did not negatively af- fect the immune response to antigens in the Pediarix, Prevnar, and Archib vac- cines given concurrently.

Dr. Melinda Wharton, a panel member and deputy director of the National Center for Immunization and Respiratory Diseases at the CDC, said that although there were fewer efficacy data on the G2 serotype, the overall data appeared to be robust.

She said the vaccine was “a very high concern” about the pneumonia deaths, but added, “it is a little concerning seeing a respira- tory disease signal in multiple studies.” Speculating on a pharmacovigilance mechanism, she said that rotavirus disease in placebo recipients may be protective against respiratory infections.

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