

UPDATE ON RECOMMENDATIONS FOR THE USE OF ROTAVIRUS VACCINES

On May 14, 2010, the U.S. Food and Drug Administration (FDA) revised its recommendations for rotavirus vaccines for the prevention of the disease in infants.

Summary:

The FDA is updating its recommendations on both Rotarix and RotaTeq vaccines for the prevention of rotavirus disease in infants. Based on careful evaluation of a variety of scientific information, the FDA has determined it is appropriate for clinicians and health care professionals to resume the use of Rotarix and to continue the use of RotaTeq.

Background:

On March 22, 2010, the FDA provided an early communication regarding Rotarix, manufactured by GlaxoSmithKline Biologicals (GSK). At that time, the FDA recommended that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix while the agency and manufacturer investigated the finding of DNA from porcine circovirus type 1 (PCV1) in the vaccine. Since that time, both the FDA and GSK have confirmed the presence of PCV1 in the vaccine.

On May 6, 2010, the FDA provided information about RotaTeq, manufactured by Merck & Co, Inc. The FDA indicated that preliminary studies conducted by Merck identified fragments of DNA from PCV1 and from a related porcine circovirus type 2 (PCV2) in RotaTeq. The FDA noted that it would seek input from its Vaccines and Related Biological Products Advisory Committee (VRBPAC) and provide updates in the near future.

Updated Recommendations:

The FDA has evaluated laboratory results from the manufacturers and its own laboratories. In addition, the FDA's VRBPAC convened on May 7, 2010, to discuss the findings of PCV1 and PCV2 DNA in rotavirus vaccines. Based on a careful evaluation of this information, a thorough review of the scientific literature, and input from scientific and public health experts, the agency is revising its recommendation to temporarily suspend use of the Rotarix vaccine. FDA has determined it is appropriate for clinicians and healthcare professionals to resume the use of Rotarix and to continue the use of RotaTeq.

The FDA considered the following information in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of recipients. The FDA has no evidence that either PCV1 or PCV2 poses a safety risk in humans, and notes that neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of hospitalization for severe rotavirus disease in the U.S. and of death in other parts of the world. The benefits of the vaccines, which are known, outweigh the risk, which is theoretical.

The FDA will keep the public and clinical community updated through <http://www.fda.gov/> and other communications.

For more information: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm205585.htm>